European Health Care News

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Observatory

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1 Public health

European Commission: study on 'Health literacy' in the EU

This report, 'Study on sound evidence for a better understanding of health literacy in the European Union', concludes that the topic of 'health literacy' is receiving growing attention, but that there are often shortcomings in the coordination and evaluation of health literacy initiatives.

DOC EN PDF

European Commission: call for tender for assessors for the European Reference Networks

Chafea, DG SANTE's executive agency, issued a call for tender to select the bodies responsible for assessing the European Reference Network proposals and applications, on the basis of Directive 2011/24/EU on patients' rights in cross-border healthcare.

DOC EN/FR HTML

European Commission: study on the recruitment and retention of the health workforce in Europe

This study analyses and identifies effective strategies for recruiting and retaining health professionals, to serve as inspiration for the development of organisational strategies and human resources policies in Europe.

DOC EN HTML

European Commission: innovative financing opportunities for active and healthy ageing

The European Commission has published a report on the conference on 'Innovative financing opportunities for active and healthy ageing'. It considers how best to make use of public and private financial instruments, joint procurement of innovative solutions, new ways of public-private co-investments in health and innovative alternative financing tools.

DOC EN HTML

EXPH: opinion on cross-border cooperation in healthcare provision in the EU

In this opinion, the Expert Panel on Effective ways of Investing in Health (EXPH) considers areas which would potentially benefit from cross-border cooperation, identifies obstacles to successful cooperation and suggests actions which could be taken at EU level in order to help overcome some of these obstacles.

DOC EN PDF

EXPH: opinion on competition among healthcare providers

In this opinion, the Expert Panel addresses the role of competition among healthcare providers as an instrument to improve efficiency in the use of health system resources.

DOC EN PDF

EXPH: request for an expert opinion on methods for public health sector commissioning from private providers

The Expert Panel was asked to develop a typology of methods used to commission healthcare from the private sector, to provide guidance in the evaluation of which policies can best tackle inefficiencies in health systems.

DOC EN PDF

EXPH: request for an expert opinion on a framework for screening the effects of health policy reforms

The Commission requested a study from the Panel to develop a typology of health policy reforms, and a framework for evaluating the effects of health policy. This will be used to support policy evaluation and design, and act as a framework for the fiscal quantification of reform effects.

DOC EN PDF

JA on health workforce planning and forecasting: applicability of the code of practice on the international recruitment of health personnel

The joint action on health workforce planning and forecasting (JA EUHWF) published a report on the applicability in the EU of the WHO Global Code of Practice on the international recruitment of health personnel.

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2   Healthcare services in the internal market

European Commission: report on the operation of the Directive on patients' rights in cross-border healthcare

A report on the Directive on the application of patients' rights in cross-border healthcare describes the current state of play of transposition, and covers the use of prior authorisation, the level of patient mobility, reimbursement practices, information to patients and cooperation under the Directive.

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European Patients Forum (EPF): Implementation of the Directive on patients' rights in cross-border healthcare

During a conference, the EPF discussed the findings of a series of events organised in various EU countries in relation to the implementation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare.

DOC EN HTML

Ireland: implementation of the EU Directive on patients' rights in cross-border healthcare

Ireland has announced that it is to set aside 1 million Euro to pay for treatment received by patients abroad, on the basis of the EU Directive on cross-border healthcare.

DOC EN HTML

European Commission: implementing regulation for the Directive on the recognition of professional qualifications

The European Commission has published the implementing regulation on the procedure for issuing the European Professional Card and the application of the alert mechanism pursuant to Directive 2005/36/EC on the recognition of professional qualifications.

DOC EN/FR/NL HTML

CEN: adoption of standard on security management in healthcare facilities

The European Committee for Standardization (CEN) adopted a standard on security management in healthcare facilities. The standard specifies requirements for planning, establishing, implementing, operating, monitoring, reviewing, maintaining and continually improving a documented security management system.

