

1 Public health

- EXPH: opinion on application of the ‘European Reference Network’ model in European cross-border healthcare cooperation outside the rare diseases area
- European Commission: report on the state of vaccine confidence in the EU in 2018
- European Commission and OBS: study on the organization and delivery of vaccination services in the European Union
- EXPH: report on vaccination programmes and health systems in the EU
- European Parliament: written question on the use of mercury in dental fillings
- EUROSTAT: EU-SILC – statistical data on access to healthcare

2 Medicines and medical devices

- European Parliament: in favour of the establishment of a European Health Technology Assessment (HTA) system
- EMA: access to 39 medicines under threat from Brexit
- European Parliament: oral question on the implementation of the medical devices and in-vitro medical devices regulations
- EMA: harnessing the potential of real-world data through a ‘learning healthcare system’
- European Commission: launch of a public consultation on legislation on medicines for children and rare diseases
- Council: securing the supply of centrally-authorized medicines and orphan drugs
- European Parliament: draft opinion on the supplementary protection certificates (SPC) for medicinal products
- ESIP: in favour of a more ambitious text on supplementary protection certificates
- European Commission: notice to stakeholders – withdrawal of the United Kingdom and EU rules in the field of clinical trials
- European Commission: fourth stakeholder conference on biosimilar medicines
- Greece: the role of the European Commission should be strengthened to ensure the effectiveness of health and pharmaceutical policies

3 Health care services in the internal market

- European Commission: report on implementation of directive 2011/24/EU on the application of patients’ rights in cross-border healthcare

4 e-Health

- Council: the Council supports the Commission's plans to invest a billion EUR in world-class European supercomputers

5 Social policy

- European Commission: 35 national reports and a summary report on inequalities in access to healthcare
- European Commission: challenges in long-term care in Europe - a study of national policies 2018
- EESC: the situation of Roma people in relation to health and their access to healthcare are still dire

6 International agreements

- European Commission: post-programme surveillance report - Portugal
- European Parliament: report on the sustainability of health systems
- Investment plan: a first capacity-building agreement signed on employment and social innovation to support microfinance institutions
- Council of Europe: Greece should safeguard social rights for all and improve the reception and integration of migrants
- European Commission: the effect of tax and benefits reforms on poverty and inequality in Latvia

7 Competition

- France: management of infectious medical waste generated by healthcare activities
- Latvia: market study on distribution of reimbursed medicines

8 Court of Justice of the European Union

- Judgment: the dismissal of a Catholic head of internal medicine by a Catholic hospital, due to his remarriage following a divorce can constitute illegal discrimination on grounds of religion or belief
- Order: online advertising of dental care
- Judgment: medical device incorporating as an integral part a substance which, used separately, may be considered to be a medicinal product
- Judgment: public supply contract for medical diagnostic equipment and materials
- Judgment: access to a document containing information submitted as part of a request for a marketing authorisation

9 Publications

- Article: the impact of Brexit on the NHS
- Book: Free movement of patients in the EU: a patient's perspective
- OECD: use of blockchain technology in the public sector
- Friends of Europe: Smart (dis)investment choices in healthcare
- Eurohealth: special issue to mark the 20th anniversary of the European Observatory on Health Systems and Policies (OBS)
- OBS: Will population ageing spell the end of the welfare state? A review of evidence and policy options
- OBS: Ensuring access to medicines: how to stimulate innovation to meet patients' needs?
- FPS Social Security: The evolution of the social situation and social protection in Belgium 2018
- OBS: reports on the Austrian, Bulgarian, Spanish and Estonian health systems

10 Miscellaneous

- Court of Auditors: 2019 Work programme
 - EESC: the new EU investment programme – InvestEU – should enhance the social dimension
 - European Commission: 2019 Work programme
-

1 Public health

EXPH: opinion on application of the 'European Reference Network' model in European cross-border healthcare cooperation outside the rare diseases area

According to the Expert Panel on Effective Ways of Investing in Health (EXPH), while European Research Networks (ERNs) have considerable potential to improve the care of patients with rare diseases across the EU, it is not yet possible to ascertain the extent to which these goals will be achieved. According to the report, the current criteria for establishing an ERN, as a means of improving the management of patients with rare and complex diseases, are appropriate.

