

## 1 Medicines and medical devices

---

- New Commission: responsibility for medicines stays with the Commissioner for Health, and medical devices will be transferred to DG Enterprise
- EMA: new policy on publication of clinical data
- EPSCO Council: progress report on two draft regulations concerning medical devices and in-vitro diagnostic medical devices
- European Commission: final opinion on the safety of metal-on-metal joint replacements, with a particular focus on hip implants

## 2 Public health

---

- European Commission: report on the impact of information on patients' choice
- European Commission: implementation report on the 'Commission communication on rare diseases: Europe's challenge'
- HTA Network: new strategy for EU cooperation on health technology assessment
- Launch of the 4th European Code against cancer
- European Commission: implementation report on actions to address Alzheimer's disease
- EPSCO Council: Luxembourg raises the issue of admissibility criteria for certain blood donors
- EPSCO Council: vaccinations as an effective tool in public health
- EPSCO Council: conclusions on patient safety and quality of care, including the prevention and control of healthcare associated infections and antimicrobial resistance
- EPSCO Council: conclusions on care quality and innovation for the benefit of patients
- Mission letter to Vytenis P. Andriukaitis, Commissioner responsible for Health
- EXPH: opinion on a future EU agenda on quality of healthcare, with a special emphasis on patient safety
- OECD and European Commission: Health at a Glance, Europe 2014
- EPSCO Council: contribution of the health sector to the EU2020 objectives
- Council of the EU: statistics on healthcare expenditure and financing
- ECDC: increase in AIDS cases among risk-groups in the EU

## 3 Social policy

---

- EPSCO Council: equal treatment directive shelved
- EPSCO Council: mid-term review of the Europe2020 strategy, including an evaluation of the European Semester
- European Commission: draft joint employment report 2015
- European Commission: public consultation on working time
- European Commission and SPC: adequate social protection for long-term care needs in an ageing society

- SPC: review of recent social policy reforms for a fair and competitive Europe
- SPC and EMCO: joint opinion on the Europe 2020 strategy mid-term review
- European Commission: report on population ageing in Europe - facts, implications and policies

#### **4 E-Health**

---

- European Commission: overview of national laws on electronic health records
- The European Commission and the European data industry launch a €2.5 billion partnership to master big data
- eHealth network: adoption of guidelines on ePrescriptions

#### **5 Economic policy**

---

- European Parliament: the EP calls for a stricter and more democratic follow-up to the economic and budgetary policy country-specific recommendations
- EFC and EPC: mid-term review of the Europe 2020 strategy
- European Commission: identifying fiscal sustainability challenges in the areas of pension, healthcare and long-term care policies
- European Commission: are Member States responding to the European Semester country-specific recommendations?
- European Commission and Economic Policy Committee: 2015 ageing report - underlying assumptions and projection methodologies
- Latvia: sixth post-programme surveillance mission
- Latvia: benefits of the Euro and new challenges
- Ireland: second post-programme surveillance mission
- European Commission: annual growth survey 2015
- European Commission: 2015 draft budgetary plans of seven Member States at risk of non-compliance
- Mission letter from Jean-Claude Juncker to Valdis Dombrovskis, Vice-president for the Euro and social dialogue

#### **6 Court of Justice and General Court of the European Union**

---

- CJEU judgment: an ovum which is not capable of developing into a human being can be patented
- CJEU judgment: reimbursement of medical expenses incurred in another Member State
- CJEU judgment: right of a marketing authorisation holder for a reference medicinal product to oppose the marketing authorisation of a generic
- CJEU judgment: rules for calculating compensation for accidents at work unfavourable to male workers
- CJEU judgment: emergency ambulance services and cost containment
- CJEU judgment: exclusion of a public hospital from participating in tendering procedures for the award of public contracts
- GCEU judgment: the Court finds against the French Ordre national des pharmaciens for restricting competition on the clinical biology analysis market
- Opinion: method of calculating permanent invalidity pensions, reducing the amount due to part-time workers, and thus introducing discrimination on the grounds of gender, contrary to

EU law.