DOC EN HTML

CEN: European standards for osteopathy

CEN published a voluntary European standard on osteopathic training and practice, in agreement with the professional federations.

DOC EN HTML

ENMCA: European standards for healthcare services may encroach upon the competences of national authorities

In a letter sent to CEN and to the European Commission, the European Network of authorities responsible for recognising medical qualifications, ENMCA, expressed its concern as to the adoption of standards for healthcare services. The network fears that these standards could encroach upon the competences of its members.

DOC EN HTML

UK: 45% of EU doctors not successful in language tests

According to The Guardian, the General Medical Council (GMC) (UK) announced that 45% of EU doctors applying to work in the UK failed to provide evidence of their English skills, so were refused a license to practice in the country.

DOC EN HTML

3 Medicines and medical devices

European Commission: public consultation on good manufacturing practices for medicinal products for human use.

The Commission launched a public consultation concerning good manufacturing practices for medicinal products for human use.

DOC EN HTML

European Commission: public consultation on clinical trials

The Commission launched a public consultation on clinical trials on medicinal products for human use.

DOC EN HTML

Council: agreement on EU legislation on medical devices

After almost 3 years of negotiations, the Council agreed the substance of its negotiating stance on two draft regulations aimed at modernising EU rules on medical devices and in vitro diagnostic medical devices. It can begin negotiations with the European Parliament on this basis, with a view to reaching an agreement.

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Reactions to the Council agreement on medical devices

According to AIM, the European umbrella organisation of health mutuals and health insurance funds, the few added obligations for the notified bodies, as now proposed by the Council, do not ensure greater patient safety.

DOC 1 EN PDF | DOC 2 EN HTML

Conference: access to personalised medicine

The Luxembourg Presidency of the Council organised a conference on access to personalised medicine.

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EMA: public consultation on accelerated assessment procedures for medicines which address unmet medical needs

The European Medicines Agency (EMA) has revised its guidelines on the implementation of accelerated assessment and conditional marketing authorisation, two key tools in the European legislation to accelerate patients' access to medicines that address unmet medical needs.

DOC EN HTML

EUnetHTA: public consultation on an 'HTA Core Model' for rapid relative effectiveness assessments

EUnetHTA, the European network of national agencies for health technology assessment (HTA), is organising a public consultation on an 'HTA Core Model', a methodological framework for rapid relative effectiveness assessments, of both medical products and medical interventions.

DOC EN HTML

European pharmaceutical industry: complaint against the law promoting the use of Avastin as an alternative to more expensive eye treatments

The European pharmaceutical industry said it had filed a complaint with the European Commission against the French law promoting the use of Roche's cancer drug Avastin, as an alternative to more expensive eye treatments.

DOC 1 EN HTML | DOC 2 EN HTML

Belgium: 'Pact for the Future' with the pharmaceutical industry

The Belgian Minister of Social Affairs and Public Health, Maggie De Block, has concluded a 'Pact for the Future' with the pharmaceutical industry. This Pact contains agreements on

faster decision-making on patient access to innovative medicines, lower prices for off-patent drugs, a stable budgetary framework and a code of good practice for the industry. It proposes better cooperation at European level to develop criteria used to give priority to indications involving the greatest unmet medical need, as well as suggesting joint negotiations on the pricing and reimbursement of orphan drugs between Member States and companies.

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Greece: ban on the export of medicines

Greece has decided to ban the export of 25 categories of drugs, because of possible domestic shortages.

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European Parliament: study on harmonised EU assessments of the added therapeutic value of medicines

This study investigated the possibility of a harmonised EU approach concerning the assessment of the added therapeutic value of medicinal products. It reviews the current EU legal and policy framework, looks at the state of play in all 28 Member States and closes with policy recommendations.

DOC EN HTML

Greek Minister and Portuguese State Secretary: call for closer EU cooperation to drive down the price of expensive medicines

During the annual EPHA conference, the former Greek health minister Panagiotis Kouroumplis and the Portuguese state secretary for health Fernando Leal Da Costa called for closer cooperation between EU countries to drive down the price of expensive medicines.