DOC [EN](#) PDF

European Commission: report on the state of vaccine confidence in the EU in 2018

The report assesses the state of confidence in vaccines of the public in all 28 EU Member States, and among general practitioners (GPs) in 10 Member States. This confidence is assessed for vaccines in general, as well as for the measles and seasonal influenza vaccines. This is the largest ever study on attitudes to vaccines and vaccination in the EU.

DOC [EN](#) PDF

European Commission and OBS: study on the organization and delivery of vaccination services in the European Union

This report, produced by the European Observatory on Health Systems and Policies (OBS) for the European Commission, examines the current situation in the EU concerning vaccine-uptake and vaccine-preventable disease. It then reviews health system-related factors influencing vaccine-uptake. Thirdly, it provides country fiches describing the organisation and delivery of vaccination programmes in the EU Member States.

DOC [EN](#) PDF

EXPH: report on vaccination programmes and health systems in the EU

This report drawn up by the Expert Panel on Effective Ways of Investing in Health (EXPH) identifies the main factors (enablers and obstacles) influencing vaccination uptake, and assesses measures that can be expected to improve vaccination coverage.

DOC [EN](#) PDF

European Parliament: written question on the use of mercury in dental fillings

In a written question, the MEP Ivo Belet (EPP, Belgium) expresses his concern about the introduction on the EU market of possible alternatives to dental fillings. He underlines the concern expressed by dentists, who state that these alternatives may contain harmful, even carcinogenic, substances. In its reply, the European Commission declared that it would be reporting back, by 30 June 2020, on the results of its feasibility study on the gradual phasing-out of dental fillings by 2030.

DOC [EN](#) - [NL](#) HTML

EUROSTAT: EU-SILC – statistical data on access to healthcare

A new ad hoc module on access to services, including access to healthcare, introduced to the European Union Statistics on Income and Living Conditions (EU-SILC), is now available on the Eurostat website. It covers persons using healthcare services by household type, income group, and level of difficulty to afford care services.

DOC [EN](#) HTML

2 Medicines and medical devices

European Parliament: in favour of the establishment of a European Health Technology Assessment (HTA) system

The European Parliament (EP) adopted the report prepared by Soledad Cabezón Ruiz (S&D, Spain) on behalf of the Environment Committee, by 576 votes in favour to 56 against, with 41 abstentions. The report calls for the introduction of joint clinical assessments of health technologies at EU level. The EP is ready to begin negotiations with Council.

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

EMA: access to 39 medicines under threat from Brexit

The European Medicines Agency warned that there could be Brexit-related supply disruptions for 39 medicines with centralised marketing authorisations. In a press release, the Agency states that for each of these 39 products, it is analysing how to minimise supply disruptions and any resulting impact on public health.

DOC [EN](#) HTML

European Parliament: oral question on the implementation of the medical devices and in-vitro medical devices regulations

The European Commission denies that there have been any delays or particular problems with implementation of the new rules, adopted in 2017, on medical devices and in-vitro medical devices. Nevertheless, in a question for oral response put during the plenary, several MEPs expressed their concern that the deadlines would not be met and that the notified bodies had not been designated.

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

• **EMA: harnessing the potential of real-world data through a ‘learning healthcare system’**

According to the EMA’s Executive Director and Chief Medical Officer, as well as other stakeholders, real world data (RWD) hold the promise to substantially increase the effectiveness and efficiency of all processes in the development and use of medicines, from research and development, to regulatory decision-making, pricing and reimbursement decisions in medical practice. Nevertheless, to realise the full potential of RWD requires a ‘learning healthcare system’.

DOC [EN](#) HTML

• **European Commission: launch of a public consultation on legislation on medicines for children and rare diseases**

The purpose of the consultation is to assess the efficiency and effectiveness of the two regulations, particularly in light of the latest pharmaceutical developments, including the impact of the incentives for research, development and marketing of children’s and orphan medicines. The public consultation will conclude on 4 January 2019 and will help to shape the EU policy on medicines for children and rare diseases.

DOC [EN](#) HTML

• **Council: securing the supply of centrally-authorized medicines and orphan drugs**

The European health ministers met informally in Vienna. They discussed securing the supply of centrally-authorized medicines, orphan drugs for rare diseases, and digital health.

