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1 Public health

European Commission: call for applications on European Reference Networks

The European Commission has launched a first call for interest to set up a European Reference Network (ERN). Any group of at least 10 healthcare providers established in at least 8 Member States may collectively respond by the deadline with an application containing a proposal to establish a network in a given field of expertise.

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European Commission: publication of the first call for tender in the context of the Joint Procurement Agreement

Five Member States (Belgium, Cyprus, Croatia, Italy and Malta) are, for the first time, making use of the Joint Procurement Agreement, to jointly purchase personal protective equipment. The contract is for the supply, storage and dispatching of personal protective equipment for healthcare workers who might need to deal with infectious diseases.

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EXPH: disruptive innovation, considerations for health and healthcare in Europe - Final opinion

The expert panel on effective ways of investing in health (EXPH) produced its final opinion on disruptive innovation and its impact on health and healthcare in Europe.

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Expert group on rare diseases: recommendations to support the incorporation of rare diseases into social services and policies

The 'European Commission expert group on rare diseases' adopted new recommendations on the incorporation of rare diseases into social services and policies. The recommendations are intended to advise Member States and the European Commission on issues that should be considered when organising the holistic care of patients suffering from rare diseases within national health and social care systems.

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European Commission: reports on quality and safety standards for human blood, tissues and cells

These reports on the implementation of European legislation highlight some gaps and difficulties in implementing and enforcing the existing provisions in relation, for example, to definitions, donor-protection, the inspections and trials systems, and deferral criteria for new epidemiological and technological developments.

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European Commission: workshop report - Optimising continuous professional development of health professionals in Europe

This workshop was attended by 60 experts in the area of continuous professional development, including representatives of regulatory, professional and educational bodies and the European Commission. These experts discussed ways to optimise continuous professional development of health professionals in order to improve quality of care and patient safety.

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HSPA expert group: strategies to assess quality of care

The aim of the report from the Expert Group on Health Systems Performance Assessment (HSPA) is to provide useful suggestions and recommendations for policy-makers wishing to design, set up, run and evaluate a system to assess quality of care.

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➤ **EUROSTAT: over a million persons died in the EU from a heart attack or a stroke**

According to the EU statistics office (EUROSTAT), heart attacks and strokes were the cause of death for 1.1 million persons in 2013, accounting for 1 in 5 deaths. The study also confirms that the risk of dying from a heart attack or stroke increases with age.

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2 Medicines and medical devices

➤ **European Parliament: initiatives to improve access to medicines**

The European Parliament's Committee for the Environment, Public Health and Food Safety was tasked with drafting an own-initiative report on 'EU options for improving access to medicines'.

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➤ **Council and European Parliament: agreement on medical devices**

The European Parliament and the Council reached agreement on two proposals for regulations concerning quality and safety standards for medical and in vitro devices.

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➤ **EMA: launch of PRIME**

The European Medicines Agency (EMA) launched the PRIME ('Priority Medicines') programme, to enhance support for the development of medicines which target an unmet medical need. This voluntary scheme is based on enhanced interaction and early dialogue with developers of promising medicines, to optimise development plans and speed up evaluation so that these medicines can reach patients earlier.

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➤ **Working group on living kidney donation: toolbox**

The experts of the Working Group on Living Donation, set up under the EU Action Plan on organ donation and transplantation (2009 - 2015) have produced a full toolbox to provide reference guidelines to EU Member States on living kidney donation for the purpose of transplantation. The document provides guidelines and key principles concerning the legal, ethical, psychological and financial aspects of living donation.

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➤ **European Commission: launch of the EU Health Policy Platform**

The EU Health Policy Platform (HPP) is a collaborative initiative aiming to facilitate communication between the Commission services and health stakeholders. It is intended to be inclusive and to reflect the geographical and professional diversity of members. It replaces the former EU Health Policy Forum.

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➤ **Netherlands Presidency of the EU: position paper on pharmaceuticals policy**

This position paper identifies future challenges concerning the supply of medicines in the EU and makes recommendations. It addresses 6 questions which are key for the future medicines policies of EU Member States: accessibility, price, research and development, use of pharmaceuticals, balance in the pharmaceutical market and patient information.

