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1 Public health

European Commission: new platform to improve traceability of donated tissue and cells

From now on, all donated tissue and cells will be identified with a single European code. The European Commission has launched an online platform, containing all the codes across the Community. This will make it possible to trace all tissue and cells throughout the supply chain - from donor to patient - and to take appropriate measures in the event of any quality or safety issue.

DOC [EN](#) HTML

European Commission: public consultation on strengthening EU cooperation on Health Technology Assessment

The consultation is intended to gather views on the future of EU cooperation on Health Technology Assessment (HTA), as proposed in the inception Commission impact assessment. The results will be fed into the impact assessment process currently being prepared by the Commission services, in order to strengthen EU cooperation on HTA.

DOC [EN](#) HTML

European Commission: inception impact assessment on strengthening on the EU cooperation on Health Technologies Assessment

The European Commission has published an inception impact assessment on the initiative to strengthen EU cooperation on HTA.

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European Commission: Member State data on cross-border healthcare, 2015

This report gives an overview of Member State data for 2015. The data were provided by means of a questionnaire prepared as part of the follow-up to the transposition of directive 2011/24/EU.

DOC [EN](#) PDF

European Commission: report on the operation of the cross-border healthcare directive

According to the report on operation of the 'cross-border healthcare' directive, cross-border healthcare is very limited in Europe. Of the 23 Member States covered by the report, 18 have implemented mechanisms to restrict planned healthcare abroad. Belgium and Denmark have both received more than 30,000 claims for reimbursement.

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

European Commission: positive assessment of the action plan against the rising threats from antimicrobial resistance

The evaluation of the action plan, partly drawing on a contractor's report, concludes that all the actions launched were and still are 'relevant'. It is too soon to judge the effectiveness of the plan, since it will only finish at the end of the year, but it has had tangible results in the Member States, despite the considerable differences between individual countries.

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European Commission: analysis of countries' reports on the implementation of the recommendation on the prudent use of antimicrobial agents

According to the analysis of national reports on implementation of Recommendation 2002/77/EC on the prudent use of antimicrobial agents, most Member States have developed, or are in the process of developing, a strategy to promote the prudent use of antimicrobial agents.

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European Commission: second action plan to combat antimicrobial resistance

The new action plan will focus on supporting Member States, particularly in establishing, implementing and monitoring their national action plans, and strengthening the EU's leading role in global fora. This plan will bring together EU funds and instruments in order to promote innovation and research against AMR.

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European Commission: study on better cross-border cooperation for high cost/highly specialised capital investments in health

According to the study carried out by Gesundheit Österreich Forschungs-und Planungs GmbH and SOGETI, cross-border cooperation in high-cost/highly specialised medical equipment would bring economic benefits to many EU Member States, in most cases. Despite this, little action is currently being taken in this area by EU Member States.

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2 Healthcare services in the internal market

European Commission: access to medical studies in Germany

In response to a question put by a Member of the European Parliament on behalf of a Belgian student who did not meet the criteria for access to medical studies in Germany, the European Commission recalled that there is no single approach towards university admission across Europe, due to different cultural and academic traditions.

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European Commission: workshop for experts in health public procurement

A workshop for experts in health public procurement, organised by the European Commission, discussed opportunities for more effective procurement of medical devices, medicines, medical equipment and IT solutions by public hospitals to reduce the pressure on health budgets while facilitating better value for money.

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CPME, PGEU and CED: joint statement on proportionality in professional regulation

According to the Standing Committee of European Doctors (CPME), the Pharmaceutical Group of the European Union (PGEU) and the Council of European Dentists (CED), regulation of healthcare professionals should be excluded from any potential EU-wide framework for a 'proportionality test'.

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AIM and ESIP: open letter on standardisation of health and social services

In an open letter, the members of the European Social Insurance Platform (ESIP) and of the International association of mutual benefit societies (AIM) expressed their concern as to the increasing efforts at European level for standardisation of health and social services.

