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## 1 Health care services in the internal market

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### **European Commission: consultation on introducing the European Professional Card (EPC) for health professionals**

The European Commission is launching a project to consult health professionals on the European Professional Card (EPC). This card is a key element of the amended directive on the recognition of professional qualifications, which is to be implemented in the EU Member States by 18 January 2016.

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### **European Commission: overview of the regulated professions in the various Member States**

The amended directive on the recognition of professional qualifications obliges Member States to send the Commission a list of the regulated professions in their countries and to evaluate the justification for and proportionality of the rules in place. In this context, the interactive map shows the most important information on the regulation of professions in the various Member States.

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### **United Kingdom: language checks on European doctors**

Under the current British legislation, the General Medical Council cannot carry out language assessments on doctors from other countries in the European Economic Area. The changes will require doctors from these countries to provide evidence of their English skills or undergo a language assessment, if there are doubts as to their abilities to communicate effectively with their patients.

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### European Commission: recognition of a medical specialisation

A Romanian doctor, specialised in rehabilitation medicine, submitted a petition for recognition of her specialisation in the United Kingdom. The European Commission found in favour of the country. Member States are not at all obliged to include particular medical specialisations on the list of specialities covered by the automatic recognition regime.

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## 2 Medicines and medical devices

### European Commission: study of the policy mix for the reimbursement of medicinal products

The objective of this study is to investigate and analyse which policy mixes related to the reimbursement of medicines have been judged the best by stakeholders.

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### European Commission: report on the external reference pricing of medicinal products

The European Commission has published a report on the external reference pricing of medicinal products. Under this practice, the price of a medicine in one or several countries is used for the purposes of setting or negotiating the price of the product in another given country. The main objective of the report, which covers all the 28 EU Member States, is to identify and assess ERP cross-country coordination issues.

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### European Commission: regulation complementing the legislation on post-authorisation measures for medicines

A delegated act specifies the situations in which post-authorisation efficacy studies are required.

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### New legislation adopted on clinical trials

The European Parliament and the Council adopted the proposal for a regulation on clinical trials on medicinal products for human use. The purpose of this new legislation is, in particular, to facilitate cooperation between Member States. Pharmaceutical companies and academic researchers will have to post the results of their clinical trials on a publicly accessible on-line data base.

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### European Parliament: regulations on medical devices and in vitro devices

Stricter monitoring and certification procedures for medical devices, such as breast or hip implants, were agreed on by Parliament. However, due to the lack of agreement in the Council, the co-legislators were unable to begin tripartite discussions before the European elections.

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### European Parliament: e-cigarettes regulated as medicinal products

Under the new tobacco directive adopted by the European Parliament, e-cigarettes will be regulated as medicinal products if they are marketed as a tool to stop smoking.

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### Adoption of a regulation on access to genetic resources

A regulation was adopted on compliance measures for users from the Nagoya Protocol on

access to genetic resources and the fair and equitable sharing of benefits arising from their utilisation in the Union. This regulation will apply to pharmaceutical industries in particular.

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#### European Medicines Agency (EMA): new fee incentives for SMEs

The purpose of these new fees is to support SMEs that are developing medicines. They will apply to post-authorisation activities.

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#### EMA: report on pharmacovigilance activities

The European Medicines Agency (EMA) has presented to the European Commission its first report on the tasks it carried out during the first year of implementation of the EU's new pharmacovigilance legislation.

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#### Innovative Medicines Initiative 2 (IMI 2) adopted

The second innovative medicines initiative (IMI) legislation was approved by the EU Member States. With a €2 billion euro budget, IMI supports collaborative research projects and builds networks of industrial and academic experts for pharmaceutical research and development (R&D) in Europe.

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#### European Ombudsman: EMA policy on publication and access to clinical trial data

The European Ombudsman has written to the European Medicines Agency (EMA) to express his concern about a significant change to the transparency policy for clinical trial data.

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### 3 Public health

#### European Commission: Communication on effective, accessible and resilient health systems

In this communication, the Commission proposes to apply the results of the health systems performance assessment, to develop an EU agenda to address the issues impacting the quality of care, and to exchange experiences on reducing dependence on hospital care. It asks for better planning concerning the health workforce and for a more cost-effective use of medicines. The Commission intends to develop a more ambitious structure to support cooperation on HTA and to support Member States in establishing an integrated EU health information system.

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#### European Commission: public consultation on the organisation of primary care

The European Commission and the Expert Panel on Effective Ways of Investing in Health (EXPH) have launched a public consultation on the definition of a frame of reference in relation to primary care, with a special emphasis on financing systems and referral systems. The opinion should provide guidance to countries making efforts to improve the organisation and sustainability of their health systems.