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▶ AIM, ESIP and EPHA: access to innovative medicines

Three civil society associations (AIM, ESIP and EPHA) have written to the EU Health Ministers asking for discussion at EU level of safe and rapid access to new medicines, and of policies concerning the pricing and reimbursement of medicines, including those developed for small groups of patients.

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▶ EMA and EUnetHTA: report on the implementation of their joint 2012 - 2015 work plan

The report highlights the value of EMA and EUnetHTA collaboration, which fosters an approach to the generation of data on medicines, pre- and post-authorisation, reconciling regulatory and HTA requirements into one clinical development programme.

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▶ GKV: press release on patient safety

The national German association of statutory health insurance funds (GKV) published a press release, confirming that patient safety must remain a priority in the context of the on-going debate at European level to shorten the approval process for new pharmaceuticals.

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3 Healthcare services in the internal market

▶ European Parliament: resolution on non-tariff barriers in the Single Market

The resolution recalls that public services benefit from special protection in relation to internal market rules because of the general interest tasks they fulfil, and that therefore the rules set by the public authorities for their proper operation do not constitute non-tariff barriers.

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▶ Benelux Union: report on the number of cross-border patients in the Benelux region

A recent report from the Benelux Secretariat-General shows that at least 168,177 patients cross the border each year to receive care in another Benelux country, Germany or France, for both scheduled and unscheduled care. The real number is probably far higher.

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▶ European Parliament: adoption of the report on the directive on trade secrets

The European Parliament adopted the highly controversial Le Grip Report on the trade secrets directive. The purpose of the directive is to create a European framework to provide better protection in Europe for know-how, a concept which includes all manufacturing, organisational and technical procedures acquired by experience and used in the production of goods or provision of services.

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▶ EP Committee on Petitions: non-recognition of midwife qualification obtained in Belgium

The petitioner complains that her midwife diploma obtained in Belgium is being refused in France by the professional organisation representing midwives, the 'Conseil national de l'ordre des sages-femmes'. She challenges this decision, indicating that the Belgian authorities had issued a paper certifying that the qualifications she had obtained were in compliance with Article 40 of Directive 2005/36/EC on the recognition of professional qualifications. The Commission decided to investigate the matter further and requested additional information.

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➤ **EP Committee on Petitions: requirement to obtain a certificate of compliance for diplomas of medical specialists**

The petitioner has complained about the requirement to obtain a certificate of compliance of the diplomas of medical specialists wishing to practise in another Member State. In her opinion, compliance should automatically be indicated on all new diplomas. In its reply, the Commission distinguishes between the general, automatic recognition system for qualifications and the system for acquired rights, where a certificate of compliance is required.

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➤ **Public procurement: under the Belgian transposition of the European directive, a royal decree would exclude self-employed doctors from the scope of the legislation**

Public procurement: under the Belgian transposition of the European directive, a royal decree would exclude self-employed doctors from the scope of the legislation

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4 eHealth

➤ **WHO: report on the latest eHealth trends in Europe**

The WHO published a report on the latest eHealth trends in Europe. This report notes an increasing interest in eHealth among all stakeholders, and addresses a broad range of subjects such as electronic health records and eLearning. The WHO makes a number of recommendations and calls on Member States to promote the development of eHealth by providing a suitable legal environment.

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➤ **eHealth network: call for funding**

As part of the Joint Action to support the European eHealth network, (JAseHN), 21 EU Member States successfully submitted a proposal requesting € 13.1 million in EU funding from the eHealth call of the Connecting Europe Facility (CEF).

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5 Social policy

➤ **EPSCO Council: political guidance on employment and social policies**

The EPSCO Council adopted the 2016 Joint Employment Report, and conclusions based on this report and on the Annual Growth Survey, containing political guidance on employment and social policy. The conclusions call upon Member States to focus health reforms on ensuring sustainable and cost-effective health services, without compromising universal and equitable access, quality and safety, and with an increasing emphasis on prevention.

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➤ **EPSCO Council: consensual debate on the 'European Semester' and labour market segmentation**

During a discussion on the 'European Semester', ministers highlighted the need for 'inclusive' structural reforms and for a balance to be struck on the labour markets between flexibility and security, to combat market segmentation. Hungary, Finland, the United Kingdom, Belgium

and Cyprus stressed the need for sufficient room for manoeuvre in implementing these recommendations.

