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1 Health care services in the internal market

eCall system in cars: European Parliament

Emergency call devices which automatically alert emergency services to car crashes must be fitted to all new models of cars and light vans in the EU by October 2015. The Parliament voted in favour of this draft legislation on the so-called eCall system.

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Change to the public procurement rules: European Parliament and Council

The European Parliament and the Council adopted the new rules governing public procurement. Procurement of health care services is subject to a simplified procedure.

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Report on the effects of the Directive on the application of patients' rights in cross-border health care: European Commission

The European Commission published a report on the effects of the directive on the application of patients' rights in cross-border health care. In particular it considers the potential effects of prior authorisation systems and of the definition of the Member State responsible for reimbursing patients the costs of cross-border health care, for pensioners having transferred their residence to a new Member State.

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Transposition of the Directive on the application of patients' rights in cross-border health care: European Commission

The Commission presented an information note on the transposition of the Directive on the application of patients' rights in cross-border health care to the Council of Health Ministers. In the note the Commission encourages Member States to complete the transposition of the directive.

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Information brochure on cross-border health care: European Commission

The European Commission published an information brochure for patients looking to receive medical care in another Member State.

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Transparency of rates charged for medical services in the Directive on the application of patients' rights in cross-border health care: Belgium

The Belgian Council of Ministers approved a preliminary draft text on financial transparency in the area of health care. Patients will be entitled to a detailed account of the fees and services invoiced. This draft legislation transposes into Belgian law the transparency provisions contained in the European Directive on the application of patients' rights in cross-border health care.

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Implementation of the Directive on the application of patients' rights in cross-border health care: Belgium

An amendment to Belgian legislation means that henceforth the NIHDI will also publish a list of the health care providers which have signed up to the rates set in the conventions. These rates will also apply to patients from abroad.

The provisions of the Special Solidarity Fund are also being adjusted to fit the European Directive. This fund provides an additional safety net - together with medical health care insurance - in cases of important and necessary medical services which are not reimbursed and are particularly expensive.

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2 Medicines and medical devices

➤ **Clinical trials on medicinal products for human use: European Parliament**

The European Parliament's Committee on the Environment, Public Health and Food Safety (ENVI) approved the agreement reached with the Council on the regulation on clinical trials on medicinal products for human use. The Parliament added provisions to improve transparency.

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➤ **Rapid alert system for blood and blood components: European Commission**

The European Commission launched a web-based system allowing national health authorities to exchange information and warnings quickly on blood and blood components, in order to prevent or contain cross-border incidents.

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➤ **Financing of pharmacovigilance: agreement between Council and Parliament**

The Council's Permanent Representatives Committee (COREPER) approved the compromise agreed with the European Parliament on the financing of reinforced pharmacovigilance. The regulation allows the European Medicines Agency to charge fees and to remunerate national competent authorities for their work in the EU-wide pharmacovigilance assessment procedures.

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3 Public health

➤ **Conclusions on the 'Reflection process on modern, responsive and sustainable health systems': Council**

In December 2013, the Ministers of Public Health, meeting in the Council, adopted conclusions on the reflection process on modern, responsive and sustainable health systems. The conclusions invite Member States and the Commission to ensure the necessary coordination at national and EU level in order to adequately represent the health sector in the process of the European Semester. A working relationship should be established, they say, between the Working Party on Public Health at Senior Level and the Social Protection Committee.

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➤ **Agreement on the Public Health Programme (2014-2020).**

The Lithuanian EU Council Presidency, the Commission and the European Parliament reached agreement on the Public Health Programme (2014-2020).

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➤ **Patient safety and quality of care: public consultation**

The European Commission launched a public consultation on patient safety and quality of care.

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➤ **Health inequalities: Commission report**

The European Commission published a report on health inequalities. According to the Commission, the variations in life expectancy and infant mortality between the Member States are narrowing.

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Flu vaccination: Commission Working Document

The Commission published a working document providing an interim analysis of the state of play of implementation of the Council recommendation on the flu vaccination. According to the report, most Member States are not meeting the target of vaccinating 75% of the elderly population.