- Opinion: manufacturer liable for defective medical devices and damage caused by personal injury
- EFTA: letter of formal notice to Norway concerning the criteria for access to in-patient treatment in other EEA states

## **7** Competition

---

- European Commission: publication of the 5th report on the monitoring of patent settlements in the pharmaceutical sector
- Mergers: Commission approves acquisition of Covidien by Medtronic, subject to conditions
- Mergers: the Commission approves IMS Health's acquisition of parts of Cegedim, subject to conditions
- State aid: the Slovak system of compulsory health insurance involves no state aid
- State aid: in-depth investigation into part of the public financing of Brussels public IRIS hospitals
- Germany: the Bundeskartellamt strengthens competition in the sale of blood glucose strips in Westphalia-Lippe
- Bulgaria: the Commission for the Protection of Competition has recommended broader representation of interested parties in the adoption procedure for regulatory acts in healthcare
- France: the Competition Authority fines Cegedim for abusing its dominant position and refusing to sell medical information databases to pharmaceutical laboratories
- Netherlands: merger of healthcare providers Kwadrantgroep, Antonius Zorggroep en Nij Smellinghe/Pasana can go ahead

## **8** Infringement proceedings

---

- Netherlands and Portugal: full transposition of the rules on patients' rights in cross-border healthcare
- Czech Republic, Romania and Slovenia: full transposition of the rules on patients' rights in cross-border healthcare
- Romania: full transposition of the rules on the recognition of prescriptions delivered in another Member State

## **9** Miscellaneous

---

- European reference networks: conference report
- Council: partial agreement on the protection of administrative data
- Eurostat: cancer responsible for one in four deaths in the EU28 in 2011
- Eurofound: report on access to healthcare in times of crisis
- OECD: Health, Austerity and Economic crisis - assessing the short-term impact in OECD countries
- OECD: governments should tackle geographical variations in the use of healthcare
- Publication: Everything you always wanted to know about European Union health policies but were afraid to ask
- Publication: economic crisis, health systems and health in Europe - impact and implications for policy

- Initial analysis of market access offers in the TISA talks
  - TTIP: the Council of the EU declassifies the negotiating mandate
  - Publication: cross-border healthcare in Europe
  - ECDC: antimicrobial resistance a cause for concern
  - EAHP: survey on medicines shortages
  - Article: healthcare stakeholders concerned about the TTIP
  - Article: Can doctors be trained in a 48 hour working week?
  - European Parliament: state of play on the TTIP
  - Eurohealth: special Gastein Forum edition
  - Nordic Council of Ministers: endocrine disruptors a considerable burden for health budgets
- 

## 1 Medicines and medical devices

### • **New Commission: responsibility for medicines stays with the Commissioner for Health, and medical devices will be transferred to DG Enterprise**

Pharmaceutical products will remain the responsibility of DG Health. The relevant policy will be developed jointly by Vytenis Andriukaitis, the Commissioner responsible for health, and d'Elzbieta Bienkowska, Commissioner for the internal market, industry, entrepreneurship and SMEs. Responsibility for medical devices, however, will be transferred to DG Enterprise. Under the initial proposal put forward by Jean-Claude Juncker, issues relating to the pharmaceutical sector also fell within the remit of DG Enterprise. This proposal, however, met with strong opposition, particularly within the European Parliament and from special-interest groups

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

### • **EMA: new policy on publication of clinical data**

The European Medicines Agency (EMA) has decided to publish the clinical reports on which decisions on the pharmaceutical products are based. This policy will come into force on 1 January 2015, and will apply to all clinical data submitted as part of a centralised marketing authorisation application as of that date. The data will be published as soon as a decision is taken on the authorisation.

DOC [EN](#) PDF

### • **EPSCO Council: progress report on two draft regulations concerning medical devices and in-vitro diagnostic medical devices**

The Health Council took note of the progress report from the Italian Presidency on two draft regulations, one concerning medical devices and the other relating to in-vitro diagnostic devices. As no agreement was reached, the Presidency decided to pass these issues on to the Latvian Presidency, so that it could continue work on them.

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

### • **European Commission: final opinion on the safety of metal-on-metal joint replacements, with a particular focus on hip implants**

In this opinion, the European Commission and its non-food Scientific Committee on Emerging and Newly identified Health risks conclude that given the higher risk to health compared to alternative implants, the use of metal-on-metal hip implants should be carefully considered, on a case-by-case basis.

DOC [EN](#) PDF

## 2 Public health

---

### European Commission: report on the impact of information on patients' choice

This document is one outcome of a study to assess the impact of information on patients' choices in eight EU Member States, in the context of Directive 2011/24/EU.

DOC [EN](#) PDF

### European Commission: implementation report on the 'Commission communication on rare diseases: Europe's challenge'

This study reports on implementation of the strategy on rare diseases, and takes stock of the progress made and lessons learned in the process. It draws conclusions as to the ways in which the measures set out in the Commission communication and 2009 Council recommendation have been implemented, and concludes that further action is necessary to improve the lives of patients and their families.

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

### HTA Network: new strategy for EU cooperation on health technology assessment

The Health Technology Assessment (HTA) network is an independent network set up under Directive 2011/24 (Article 15), and involving all Member States and stakeholders. The joint initiative EUnetHTA provides scientific and technical support to the network. This network has adopted a new strategy for EU cooperation.

