

1 Public health

- European Commission: report on the implementation of the EU Directive on standards of quality and safety of human organs intended for transplantation
- Approval of first set of European Reference Networks for highly specialised care
- European Commission: public consultation on an action plan on antimicrobial resistance
- European Commission: report on implementation of the 2003 Council Recommendation on cancer screening
- European Parliament (EP): study on health promotion and primary prevention: exchange of good practices
- Cancon: Guide to effective cancer control
- Cancon: five policy papers on effective cancer control
- ECDC: increased efforts needed to address the spread of antimicrobial resistance
- European Commission: report on patient safety
- European Commission: conference on the cross-border healthcare directive
- Study: Big Data in the health sector
- European Commission and OECD: Health at a Glance: Europe 2016

2 Healthcare services in the internal market

- European Commission: proposal for a directive on a proportionality test before adoption of a new regulation of professions
- European associations of healthcare providers: proposal for a directive on proportionality tests for professional regulation threaten the quality and safety of patient care
- The Netherlands: evidence of language ability required for health professionals
- HPCB: conference on promoting patient safety across borders
- HPCB: mapping of national sanctions relating to fitness-to-practice of care providers

3 Medicines and medical devices

- EP: motion for a resolution on EU options for improving access to medicines
- EP: resolution on paediatric medicines
- European Commission: report on the monitoring of patent settlements in the pharmaceutical sector
- Interest groups: recommendations to help tackle medicines shortages
- EP: overview of possible public health issues arising from Brexit
- Council: impact of incentives in the medicines sector on innovation, availability and accessibility of medicinal products in the EU
- EMA: report on conditional marketing authorisations for medicines for unmet medical needs
- EMA: public consultation on its policy on access to documents
- European Commission: evaluation of EU blood, tissues and cells legislation
- German certifying body found guilty of approving defective breast implants

4 Social policy

- EP: resolution on a European Pillar of Social Rights
- NGOs: health should be one of the core concerns of the Pillar of Social Rights
- European Commission: proposal for a revision of the EU legislation on social security coordination
- ESPN: report on sick pay and sickness benefit

5 Economic policy

- European Commission: updated factsheet on health systems, as part of the European Semester
- European Commission: annual analysis of the economic and social situation in the Member States

6 Court of Justice of the European Union

- Judgment: breast implants made of inferior quality industrial silicone
- Judgment: parallel import of medical devices
- Judgment: scope of the directive on temporary agency work (2008/104/EC)
- Judgment: social advantages for the child of a cross-border worker's partner
- Judgment: care component of the disability living allowance is a sickness benefit

7 Competition

- Acquisition of St. Jude Medical by Abbott Laboratories approved
- Acquisition of Alere by Abbott approved
- European Commission: study on the financing models for public services in the EU

8 Infringement proceedings

- Slovakia: delayed payments in the public health sector
- Latvia and Romania: transposition of EU rules on recognition of professional qualifications

9 Publications

- EP: Brexit implications for employment and social affairs
- ENISA: cybersecurity for hospitals
- Eurofound: Delivering hospital services: a greater role for the private sector?
- Pharmaceutical regulation in 15 European countries (2016)
- WHO: toolkit to strengthen Europe's health response to migration
- WHO: improving access to medicines through efficient public procurement
- OECD: tackling wasteful spending on health
- France: patients receiving healthcare abroad with social insurance cover
- OECD: report on new approaches to tackle rising drug prices
- The consequences of the economic crisis on health
- Bertelsmann Stiftung: Social policy in the EU - reform barometer

10 Miscellaneous

- OECD: meeting of ministers of health
- Benelux: decision on the provision of urgent cross-border medical assistance
- EP: overview of EU trade agreements under negotiation

1 Public health

European Commission: report on the implementation of the EU Directive on standards of quality and safety of human organs intended for transplantation

The Commission published an official report and a background document on the implementation of Directive 2010/53/EU on standards of quality and safety of human organs intended for transplantation.

DOC 1 [EN](#) PDF | DOC 2 [EN](#) PDF

Approval of first set of European Reference Networks for highly specialised care

A first series of 24 initiatives was approved by the Board of Member States as European reference networks for highly specialised care. These involve 370 hospitals and almost 1000 highly specialised healthcare units from 26 countries.