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Opinions requested from the Expert Panel on effective ways of investing in health

The European Commission asked the Expert Panel on effective ways of investing in health to produce an opinion investigating policy options regarding competition among providers of health care services, and another on the future EU agenda on quality of health care.

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Chronic diseases: Joint action

The 'CHRODIS' Joint Action, addressing chronic diseases and promoting healthy ageing, started its work.

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4 Social policy

Social aspects of the European Semester: European Parliament

The European Parliament's Committee on Employment and Social Affairs adopted a report on the employment and social aspects in the Annual Growth Survey 2014. The Parliament notes that the scoreboard with social indicators is not binding, unlike the Macroeconomic Imbalance Procedure scoreboard, and asks that this situation be assessed in the light of the growing social imbalances in the EU. The report calls for the social scoreboard to include additional indicators, including on access to health care.

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Open method of coordination in the area of health care in the JAF: European Commission

The Commission gave an overview of the actions it has undertaken as part of the Social Investment Package. It also published a roadmap of planned initiatives. In this, it announced that it is looking into whether to add the open method of coordination in the field of health care to the 'Joint Assessment Framework' (JAF). The Commission plans to discuss this possibility in the course of the year with the Indicators Sub-group of the Social Protection Committee.

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5 e-Health

Resolution on the eHealth action plan: European Parliament

The European Parliament adopted a resolution on the eHealth action plan 2012-2020.

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6 Economic policy

Review of the economic adjustment programme: Ireland

In its twelfth and final review of the economic adjustment programme for Ireland, the European Commission notes that the 2013 deficit is just below the level set for the excessive deficit procedure, despite overruns in the health sector. These deficits are largely due to delays in implementing the budgetary measures.

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Review of the economic adjustment programme: Portugal

The eighth and ninth review of the economic adjustment programme for Portugal carries out an extensive assessment of reforms in the health sector (cf. pp. 25 and following).

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Second review of the economic adjustment programme: Cyprus

The second review of the economic adjustment programme for Cyprus also assesses the reforms to be carried out in the health sector (cf. pp. 31/32).

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Precautionary balance-of-payments assistance: Romania

The Council approved medium-term financial assistance for Romania, to be provided by the EU together with the IMF, to anticipate balance of payment risks, on the basis of a new balance of payments precautionary assistance programme. Romania, in its turn, has undertaken, on the basis of a new memorandum of understanding, to carry out a series of reforms, including in the health care sector (cf. Memorandum of Understanding pp. 15-16).

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Economic Partnership Programmes: Spain, France, Malta, the Netherlands, Slovenia

As part of the enhanced surveillance of Eurozone Member States with an excessive deficit, Spain, France, Malta, the Netherlands and Slovenia submitted Economic Partnership Programmes. These programmes were assessed by the European Commission, and the Council adopted conclusions, on the basis of a Commission proposal, on each of them. Every programme contains a section referring to reforms in the health sector.

(click on each country in the "Most recent updates (15 November 2013)" section):

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Macro-economic conditionality in the cohesion policy package, 2014-2020: Council

In December 2013, the Council adopted the cohesion policy package for 2014-2020. This package contains legislation concerning partnership agreements between the Commission and each Member State, whereby Member States undertake to use the funds towards the achievement of the Europe 2020 objectives. On the basis of these partnership agreements, funding from the structural and investment funds is also made subject to macro-economic conditionality. If a Member State does not sufficiently respect these conditions, the Commission can ask the Council to suspend a part or all of the payments.

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Partnership agreement and programmes for cohesion policy: Commission position paper for each Member State

The European Commission prepared for each Member State a position paper on the development of a Partnership Agreement and programme for 2014-2020. These agreements and programmes form the basis for delivery of the EU structural and investment funds. Each of these position papers refers to measures in the health care sector.