DOC [EN](#) PDF

• **European Parliament: draft opinion on the supplementary protection certificates (SPC) for medicinal products**

The European Parliament’s Committee on the Environment, Public Health and Food Safety published its opinion on the proposal for a regulation concerning supplementary protection certificates (SPC) for medicinal products. The rapporteur Tiemo Wölken wishes to restore a level playing-field between EU-based generic and biosimilar manufacturers and those based outside the EU.

DOC [FR](#) - [EN](#) - [NL](#) PDF

• **ESIP: in favour of a more ambitious text on supplementary protection certificates**

The European Social Insurance Platform (ESIP) calls on EU legislators to ensure that patients’ access to high-quality and affordable healthcare is put at the centre of the discussions on the Commission proposal to amend the EU regulation on Supplementary Protection Certificates (SPCs) for medicinal products.

DOC [EN](#) HTML

• **European Commission: notice to stakeholders – withdrawal of the United Kingdom and EU rules in the field of clinical trials**

The European Commission issued a notice to stakeholders on the consequences of the withdrawal of the United Kingdom from the EU, and on EU rules in the field of clinical trials.

DOC [EN](#) PDF

• **European Commission: fourth stakeholder conference on biosimilar medicines**

The European Commission and the European Medicines Agency (EMA) organised another multi-stakeholder event on biosimilar medicines, to promote the exchange of knowledge and best practices on the use of biosimilars. At this event, the 2018 report on the impact of biosimilar competition in Europe was presented.

DOC [EN](#) HTML

Greece: the role of the European Commission should be strengthened to ensure the effectiveness of health and pharmaceutical policies

The Greek health minister declared that achieving a fair pharmaceutical policy was a 'difficult equation'. The issue, he said, has three parameters: encouraging innovation to produce effective medicines with added therapeutic value, guaranteeing universal and equal access for all EU citizens to new therapeutic regimes and, thirdly, having sustainable health systems. In his view, an intervention was needed covering all three parameters, adding that an upgraded European policy on health and medicine was required.

DOC [EN](#) HTML

3 Health care services in the internal market

European Commission: report on implementation of directive 2011/24/EU on the application of patients' rights in cross-border healthcare

Over the last three years, the directive on cross-border healthcare (2011/24/EU) has proven to clarify and guarantee patients' rights to receive healthcare in another Member State, according to the latest implementation report from the European Commission. The Commission is concerned that some transposition measures relating to reimbursement limit the level of reimbursement of cross-border healthcare services when these services are supplied by private or non-contracted healthcare providers.

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

4 e-Health

Council: the Council supports the Commission's plans to invest a billion EUR in world-class European supercomputers

The Council of Ministers officially approved the Commission's plans to invest jointly with Member States to establish a world-class supercomputing infrastructure at European level. Supercomputers are necessary to process the ever-increasing volumes of data and to find ways of resolving complex issues in areas such as health or security.

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

5 Social policy

European Commission: 35 national reports and a summary report on inequalities in access to healthcare

The European Social Policy Network (ESPN) drafted, for the European Commission, 35 national reports and a synthesis report on inequalities in access to healthcare. The reports describe the main features of health systems enabling access to healthcare, and identify the main challenges related to access to healthcare in the European countries.

DOC [EN](#) HTML

European Commission: challenges in long-term care in Europe - a study of national policies 2018

This study, drawn up by ESPN, and which includes study reports and a synthesis report, provides a brief description of the main features of the national long-term care systems in 35 European countries – EU and EFTA Member States as well as candidate countries.

DOC [EN](#) HTML

EESC: the situation of Roma people in relation to health and their access to healthcare are still dire

At a hearing, stakeholders from European organisations and representatives of the European Economic and Social Committee (EESC) took stock of the health situation of the Roma and of their access to healthcare, assessing in particular the situation of women and children. A number of issues were highlighted, such as discrimination in access to healthcare, differences in life-expectancy between Roma and non-Roma people, poverty and its effects on health and, regarding women and children, forced sterilisations, pregnancy, infant and maternal mortality and the vaccination of children.

DOC [EN/FR](#) HTML

6 Economic policy

European Commission: post-programme surveillance report - Portugal

The report presents the conclusions of the eighth post-programme surveillance mission to Portugal, and identifies the challenges still remaining for the Portuguese economy. According to the report, work is still being done to improve cost-effectiveness in the field of health, but the recurrent accumulation of hospital arrears was only temporarily halted by cash injections.