DOC [EN](#) HTML

European Commission: public consultation on an action plan on antimicrobial resistance

The Commission is consulting stakeholders on proposals for an action plan to counter antimicrobial resistance.

DOC [EN](#) HTML

European Commission: report on implementation of the 2003 Council Recommendation on cancer screening

The Commission published a report on the implementation of the 2003 Council Recommendation on cancer screening. This shows a steep increase in national screening programmes for breast, cervical and colorectal cancer.

DOC 1 [EN](#) PDF | DOC 2 [EN](#) PDF

➤ **European Parliament (EP): study on health promotion and primary prevention: exchange of good practices**

This report gives an overview of the presentations and discussions which took place at a workshop on health promotion and primary prevention, held at the European Parliament.

DOC [EN](#) PDF

➤ **Cancon: Guide to effective cancer control**

This guide is the result of the EU co-funded Joint Action Cancon, with experts from 25 countries and 126 partner organisations. The guide gives recommendations on cancer control in Europe.

DOC [EN](#) HTML

➤ **Cancon: five policy papers on effective cancer control**

Cancon also published policy recommendations in five areas. These policy papers were coordinated by a platform of Member States. They deal with the following topics: a public health genomics approach to 'omics' in oncology; common European objectives for national cancer control plans; enhancing cancer care by a more appropriate use of healthcare interventions; an impact evaluation system to assess prevention outcomes; and equity mainstreaming in cancer control.

DOC [EN](#) HTML

➤ **ECDC: increased efforts needed to address the spread of antimicrobial resistance**

According to the European Centre for Disease Prevention and Control (ECDC), increased efforts are needed to address the spread of *Acinetobacter baumannii*. *Acinetobacter baumannii* is the cause of difficult-to-treat infections in healthcare due to its increasing resistance to antimicrobial agents.

DOC [EN](#) HTML

➤ **European Commission: report on patient safety**

A European Commission report drafted by Gesundheit Österreich Forschungs- und Planungs GmbH and SOGETI assesses the costs of unsafe care and the cost effectiveness of patient safety programmes in healthcare systems in the EU Member States.

DOC [EN](#) PDF

➤ **European Commission: conference on the cross-border healthcare directive**

The presentations and the report on this conference, organised by the Commission in October 2016, are available.

DOC [EN](#) HTML

➤ **Study: Big Data in the health sector**

A study on Big Data in public health, telemedicine and healthcare, financed by the European Commission, identifies examples of the use of Big Data in the health sector, and makes recommendations.

DOC [EN](#) HTML

➤ **European Commission and OECD: Health at a Glance: Europe 2016**

The publication "Health at a Glance: Europe 2016" gives an updated analysis of the health status of EU citizens and the performance of health systems in the EU. It also examines in more detail the strengthening of primary care systems.

DOC [EN](#) HTML

2 Healthcare services in the internal market

European Commission: proposal for a directive on a proportionality test before adoption of new regulation of professions

According to this proposal, Member States must carry out a comprehensive proportionality test before adopting or amending national rules on professional services. The directive applies to professions to which access is conditional on specific qualifications or a specific legally-protected title, including most health professions. In the view of the Commission, unnecessarily burdensome and outdated rules often hamper access to these professions.

DOC 1 [EN/NL/FR](#) HTML | DOC 2 [EN](#) HTML | DOC 3 [EN](#) - [FR](#) - [NL](#) PDF

European associations of healthcare providers: proposal for a directive on proportionality tests for professional regulation threaten the quality and safety of patient care

According to the European associations of dentists, doctors and pharmacists, the proposed directive on proportionality tests for professional regulation ignores the public interest and represents a threat to the quality and safety of patient care.

DOC [EN](#) HTML

The Netherlands: evidence of language ability required for health professionals

Since 1 January 2017, care providers wishing to register in the Netherlands must provide evidence of language ability.

DOC [NL](#) HTML

HPCB: conference on promoting patient safety across borders

Healthcare Professionals Crossing Borders (HPCB), an informal partnership of professional healthcare regulators in Europe, organised a conference on promoting patient safety across borders. The presentations are available online.

DOC [EN](#) HTML

HPCB: mapping of national sanctions relating to fitness-to-practice of care providers

HPCB invites professional healthcare regulators to take part in a survey to map fitness-to-practice sanctions for healthcare providers in Europe. The aim is to exchange information with a view to implementation of the alert mechanism introduced as part of the revised directive on recognition of professional qualifications (2013/55/EU).

