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## 1 Public health

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### **Court of Auditors: audit on cross-border healthcare**

The European Court of Auditors is conducting an audit of cross-border healthcare arrangements in the EU. The auditors will examine the European Commission's monitoring and support for putting the EU legislation on cross-border healthcare access into effect, the results achieved to date for patients, and the effectiveness of the EU funding framework and of the actions funded.

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### **Expert group on health systems performance assessment: report on primary care**

This report, entitled 'A new drive for primary care in Europe: rethinking the assessment tools and methodologies', examines the essential aspects of high-performing primary care systems, emphasising key functions such as access, coordination and continuity of care.

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### **European Commission: study on cross-border cooperation in healthcare**

This study, entitled 'Study on cross-border cooperation: capitalising on existing initiatives for cooperation in cross-border regions', maps the EU-funded cooperation initiatives carried out over the period 2007-2017 in the EU and EEA countries and in Switzerland. It describes the opportunities and challenges related to healthcare-related cross-border cooperation, and offers some advice to local and regional authorities, and to other parties interested in launching a healthcare cooperation project.

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

### **European Commission: stronger cooperation against diseases preventable by vaccine**

The European Commission presented twenty measures to step up the fight against diseases which can be prevented by vaccines. Its proposal, taking the form of a recommendation, focuses on three main pillars for action: (1) tackling vaccine hesitancy and improving vaccination coverage; (2) establishing sustainable vaccination policies in the EU and; (3) improving EU coordination and its contribution to global health.

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### **European Parliament: concern about the fall in vaccination rates in Europe**

The European Parliament notes with concern that epidemiological data show important gaps in the acceptance of vaccines, and that vaccination coverage rates are insufficient to ensure adequate protection of the public against diseases which can be prevented by vaccination.

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### **European Commission: health policies in the future EU budget**

The European Commission adopted a legislative proposal for a new European Social Fund + (ESF+) programme, based on the proposed multiannual financial framework for 2021-2027. The ESF+ will include the financing of health-related activities, which will replace the specific health programmes of the previous periods (2003-2007 and 2008-2013). The health strand of the ESF programme aims to support public health policies and access to medicinal products.

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➤ **EXPH: mandate on vaccination programmes and health systems in Europe**

The Expert Panel on Effective ways of Investing in Health (EXPH) will review information on the effectiveness and efficiency of different vaccination programmes; identify and characterise the main factors (enablers and obstacles) influencing the outcomes in vaccination uptake and; select and assess measures and actions that can be expected to improve vaccination coverage.

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➤ **EXPH: mandate to assess the impact of the digital transformation of health services**

The Expert Panel opinion on assessing the impact of digital transformation of health services should support EU Member States in their decision-making in the domain of health, social and fiscal policies. The opinion should also help the Commission to shape further activities to improve uptake of digital health services at the EU level.

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➤ **EXPH: request for an opinion on application of the European Reference Networks (ERN) model outside the area of rare diseases**

The Expert Panel opinion on application of the ERN model in cross-border European cooperation to areas outside the field of rare diseases should help prepare future calls for new networks, by presenting the possibilities, outcomes and expected difficulties of broader cooperation.

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➤ **EPF-EPHA: joint statement on the EC's proposal for a multiannual financial framework post-2020**

The European Patients' Forum (EPF) and the European Health Alliance (EPHA) signed a joint statement on the EC's proposal for a multiannual financial framework post-2020. They are pleased to see that the Commission is planning for continued investment in health.

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➤ **BEUC: future EU health programme urgently needs financial support**

In a letter sent to Commissioner Andriukaitis, BEUC recalls that an ambitious European health policy will be crucial to address the challenges and meet the health-related expectations of European citizens. A future health programme is the best way for the EU to demonstrate to its citizens that it provides the overall population with tangible benefits.

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## 2 Health care services in the internal market

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➤ **European Parliament and Council: provisional agreement on the directive on a proportionality test before adoption of new regulation of professions**

Representatives from the European Parliament and the Council of the EU reached a provisional agreement on the directive on a proportionality test before adoption of new regulation of professions, obtaining a deal on the health sector. They agreed to allow Member States greater leeway to introduce restrictive rules on the health professions.