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Contractual agreements between the EU institutions and the Member States: European Council

The conclusions of the Heads of State and Government, meeting in the European Council of December 2013, contain an outline agreement concerning contractual arrangements negotiated between the Member States and the EU institutions, as well as a solidarity mechanism to support countries before they face severe difficulties. This system would be embedded in the European Semester. It would apply to all Eurozone Member States, except for those subject to a macroeconomic adjustment programme, and would be open to non-Eurozone Member States. The agreements would be based on the National Reform Programmes, and would take account of the EU economic priorities and the Country-specific Recommendations. A re-worked proposal will be made available around October 2014.

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7 Insurance

Sales of insurance products: European Parliament

The European Parliament voted on amendments to the proposal changing the European rules on information and advice to be provided by insurance brokers and sellers. Agreement is yet to be reached with Council on this proposal.

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8 Court of Justice of the European Union

Ban on prescription-only medicinal products in para-pharmacies: judgment

In its judgment on the joined cases C-159/12 till 161/12, the Court holds that the prohibition on the sale in para-pharmacies of prescription-only medicinal products is compatible with EU law. Such a prohibition is justified when its objective is to ensure that the supply of medicinal products to the public is reliable and of good quality.

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Demographic criteria in relation to the opening of new pharmacies: judgment

In Austria, opening a new pharmacy requires a prior authorisation which is subject to the existence of a 'need'. In its judgment on case C-367/12, the Court holds that the freedom of establishment - in particular the requirement that the desired objective be achieved in a consistent manner - precludes legislation which does not allow the competent authorities to take account of particular local conditions.

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Interaction between maternity leave and parental leave: judgment

In the joined cases C-512/11 and C-513/11, the Court gives its findings on a number of questions relating to the interaction between maternity leave and parental leave, in application of Directive 96/34/EC.

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➤ **Prior earmarking of tax revenue for health care expenditure: judgment**

In the view of the Court, national legislation introducing a tax on the retail sales of mineral oils is not compatible with the European Excise Duty Directive, since this tax, to be used to finance the exercise by the authorities of their competences in the area of health care and the environment, is not itself directed at protecting health and the environment.

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➤ **Supplementary protection certificate for medicinal products: judgment**

In case C-493/12 the Court gives its findings on a number of questions relating to the application of Regulation 469/2009 concerning the supplementary protection certificate for medicinal products.

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➤ **Supplementary protection certificate for medicinal products: judgment**

In the view of the Court in case C-484/12, the holder of a basic patent and a supplementary protection certificate for a medicinal product consisting of a combination of several active ingredients may also obtain a supplementary protection certificate for one of those active ingredients which, individually, is also protected as such by that patent.

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➤ **Supplementary protection certificate for medicinal products: judgment**

In case C-443/12 also, the Court gives its findings on a number of questions relating to the application of Regulation 469/2009 concerning the supplementary protection certificate for medicinal products.

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➤ **Supplementary protection certificate for medicinal products: order**

In case C-555/13, the Court again responds to a series of questions relating to the application of Regulation 469/2009 concerning the supplementary certificate for medicinal products.

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➤ **Rules on professional conduct for doctors: judgment**

In the view of the Court in case C-475/11, rules on professional conduct for doctors, setting out the fees to be applied and to be calculated on the basis of the official regulation on doctors' fees, and which prohibit doctors from engaging in unprofessional advertising, should pursue a legitimate objective in the public interest, be appropriate to ensuring the attainment of the objective pursued, and not go beyond what is necessary for attaining it.

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➤ **Application of the services directive to day-care and night-care centres for the elderly: judgment**

In case C-57/12, the Court considers the exclusion of health care services from the scope of Directive 2006/123/EC on services in the internal market. In the view of the Court, day-care and night-care centres providing assistance and care to elderly persons are excluded from the scope of this directive, if the activities carried out by health care professionals in those centres constitute a principal part of the services offered by the centres.