DOC [EN](#) PDF

3 Medicines and medical devices

EP: motion for a resolution on EU options for improving access to medicines

This motion for a resolution endorses the 2016 Council conclusions on strengthening the balance in pharmaceutical systems in the EU. It asks for a strengthening of the Member States' bargaining position, in order to guarantee affordable access to medicines, and calls on the Commission to revise the transparency directive and report on the balance and proportionality of incentives for the reallocation of medicines.

DOC [EN](#) HTML

EP: resolution on paediatric medicines

In this resolution, the Parliament stresses the urgent need to assess how different types of funding and rewards can be best used to drive and accelerate paediatric drug development,

particularly drugs for neonatology and childhood cancers. The Parliament also calls for a strengthening of the role of European networking for paediatric clinical research.

DOC [EN/NL/FR](#) HTML

European Commission: report on the monitoring of patent settlements in the pharmaceutical sector

According to this report, drawn up in the wake of the 2008 sector inquiry on distortion of competition in the pharmaceutical sector, the number of settlements potentially distorting competition (whereby remuneration was paid by the producer of the branded product to the generic company in order to restrict market access of the generic products) has stabilised at a low level.

DOC [EN](#) HTML

Interest groups: recommendations to help tackle medicines shortages

The European associations representing manufacturers of medicinal products, parallel distributors, pharmaceutical wholesalers and pharmacists have announced a series of recommendations to help tackle medicines shortages.

DOC [EN](#) HTML

EP: overview of possible public health issues arising from Brexit

The European Parliament's Committee on the Environment, Public Health and Food Safety has drawn up a list of questions within its remit requiring a response from the Brexit negotiations. These include regulation on medical devices, clinical trials, cross-border healthcare as well as the relocation of the European Medicines Agency.

DOC [EN](#) PDF

Council: impact of incentives in the medicines sector on innovation, availability and accessibility of medicinal products in the EU

The European Commission has informed ministers of how it intends to respond to the Council's request of June 2016 to analyse the impact of pharmaceutical incentives and rewards on innovation, availability and accessibility of medicinal products.

DOC [EN](#) PDF

EMA: report on conditional marketing authorisations for medicines for unmet medical needs

The European Medicines Agency (EMA) published a report on its ten years' experience with conditional authorisations for medicines tackling unmet medical needs.

DOC [EN](#) HTML

EMA: public consultation on its policy on access to documents

The EMA launched a public consultation on the proposed revision of its policy on access to documents.

DOC [EN](#) HTML

European Commission: evaluation of EU blood, tissues and cells legislation

The Commission published a roadmap for assessment of the EU legislation on blood, tissues and cells. This process will be supported by an external study.

DOC [EN](#) HTML

German certifying body found guilty of approving defective breast implants

The commercial court of Toulon (France) ordered the German certifying body TUV, which certifies medical devices, to pay €60 million in damages to 20,000 women who received defective breast implants which it had approved.

DOC 1 [FR](#) HTML | DOC 2 [EN](#) HTML

4 Social policy

EP: resolution on a European Pillar of Social Rights

According to the European Commission, this pillar is to establish a number of fundamental principles underpinning well-functioning labour markets and social security systems. The Parliament emphasises that the pillar should empower national welfare states to maintain social cohesion and equality through adequate, accessible and financially sustainable social protection systems and social inclusion policies. This also includes universal access to healthcare.

DOC 1 [EN/FR/NL](#) HTML | DOC 2 [EN](#) HTML

NGOs: health should be one of the core concerns of the Pillar of Social Rights

23 social and health NGOs are urging the European Union to make health and health equity a central consideration of the 'Pillar of Social Rights'.

DOC [EN](#) PDF

European Commission: proposal for a revision of the EU legislation on social security coordination

This proposal introduces specific coordination rules for long-term care, following the same logic as the existing rules on health costs. Under these rules, the Member State where the person is insured would pay long-term care benefits in cash, and reimburse benefits in kind supplied by the Member State of residence.

DOC 1 [EN/FR/NL](#) HTML | DOC 2 [EN](#) - [NL](#) - [FR](#) PDF

ESPN: report on sick pay and sickness benefit

This report, "Sick pay and sickness benefit schemes in the European Union", produced for the Social Protection Committee, sheds light on the huge variations in the way Member States address absence from work due to sickness.