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HOPE, CPME, CED, EPSU and ETUC: open letter on standardisation of health and social services

In an open letter, the European Hospital and Healthcare Federation (HOPE), the Standing Committee of European Doctors (CPME), the Council of European Dentists (CED), the European Federation of Public Service Unions (EPSU) and the European Trade Union Confederation (ETUC) expressed their concern as to the increasing efforts at European level for standardisation of health and social services.

DOC [EN](#) PDF

3 Medicines and medical devices

European Commission: public consultation on medicines for children

With a view to the drafting of the forthcoming European Commission report (2017) on paediatric regulation, a public consultation open to all stakeholders has been launched.

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European Parliament : study on EU options for improving access to medicines

The document summarises presentations and discussions from a workshop on access to medicines organised by the European Parliament's Committee on the Environment, Public Health and Food Safety.

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European Parliament: draft report on EU options for improving access to medicines

In her draft report for the Committee on the Environment, Public Health and Food Safety, Soledad Cabezón Ruiz denounces the exorbitant prices of innovative medicines, such as Sovaldi, which is sold at a price of approximately 50,000 euros per patient for a 3-month cure against hepatitis C. The MEP calls for a general review of the current system and for action to be taken concerning the authorisation mechanisms, competition rules and support for research.

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European Patent Office: partial revocation of Gilead's patent for sofosbuvir

The European Patent Office (EPO) took its decision following opposition from Doctors of the World to the patent for sofosbuvir (Sovaldi, for the treatment of hepatitis C), from Gilead Sciences. Doctors of the World have welcomed the EPO's decision to partially revoke the patent held by Gilead.

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European Medicines Agency: collaboration between the EU and the US to boost development of medicines for rare diseases

The European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) have set up a new 'cluster' on rare diseases in order to share experience and best practices.

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European Medicines Agency: public access to clinical reports

EMA is now giving open access to clinical reports on new medicines for human use authorised in the European Union (EU). For each new medicine, citizens, including researchers and academics, will be able to access directly the clinical reports submitted to the EMA by the pharmaceutical companies in the context of marketing authorisation applications.

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European Medicines Agency: publication of an overview of global initiatives on medicine regulation

This mapping exercise was carried out by the EMA on behalf of the International Coalition of Medicines Regulatory Authorities (ICMRA). It lists all international projects and provides international regulatory agencies with comprehensive details on the number and scope of global initiatives that can support decision-making regarding future engagement, prioritisation and coordination.

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• **Civil society organisations: open letter on the Council conclusions on ‘Strengthening the balance in the pharmaceutical systems in the EU and its Member States’**

A number of civil society organisations sent an open letter to the European Commission on the follow-up of the June 2016 EU Council conclusions on ‘Strengthening the balance in the pharmaceutical systems in the EU and its Member States’.

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• **European Medicines Agency: principles governing first-in-human clinical trials on humans put out for consultation**

The European Medicines Agency (EMA) is proposing to update its guideline on first-in-human clinical trials.

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4 Social policy

• **European Parliament: workshop on the impact of the economic crisis on access to healthcare and medicines**

The EP organised a workshop on the impact of the economic crisis on access to healthcare and medicines. The issues of cuts to healthcare budgets, high prices for medicines, inequality of access to various treatments, and medicines as financial products were all discussed.

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• **Social Protection Committee: main messages on the social situation and priorities for social policy reforms at EU level**

The report reveals that there are still significant differences in access to good quality healthcare, depending on income. Political efforts are required at national level to ensure universal access to high-quality health services, while securing adequate and sustainable financing, and making use of innovations and technological developments.

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

• **Social Protection Committee: report on key social challenges**

According to the SPC, most of the challenges facing the Member States concern long-term budgetary sustainability, the inefficient use of resources, access and inequalities of access to healthcare, availability of a qualified workforce in the health sector, insufficient public financing and the worrying health situation.