DOC [EN](#) PDF

### Launch of the 4th European Code against cancer

The new European Code against cancer sets out twelve recommendations to help prevent cancer, in particular avoiding tobacco, alcohol and excessive sun exposure, maintaining a healthy body weight and being physically active. The code also recommends participation in organised programmes for bowel, breast and cervical cancer screening.

DOC [EN](#) HTML

### European Commission: implementation report on actions to address Alzheimer's disease

This report presents the key activities which have taken place since 2009 and summarises the main achievements. A wide range of activities have been implemented as part of this strategy, in the context of EU health policy and of other EU policy areas.

DOC [EN](#) PDF

### EPSCO Council: Luxembourg raises the issue of admissibility criteria for certain blood donors

At the EPSCO Council of health ministers on 1 December 2014, Luxembourg submitted a note on the access of homosexuals to giving blood, emphasising that exclusion from blood donation should be based on high-risk behaviour and not on sexual orientation.

DOC [EN](#) PDF

### EPSCO Council: vaccinations as an effective tool in public health

In their conclusions on vaccinations, the health ministers call for increased vaccination of healthcare professionals, and further research on new vaccines. Faced with 'increasing refusal of vaccination in some Member States', they recall that 'the public should be aware of the value of vaccination'.

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

➤ **EPSCO Council: conclusions on patient safety and quality of care, including the prevention and control of healthcare associated infections and antimicrobial resistance**

The Council invites Member States to take steps including the promotion of education and training of healthcare staff on healthcare associated infections, as well as the development of voluntary guidelines containing patient safety measures.

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

➤ **EPSCO Council: conclusions on care quality and innovation for the benefit of patients**

The Council invites Member States to increase the effective sharing of information on prices of and expenditure on medicinal products, including innovative medicinal products, and to support research to 'provide a better understanding of how pharmaceutical pricing may be applied'.

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

➤ **Mission letter to Vytenis P. Andriukaitis, Commissioner responsible for Health**

In his mission letter, Jean-Claude Juncker recommends to the Health Commissioner that he develop expertise on performance assessments of health systems, drawing lessons from recent experience and from EU-funded research projects to build up country-specific information to inform policies at national and European level. According to the letter, this expertise can also provide useful input to the work of the European Semester.

DOC [EN](#) PDF

➤ **EXPH: opinion on a future EU agenda on quality of healthcare, with a special emphasis on patient safety**

In its opinion, the expert panel set up to provide advice on effective ways of investing in health (EXPH) identified a subset of commonly accepted dimensions of quality and safety applicable to all health services. These should be prioritised at EU level, in order to improve the quality of healthcare. Regardless of the level of healthcare provided, all services must be effective, safe, appropriate, patient-centred and equitable.

DOC [EN](#) PDF

➤ **OECD and European Commission: Health at a Glance, Europe 2014**

Health at a Glance: Europe 2014 presents the latest information on the state of health of the population, health risk-factors and access to quality healthcare in all EU Member States, the candidate countries and European Free Trade Association (EFTA) countries.

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

➤ **EPSCO Council: contribution of the health sector to the EU2020 objectives**

The Health Council launched a discussion, guided by a note from the Presidency, on the contribution made by the health sector to the Europe 2020 strategy. Member States acknowledged that health is not only an important factor for social well-being, but also makes an important contribution to economic growth and employment. A number of delegations called for deeper reflection on the role played by a healthy population in achieving the objectives of the Europe 2020 strategy, notably those linked to employment, research and education. However, the idea of adding a specific headline target on health was not supported.

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

➤ **Council of the EU: statistics on healthcare expenditure and financing**

The Council decided not to oppose the adoption of a Commission regulation setting out rules for the systematic production of European statistics in the area of healthcare expenditure and financing.

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

### ECDC: increase in AIDS cases among risk-groups in the EU

According to the latest figures published by the European Centre for Disease Prevention and Control (ECDC), there has been an increase in the number of new HIV cases diagnosed in Europe, contrary to a global downwards trend. In the European Union and the European Economic Area (EEA), 29,000 new HIV infections were reported in 2013.

DOC [EN](#) PDF

## 3 Social policy

### EPSCO Council: equal treatment directive shelved

The exchange of views between European ministers of employment on the proposal for a directive on equal treatment showed that progress has been made, but that Member States are still far from reaching agreement on this issue. Belgium, the United Kingdom and Slovakia still have misgivings, particularly as to social protection (including healthcare) and education. If the directive were to touch upon these two areas, insisted several ministers, it should only do so in terms of one issue, that of physical accessibility.