DOC [EN](#) PDF

European Parliament: report on the sustainability of health systems

This report summarises the presentations and discussions of a workshop on the sustainability of health systems, held at the European Parliament in Brussels on Tuesday 15 May 2018.

DOC [EN](#) PDF

Investment plan: a first capacity-building agreement signed on employment and social innovation to support microfinance institutions

On 30 November, the EIB and Newron Pharmaceuticals S.p.A, a biopharmaceutical company focused on the development of novel therapies for patients with diseases of the central and peripheral nervous system, signed a financing agreement which will allow the company to borrow up to 40 million EUR over the coming years, subject to meeting a set of agreed performance criteria.

DOC [EN](#) HTML

Council of Europe: Greece should safeguard social rights for all and improve the reception and integration of migrants

According to the Council of Europe's Commissioner for Human Rights, Greece should take urgent measures and adopt long-term policies to improve the reception and integration of migrants and to reverse the adverse effects of austerity measures on access to healthcare and education. The report on her visit to Greece states that the Greek health system, with shortages of staff and equipment, has operational problems. Together with the general fall in pay and pensions, these problems have hampered access to care.

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

European Commission: the effect of tax and benefits reforms on poverty and inequality in Latvia

Despite a reduction since 2011, the share of people at risk of poverty or social exclusion in Latvia remains high compared to other EU Member States. These inequalities are also reflected in non-financial aspects such as access to healthcare and education.

DOC [EN](#) PDF

7 Competition

France: management of infectious medical waste generated by healthcare activities

The French competition authority fined the company Sanicorse for a sudden, significant, permanent and unjustified increase in the prices it charged to dispose of waste from hospitals and clinics in Corsica between 2011 and 2015.

DOC [FR](#) PDF

Latvia: market study on distribution of reimbursed medicines

The conclusions of the market study highlight the systemic problems in the distribution and allocation of the medicines reimbursed by the State. According to the Latvian competition authority, the institutions responsible should consider the possibility of establishing a register in which medicine wholesalers and pharmacies would have to provide information on their medicine stocks.

DOC [EN](#) HTML

8 Court of Justice of the European Union

Judgment: the dismissal of a Catholic head of internal medicine by a Catholic hospital, due to his remarriage following a divorce can constitute illegal discrimination on grounds of religion or belief

The dismissal of a Catholic doctor from a management post, by a Catholic hospital, due to his remarriage following a divorce may constitute illegal discrimination on grounds of religion or belief, stated the Court of Justice of the EU in its judgment on case C-68/17.

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

Order: online advertising of dental care

In a dispute between the Haute-Garonne departmental council of surgeons and dentists (France) and a dental surgeon accused of using online advertising processes on a website, infringing national legislation banning any advertising relating to the dental profession (case C-296/18), the Court found that directive 2000/31/EC, known as the 'E-commerce' directive, prohibits such national legislation imposing a general and absolute ban on any advertising by members of the dental profession.

DOC [FR](#) HTML

Judgment: medical device incorporating as an integral part a substance which, used separately, may be considered to be a medicinal product

In the case between Boston Scientific Ltd and Deutsches Patent- und Markenamt (C-527/17), the Court found that in accordance with Regulation 469/2009/EC concerning the supplementary protection certificate for medicinal products, a prior authorisation procedure for a device incorporating a substance as an integral part cannot be treated in the same way as a marketing authorisation procedure for that substance, even if that substance was the subject of an assessment.

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

Judgment: public supply contract for medical diagnostic equipment and materials

Directive 2014/24/EU on public procurement does not require the contracting authority, in establishing technical specifications in a procurement procedure concerning the acquisition of medical supplies, to prioritise, as a point of principle, either the importance of the individual characteristics of the medical supplies or the importance of the result of their functioning, but requires the technical specifications, as a whole, to comply with the principles of equality of treatment and proportionality (case C-413/17).

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

Judgment: access to a document containing information submitted as part of a request for a marketing authorisation

Amicus Therapeutics submitted documents to the EMA as part of the request for authorisation to place the medicinal product Galafold on the market (case T-33/17). In 2016, the EMA received a request from a pharmaceutical company, pursuant to Regulation 1049/2001/EC regarding public access to documents, seeking access to several documents relating to the request for a marketing authorisation for this medicine. The EMA decided to grant this request. Amicus Therapeutics contested this decision, invoking a general presumption of confidentiality. The Court dismissed the action.