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#### Expert Panel on Effective Ways of Investing in Health (EXPH): three opinions

The EXPH has issued its first three opinions:

- Definition of a frame of reference in relation to primary care.
- Definition and endorsement of criteria to identify priority areas when assessing the performance of health systems.

- Health and economic analysis for an evaluation of the public-private partnerships in health care delivery across Europe.

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#### **European Commission: enhanced AIDS action plan 2014-2016**

This strategy, developed by the EU and neighbouring countries, aims at improving the coverage of prevention measures, voluntary testing, and early treatment in the event of infection.

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#### **EU Health Programme 2014-2020 adopted**

The 3rd EU Health Programme has been published. This programme is based on four objectives: 1) promoting health and preventing disease, 2) protecting citizens from serious cross-border health threats, 3) contributing to innovative, efficient and sustainable health systems, and 4) facilitating access to better and safer health care.

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#### **European Commission: mid-term review of the action plan on organ donation and transplantation (2009-2015)**

The Commission's report points to a clear increase in the number of transplants carried out in Member States between 2007 and 2012, despite the differences remaining between countries. The Commission wishes to strengthen the action plans by 2015.

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#### **European Commission: joint purchasing of vaccines and medicines**

The Commission concluded a joint procurement agreement to enable all EU countries to procure pandemic vaccines and other medical counter-measures as a group, rather than individually.

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#### **Transatlantic Task Force on Antimicrobial Resistance (TATFAR): report**

The report describes the progress made during the first TATFAR implementation period, 2011 - 2013. It renews the commitment of US and EU health authorities to pursue specific goals in their joint battle against antimicrobial resistance.

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#### **Informal Health Council**

During this informal meeting, Health Ministers proposed an exchange of good practice and information in a number of areas, including the cost and pricing of pharmaceutical products, the basket of basic health care services mainly covering the most vulnerable groups, investing in prevention and health care cost reduction, and health systems performance assessment. The deeper involvement of health issues and Health Ministers in the European Semester was also a topic of discussion.

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#### **Informal Council: migration and public health**

The Health Ministers of the Member States decided that the Health Security Committee (HSC) should make recommendations with respect to 'when, how and for what diseases' migrants should be screened. The overall intent is to focus on prevention of infectious diseases.

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#### **Conference: European joint action on health workforce planning and forecasting (JA EUHWF)**

This collaborative project includes most EU Member States, several international bodies, and federations representing health professionals. During the conference, the main objectives of the project and the minimum conditions for planning data were officially presented.

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#### **European Commission: Decisions concerning the setting up of European Reference Networks (ERNs)**

Two decisions came into force concerning ERNs between health care providers and centres of expertise in the EU Member States:

- A delegated decision that sets out criteria and conditions to be fulfilled by networks and health care providers wishing to join an ERN.
- Another decision that sets out criteria for establishing and evaluating ERNs and their members and for facilitating the exchange of information and expertise on establishing and evaluating the networks.

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## **4 e-Health**

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#### **European Commission: situation of e-Health**

The European Commission carried out two surveys of doctors and hospitals to assess the use of e-Health.

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#### **European Commission: consultation on mobile health**

The Commission is launching a green paper and call for responses on mobile health. The consultation concerns the use of mobile devices such as mobile phones, tablets, patient monitoring devices and other wireless devices.

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#### **Seven European regions join the 'BeyondSilos' project**

The BeyondSilos project, an initiative co-funded by the European Union, uses new technologies to support the provision of social care and health care services to elderly people in Northern Ireland, Bulgaria, Spain, Italy, Portugal and Germany. The project has an overall budget of 5.47 million euros.

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#### **European Commission: launch of a project for the deployment of integrated care**

The INCA project aims to coordinate the social and health services provided by different administrations. The purpose of this initiative, supported by the European Commission, is to provide innovative solutions in the treatment of chronic diseases.

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## **5 Social policy**

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#### **European Commission: national social reports for 2014**

The Commission is beginning to publish the 2014 national social reports (NSR). These reports are part of the social Open Method of Coordination (OMC) process and add to the national reform programmes (NRP). They provide information on social welfare policy, on the

basis of shared OMC objectives in the areas of social inclusion, pensions, health care and long-term care.

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The Belgian NSR was also published in Dutch and French:

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#### **Council: conclusions on the 2014 Annual Growth Survey and the Joint Employment Report**

The EPSCO Council adopted conclusions on the 2014 Annual Growth Survey and the Joint Employment Report, thus giving guidance in the area of employment and social policy. With regard to health care, the Council called on Member States to carry out reforms to improve the accessibility, quality, effectiveness and sustainability of health care services.