DOC [EN](#) PDF

### EPSCO Council: mid-term review of the Europe2020 strategy, including an evaluation of the European Semester

The Council of social affairs ministers held a policy debate on the mid-term review of the Europe 2020 strategy and the European Semester. They recognised that there should be better coordination and a better balance struck between economic and budgetary policies, on the one hand and social policy, on the other, in order to attain sufficient levels of growth, job-creation and social cohesion.

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

### European Commission: draft joint employment report 2015

This draft report, published together with the 2015 annual growth survey, shows that Member States are reviewing their healthcare expenditure, and seeking ways to improve value for money and effective outcomes, while introducing better instruments for cost containment. In some Member States, people in vulnerable situations and with low incomes continued to experience difficulties in access to healthcare.

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

### European Commission: public consultation on working time

On 21 November, the European Commission launched a public consultation on working time. This initiative is taking place in the context of the review of Directive 2003/88/EC concerning certain aspects of the organisation of working time, and of any future changes to this directive. The issue of time spent 'on call' in the medical sector is particularly important.

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

### European Commission and SPC: adequate social protection for long-term care needs in an ageing society

This report, prepared jointly by the Social Protection Committee (SPC) and the European Commission, calls for adequate social protection against the risk of long-term care dependency. It analyses the services currently on offer, the challenges, planned future developments and political ideas on the subject. An annex contains fact-sheets for each EU Member State, listing the needs and services currently available.

DOC [EN](#) HTML

### SPC: review of recent social policy reforms for a fair and competitive Europe

The EPSCO Council adopted the 2014 report of the SPC on the social policy reforms implemented for a fair and competitive Europe, which contains key messages for the 2015 annual growth survey. Chapter 4 of this report examines recent reforms for accessible, high-quality and sustainable healthcare and long-term care. This chapter gives a comprehensive strategic overview of reforms implemented in these areas, which represent a key strand of the open method of coordination.

DOC [EN](#) PDF

### SPC and EMCO: joint opinion on the Europe 2020 strategy mid-term review

The Council adopted a joint submission from the Employment Committee (EMCO) and the Social Protection Committee. This opinion emphasises the primary responsibility of the Employment and ECFIN Councils for implementation of the European Semester, on the basis of an equitable partnership. The EMCO and the SPC wish to provide better support to these two councils in the areas of pensions, healthcare and long-term care. Both Council formations should debate all issues relevant to their area of competence, without interfering in each other's domain, particularly in discussions relating to the macroeconomic imbalances procedures. The opinion also stresses the need to extend networks with a wide range of other important actors. It suggests ways of improving the procedure used to adopt country-specific recommendations, Commission staff working documents, multilateral surveillance and peer pressure.

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

### European Commission: report on population ageing in Europe - facts, implications and policies

This publication aims to address the question of how Europe is prepared to address the ageing of its population. It gives the broader context, analysing the European approach to demographic change and population ageing, and addresses a number of questions in relation to economic growth, the labour market, well-being and retirement.

DOC [EN](#) PDF

## 4 E-Health

### European Commission: overview of national laws on electronic health records

This study gives an overview of national laws on electronic health records (EHRs) in the EU Member States, and assesses the interaction of these national laws with the provision of cross-border eHealth services mentioned in the directive on patients' rights in cross-border healthcare (2011/24/EU). A specific report on each Member State gives the legal requirements applicable to EHRs.

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

### The European Commission and the European data industry launch a €2.5 billion partnership to master big data

The purpose of the PPP is to support research and innovation in game-changing big data ideas, in sectors such as health, to deliver services such as, for example, predictive analytics and personalised medicine.

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

### eHealth network: adoption of guidelines on ePrescriptions

The eHealth network adopted guidelines on ePrescriptions, in order to facilitate interoperability between Member States. These guidelines lay out the type of data needed to share prescriptions across borders. They also describe how data should be transferred,

provided the patient gives his or her consent to use the ePrescription service. The guidelines can be used by Member States on a voluntary basis.

DOC [EN](#) PDF

## 5 Economic policy

### European Parliament: the EP calls for a stricter and more democratic follow-up to the economic and budgetary policy country-specific recommendations

The European Parliament adopted the 'De Backer' report on the European Semester, and called for a stricter and more democratic follow-up to the economic and budgetary policy country-specific recommendations. The report, adopted on 22 October 2014 at the plenary session, calls on the Commission to submit quarterly reports to the European Parliament on measures taken to ensure progress in implementation of the country-specific recommendations, and on the progress already achieved.

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

### EFC and EPC: mid-term review of the Europe 2020 strategy

The Economic and Financial Committee (EFC) and the Economic Policy Committee (EPC) have issued a joint opinion on the mid-term review of the Europe 2020 strategy and its implementation through the European Semester. The committees make a number of suggestions, including greater effort at national and European level to engage in a structured dialogue with national parliaments and social partners.