DOC EN HTML

4 e-Health

European Commission: decision on the identification of 'Integrating the Healthcare Enterprise' profiles for referencing in public procurement

The Commission identified 'Integrating the Healthcare Enterprise' profiles. The 27 IHE profiles must be identified as technical ICT specifications to be used as references for public procurement. The purpose is to enhance the interoperability of eHealth services and applications.

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5 Social policy

Council: policy debate on the European Semester

In the EPSCO Council, the Ministers of Social Affairs held a policy debate on the European Semester. According to the Council, the Country-Specific Recommendations (CSRs) concerning social issues must be maintained within the EPSCO remit and should not systematically become a part of the Macroeconomic Imbalances (MIP) procedure.

DOC EN PDF

SPC: assessment of the draft 2015 CSRs, and of the implementation of the 2014 CSRs relating to social protection and social integration

The Social Protection Committee (SPC) gave its opinion on the Commission proposals for CSRs, and on the implementation of the 2014 CSRs in the area of social protection and social integration. The opinion also discusses reforms of healthcare systems. This document was endorsed by the Council.

DOC EN PDF

European Commission: social impact of the Memorandum of Understanding (MoU) with Greece

The Commission published an analysis of the social impact of the new MoU with Greece. It assesses, among other things, the impact of the MoU on access to healthcare.

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European Commission: public consultation on the coordination of social security systems

The European Commission launched a public consultation on the functioning of the EU rules on social security coordination, in cross-border situations.

DOC 1 EN HTML | DOC 2 EN/NL/FR HTML

European Commission: EU Working Time Directive does not apply to self-employed doctors

An Italian doctor working in Poland claimed that Poland was circumventing the EU Working Time Directive by hiring doctors already established as self-employed, instead of recruiting doctors directly via the health service. In its response, the Commission confirmed that the rights contained in the Directive do not apply to self-employed persons.

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SPC: thematic review of health policy reforms

The Working Party on Public Health at Senior Level (WPPHSL), at its meeting on 15 July, was informed that in November, the SPC would conduct a thematic review of national health policy reforms, focusing on access to healthcare. Senior officials from the WPPHSL Member States have been invited to participate in this exercise.

DOC EN PDF

SPC: social protection performance monitor

This report, drawn up by the SPC, presents an overview of recent developments in the social situation in EU Member States, based on the results from the latest edition of the Social Protection Performance Monitor (SPPM). According to the report, unmet need for medical care, as reported by respondents with reference to their own situation, increased in nine Member States between 2008 and 2013.

DOC EN HTML

6 Economic policy

Council: country-specific recommendations approved

The Council of 14 July 2015 issued country-specific recommendations (CSRs) containing opinions on the economic, fiscal and social policies of the Member States. Several Member States received a recommendation to reform their healthcare systems. Adoption of the texts, endorsed by the European Council in June, concluded the 2015 European Semester policy monitoring process.

DOC 1 EN/FR/NL HTML | DOC 2 EN PDF | DOC 3 EN - FR PDF

European Parliament: comparison of the country-specific recommendations proposed by the Commission and approved by the Council

The European Parliament published a comparative table showing CSRs as proposed by the Commission and as they were finally approved by the Council. In the area of healthcare, the CSR for Ireland was the only one amended by the Council.

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European Parliament: overview of the Commission assessment of implementation of the 2014 CSRs

This table gives an overview of the country assessments carried out by the European Commission in February. Bulgaria, the Czech Republic, Latvia, Poland, Croatia, Malta, Romania, Germany, France and Slovakia are deemed to have made insufficient progress in improving the cost-effectiveness of their care systems, while Ireland, Spain, Austria, Slovenia and Finland are said to have made some progress.

DOC EN PDF

European Commission: Memorandum of Understanding (MoU) with Greece

The new MoU with Greece, signed on 1 August, contains detailed guidelines on reforming healthcare.