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• **Social Protection Committee: 2016 annual report**

Annex 2 to the SPC report gives a detailed review of recent reforms to ensure accessible, high-quality and sustainable healthcare. Annex 3 contains a thematic review of access to healthcare in the European Union, while Annex 5 contains country profiles, including details on health systems.

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• **European Parliament: question on the reimbursement of cross-border healthcare costs in the case of a temporary stay**

In response to a question from the EP on the reimbursement of cross-border healthcare for patients who have been resident in a country for more than three months, but on a temporary basis, the European Commission confirmed that the social security legislation is

designed to ensure coverage of patients crossing borders. There is therefore no set time limit to define the duration of a 'temporary stay', which can thus be longer than three months.

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5 Economic policy

European Commission: annual growth survey 2017

According to the policy guidelines for 2017, contained in the annual growth survey, health policies should support and reinforce social security nets and active inclusion strategies, through preventive, but also curative and rehabilitation policies.

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European Commission: draft joint employment report 2017

The annual growth survey is accompanied by several policy reports, including an in-depth analysis of the economic and social situation and the labour market. According to this latter report, health reforms have been implemented in a number of Member States to boost the supply of and access to effective primary healthcare services, to streamline and increase the sustainability of specialist and hospital care and to improve access to affordable medicines. In many Member States, a significant share of the population still has difficulties accessing healthcare, particularly low-income households.

DOC [EN](#) PDF

DG ECFIN and the Economic Policy Committee: joint report on health and long-term care systems and financial sustainability

This report sets out the political challenges and options, for healthcare and long-term care, to ensure fiscally sustainable access to good-quality services for all.

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ECOFIN Council: conclusions on the joint report from the Economic Policy Committee (EPC) and the Commission on healthcare and long-term care in the EU

The EU finance ministers welcomed the joint report exploring ways to ensure both budgetary sustainability and access to quality health services for all. The Council invited Member States and the Commission to take account of these findings in the European Semester.

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European Commission: video - 'Health and the EU. Spending on healthcare and long term care'

The newest episode in the series of videos 'European Economy Explained' looks at how best to meet the challenges facing health systems in the EU.

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

European Commission: discussion document on cost-containment policies in hospital expenditure in the European Union

This document gives an overview of documented evidence on a number of policies to contain costs in the hospital sector.

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6 International trade agreements

TTIP: significant progress on regulatory cooperation

At the close of the 15th round of negotiations, encouraging progress has been made in some areas, particularly the updating of the existing mutual recognition agreement on good manufacturing practices in the pharma sector.

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TiSA: technical discussions continue

During the 20th negotiating round on the Trade in Services Agreement, TiSA, the parties examined all the annexes on transport, professional services, state-owned enterprises and delivery services, as well as institutional arrangements, including state-to-state dispute settlement.

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MERCOSUR: beginning of free trade talks

The 14th round of negotiations with a view to a free trade agreement between the EU and MERCOSUR (Argentina, Brazil, Paraguay and Uruguay, without Venezuela) were held in Brussels in October 2016. This was the first full negotiation round since 2012, and the first to be held since the exchange of market access offers (covering goods, services and public procurement).

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ASEAN: the countries of the EU and South-East Asia wish to move towards a strategic partnership

The countries of the EU and ASEAN (Burma/Myanmar, Brunei, Cambodia, Indonesia, Laos, Malaysia, Philippines, Singapore, Thailand and Vietnam) have resolved to accelerate efforts in working towards a strategic partnership to govern bilateral relations, strengthening cooperation in traditional areas (trade, connectivity, development, energy and research), and in the field of security policy.

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TTIP: a barrier to sustainable access to medicines?

A joint report from Public Citizen, Commons Network and Health Action International focuses on the potential risks resulting from TTIP in regard to access, for Europeans, to affordable medicines and healthcare.

DOC [EN](#) PDF

TTIP: Commission attempts to provide reassurance on TTIP and health

In a written answer to the MEP Ms Rodríguez-Piñero Fernández, the European Commission promises that European health services will not be negatively affected by the Transatlantic Trade and Investment Partnership (TTIP), and that governments will keep control of their health systems, including of the choice as to whether to re-nationalise a previously privatised service.