DOC [EN](#) PDF

### European Commission: identifying fiscal sustainability challenges in the areas of pension, healthcare and long-term care policies

This paper presents a horizontal assessment framework used by the Commission services to identify structural-fiscal reforms that are deemed necessary to address fiscal sustainability challenges in the Member States in the fields of: i) pension policy, ii) healthcare policy and iii) long-term care policy. This assessment framework is the first step towards defining country-specific recommendations as part of the European Semester.

DOC [EN](#) PDF

### European Commission: are Member States responding to the European Semester country-specific recommendations?

For the past four years, the EU has issued country-specific recommendations for economic reform to Member States under the European Semester. According to a publication from DG ECFIN, over the whole of the EU slightly more than 40% of these recommendations have been implemented, but only 35% of the recommendations on healthcare.

DOC [EN](#) PDF

### European Commission and Economic Policy Committee: 2015 ageing report - underlying assumptions and projection methodologies

This first report describes the underlying macroeconomic assumptions and projection methodologies used to calculate age-related expenditure. In 2015, a second report will draw on this analysis to calculate age-related expenditures, including those related to healthcare and long-term care. On the basis of these projections, country-specific recommendations will be issued as part of the European Semester.

DOC [EN](#) HTML

### ▶ **Latvia: sixth post-programme surveillance mission**

The assessment carried out by the Commission services shows that the reforms implemented to tackle social inequalities and inadequate healthcare access for the poorest have barely advanced.

DOC [EN](#) HTML

### ▶ **Latvia: benefits of the Euro and new challenges**

This Country Focus analyses price dynamics, unit labour costs, investments, banking sector developments and structural reforms in Latvia before and after the introduction of the euro in Latvia on 1 January 2014. Despite commitments entered into at the time of euro-area accession, the reform momentum has slowed down, and the Latvian authorities have failed to make significant progress in key sectors such as access to healthcare and social inequality.

DOC [EN](#) PDF

### ▶ **Ireland: second post-programme surveillance mission**

The European Commission and the ECB report that budgetary overruns in the healthcare sector increased compared to last year. Key strands of reforms in healthcare are, however, progressing, but further advances will be necessary to reap additional efficiency gains and better control health expenditure without compromising healthcare delivery. Despite significant progress, the macroeconomic adjustment process needs to continue and important challenges remain.

DOC [EN](#) HTML

### ▶ **European Commission: annual growth survey 2015**

The adoption of the annual growth survey 2015 launches the European Semester of economic and budgetary policy coordination. In it, the Commission outlines the main features of its new jobs and growth agenda, including in the healthcare sector.

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

### ▶ **European Commission: 2015 draft budgetary plans of seven Member States at risk of non-compliance**

The European Commission has completed its assessment of 16 euro area countries' 2015 draft budgetary plans, focusing on their compliance with the provisions of the Stability and Growth Pact. For seven countries (Belgium, Spain, France, Italy, Malta, Austria and Portugal), the Commission's opinion points to a risk of non-compliance. It asks them to take the necessary measures within the national budgetary process to ensure that the budget will be compliant with the Pact.

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

### ▶ **Mission letter from Jean-Claude Juncker to Valdis Dombrovskis, Vice-president for the Euro and social dialogue**

In this mission letter, the President of the European Commission asks him, during his mandate, to pay particular attention to strengthening the multilateral nature of the economic governance process at EU level, engaging a broader range of national actors, and to deepening the country-specific knowledge within the Commission. He also suggests that the 'troika' be replaced by a more democratically legitimate and accountable structure, as well as the preparation of social impact assessments in addition to fiscal sustainability assessments.

DOC [EN](#) PDF

### ➤ **CJEU judgment: an ovum which is not capable of developing into a human being can be patented**

According to the Court in the case International Stem Cell Corporation (C-364/13), an organism which is incapable of developing into a human being does not constitute a human embryo within the meaning of the directive on the legal protection of biotechnological inventions. Therefore, uses of such an organism for industrial or commercial purposes may, as a rule, be patented.

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

### ➤ **CJEU judgment: reimbursement of medical expenses incurred in another Member State**

According to the Court in the Petru judgment (C-268/13) the reimbursement of medical expenses incurred in another Member State cannot be refused where a lack of basic medical supplies makes it impossible for the insured person to receive hospital treatment in good time in his Member State of residence. The question as to whether it is impossible must be assessed by reference to all the hospital establishments capable of providing the treatment in his Member State and to the period within which the treatment could be received.