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➤ **European Commission: mobility of health professionals**

Social Agenda no. 51 focuses on the free movement of workers in Europe (pp 14 and 28) and presents the 2017 annual report (published in March 2018) on labour force mobility within the EU. This report provides and analyses the most recent figures, and reveals that

Member States do not make greater use of health professionals (doctors, nurses and personal care workers) coming from other Member States than they do of professionals from other sectors.

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### 3 Medicines and medical devices

#### **European Commission: more flexible intellectual property rules in the pharmaceutical sector**

The European Commission announced a targeted amendment of the regulation on Supplementary Protection Certificates (SPCs) for medicines (Regulation 469/2009). This proposal would introduce a waiver for manufacturers of generic and biosimilar medicines produced for non-European markets. Under the amended regulation, European manufacturers will be able to avoid losing their international market share, and can prepare for the surge in international competition expected to take place on the internal market between now and 2020, when many patents will expire.

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#### **European Commission: study supporting the evaluation of the European Medicines Agency fee system**

The Commission has launched a public consultation as part of a study supporting the evaluation of the fee system used by the European Medicines Agency (EMA) for the authorisation and monitoring of medicinal products for human and veterinary use. Responses to the consultation will help the study team to assess the extent to which the EMA's current fee system is fair, proportionate and cost-based.

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#### **European Commission: according to a public consultation, EU legislation makes blood, tissues and cells safer**

The open public consultation evaluating the EU legal frameworks on blood, tissues and cells has found that the majority of the respondents, who included both individual citizens and various groups, such as professional societies, donor and patient organisations and national authorities, consider that the legislation has made blood, tissues and cells safer in the EU.

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#### **European Commission: technical expert seminar on pharmaceuticals-related matters, following UK withdrawal**

The pharmaceutical sector is concerned about the prospect of Brexit. According to this report, drafted at an expert meeting, many authorisation documents currently in circulation will not function properly once the UK leaves the EU. The main problem highlighted at the technical meeting was that pharmaceutical companies are not properly prepared for Brexit. The report also took stock of the situation concerning medicines.

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#### **European Commission: study on the economic impact of pharmaceutical incentives and rewards in Europe**

This study, produced by Copenhagen Economics, gives an overview of existing pharmaceutical incentives, and provides economic evidence of the way in which supplementary protection certificates and the protection of regulatory data work in practice, as well as pointing to their overall impact on innovation, availability and accessibility of medicines.

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### European Parliament: publication of the draft report on health technology assessment (HTA)

The European Parliament's Committee on the Environment, Public Health and Food Safety (ENVI) published its draft report on health technology assessment (HTA). The draft report, drawn up by Soledad Cabezon Ruiz (S&D), includes stricter requirements on the transparency of data to be used for clinical assessment.

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### European Parliament: briefing paper on the Commission's proposal on cooperation in health technology assessment

This briefing paper from the European Parliament's Think tank discusses the Commission's proposal for a regulation on health technology assessment (HTA). The proposal covers new medicines and certain medical devices, and would provide the basis for permanent EU-cooperation in four areas: joint clinical assessments, joint scientific consultations, identification of emerging health technologies and voluntary cooperation on other aspects of HTA.

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### EMA: PRIME: a two-year overview

This report presents the results of the first two years of PRIME (the Priority Medicines scheme). It explains how the eligibility criteria for the scheme have been applied, and the types of support that applicants have received to date.

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## 4 e-Health

### European Commission: measures to stimulate investment in the artificial intelligence (AI) sector

The Commission presented a series of measures aiming to stimulate investment in the AI sector and to set ethical guidelines. It is calling on European companies and governments to invest in the sector, giving priority to health. AI can be used in the field of healthcare, e.g. by helping to diagnose diseases more accurately, allowing surgeons to operate on patients more precisely and reducing post-surgery trauma.

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### European Commission: increasing the availability of data and promoting the sharing of healthcare data

The Commission has announced its short-term projects to promote the sharing of patient data. Its Communication is based around three main aims: ensuring that sick patients can have access to their health records when abroad, encouraging Member States to cooperate in a move towards equivalent levels of data processing capacity, and promoting new technologies to emphasise prevention.

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### European Commission: artificial intelligence, start of the work to marry cutting-edge technology and ethical standards

The Commission has set up a group on artificial intelligence to gather expert input and rally a broad alliance of stakeholders. The group will draw up a proposal for guidelines on AI ethics.