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➤ **European Commission: public consultation on the European Pillar of Social Rights**

The European Commission has launched a public consultation on the European Pillar of Social Rights. This pillar will set out a number of essential principles to support well-functioning and fair labour markets and welfare systems within the euro area. In an annex to its Communication, the Commission presents a first preliminary outline of this European Pillar. The provisions on health refer to access to good quality preventive and curative healthcare, improving the cost-effectiveness of care and entitlement to sick leave.

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6 Economic Policy

➤ **European Commission: country-specific recommendations in the context of the European Semester**

According to the European Commission, the Member States are making progress in their reforms and in correcting macroeconomic imbalances, but more must still be done to consolidate the recovery in Europe. The Commission addressed a specific recommendation on healthcare and/or long-term care to 14 Member States.

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➤ **European Commission: thematic fiche on health and health systems as part of the European Semester**

These thematic fiches are intended to provide an overview of the main policy themes relevant to boosting investment, accelerating structural reforms and pursuing fiscal consolidation. They present statistical data and assess the challenges facing Member States in these areas.

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➤ **European Commission: macroeconomic imbalances, twelve countries still under surveillance**

Of the sixteen Member States subject to in-depth reviews of their macroeconomic imbalances, twelve are still under surveillance. Five Member States - Bulgaria, Croatia, France, Italy and Portugal - are still experiencing macroeconomic imbalances considered to be excessive. These Member States must continue their efforts to reduce high levels of public and private debt, address inefficiencies in the labour market and ensure sustainability of social systems.

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➤ **France: 2016-2019 stability programme**

Michel Sapin and Christian Eckert presented the 2016-2019 stability programme: meeting our commitments over time. This programme sets out the main principles of the public finance strategy and sets key objectives. One section addresses how to control expenditure on health.

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➤ **Council: report from the Netherlands Presidency in relation to the European Semester**

The Netherlands Presidency produced a synthesis report on the contributions made by the various Council configurations involved in the current European Semester. The Presidency decided to organise specific debates in a number of Council configurations on implementation

of the country-specific recommendations, and would like this exercise to become a regular feature of the Semester.

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ECOFIN Council: conclusions on fiscal sustainability

In its 8th March conclusions, the ECOFIN Council calls on Member States to balance the increasing need for universal healthcare and long-term care in the coming decades with the need to reduce high public debt levels. This highlights the need to assess the performance of health and long-term care systems and to implement the necessary reforms to improve the quality of public finances.

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European Court of Auditors: Commission too lax in the implementation of budgetary rules

According to the report of the European Court of Auditors, the European Commission is not strict enough in its implementation of the excessive deficit procedure linked to the Stability and Growth Pact. The report is based on a study of six EU countries: Italy, France, Germany, the Czech Republic, Cyprus and Malta, between 2009 and 2015.

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EUROSTAT: government expenditure on social protection accounted for 20% of GDP in 2014

EUROSTAT published a detailed breakdown of government expenditure in the European Union by main functions for 2014. The 'social protection' function (19.5% of GDP) was by far the most important, followed by health (7.2%). With regard to health, the countries with the highest health expenditure as a percentage of GDP are: Denmark (8.7%), Finland (8.3%), France (8.2%), Belgium and the Netherlands (both 8.1%).

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7 International trade agreements

TISA: the European Commission published its revised offer on access to the services market

The European Commission published its revised offer on access to the services market under the Trade in Services Agreement (TISA). The offer includes specific measures on both public and private healthcare services (pages 26-28).

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TISA: nine negotiating documents posted online by WikiLeaks

These documents include the annex on domestic regulation, setting out new reasons to challenge regulations which are more restrictive than necessary to ensure quality of service, as well as the annex on 'state owned enterprises', stipulating prior publication of any draft regulations, so that third parties may see whether their commercial interests could be affected.

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TTIP/CETA: Belgian civil society united against these agreements

In a joint declaration, Belgian civil society organisations, including the health insurance funds, express their reservations as to the impact of the transatlantic agreements on individual citizens, consumers, workers and health.

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➤ **EU/Philippines Agreement: impact on public health and access to medicines**

Civil society organisations in Europe and the Philippines are concerned about the impact of the future EU/Philippines free trade agreement on public health and access to medicines in the Philippines.

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➤ **EU-Mexico Agreement: analysis of the upcoming modernisation of the trade pillar**

This analysis, published by the European Parliament, refers to the provisions included in the CETA Agreement between Canada and the EU on the protection of pharmaceutical patents (p. 33).