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#### **Social Protection Committee (SPC): assessment framework in the area of health**

The SPC Indicators Sub-Group drew up a report on the development of an assessment framework for the health sector, based on the Joint Assessment Framework (JAF) methodology.

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#### **Council: conclusions on the social situation in the EU**

The Council of Social Affairs Ministers took note of the report from the Social Protection Committee on the social situation in the EU. Relevant conclusions were adopted.

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## **6 Economic policy**

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#### **European Commission: proposals for country-specific recommendations**

The 2014 European Semester is in full swing. The Member States have submitted their national reform programmes and their stability or convergence programmes, and the Commission has published its proposals for country-specific recommendations. These documents include reforms in the field of health care and long-term care.

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#### **Cyprus: first activity report from the support group**

This report, which covers the period between September and December 2013, presents the state of play in six key policy areas, including the social protection and health care systems. The initial technical assistance activities have been financed through the Union budget, notably through the European Social Fund and the European Regional Development Fund.

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#### **European Parliament: the role of the Troika in economic governance**

Two reports adopted by the Parliament assess the role and operations of the Troika in the euro area programme countries. The reports express regret that the programmes for Greece, Ireland and Portugal contain a number of detailed prescriptions on health system reform as well as expenditure cuts that have had an impact on the quality and accessibility of services. The Parliament regrets also that the programmes are not bound by the EU Charter of Fundamental Rights or by the provisions of the Treaties, notably Article 168(7) TFEU. It calls for a reassessment of the decision-making process of the Eurogroup so as to ensure appropriate democratic accountability in the implementation of the measures concerned.

### European Commission and European Central Bank: launch of the surveillance programme for Ireland

Following the completion of the EU/IMF financial assistance programme for Ireland, the surveillance programme for Ireland was launched. The statement released announced that further reforms in the health sector are still needed to improve budget control and tackle overspending on pharmaceuticals.

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### European Commission: guidance on ex-ante conditionalities for the European Structural and Investment funds 2014-2020

These conditions may apply in the areas covered by the country-specific recommendations, which the Member States receive as part of the European Semester and with which they must comply.

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### Task-force for Greece: sixth activity report

Greece receives, in particular, technical assistance for structural reforms in the health care sector, enabling it to implement the measures agreed upon in the economic adjustment programme.

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## 7 Court of Justice of the European Union

### Judgment: human blood derivatives

European legislation allows the maintenance or introduction of national provisions which make plasma prepared by a method involving an industrial process subject to a more rigorous regime than that to which medicinal products are subject solely with respect to its collection and testing.

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### Judgment: maternity leave for women who have had a baby through a surrogacy arrangement

EU law does not require that a commissioning mother who has had a baby through a surrogacy arrangement should be entitled to maternity leave or its equivalent. This principle applies even in circumstances in which the mother may breastfeed the baby following the birth or in which she is still breastfeeding the baby.

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### Judgment: value added tax on medicinal products

A supply of goods, such as the cytostatic drugs prescribed in the course of outpatient cancer treatment by doctors working in an independent capacity in a hospital, may not be exempt from value added tax, unless that supply is physically and economically indissociable from the principal supply of medical care.

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### Judgment: mutual recognition of professional qualifications

Member States may not require the holder of a professional qualification, subject to the mutual recognition of professional qualifications in accordance with Directive 2005/36/EC, to undertake a traineeship, or to prove that he possesses equivalent professional experience, in

order to be authorised to practise his profession. The court specified that the previous directive did include the option to require participation in further training, but the new professional qualifications directive has now removed that possibility.

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#### **Judgment: value added tax on the 'healthcare lump sum' paid to residential care homes for the elderly**

A lump sum payment, such as the 'healthcare lump sum' paid by a national sickness insurance fund, constitutes the consideration for the healthcare provided for consideration by a residential care home for the elderly to its residents, and, on that basis, falls within the scope of value added tax.

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#### **Judgment: the concept of 'medicaments' in the Regulation on the tariff and statistical nomenclature and on the Common Customs Tariff**

The term 'medicaments', within the meaning of this regulation, includes food preparations intended exclusively to be administered enterally (by means of a stomach tube) under medical supervision to persons who are receiving medical care, providing that that product is administered as part of the control of the disease or ailment affecting them in order to prevent or control their malnutrition.

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## **8 Competition**

#### **Commission approves acquisition of Phunciona by LBEIP, Global Vía Infraestructuras and Obrascón Huarte Laín in the Spanish health sector**

The Commission has cleared the acquisition of Phunciona Gestión Hospitalaria, S.A. in Spain by LBEIP (Holdco) B.V of The Netherlands and Global Vía Infraestructuras, S.A. and Obrascón Huarte Laín, S.A. (OHL), both of Spain. Phunciona manages and operates a public concession for the provision of non-health services to Hospital del Sureste, a public hospital in Madrid.