DOC EN PDF

European Commission: report giving (in)efficiency estimates of healthcare systems in the EU

In this report, the Commission concludes that there is considerable waste in healthcare systems in the EU. In the view of the authors, efficiency gains could translate into a 0.5% reduction in the annual growth rate of public health expenditure, which in the long term could halt the increase in the public health care expenditure-to-GDP ratio. This report lists Belgium as one of the top 7 best performing systems.

DOC EN PDF

Ireland: ex-post evaluation of the economic adjustment programme

The European Commission published an ex-post evaluation of the economic adjustment programme for Ireland (2010-2013), with a view to drawing lessons for the future. The report regrets that healthcare reforms were only included in the programme at the end of 2013, which means that important milestones will only be reached in the post-programming period.

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Portugal: report on the second post-programme surveillance mission to Portugal

This European Commission report presents the findings of the second post-programme surveillance mission to Portugal, and identifies remaining challenges for the Portuguese economy. According to this report, the sustainability of the healthcare system has improved markedly since 2011, but considerable challenges remain.

DOC EN HTML

Cyprus: sixth review of the economic adjustment programme

This review, the sixth of its kind, assesses the progress made in five areas, and makes a number of recommendations as to where improvements could be made. It includes a section on reforms to the national health system (3.3.1) and reports that the reforms have been delayed to 2017.

DOC EN HTML

European Parliament: macroeconomic imbalance procedure

The European Parliament has published an overview of the Member States' situation with respect to the Macroeconomic Imbalance Procedure (MIP). In 2015, under the European

Semester, five Member States - Bulgaria, Spain, Croatia, Romania and Slovenia - received a country-specific recommendation on their healthcare systems based on the MIP.

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7 Competition

European Commission: 2014 report on competition policy

The Commission published its annual report on competition policy, for 2014. The accompanying background document (Staff working paper) contains a specific chapter on the pharmaceutical and health services sector. The issues discussed in this chapter include the 'Iris' case, concerning the financing of public hospitals in Brussels, and the case relating to Slovak compulsory health insurance.

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European Commission: acquisition of Hospira by Pfizer approved

The Commission has approved the acquisition of Hospira by Pfizer, subject to conditions.

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European Commission: approval of acquisition of joint control over Hospital Universitari Son Espases, SA (HSE), of Spain

The European Commission cleared the acquisition of joint control over HSE by Aberdeen Infrastructure (HoldCo) BV, of the Netherlands, together with the current Spanish parent, Iridium Concesiones de Infraestructuras, SA (Iridium).

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European Commission: approval of acquisition of Labco SA, of France, by Cinven Capital Management, of Guernsey

The European Commission approved the acquisition of Labco SA of France, by Cinven Capital Management of Guernsey.

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European Commission: approval of acquisition of Perrigo, of Ireland, by Mylan, of the Netherlands

The European Commission cleared the acquisition of Perrigo, of Ireland, by Mylan, of the Netherlands. Mylan is a producer of prescribed generic pharmaceuticals. Perrigo is specialised in the sale of over-the-counter (OTC) drugs, available without prescription in pharmacies.

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European Commission: approval of acquisition of Sigma-Aldrich by Merck

The European Commission has approved the acquisition of Sigma-Aldrich by Merck. Both companies are active worldwide in the life science sector.

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UK: abuse of dominant position by Pfizer and Flynn Pharma

CMA, the British competition authority, alleges that the pharmaceutical companies Pfizer and Flynn Pharma have abused their dominant position by charging 'excessive and unfair' prices for their anti-epilepsy drug.

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Belgium: Competition authority rejects an appeal by a pharmacist concerning alleged abuse of a dominant position by Omega Pharma

The decision refers to a complaint brought by a pharmacist, Mr Cuyckens, against Omega Pharma, alleging that it had abused its dominant position in the pricing and assumed reduction in the range of raw materials for magistral preparations and packaging material that is used by pharmacists.