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

### ➤ **CJEU judgment: right of a marketing authorisation holder for a reference medicinal product to oppose the marketing authorisation of a generic**

The Court found in case C-104/13 that the manufacturer of a 'reference medicinal product' may, in certain circumstances, legally challenge a marketing authorisation for a generic medicinal product. The right to this legal remedy is guaranteed by the Charter of Fundamental Rights of the EU.

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

### ➤ **CJEU judgment: rules for calculating compensation for accidents at work unfavourable to male workers**

In case C-318/13, the Court of Justice ruled against the Finnish accident insurance regime, which applies calculation rules unfavourable to male workers, by taking into account an actuarial factor based on the statistically shorter life expectancy of men compared to women. Such a criterion was found to be contrary to Directive 79 /7/EEC on the principle of equal treatment for men and women in matters of social security.

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

### ➤ **CJEU judgment: emergency ambulance services and cost containment**

In case C-113/13, the Court of Justice found that in order to ensure the social purpose of emergency ambulance services and for reasons of budgetary efficiency, Member States may entrust these services on a preferential basis, and award them directly, to voluntary associations.

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

### ➤ **CJEU judgment: exclusion of a public hospital from participating in tendering procedures for the award of public contracts**

In case C-568/13, the Court of Justice found that national legislation excluding a public hospital from participating in tendering procedures for the award of public contracts, as a result of its status as a public economic entity, was contrary to EU law if that entity is authorised to operate on the market in accordance with its institutional and statutory objectives.

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

### ➤ **GCEU judgment: the Court finds against the French Ordre national des pharmaciens for restricting competition on the clinical biology analysis market**

In case T-90/11, the General Court of the European Union confirmed that the French Ordre

national des pharmaciens restricted competition on the clinical biology analysis market. The General Court nevertheless reduced the fine imposed by the Commission from 5 to 4.75 million euros.

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

➤ **Opinion: method of calculating permanent invalidity pensions, reducing the amount due to part-time workers, and thus introducing discrimination on the grounds of gender, contrary to EU law.**

According to the opinion of Advocate General Yves Bot, in case C-527/13, a provision of the Spanish law on the calculation of permanent invalidity pensions is contrary to EU law. This provision, which has the effect of reducing the permanent invalidity pension payable to some part-time workers, introduces indirect discrimination on the grounds of gender.

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

➤ **Opinion: manufacturer liable for defective medical devices and damage caused by personal injury**

According to the opinion of Advocate General Bot in case C-503/13, a medical device implanted in the body of a patient must be considered defective when it has the same characteristics as other devices which have been shown to entail a significantly increased risk of failure, or if malfunction has already occurred in a significant number of devices in the same series. The manufacturer of the defective product is liable for any personal injury, where a direct causal link exists with the defect.

DOC [FR/NL](#) HTML

➤ **EFTA: letter of formal notice to Norway concerning the criteria for access to in-patient treatment in other EEA states**

The EFTA Surveillance Authority has concluded that the Norwegian legislation establishing criteria for access to healthcare in other EEA states is contrary to Article 20 of Regulation 883/2004.

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

## 7 Competition

➤ **European Commission: publication of the 5th report on the monitoring of patent settlements in the pharmaceutical sector**

On 5 December, the European Commission presented its 5th report on the monitoring of patent settlements in the pharmaceutical sector. While the number of settlements is increasing, those which might attract competition law scrutiny have stabilised at a low level.

DOC [EN](#) PDF

➤ **Mergers: Commission approves acquisition of Covidien by Medtronic, subject to conditions**

The Commission authorised the proposed acquisition of Covidien, an Ireland-based manufacturer of medical devices with worldwide activities, by Medtronic, a US-based company active in medical technologies and therapies.

DOC [EN/FR](#) HTML

➤ **Mergers: the Commission approves IMS Health's acquisition of parts of Cegevim, subject to conditions**

The European Commission has cleared the proposed acquisition of part of Cegevim S.A.s customer relationship management and strategic data business by IMS Health. The decision is conditional on IMS's commitment to divest parts of its primary market research business

and to grant third-party access to the so-called 'brick structure' underlying its sales tracking data.

DOC [EN/FR](#) HTML

➤ **State aid: the Slovak system of compulsory health insurance involves no state aid**

Following an in-depth investigation, the European Commission has concluded that the Slovak system of compulsory health insurance does not contain elements of state aid.

DOC [EN/FR](#) HTML

➤ **State aid: in-depth investigation into part of the public financing of Brussels public IRIS hospitals**

The European Commission has opened an in-depth investigation to ascertain whether specific deficit-financing measures granted by the Brussels public authorities only to the public IRIS hospitals in the Brussels Capital region, and not to private hospitals in the same region, are in line with EU state aid rules.