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➤ **TTIP: the European Commission published a report on the outcome of the 13th round**

The report describes the progress made during the 13th TTIP negotiating round, as well as describing the proposal on regulatory cooperation in the field of pharmaceuticals, put to the United States during the latest round. Progress has also been made on services, on mutual recognition agreements for professional services.

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➤ **TTIP: interim report on the Sustainability Impact Assessment (SIA) open for public consultation**

This report, drafted by the consultant ECORYS for the European Commission, includes a case study on human health addressing the impact of regulatory cooperation on the costs of new medicines and medical devices, and another on public health services.

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➤ **TTIP: report on US-EU regulatory cooperation**

This report, produced by the George Washington Regulatory Studies Center examines how regulatory cooperation already works, in practice, between three US regulatory agencies and their EU counterparts. One section deals with improving cooperation between the FDA (Food and Drug Administration) and the EU.

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➤ **TTIP: confidential documents reveal the progress of the negotiations**

The documents, obtained by Greenpeace Netherlands, address almost all the aspects of these very broad negotiations: the reduction in customs tariffs, but, above all, regulatory cooperation between the two parties. They cover 13 chapters, from telecoms to pesticides, as well as regulatory cooperation. The documents confirm that TTIP could infringe the precautionary principle, whereby Europe can refuse certain products for health reasons.

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➤ **TTIP: proposal on regulatory cooperation on generic medicines**

The European Commission published its proposal for TTIP on regulatory cooperation in the field of generic medicines.

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➤ **TTIP: European Commission report on the state of play of negotiations**

This 10-page document describes the state of play of negotiations. There are already consolidated texts for 17 chapters. The pharmaceutical sector is the only sector for which a proposal exists on regulatory cooperation.

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▶ **TTIP: NHS could be excluded**

According to T. Hervey of Sheffield University, the UK government could include a reservation in the Transatlantic Trade and Investment Partnership (TTIP) to exclude the NHS from its scope.

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▶ **EU/Tunisia agreement: publication of the proposed texts**

The EU and Tunisia have jointly made public the initial texts of the future Deep and Comprehensive Free Trade Area (DCFTA) as proposed by the EU. The texts, covering 11 areas, are accompanied by an explanatory note.

DOC [EN](#) HTML

8 EU Court of Justice and the General Court

▶ **Judgment: alternative therapies and exemption from VAT**

According to the judgment of the EU Court of Justice in the Gabarel case (C-555/15), a physiotherapist who, in the exercise of his health profession, uses either or both physiotherapy and osteopathic treatments, should be exempted from VAT on both the former activities, and on the latter, where excluding these from the activities carried out in the exercise of his paramedical profession and thus benefiting from a VAT exemption goes beyond the discretionary power granted to Member States by this provision.

DOC [FR](#) HTML

▶ **Judgment of the General Court: refusal of the citizens' initiative on long-term care**

According to the judgment of the EU General Court (case T-44/14), the European Commission did not commit a legal error by refusing, in 2013, the European citizens' initiative asking the EU to guarantee adequate life-long social protection and access to quality long-term care.

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▶ **Opinion of the Advocate General in the Genentech Inc. case**

This opinion concerns the interpretation of Article 101 TFEU on competition, and addresses the question of whether this article precludes an obligation imposed on a licensee under a patent licence agreement to pay royalties for the entire duration of the agreement until its termination, notwithstanding the absence of infringement or the revocation of the licensed patent or patents.

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

9 Competition

▶ **France: ruling on management of the electronic data entry system for medical data**

The Paris Court of Appeal has confirmed that the Competition Authority is not competent to deal with practices concerning management of the electronic data entry system for health insurance. It has not identified any procedural flaw which would justify annulment of the decision on inadmissibility concerning referral of a company specialised in the collection and dissemination of information on the products sold at dispensing pharmacies (Celtipharm).

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➤ The Commission approves, subject to conditions, acquisition of Allergan Generics by Teva

The European Commission has approved, under the EU merger regulation, the proposed acquisition of the generics business of Allergan of Ireland by Teva of Israel, subject to conditions. Both companies are among the top four generic pharmaceuticals manufacturers worldwide.