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CETA: Canadian trade unions call for rejection of CETA

The Canadian trade unions representing civil servants, healthcare workers, metalworkers and those employed in the railway and aerospace sectors have called upon their government not to ratify the EU-Canada free trade agreement (CETA).

DOC [EN](#) HTML

7 Court of Justice of the European Union

Judgment: recourse to successive fixed-term contracts to cover permanent needs in the healthcare sector is contrary to EU law

In case C-16/15, the Court of Justice concluded that recourse to successive fixed-term contracts to cover permanent needs in the healthcare sector is contrary to EU law. The use of such contracts can only be justified by a need to cover temporary shortages.

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Opinion of the Advocate General: case involving a dispute between the German certification agency for PIP implants and a patient

In the opinion of the Advocate General, liability for defective products may be extended to actors other than the manufacturer itself, particularly notified bodies. 'Such bodies', therefore, 'may be liable to patients and users for a culpable failure to fulfill their obligations resulting from EU product safety rules'.

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Judgment: the fixed prices set in Germany for prescription-only medicinal products are contrary to EU law

In case C-148/15, the Court ruled on the lawfulness of German legislation setting fixed prices for prescription-only medicinal products dispensed by pharmacies. In the view of the Court, this type of legislation is incompatible with the European principle of free movement of goods, and cannot be justified on grounds of protection of the health and life of humans, nor by claims that it ensures better geographical distribution of traditional pharmacies.

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Judgment: confirmation of the Commission's decision to fine Lundbeck for delaying the marketing of generic medicines

The General Court of the EU has confirmed the fines of almost € 150 million imposed by the European Commission on several undertakings (Generics (UK), Alpharma, Arrow and Ranbaxy), in the context of an agreement intended to delay the marketing of generic versions of the antidepressant citalopram. The Commission concluded that the Danish pharmaceutical company Lundbeck, and four competitors active in the production or sale of generics, had concluded agreements against the interests of patients and healthcare systems.

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Judgment: supplementary pension regime, capital, Belgian health insurance and solidarity levies

In case C-269/15, the Court ruled that Belgium is not authorised to charge health levies (3.55%) and solidarity levies (2%) on payments made under supplementary pension schemes if the beneficiary of these supplementary pensions is not resident in that Member State and is subject to the social security legislation of the Member State of residence.

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

Judgment: taxation of supplies of plasma to be used for the manufacture of medicinal products

In case C-412/15, the Court concluded that supplies of human blood which Member States are required to exempt by virtue of the VAT directive (Article 132(1)(d)) do not include supplies of plasma obtained from human blood, where that plasma is intended to be used not for direct therapeutic purposes but exclusively for the manufacture of medicinal products.

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

➤ **Opinion of the Advocate General: compatibility of the Belgian ban on advertising dental care with EU law**

In case C-339/15, the Advocate General concluded that Belgian legislation prohibiting providers of dental care from advertising their services to the public constitutes a restriction on freedom of establishment and the freedom to provide services. This restriction is justified on grounds of the protection of public health, since the national legislation at issue does not have the effect of prohibiting such service providers from giving, in a telephone directory or other source of information accessible by the public, basic details making known their existence as professionals.

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➤ **Judgment: medicines prepared industrially or manufactured by a method involving an industrial process**

In case C-276/15, the Court found that according to Directive 2001/83/EC, a medicinal product for human use which does not require a marketing authorisation by reason of the proven frequency with which it is prescribed by doctors or dentists, where the essential manufacturing steps take place in a pharmacy as part of normal pharmacy business and in reasonable quantities, and is intended for supply under the existing pharmacy operating license, cannot be regarded as having been prepared industrially or manufactured by a method involving an industrial process, within the meaning of that provision, and consequently does not come within the scope of that directive.