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### European Commission: study on the Silver Economy

This study, produced by Technopolis and Oxford Economics, examines the challenges and opportunities involved in developing the Silver Economy (the part of the economy relevant to the demands and needs of the over-50s) in Europe. 10 case studies were carried out, concerning areas in which there is strong potential for growth, including that of connected health. The study shows that in the next 10 years, national health services in Europe will have to invest massively in connected health systems, in services such as medical records and on-line prescriptions.

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### Digital Day 2018: 13 states commit to delivering cross-border access to their genomic information

The declaration sets out a threefold aim: to bring together fragmented infrastructure and expertise; to leverage and maximise the investments already made by Member States at national and EU level, particularly in sequencing, bio banking and data infrastructure; to reach a larger cohort, which will provide sufficient scale for new, clinically impactful research.

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### European Commission: synopsis report of the public consultation on Digital transformation of health and care in the context of the Digital Single Market

The results of the public consultation on the digital transformation of health and care in the context of the digital single market (20 July - 12 October 2017) are now available. 1464 responses were received from the 28 EU Member States and 7 other countries.

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### European Commission: letter from the Chair of the Article 29 Working Party to the mHealth network

The European Commission's 'Article 29' working party, made up of experts responsible for interpreting the provisions of the data protection legislation, has sent a letter to the mHealth network. The letter follows a request from the network for a legal assessment of the European interoperability framework developed recently for online cross-border health information services.

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### European Commission: best eHealth practices funded by the EU

The best practice portal on health promotion, disease prevention and management of non-communicable diseases is now online. It brings together good practices collected in previous EU Health Programme actions in the following areas: nutrition, physical activity, mental health, health inequalities, reducing alcohol-related harm, and integrated care.

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## 5 Social policy

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### EESC: Europe needs a proactive policy for the long-term care sector

The EESC held the second of its meetings on the live-in care sector in the EU, revealing dire conditions of care workers employed in German households.

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**European Commission: strengthening the link between the ESF+ and the European Semester after 2020**

The European Commission presented the future regulation governing the distribution of the European Social Fund +. The Commission wished to strengthen the link between the European Social Fund post-2020 and the country-specific recommendations coming from the European Semester, while leaving considerable scope for flexibility during negotiations. The Commission has chosen to merge five funds: the European Social Fund, the Youth Employment Initiative, the Fund for European Aid to the Most Deprived, the EU Programme for Employment and Social Innovation (EaSI), and the EU Health Programme.

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**European Commission: proposal for a Council recommendation on access to social protection**

The Commission has presented a proposal for a Council recommendation on access to social protection for workers and the self-employed. In line with the European Pillar of Social Rights, the proposal aims to set a direction for Member States to support access to social protection for all workers and self-employed, in particular for those who, due to their employment status, are not sufficiently covered by social security schemes.

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**Council of the EU: conclusions on the 2018 Annual Growth Survey and Joint Employment Report**

The Council adopted conclusions on the 2018 Annual Growth Survey and the Joint Employment Report. Access to healthcare is one of the issues addressed in these documents.

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## 6 Economic policy

**Council of the EU: ex ante conditionalities and performance reserve in Cohesion**

The Council adopted conclusions on the special report from the European Court of Auditors, 'Ex ante conditionalities and performance reserve in Cohesion: innovative but not yet effective instruments'. Healthcare reforms have also been made subject to ex ante conditions.

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**European Commission and ECB: statement following the fourth post-programme surveillance mission to Cyprus**

European Commission staff, in liaison with staff from the European Central Bank (ECB), visited Cyprus to carry out the fourth post-programme surveillance (PPS) mission. The mission encouraged the authorities and other stakeholders to step up progress in essential areas, including implementation of the national healthcare system in a fiscally-sustainable way.

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**European Commission: a modern budget for a Union that protects, empowers and defends**

The European Commission has proposed the creation of two new budgetary instruments, designed to enhance stability and economic convergence within the Economic and Monetary Union. One of these is a new Reform Support Programme, which, with an overall budget of € 25 billion, will provide financial and technical support to all Member States for the pursuit of priority reforms, particularly in the context of the European Semester. These measures will have been discussed in a dialogue between the Member States and the Commission, on the basis of the country-specific recommendations.