DOC [EN/FR](#) HTML

➤ **Germany: the Bundeskartellamt strengthens competition in the sale of blood glucose strips in Westphalia-Lippe**

The German competition authority, the Bundeskartellamt, has concluded its cartel proceeding against the pharmacists' association in Westphalia-Lippe (AVWL) in Münster. This association had reached an agreement with the major health insurance funds that patients be supplied with blood glucose strips preferably via pharmacies in Westphalia-Lippe, and for this purpose had concluded a clause prohibiting the health insurance funds from controlling and influencing the procurement of these strips.

DOC [EN](#) HTML

➤ **Bulgaria: the Commission for the Protection of Competition has recommended broader representation of interested parties in the adoption procedure for regulatory acts in healthcare**

The Commission for the Protection of Competition (CPC) adopted an advocacy opinion stating that the legal framework regulating the decision-making process in the compulsory health insurance sector should be clarified, and that all the entities which may be affected by regulatory acts setting conditions, volumes and prices of the reimbursed medical services should be involved in the process of formulating and adopting these acts (patients, hospitals, etc.).

DOC [EN](#) PDF

➤ **France: the Competition Authority fines Cegedim for abusing its dominant position and refusing to sell medical information databases to pharmaceutical laboratories**

The Competition Authority imposed a fine of € 5,700,000 on Cegedim SA, for abusing its dominant position on the market for medical databases, used by pharmaceutical companies to manage their visits to doctors and pharmacies in France.

DOC [FR](#) PDF

➤ **Netherlands: merger of healthcare providers Kwadrantgroep, Antonius Zorggroep en Nij Smellinghe/Pasana can go ahead**

The Netherlands Authority for Consumers and Markets (De Autoriteit Consument en Markt - ACM) has authorised this merger in Friesland.

DOC [NL](#) PDF

## 8 Infringement proceedings

---

### ➤ **Netherlands and Portugal: full transposition of the rules on patients' rights in cross-border healthcare**

The Commission has sent a reasoned opinion to the Netherlands and Portugal, formally requesting full transposition of directive 2011/24/EU, which gives patients the right to choose to receive healthcare in another Member State, and to claim reimbursement for this care at home.

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

### ➤ **Czech Republic, Romania and Slovenia: full transposition of the rules on patients' rights in cross-border healthcare**

On 25 September, the European Commission sent a formal request to the Czech Republic, Romania and Slovenia, asking that they notify full transposition of directive 2011/24/EU concerning patients' rights in cross-border healthcare.

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

### ➤ **Romania: full transposition of the rules on the recognition of prescriptions delivered in another Member State**

The European Commission has sent Romania a formal request, urging it to complete transposition of the directive laying down measures to facilitate the cross-border recognition of medical prescriptions (2012/52/EU). This directive aims to increase the ability of pharmacists to understand and dispense prescriptions issued in another EU Member State to patients exercising their right to cross-border healthcare.

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

## 9 Miscellaneous

---

### ➤ **European reference networks: conference report**

This report, published in October, gives an account of the discussions which took place during a conference organised by DG SANCO on 23 June. This conference brought together healthcare experts and professionals, national authorities and decision-makers to discuss the organisation of highly specialised networks and their members across the EU.

DOC [EN](#) PDF

### ➤ **Council: partial agreement on the protection of administrative data**

With respect to the future regulation on data protection, most Member States support the Presidency approach concerning data collected by the public authorities. The Presidency's partial general approach gives Member States greater leeway to make exceptions from the future legislation for administrative data (health, employment, etc.). While supporting the text, many Member States expressed concerns in relation to specific points contained in it. Belgium would have preferred clearer definitions in relation to health.

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

### ➤ **Eurostat: cancer responsible for one in four deaths in the EU28 in 2011**

In the EU28 in 2011, cancer was the cause of 1.281 million deaths. It was therefore responsible for more than a quarter of all deaths (26.3%), reported Eurostat on 25 November.

DOC [EN](#) PDF

### ➤ **Eurofound: report on access to healthcare in times of crisis**

The report examines which population groups have experienced reduced access to

healthcare as a result of the crisis. It presents examples of measures taken by governments and service providers to maintain access for groups in vulnerable situations.

DOC [EN](#) PDF

#### **OECD: Health, Austerity and Economic crisis - assessing the short-term impact in OECD countries**

This document looks at the impact of the economic crisis on health and healthcare. It summarises findings from the published literature on the effects of the economic crises which have taken place over the last few decades, and describes recent health policy reforms, focusing on those countries where the economic crisis has hit hardest. Finally, it analyses the empirical relationship between unemployment and healthcare use, quality and health outcomes.