DOC [EN](#) HTML

5 Economic policy

European Commission: updated factsheet on health systems, as part of the European Semester

The Commission draws up thematic factsheets on the most important policy areas covered by the European Semester. These contain information on economic and social challenges, policies to address these, and examples of good practice. The factsheet on health systems was recently updated.

DOC [EN](#) HTML

European Commission: annual analysis of the economic and social situation in the Member States

As part of the European Semester, the Commission published its annual analysis of the economic and social situation in the Member States. According to the Commission, Ireland, Lithuania, Austria, Portugal, Romania, Slovenia and Finland have made some progress in addressing the country-specific recommendations to improve the cost-effectiveness of their healthcare systems. Others have made only limited progress.

DOC 1 [EN/NL/FR](#) HTML | DOC 2 [EN](#) HTML | DOC 3 [EN](#) HTML

6 Court of Justice of the European Union

Judgment: breast implants made of inferior quality industrial silicone

In case C-219/15, the Court has ruled that a notified body responsible for granting an EU declaration of conformity for a medical device is not required to carry out inspection visits. However, if there are indications that a product is not in line with the requirements set out in EU directive 93/42 on medical devices, the notified body must take all the steps necessary to ensure that it fulfils its obligations under the directive. If these obligations are not met, it may be liable vis-à-vis end users, in line with national law.

DOC 1 [EN](#) - [NL](#) - [FR](#) PDF | DOC 2 [EN/NL/FR](#) HTML

Judgment: parallel import of medical devices

In the view of the Court in case C-662/15, a parallel importer of a medical device bearing a CE marking pursuant to the medical devices directive (93/42/EEC) is not required to carry out a further assessment to certify the conformity of the information allowing it to be identified with a view to it being placed on the market in the importing Member State.

DOC [EN/FR/NL](#) HTML

Judgment: scope of the directive on temporary agency work (2008/104/EC)

Ruhrlandklinik concluded an agreement with DRK Essen whereby the latter would supply nursing staff to work in the clinic in return for financial compensation. In this case (C-216/15), the Court has ruled that if a not-for-profit organisation assigns one of its members to a user undertaking, for the purposes of carrying out work as his main occupation and in return for remuneration, this arrangement falls within the scope of the directive on temporary agency work (2008/104/EC), even if this member does not have the status of worker under national law.

DOC [EN/FR/NL](#) HTML

Judgment: social advantages for the child of a cross-border worker's partner

The child of the spouse or registered partner of a cross-border worker can also claim the indirect social advantages stemming from the free movement of workers, such as study grants, if the cross-border worker contributes to the maintenance of the child.

DOC 1 [EN](#) - [NL](#) - [FR](#) PDF | DOC 2 [EN/FR/NL](#) HTML

Judgment: care component of the disability living allowance is a sickness benefit

In case C-430/15, the Court has found that the care component of the disability living allowance is a sickness benefit for the purposes of Council Regulation (EEC) No. 1408/71 on the coordination of social security rules. Receipt of this benefit cannot be made subject to a condition such as residence and presence on the territory of the Member State.

DOC [EN/FR/NL](#) HTML

7 Competition

Acquisition of St. Jude Medical by Abbott Laboratories approved

The European Commission has approved the proposed acquisition of St. Jude Medical by Abbott Laboratories, both US-based companies that develop and market medical devices. This approval is conditional on Abbott divesting two devices used in cardiovascular treatment.

DOC [EN/FR](#) HTML

Acquisition of Alere by Abbott approved

The European Commission has approved the acquisition of Alere by Abbott, both suppliers of clinical test systems. The decision is conditional on the divestment of Alere's Epop and Triage tests, as well as Alere's BNP reagents business.

DOC [EN/FR](#) HTML

European Commission: study on the financing models for public services in the EU

The Commission published a study of the financing models for public services in the EU and the impact on competition. This study, drawn up by Ecorys, includes a chapter on healthcare.

DOC [EN](#) PDF

8 Infringement proceedings

Slovakia: delayed payments in the public health sector

The Commission is urging Slovakia to take action to correct the excessively delayed payments in the health sector, to comply with the late payment directive (2011/7/EU).