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🔵 **European Commission: country-specific recommendations on health put to 12 Member States in the context of the European Semester**

The Commission adopted proposals for country-specific recommendations on health in the context of the European Semester. The Commission recommended to 12 Member States (AT, BG, CY, FI, IE, LT, LV, MT, PT, RO, SI, SK) that they improve the efficiency of their national health systems, increase their accessibility and strengthen their resilience.

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🔵 **European Commission: communication on the European Semester and the country-specific recommendations**

This communication sets out the main objectives of the 2018 recommendations, as well as reporting on the progress made in implementation of the previous recommendations. It reports that in the fields of health and long-term care, limited progress has been made on implementation.

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🔵 **European Commission: 2018 Ageing Report– Economic and budgetary projections**

The report shows that long-term care and healthcare costs are expected to contribute the most to the rise in age-related spending, increasing by 2.1 percentage points. Public spending on pensions is expected to rise until 2040, before returning to close to current levels by 2070. Spending on education is forecast to remain at the same level until 2070, while unemployment benefit expenditure is expected to decline by 0.2 percentage points.

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🔵 **European Commission: country-specific recommendation to Belgium on long-term care**

The Commission has called upon Belgium to contain the projected increase in long-term care expenditure. According to the Commission, long-term care expenditure is expected to increase, from an average which is already above 2.3% of GDP to 4.0% of GDP by 2070. Reducing the fragmentation in the organisational landscape of long-term care due to the distribution of competences across various administrative levels, has the potential to increase the efficiency of spending in this area.

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🔵 **EIB: 24 million euros for a new medical centre at the Medical University of Warsaw**

The Medical University of Warsaw is receiving a 100 million PLN (24 million euro) loan from the European Investment Bank (EIB) to modernise key elements of its main Warsaw campus. The project consists of the design, construction and implementation of a state-of-the-art new medical simulations centre on WUM's main campus in Warsaw. The new centre will be used for training and research.

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🔵 **EIB: 20 million euros to the innovative company MedinCell**

This 20 million euro loan will enable MedinCell to develop new controlled, long-acting injectable treatments to significantly enhance patient care and quality of life.

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🔵 **EIB: expanded financing for care properties in Finland**

The European Investment Bank (EIB) and Finnish care facilities provider Hoivatilat have agreed on 50 million euros of long-term financing. This loan will support the construction of 58 new care establishments, particularly homes for the elderly and day-care facilities. Hoivatilat's activity covers almost 95% of the Finnish population.

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## **European Parliament: question on reimbursement of the Greek pharmaceutical sector**

A Greek MEP has asked the Commission how patients' access to innovative medicines will be affected if companies decide to no longer launch their products in Greece, following measures taken under the supplementary memorandum of understanding of the third bailout agreement between Greece and its creditors.

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## **7 Competition**

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### **Finnish competition and consumer authority: health service marketing promotes competition and customers' freedom of choice**

The FCCA, the Finnish competition and consumer authority, has been studying how health service marketing is currently regulated and what kinds of challenges the reform of health and social services is creating for this type of marketing.

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### **Finland: Tradeka-Yhtiöt Oy's acquisition of Med Group Holding Oy**

The Finnish competition and consumer authority (FCCA) has approved Tradeka-Yhtiöt Oy's acquisition of Med Group Holding Oy. The companies owned by Tradeka-Yhtiöt Oy are active in the restaurant business, investment activities and press distribution. Med Group Holding Oy is active in the Finnish social welfare and healthcare sector. Med Group business areas include home care services, emergency care, public healthcare and private oral healthcare.

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## **8 Court of Justice of the European Union**

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### **Judgment: annulment of an EMA decision on an orphan medicinal product**

In case T-80/16, between Shire Pharmaceuticals Ireland Ltd and the European Medicines Agency (EMA), the General Court of the EU annulled the European Medicines Agency (EMA) decision of 15 December 2015, refusing to validate the application submitted by Shire Pharmaceuticals Ireland Ltd seeking the designation of Idursulfase-IT as an orphan medicinal product.

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### **Judgment: clarification of the conditions for obtaining subsidiary protection in the EU**

In case C-353/16, the Court decided that a person who had been tortured by the authorities of his country of origin is eligible for 'subsidiary protection' if there was a real risk of him being intentionally deprived, in his country of origin, of appropriate physical and psychological care.