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➤ **Exclusion of care professionals from the law on commercial practices: opinion of the Advocate-General**

In the view of the Advocate-General in case C-421/12, Belgian legislation is not compatible with the European Directive concerning unfair commercial practices. His conclusions include a finding that the exclusion of members of the liberal professions such as dentists and physiotherapists from the scope of the law of 5 June 2007 on commercial practices is contrary to the European legislation.

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➤ **Public procurement and in-house awarding of contracts: opinion of the Advocate-General**

In case C-574/12, the Advocate-General clarifies the application of the rules concerning the in-house awarding of contracts to a contractor which is a legal entity governed by private law, the members of which include persons with private business interests. In the view of the Advocate-General, the in-house exception cannot apply in cases where a contractor, according to its statutes, can supply services on a competitive basis to non-member public bodies and individuals, for an amount equivalent to 20% of the previous year's total annual turnover.

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➤ **Public contracts for the management of public health care services: request for a preliminary ruling**

In case C-552/13, the Court was asked whether the requirement in public contracts for the management of public health services that the services in question be carried out only in a determined municipality, which is not necessarily the municipality in which the patients reside, is compatible with European Union law.

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➤ **Medical care insurance with retroactive effect: request for a preliminary ruling**

In case C-543/13, questions are put to the Court in connection with restrictions in the Netherlands legislation concerning medical care insurance with retroactive effect.

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9 Competition

➤ **Report on patent settlement agreements in the pharmaceutical sector: European Commission**

The European Commission published its 2012 report on patent settlement agreements between originator and generic companies. According to the Commission, the number of potentially problematic agreements is falling every year.

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➤ **Delays in the market entry of a generic pain-killer: European Commission**

The European Commission has imposed a fine on Johnson & Johnson and Novartis for delaying the market entry of a generic pain-killer.

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➤ **Opinion on the distribution chain for medicinal products: France**

The French competition authority published an opinion on the distribution chain for medicinal products.

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➤ **Anti-competitive agreements between wholesalers of pharmaceuticals: Slovenia**

The Slovenian Competition Protection Agency issued a decision finding that four Slovenian wholesalers had concluded anti-competitive agreements.

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➤ **Fine imposed for impeding the marketing of a generic product: France**

The French competition authority is imposing a €15.3 million fine on the pharmaceutical company Schering-Plough, for impeding the market entry of the generic version of its originator medicinal product Subutex.

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➤ **Support for telemedicine services: Germany**

The European Commission found that German plans to support the set up of a platform for telemedicine services in Saxony are in line with EU state aid rules.

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➤ **Regulation of chiropractors and physiotherapists: Denmark**

The Danish competition authority is of the view that regulation of the chiropractor and physiotherapist sector restricts competition in this sector.

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➤ **Price agreements for dental devices: Hungary**

The Hungarian competition authority is imposing a fine on W&H Dentalwerk Bürmoos GmbH and some of its distributors for concluding agreements fixing minimum resale prices for dental devices.

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➤ **Greater competition in the hospital services market: Bulgaria**

The Bulgarian Commission on Protection of Competition considers that setting a maximum number of beds per type of care distorts competition and removes incentives to improve quality. It is also of the opinion that the system whereby the health insurance fund concludes contracts with all hospitals that fulfil the minimum requirements distorts competition. Finally the Commission considers that all care providers meeting medical standards for emergency medical treatment - regardless of their legal status - should be allowed to provide that service and may receive state financing for this.

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➤ **Competition concerning ambulatory care: Bulgaria**

The Bulgarian Commission on Protection of Competition considers that the ban on departmental hospitals providing ambulatory medical care financed by the national health insurance fund restricts competition.

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➤ **Hospital merger approved: the Netherlands**

The Autoriteit Consument & Markt (ACM) in the Netherlands has approved the merger between the Medisch Centrum Haaglanden (MCH) and Bronovo hospitals in The Hague.

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➤ **Use of more highly-qualified nursing staff than the minimum foreseen in the tender specifications: Sweden**

The Swedish competition authority finds that the exclusion from a tender of suppliers who use more highly-qualified nursing staff than the minimum set out in the tender specifications is a breach of the principle of proportionality.