DOC [EN/FR](#) HTML

Latvia and Romania: transposition of EU rules on recognition of professional qualifications

The European Commission has sent reasoned opinions to Latvia and Romania, requesting that they transpose directive 2013/55/EU on the recognition of professional qualifications.

DOC [EN/FR/NL](#) HTML

9 Publications

EP: Brexit implications for employment and social affairs

This publication contains facts and figures on migration streams between the United Kingdom and the rest of the EU. It also investigates the impact of the EU-27 population on the British social security and healthcare systems, and, on the other hand, of the British population on systems in the other Member States.

DOC [EN](#) PDF

ENISA: cybersecurity for hospitals

The European Union Agency for Network and Information Security (ENISA) published a study on cybersecurity for hospitals. The study makes recommendations on how to enhance information security in hospitals.

DOC [EN](#) HTML

Eurofound: Delivering hospital services: a greater role for the private sector?

This publication examines the role and contribution of the private provision of hospital services (both for-profit and non-profit) in the European Union. The report maps the extent of private provision across Europe, examines the drivers for increased private provision, describes how it takes place and presents the views of different stakeholders.

DOC [EN](#) HTML

Pharmaceutical regulation in 15 European countries (2016)

This publication of the European Observatory on Health Systems and Policies investigates a broad range of regulatory measures, spanning marketing authorisation to generic substitution, to understand their influence on the price and utilisation of medicines.

DOC [EN](#) HTML

WHO: toolkit to strengthen Europe's health response to migration

This toolkit is designed to help countries to analyse and improve their health capacity and first response to large-scale migration.

DOC [EN](#) HTML

WHO: improving access to medicines through efficient public procurement

This report provides insight into how European countries can improve access to medicines and reduce prices through strategic and well-planned procurement processes. The report examines the effect of different public procurement practices on supply security and prices for pharmaceuticals.

DOC [EN](#) HTML

OECD: tackling wasteful spending on health

According to this report, 'Tackling wasteful spending on health', a considerable part of health expenditure makes little or no contribution to improving people's health. The report systematically reviews strategies put in place by countries to limit ineffective spending and waste.

DOC [EN](#) HTML

France: patients receiving healthcare abroad with social insurance cover

The French General Social Affairs Inspectorate (IGAS) and General Financial Inspectorate (IGF) have carried out an analysis of the reimbursement costs incurred by patients insured in France who have received healthcare abroad.

DOC [FR](#) HTML

OECD: report on new approaches to tackle rising drug prices

According to this report, governments should work together with the industry and regulators to define a new approach to the development and use of new technologies that encourages innovation while also delivering value for money.

DOC [EN](#) HTML

The consequences of the economic crisis on health

This special issue of Health Economics looks in more detail at various aspects of the consequences of the economic crisis on health.

DOC [EN](#) HTML

Bertelsmann Stiftung: Social policy in the EU - reform barometer

The Bertelsmann Stiftung invited more than 1,000 social scientists to take part in a survey on the need for social reforms in the Member States and the reforms which have actually taken place. Socio-political reforms in five sectors, including health, were analysed. The foundation published a report on the findings and a social inclusion monitor.

DOC 1 [EN](#) PDF | DOC 2 [EN](#) HTML

10 Miscellaneous

OECD: meeting of ministers of health

At their meeting on 17 January, the ministers of the OECD countries issued a statement on the next generation of health reforms.

The ministers also endorsed the recommendations of the High-level reflection group on the future of health statistics.

DOC 1 [EN](#) HTML | DOC 2 [EN](#) HTML

Benelux: decision on the provision of urgent cross-border medical assistance

A decision has been taken by the Benelux to facilitate cross-border transport by ambulance and SAMU/MUG (mobile emergency services) as well as organ transport between Belgium and Luxembourg.

DOC [NL/FR](#) HTML

EP: overview of EU trade agreements under negotiation

On its website, the European Parliament published an overview of the trade agreements with the EU which are still in the pipeline.

DOC [EN](#) HTML

«European Health Care News»

is an electronic newsletter published by the European Social Observatory (OSE), commissioned by the National Institute for Health and Disability Insurance (NIHDI).

Editors: Rita Baeten and Dalila Ghailani

E-mail: baeten@ose.be

Website: <http://www.ose.be>

To subscribe to the mailing list :

http://www.ose.be/health_newsletter/