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8 **Jurisprudence of the Court of Justice of the EU and the General Court**

Judgment: application of the Working time directive to the training time of doctors in training

In case C-87/14, the Court dismisses the Commission's action against Ireland concerning application of the Working time directive 2003/88/EC to doctors in training (non-consultant hospital doctors-NCHD). In the view of the Court, the Commission has not succeeded in establishing that training time is 'working time' in the meaning of the Directive.

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Judgment: VAT exemption for the transportation of human organs and samples of human origin for medical analysis

In case C--334/14, the Court finds that the exemptions set out in the VAT Directive (77/388/EEC) for certain activities of general interest do not apply to the transportation, for clinics and laboratories, of human organs and samples of human origin for medical analysis or medical or therapeutic care, by a third party who is self-employed and whose services are covered by the reimbursement made by the social security system.

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Judgment: incomplete transposition of the EU legislation on human tissues and cells

In case C-29/14, the Court declares that Poland has failed to fully transpose the EU legislation on human tissues and cells, by excluding reproductive cells, foetal tissues and embryonic tissues from the scope of national legislation transposing the EU directive.

DOC EN/FR/NL HTML

Judgment: annulment of market authorisation for the orphan drug Kolbam

In case T-452/14, the Court annuls the market authorisation for the orphan drug Kolbam, and rules that Laboratoires CTRS have ten years market exclusivity for Orphacol.

DOC EN/FR HTML

Judgment: no possibility of retroactive affiliation to compulsory healthcare insurance

In case C--543/13, the Court rules on whether a national provision, whereby a person entitled to a pension with a retroactive effect of one year is not permitted to become affiliated to compulsory health insurance with the same retroactive effect, is compatible with Regulation 1408/71 on the coordination of social security legislation. In the view of the Court, such a provision is precluded if it has the effect of depriving that person of all social security cover, without all the relevant circumstances, in particular those relating to that person's personal situation, being taken into account.

DOC EN/FR/NL HTML

Judgment: medicinal products for human use issued in accordance with a medical prescription and for which no marketing authorisation has been granted

In case C--545/13, the Court finds that medicinal products for human use, issued in

accordance with a medical prescription and for which no marketing authorisation has been granted, fall within the scope of the Community code on medicinal products for human use, if they have been prepared industrially or manufactured by a method involving an industrial process. These medicinal products are only covered by the exception in Article 3 of the Directive if they have been prepared in accordance with a medical prescription issued before their preparation, specifically for a previously-identified patient, and are delivered directly to patients by the pharmacy which prepared them. Advertising practices relating to these medicinal products can also fall within the scope of the EU Directive on unfair commercial practices.

DOC EN/FR/NL HTML

9 Infringement proceedings

Lithuania: transposition of the EU Directive on quality and safety standards for human tissues and cells

The European Commission has called upon Lithuania to transpose into its national law the provisions on quality and safety applicable to reproductive cells under EU law setting quality and safety standards for human tissues and cells.

DOC EN/NL/NFR HTML

10 International trade agreements

India–EU Broadbased Trade and Investment Agreement (BTIA): talks halted over suspension of the EU marketing authorisation for medicines

The Indian government has suspended talks on a broadbased trade agreement with the European Union in response to withdrawal of the authorisation for around 700 medicines tested in India.

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European Parliament: resolution on TTIP

The European Parliament adopted a resolution in support of the Transatlantic Trade and Investment Partnership TTIP. In a compromise on private arbitration in investor-state disputes (ISDS), the Parliament asks for the proposed system to be replaced by a system with publicly-appointed judges, subject to proper scrutiny and transparency rules. The Parliament also asks for public services (including healthcare) to be excluded from the scope of the agreement.

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AIM: reaction to the EP resolution on TTIP

AIM, the European umbrella organisation of health mutuals and health insurance funds, reacted positively to the Parliament position and its call to exclude health services from the agreement. However, it deplores the Parliament's decision not to unequivocally reject the ISDS.

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HAI: reaction to the EP resolution on TTIP

Health Action International (HAI) also regrets the compromise struck in the European Parliament on ISDS, and fears that the safety and affordability of medicines may be

jeopardised.