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➤ Latvia: reduction in the price of medical services

In the context of a sector inquiry into the market for medical services, the Latvian Competition Council (CC) identified gaps in the sector regulation and governance which distort competition, and hinder price reduction and increase of service availability.

DOC [EN](#) HTML

➤ Italy: referral for a preliminary ruling to the EUCJ on competition between the medicines Avastin and Lucentis

The Italian Council of State has made a referral to the European Court of Justice for a preliminary ruling in a case regarding an agreement to artificially differentiate between competing drugs (Roche / Novartis).

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10 Infringement proceedings

➤ Portugal and Slovakia: unjustified restrictions on the export of medicines

The European Commission is urging Portugal and Slovakia to remove unjustified and disproportionate notification requirements related to the export of medicinal products for human use to other Member States.

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➤ Finland: rules on the reimbursement of healthcare

In Finland, the reimbursement of healthcare received abroad is calculated according to the conditions governing the private healthcare scheme. The European Commission has sent Finland a reasoned opinion asking the Finnish authorities to ensure that the costs of healthcare received in another EU Member State under the Cross-border healthcare directive are reimbursed up to the level of the refund made in Finland by the public healthcare scheme.

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11 Publications

➤ Trans-Pacific Partnership Provisions in Intellectual Property, Transparency, and Investment Chapters Threaten Access to Medicines in the US and Elsewhere

Baker analyses the negative impact, in case of ratification, of several provisions contained in various chapters of the Trans-Pacific Partnership (TPP) on access to medicines in the United States and elsewhere.

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➤ **Special section on the consequences of austerity policies on the health and well-being of populations**

The April edition of the International Journal of Health Services contains a special section on the consequences of austerity policies on the health and well-being of populations.

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➤ **EUROHEALTH: articles on the nursing sector**

The most recent edition of EUROHEALTH contains many articles on this sector, including the migration of nurses, the impact of EU accession on the profession, and the issue of an EU framework for nursing training. It also contains an assessment of the scientific value of the Euro Health Consumer Index.

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➤ **Varieties of healthcare reform: understanding EU leverage**

Stamati and Baeten's contribution to the book 'Social developments in the European Union 2015', describing the main events and discussions taking place in the field of health policy, and comparing reform trends through ten representative case studies, is now also available in French.

DOC [FR](#) HTML

➤ **Comparative European politics: special edition on healthcare in the EU**

The March edition of Comparative European Politics examines healthcare in the EU. The various articles cover economic surveillance, European integration, the case law of the ECJ and patient mobility. In one of the articles, Baeten and Vanhercke open up the black box of the EU's economic surveillance of national health systems, and describe the complex political structure of the EU's newly acquired role in this area.

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➤ **Impact of the cross-border healthcare Directive on dentists**

In her publication entitled Die europäische Patientenrichtlinie aus vertragszahnärztlicher Perspektive, Katja Brausse examines the practical implications for dentists of the directive on cross-border healthcare.

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➤ **European Observatory on Health Systems and Policies: United Kingdom Health Systems in Transition report**

This analysis of the United Kingdom's health system looks at national health services in the four regions of the United Kingdom (England, Northern Ireland, Scotland and Wales).

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12 Miscellaneous

➤ **Council: adoption of the general data protection regulation**

The regulation sets out the rights of individuals, and the obligations on those carrying out data processing and those responsible for such processing. Doctors and hospitals are given two years to comply with these provisions. The regulation requires hospitals to keep a record of treatments, to appoint a data protection officer and to carry out impact assessments on data protection.

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➤ **Health organisations denounce a ‘two-tier health system’ in Europe**

To mark World Health Day, the European Federation of Public Service Unions (EPSU), the European Network against privatisation and commercialisation of health and social protection, the ‘People’s Health Movement’, the ‘Alter Summit’ movement and the Belgian ‘Plate-forme d’action Santé et solidarité’ condemned the marketisation, commercialisation and privatisation of health and social protection.

DOC [EN/FR](#) HTML

➤ **A petition calls for a stop to the ‘Medical Grexit’**

A group of Belgian health professionals, supported by hospitals in Brussels and Doctors of the World Greece, have come together to sound the alarm concerning the medical crisis in Greece. Under the name of ‘Urgences Grèce/Emergency Greece’, they are appealing for donations and organising a petition to help the Greek people and convince the EU to exempt the medical sector from budgetary cuts.

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