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#### **Italy: heavy fines for the two pharmaceutical companies Roche and Novartis**

The Italian competition authority imposed a fine totalling 182.5 million euros on the Swiss pharmaceutical giants Roche and Novartis for operating a cartel concerning Avastin, a drug to treat eye diseases. The pharmaceutical companies, it found, were attempting to boost sales of 'Lucentis, a far more expensive drug, by arguing on the basis of artificial differences between the two products', including by presenting Avastin to health services and doctors as a more dangerous product.

The European Consumer Organisation, BEUC, is calling upon the European Commission to carry out a similar investigation at European level.

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#### **Romania: fines imposed on companies active on the dental market**

The Romanian Competition Council has imposed fines totalling 102 613 € on five companies for agreeing on a maximum discount to be offered by Romanian distributors of certain dental products to their customers.

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#### **Sweden: call for fines to be imposed in the care and treatment sector**

The Swedish competition authority has called for fines to be imposed on three companies

active in the care and treatment sector - Diagnostik AB (Aleris), Capio St Görans Sjukhus AB (Capio) and Hjärtkärgruppen Sverige AB (Hjärtkärgruppen) - for collusion in public procurement bidding.

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#### **Germany: prohibition of the merger of hospitals in Esslingen**

The German federal cartel office has prohibited the town of Esslingen from merging the Esslingen district clinics with its clinical centre. According to the Bundeskartellamt, such a merger would lead to a substantial restriction in competition on the hospital markets of Esslingen and Kirchheim/Nürtingen.

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## **9 Infringement proceedings**

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#### **Denmark, Italy, the Netherlands and Slovenia: transposition of the pharmacovigilance directive**

The Commission is calling on four Member States to inform it of the measures taken to transpose the EU rules on pharmacovigilance.

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#### **France: Working time directive**

The European Commission has asked France to respect the rights of doctors in training to minimum rest periods and limits on their working hours, as required by the Working Time Directive.

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## **10 Miscellaneous**

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#### **Report from the Commission and the SCHER Scientific Committee: the impact of mercury in dental amalgam on the ecosystem**

The European Commission and the Scientific Committee on Health and Environmental Risks (SCHER) published a report asserting that mercury in dental amalgam could, in extreme local conditions, pose a risk to the ecosystem.

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#### **Report by civil society organisations: the TTIP would result in increased costs for medicines**

A report published by the Commons Network and civil society partners states that the pharmaceutical industry's wish-list for the EU/US Transatlantic Trade and Investment Partnership (TTIP) would, notably, increase the cost of medicines. Transparency for clinical trials would also be restricted.

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#### **European Commission: position on pharmaceutical products in the TTIP negotiations**

The European Commission is publishing negotiating positions on five topics following negotiations with the US on a free trade agreement, the TTIP. These include an EU position on pharmaceutical products.

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➤ **Commission consultation: tax exemptions in the public interest**

The Commission is organising a consultation to review existing VAT legislation on public bodies and tax exemptions in the public interest. This document also concerns health services.

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➤ **European Parliament: a European Citizens' Initiative calls for the protection of human embryos**

The 'One of Us' initiative has exceeded in 18 Member States the minimum number of signatures required for a European Citizens' Initiative. The organisers are calling upon the European Union to ban and bring to an end the financing of activities that presuppose the destruction of human embryos. In its response, the Commission rejects this demand.

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➤ **European Parliament: general data protection regulation**

The European Parliament has adopted the revised European legislation on data protection. Specific provisions apply to medical data.

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➤ **OECD: health spending continues to stagnate in many countries**

This report highlights the most recent trends in health spending.

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➤ **International conference on the occasion of the 50th anniversary of the Belgian Statutory Health Insurance Act**

This conference considered the future of health insurance in Europe, particularly the issue of the concepts of solidarity and accountability. The presentations are available online.

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➤ **European Ombudsman: investigation opened into the composition of the Commission's expert groups**

The European Ombudsman, Emily O'Reilly, has opened an investigation into the composition and transparency of the Commission's expert groups. She is asking interested persons and organisations for feedback on how balanced the representation of relevant areas of expertise and interests is in different groups, how transparent the groups are and how well the application procedures work.

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➤ **European Commission: guidance on European Structural and Investment Funds 2014-2020**

The European Commission has published its theme-by-theme guidance for the European structural and investment funds, including for investments in the health sector.

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Editor: Rita Baeten  
E-mail : [baeten@ose.be](mailto:baeten@ose.be)  
Website: <http://www.ose.be>

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