DOC [EN](#) HTML

#### **OECD: governments should tackle geographical variations in the use of healthcare**

Governments should step up their efforts to improve their healthcare systems, in order to avoid unnecessary procedures, and ensuring that anyone, wherever he or she lives, has the same access to quality healthcare, according to a new OECD report. 'Geographic Variations in Health Care' analyses the geographical variations observed for various high-cost and high-volume healthcare procedures.

DOC [EN](#) HTML

#### **Publication: Everything you always wanted to know about European Union health policies but were afraid to ask**

This book examines EU health policy as a whole (in all its complexity), with a view to facilitating political and technical discussion on the issue. To this end, it concentrates on 4 aspects of health policy: EU institutions, processes and powers with respect to health; action taken by the EU by virtue of its competences in this area; other European actions affecting health and health systems; and, due to its increasing importance, fiscal governance and what it means for health systems.

DOC [EN](#) PDF

#### **Publication: economic crisis, health systems and health in Europe - impact and implications for policy**

This document summarises the conclusions of a study carried out by the European Observatory on Health Systems and Policies, analysing the impact of health policy responses to the crisis in Europe from 2008 to 2013.

DOC [EN](#) PDF

#### **Initial analysis of market access offers in the TISA talks**

The EU chaired a cycle of multilateral negotiations on the trade in services agreement (TISA) in Geneva from 21-25 September 2014. Analysis of the market access offers put forward by the participating countries was linked to discussions of the regulatory texts in the specific service sectors. The discussions focused on four key regulatory disciplines: financial services, telecommunications, domestic regulation and transparency, and the movement of natural persons acting as service-providers. According to the *Agence Europe* report of 22 September 2014, three new proposals have been presented, concerning, in particular, environmental services and health-related services.

DOC [EN](#) HTML

#### **TTIP: the Council of the EU declassifies the negotiating mandate**

The EU Council has declassified the mandate for confidential negotiations of the Transatlantic Trade and Investment Partnership with the United States.

DOC [EN](#) PDF

➤ **Publication: cross-border healthcare in Europe**

This new Policy Summary explains how European health systems are responding to the increase in patient-numbers and professional mobility in the European Union.

DOC [EN](#) PDF

➤ **ECDC: antimicrobial resistance a cause for concern**

The European Centre for Disease Prevention and Control published its latest European data on antimicrobial resistance. The published data for 2013 show, for the first time, resistance to colistin, a last resort medicine against germs which are multi-resistant to antibiotics.

DOC [EN](#) PDF

➤ **EAHP: survey on medicines shortages**

According to a report by the European Association of Hospital Pharmacists (EAHP), 86% of pharmacists report supply difficulties with medicines. The Member States most affected are Belgium, Ireland, Portugal, Spain and Italy. The EAHP calls upon the European Union to take coordinated action to tackle shortages of medicines.

DOC [EN](#) PDF

➤ **Article: healthcare stakeholders concerned about the TTIP**

According to this article published in 'The Lancet', healthcare stakeholders are concerned about the possible health repercussions of the transatlantic partnership, currently being negotiated.

DOC [EN](#) HTML

➤ **Article: Can doctors be trained in a 48 hour working week?**

According to an article published in the British Medical Journal, implementation of the Working Time Directive has not led to a decline in the quality of medical training. The article reveals, however, that the 48 hour limit does not give enough time for proper training in certain specialisations.

DOC [EN](#) HTML

➤ **European Parliament: state of play on the TTIP**

The European Parliament published a state of play on the TTIP negotiations, which gives a rapid overview of the main objectives of and issues relating to the partnership.

DOC [EN](#) PDF

➤ **Eurohealth: special Gastein Forum edition**

Most of the articles in this special edition relate to health and European integration; building EU health policy for the future; telemedicine, being in the business of change and meaning business, and the EU's contribution to health system performance.

DOC [EN](#) PDF

➤ **Nordic Council of Ministers: endocrine disruptors a considerable burden for health budgets**

In a report entitled 'The Cost of inaction: a socioeconomic analysis of costs linked to effects of endocrine disrupting substances on male reproductive health', the Nordic Council of Ministers of Denmark, Finland, Iceland, Norway and Sweden highlight the impact of endocrine disruptors on male reproductive health, and the considerable costs they represent for health budgets. Endocrine disruptors are chemical substances which interfere with hormone systems, which can have damaging effects on health and the environment.

Following several delays in implementation of the legislation on endocrine disruptors, the European Commission launched a consultation on 29 September, concerning the establishment of criteria to identify these biocide and pesticide substances.

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

Editor: Rita Baeten and Dalila Ghailani

E-mail : [baeten@ose.be](mailto:baeten@ose.be)

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

To subscribe to the mailing list :

[http://www.ose.be/health\\_newsletter/](http://www.ose.be/health_newsletter/)