DOC EN PDF

European Commission: report on the 10th round of TTIP negotiations

This report summarises the progress made in talks, including on the area of medicines and medical devices.

DOC EN PDF

TTIP: EU negotiating proposal for services, investment and e-commerce

The most recent text of the EU negotiating proposal on services, investment and e-commerce, tabled for discussion with the US in the negotiating round of 12 -17 July 2015, was made public.

DOC EN PDF

EPHA: conference on TTIP and health

The European Public Health Alliance (EPHA), together with Demeter, organised a conference on TTIP and health. The conference report contains, among other things, a summary of discussions on the impact of TTIP on healthcare systems.

DOC EN PDF

European Commission: Hepatitis C and the TRIPS agreement

MEP Ernest Urtasun asked the Commission whether the EU can withdraw the patent for the expensive drug Sovaldi. In its answer, the Commission states that it is up to Member States to interpret their own national patent law, and to assess whether the applicable conditions for exemptions and restrictions are met.

DOC EN HTML

BEUC: TTIP and medicines and medical devices

The European Consumers' organisation, BEUC, published its position on TTIP and health. It focuses principally on the possible consequences of an agreement on autonomy of decision-making in relation to medicines and medical devices.

DOC EN PDF

Minister de Block: TTIP may influence the use charges and reimbursement of medicines

The Belgian Minister of Social Affairs also commented that the TTIP may have an impact on the use charges and the reimbursement of medicines.

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Wikileaks: secret healthcare annex to the Trans-Pacific Partnership Agreement (TPP) published

WikiLeaks published the healthcare annex to the secret draft chapter of the TPP (between the United States and certain South East Asian countries), together with each country's negotiating position. The document focuses on medicines and medical devices. It forces healthcare authorities to give large pharmaceutical companies more information about national decisions on public access to medicines, and grants corporations greater powers to challenge decisions they perceive as harmful to their interests.

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11 publications

Book: 'Economic crisis, health systems and health in Europe'

The European Observatory on Health Systems and Policies published a book on the impact of the economic crisis on health systems and health in various European countries. One chapter focuses on Belgium.

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12 Miscellaneous

Council: agreement on the EU data protection regulation

EU ministers agreed on a general approach to the revision of the regulation on the protection of personal data. A specific approach has been foreseen for health data. Negotiations with the European Parliament will begin on the basis of this text, with a view to reaching a general agreement towards the end of 2015.

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Research institutes: EU data protection regulation and scientific health research

A number of Dutch research institutes have called for a research-friendly approach in the EU regulation on data protection. The text adopted in the European Parliament restricts the processing of personal data by requiring informed consent, regardless of the purpose the data will be used for and regardless of whether or not privacy enhancing technologies are applied.

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European Commission: Eurobarometer on data protection

When it comes to the protection of personal data, people trust medical institutions more than, for example, banks or telecom companies, according to a Commission survey. Almost three quarters say that they trust hospitals.

DOC EN PDF

Eurostat: Health in the European Union - facts and figures

This online publication provides recent statistics on various aspects of health in the European Union: state of health, health determinants, healthcare, etc.

DOC EN HTML

European Commission: Interreg programme in the border regions of Serbia and Croatia

The EU is investing €34 million, through an Interreg programme, in the border regions of Croatia and Serbia. An important part of this programme will be to improve the quality of public social and health services.

DOC EN HTML

OECD: health statistics 2015

Many European countries saw further reductions in health spending in 2013, according to OECD Health Statistics 2015. Most countries in the European Union reported real per capita health spending below the levels of 2009, while outside Europe health expenditure has been growing at about 2.5% per year since 2010. On the basis of this data, the OECD has drawn up detailed country notes.

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WHO: support tool to assess health information systems and develop and strengthen health information strategies

The WHO Regional Office for Europe published a support tool to assess health information systems and develop and strengthen health information strategies.

DOC EN PDF

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