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10 Infringement proceedings

Working time directive: Italy

The Commission is referring Italy to the Court of Justice for failing to apply correctly the working time directive to doctors in public health services.

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Working time directive: Spain

The European Commission has asked Spain to respect the rights of forensic doctors to limits on their working hours and minimum rest periods, as set out in the working time directive (2003/88/EC).

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EU directive on the prevention of injuries from sharp medical instruments: Cyprus

The Commission has asked Cyprus to transpose into national law the EU directive on prevention of injuries from sharp medical instruments in the hospital and health care sector (2010/32/EU).

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11 Miscellaneous

Launch of the EU framework programme for research and innovation, Horizon 2020

Horizon 2020, the EU framework programme for research and innovation for 2014-2020 was launched, with the publication of the work programmes for 2014-2015. Research on health and well-being is also funded by this programme.

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Advisory group on the Transatlantic Trade and Investment Partnership (TTIP): European Commission

The Commission launched a special advisory group of experts representing a broad range of interests, including the health sector. Their role is to provide EU trade negotiators with advice concerning the TTIP talks.

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TTIP negotiators discuss regulatory barriers for medicinal products and medical devices

In the second round of negotiations on the EU/US free trade agreement, the parties held detailed talks on technical and regulatory barriers in a number of sectors, including the medicinal products and medical devices sector.

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Weekly news feed on the health-related aspects of the TTIP: EPHA

EPHA is starting a weekly news feed on developments in the negotiations concerning the Transatlantic Trade and Investment Partnership (TTIP), and their possible negative effects on public health.

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Health care provision in the TTIP negotiations: BMA

European Commission services and the UK Minister of Health responded to the concerns of the British Medical Association (BMA), reassuring it that health services would not be

addressed in the TTIP talks.

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Free trade agreement may lead to an increase in the price of medicines, warn trade unions

The European Trade Union Confederation and its international counterparts are expressing their concerns that the US proposals for the TTIP and TTP would enable manufacturers to appeal against decisions made by the authorities concerning the price and reimbursement levels of pharmaceutical products.

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Proposed data protection legislation: parliamentary question

In a parliamentary question, the Belgian MEP Marc Tarabella (S&D) puts a number of queries as to draft data protection legislation, and in particular on the lack of specific provisions concerning the storage and exchange of public health related data.

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Data protection regulation a threat to medical science, according to a coalition of scientists

A coalition of medical research organisations is warning that scientific research in the health sector faces a serious threat if amendments proposed in the European Parliament to the Data Protection Regulation are adopted.

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VAT legislation on public services and tax exemptions in the public interest: public consultation

The European Commission is organising a public consultation on a review and possible revision of the VAT rules on public services and tax exemptions in the public interest.

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Anti-corruption report: European Commission

The European Commission published an anti-corruption report. The report refers to health care as a sector which is vulnerable to corruption.

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Awarding of European Research Infrastructure Consortium status: European Commission

The European Commission has awarded the status of European Research Infrastructure Consortium to four consortia carrying out research in the fields of health and social sciences.

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Causes of death in the EU in 2010: Eurostat

Eurostat published an overview of the most significant causes of death in the EU in 2010.

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Cross-border health care: Eurohealth

The most recent issue of Eurohealth explores various topics related to the European Directive on the application of patients' rights in cross-border health care.

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Impact of the crisis on access to health care: Eurofound

Eurofound published a Working Paper on the impact of the crisis on access to health care.

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➤ **Loan for health infrastructure in the Czech Republic: European Investment Bank**

The European Investment Bank approved a loan to the Czech region of South Moravia for co-financing projects, including health infrastructure projects.

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➤ **Loan for Graz Hospital: European Investment Bank**

The European Investment Bank is extending a loan to Graz University Hospital, Austria, to finance its multiannual investment programme.

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➤ **Agreement on a 'Hospitals of the Future' programme in France: European Investment Bank**

The French authorities signed a Memorandum of Understanding with the European Investment Bank on a 'Hospitals of the Future' programme.

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