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• **Judgment: training criteria for persons entrusted with assessing the safety of cosmetics for human health**

In case C-13/17, the Court decided that, as part of the equivalence regime for the training of persons entrusted with assessing the safety of cosmetics for human health, a Member State may determine disciplines that are 'similar' to medicine, pharmacy or toxicology, as long as the course results in a qualification which guarantees a high level of protection of human health.

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• **Opinion: a Catholic Head of Department of a Catholic hospital may not be dismissed because of his divorce and remarriage**

In the opinion of the Advocate-General in case C-68/17, the principle of equal treatment means that respect for the indissolubility of marriage cannot be understood as constituting a real occupational requirement for a Catholic Head of Department employed by a Catholic hospital.

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• **Judgment: decentralised procedure for marketing authorisation for a medicinal product**

The Court issued a judgement in case C-557/16, between Astellas Pharma GmbH and the Finnish medicines agency, concerning a marketing authorisation for a generic medicine. It found that, in accordance with Directive 2001/83/EC on the Community code relating to medicinal products for human use, as part of a decentralised procedure for issuing a marketing authorisation to a generic drug, the competent authority of a Member State concerned by that procedure cannot itself determine the point in time from which the data exclusivity period for the reference medicinal product starts to run, when adopting its decision on the placing on the market of that generic medicinal product in that Member State.

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• **Judgment: details on public contracts**

Case C-65/17 involves Oftalma Hospital Srl, and, on the other side, the Commission of Waldensian Hospital Institutions (CIOV), Italy, and the Piemonte Region. It concerns remuneration for care provided by Oftalma under a contract concluded with the CIOV. The Court found that a contracting authority, when it awards a public service contract that falls within the scope of Article 9 of Directive 92/50/EEC, must comply with the principles of equal treatment and non-discrimination on the grounds of nationality, and the consequent obligation of transparency, provided that, on the date of its award, the contract had certain cross-border interest, which it is for the referring court to verify.

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## 9 Infringement proceedings

• **European Commission: referral of Italy to the Court over the transposition of certain technical requirements on testing of human tissues and cells**

The Commission has decided to refer Italy to the Court of Justice for its failure to notify the national transposition measures for EU rules amending the existing requirements applicable to the testing of human tissues and cells (Commission directive 2012/39/EU). Italy has still not notified the Commission of the national legal measures taken to transpose this directive, despite a formal request to do so, dated 17 June 2014.

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**Parallel trade in medicines: the Commission closes infringement proceedings and complaints against Poland, Romania and Slovakia**

The European Commission has closed its infringement proceedings and the treatment of complaints concerning parallel trade in medicines for human use against Poland, Romania and Slovakia. Following a detailed examination, the Commission decided that there is a need to look for ways other than infringements to adequately resolve this complex situation, in order to swiftly and efficiently deal with an issue that might have a negative impact on the health of European citizens.

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**Professional qualifications: the Commission asks France to change its practices regarding psychomotor therapists trained in Belgium**

The Commission is sending a reasoned opinion to France, requesting that it change the way in which it regards psychomotor therapists trained in Belgium. The French authorities refuse to recognise these qualifications, on the grounds that in Belgium, unlike in France, the profession is not classified as a health profession. This practice by France does not respect the directive on recognition of professional qualifications.

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

## 10 Publications

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**European Observatory on Health Systems and Policies: Organization and financing of public health services in Europe. Country reports**

This book compares the experiences of nine European countries (UK, FR, DE, IT, NL, SI, SE, PL and the Republic of Moldova), in the ways they organise, finance and staff their public health services. The book presents the main structures, examines common trends and depicts the major differences between the countries.

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**General Medical Council: Regulatory approaches to telemedicine**

Europe Economic was commissioned by the General Medical Council (UK) to examine the regulatory approaches to telemedicine in the world. The aim of this work is to understand how the various regulators define telemedicine, the types of requirements they impose on doctors, and how they deal with situations where doctors falling under another jurisdiction may provide medical services remotely to patients.

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## 11 Miscellaneous

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**Brexit: potential consequences for the NHS**

This report, Brexit et le NHS, argues that while the NHS already faces funding pressures, these might increase as a result of leaving the EU. Brexit might reduce the funds available for healthcare, which will have direct knock-on effects on waiting times, recovery rates and quality of care.

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