DOC [EN/FR](#) HTML

9 Publications

Article: the impact of Brexit on the NHS

According to the article entitled The National Health Service at a critical moment: when Brexit means hectic, Brexit is deepening the financial crisis of the NHS by increasing hiring costs, imposing new transaction costs to accommodate patient cross-border mobility and international public health needs. Given the weak sustainability of the NHS, this could pave the way for major system reform.

DOC [EN](#) HTML

Book: Free movement of patients in the EU: a patient's perspective

The authors examine in detail the complex issues European patients face when obtaining healthcare abroad. They shed light on both the legal and non-legal obstacles to cross-border patient mobility, while focusing primarily on the needs and interests of the patients.

DOC [EN](#) HTML

OECD: use of blockchain technology in the public sector

The OECD published a study entitled Blockchains Unchained - Blockchain technology and its use in the public sector, which assesses how 'blockchains', currently one of the hottest tech disruption buzzwords, could affect the public sector, giving rise to new opportunities but also challenges.

DOC [EN](#) PDF

Friends of Europe: Smart (dis)investment choices in healthcare

The report entitled Smart (dis)investment choices in healthcare takes ideas and contributions from a diverse group of high-level stakeholders from throughout Europe, examining in-depth the complementary issues of smart investment in better health, and how to stop investing in health initiatives which are inefficient and outdated.

DOC [EN](#) PDF

Eurohealth: special issue to mark the 20th anniversary of the European Observatory on Health Systems and Policies (OBS)

This special issue offers a range of reflections arising from the Observatory's experience in assessing health systems, working with policymakers, and, ultimately, striving to address the very complex interface between evidence and policy practice. The issue contains various articles, including one on European integration and health policy, and another examining 20 years of health system reforms in Europe.

DOC [EN](#) HTML

OBS: Will population ageing spell the end of the welfare state? A review of evidence and policy options

This document reviews the main evidence on the health and long-term care costs associated with ageing populations, to better understand the expected cost pressures due to changing demographics.

DOC [EN](#) PDF

OBS: Ensuring access to medicines: how to stimulate innovation to meet patients' needs?

This policy brief, prepared for the Austrian Presidency of the EU, is part of a series on addressing market and policy failures in the pharmaceutical sector. It aims to inform discussions about stimulating more meaningful productivity in terms of R&D, and explores specific options for strengthening cooperation between the EU Member States in this context.

DOC [EN](#) PDF

FPS Social Security: The evolution of the social situation and social protection in Belgium 2018

This report, based on the European social indicators, shows that despite the many measures in place to prevent people being unable to access healthcare for financial reasons, unmet medical and dental needs have increased substantially over the last decade.

DOC [EN](#) PDF

OBS: reports on the Austrian, Bulgarian, Spanish and Estonian health systems

These analyses review recent developments in healthcare organisation, governance and financing, the provision of healthcare, health reforms and health system performance.

DOC 1 [EN](#) HTML | DOC 2 [EN](#) HTML | DOC 3 [EN](#) HTML | DOC 4 [EN](#) HTML

Court of Auditors: 2019 Work programme

The Court of Auditors' work programme for next year was published on Tuesday 16 October. The subjects on which an opinion is expected in 2019 include organic food, CAP income stabilisation, antimicrobial resistance, nuclear safety and cross-border healthcare.

DOC [EN](#) HTML

EESC: the new EU investment programme – InvestEU – should enhance the social dimension

According to an opinion from the European Economic and Social Committee (EESC), the InvestEU proposal put forward by the European Commission in the package of regulations on the future multiannual financial framework should contribute to strengthening investment activity in the EU, and thus innovation and job creation.

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

European Commission: 2019 Work programme

The European Commission presented its work programme for 2019, setting out three main priorities: reaching swift agreement on the legislative proposals already presented; adopting a limited number of new initiatives to address outstanding challenges; and presenting several initiatives looking towards a Europe of 27 which strengthen the foundations for a strong, united and sovereign Europe. The new initiatives include a Commission Recommendation to establish a format for the European electronic health record, and a Communication on a comprehensive European Union framework on endocrine disruptors.

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

“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/