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

➤ **Judgment: pharmaceutical product placed on the export market and the import market by the trade mark proprietor with the same types of packaging**

In case C-297/15, the Court found that a trade mark proprietor may object to the continued marketing of a medicinal product by a parallel importer where the latter has re-packaged that medicine in new outer packaging and reattached the trade mark, where, first, the medicinal product at issue can be marketed in the importing state in the same packaging, and, secondly, the importer has not demonstrated that the imported product can only be marketed in a limited part of the importing state's market.

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➤ **Judgment: non-contractual liability regime**

In case C-268/15, involving an action brought against the Belgian State by a clinical biology laboratory, the Court found that a Member State's system of non-contractual liability for damage caused by a breach of EU law does not apply in the case of damage allegedly caused to an individual as the result of an alleged breach of a fundamental freedom laid down in Articles 49, 56 or 63 TFEU by national legislation which is applicable without distinction to the State's own nationals and those of other States, where, in a situation which is confined in all respects within a single Member State, there is no link between the subject or circumstances of the dispute in the main proceedings and those articles.

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

8 Competition

➤ **The Commission authorises the acquisition of Boehringer Ingelheim's consumer health service by Sanofi, subject to conditions**

The European Commission has cleared the proposed acquisition of the consumer health service of Germany's Boehringer Ingelheim by the French undertaking Sanofi, subject to certain conditions being met. Both companies are active in the pharmaceutical sector.

DOC [FR/EN](#) HTML

▶ **United Kingdom: the CMA investigates suspected unfair pricing in the supply of certain pharmaceutical products**

The British Competition and Markets Authority (CMA) has launched an investigation into presumed infringements of competition law in the pharmaceutical sector. The investigation concerns suspected unfair pricing by way of charging excessive prices in the supply of certain pharmaceutical products, including to the National Health Service.

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▶ **European Commission: study on the financing models for public services in the EU and their impact on competition**

This study evaluates the way in which public services are financed and when these arrangements may cause competition problems. It includes a chapter on healthcare which emphasises the possible effects of public financing on competition in the hospital services market.

DOC [EN](#) PDF

▶ **Italy: the ICA imposes a €5 million fine on the multinational company Aspen**

The Italian Competition Authority (ICA) has imposed a fine of more than € 5 million on the multinational pharmaceutical company Aspen, following price increases of up to 1,500% for drugs irreplaceable in the treatment of oncohaematological patients, particularly children and older people.

DOC [EN](#) HTML

▶ **France: the Supreme Court upholds Sanofi's generic denigration fine**

The French Supreme Court (Cour de Cassation) upheld the € 40.6 million imposed on Sanofi by the competition authority in May 2013, and confirmed the judgment of the Paris Court of Appeal. It found that Sanofi abused its dominant position by denigrating generic competitors of its drug Plavix on the French clopidogrel market.

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▶ **Poland: price-fixing agreement by association of enterprises condemned**

The Polish Office for Competition and Consumer Protection (OCCP) applied sanctions linked to an anti-competitive agreement entered into by the Association of Polish Centres for Infertility treatment and Reproduction Development.

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▶ **Germany: sector inquiry into hospitals**

The German competition authority has launched a sector inquiry into the hospital service, to examine and analyse competitive conditions in the sector, and to further develop examination criteria for the authority's merger control proceedings.

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▶ **State aid: Commission gives guidance on local public support measures that do not constitute state aid**

The Commission has found that five measures for purely local operations in Germany, Spain and Portugal involve no state aid because they are unlikely to affect trade between Member States. One of these decisions applies to Santa Casa da Misericórdia de Tomar (Portugal), which provides social assistance services to elderly and disabled people, as well as long-term care.

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9 Infringement proceedings

Transposition of the EU rules on the recognition of professional qualifications

The European Commission has addressed reasoned opinions to 14 Member States including Belgium with regard to transposition of the directive on recognition of professional qualifications. These Member States have two months to notify the Commission of the transposition.

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

10 Publications

Research paper: Programmed healthcare abroad. Authorisations issued by Belgian sick funds

The EU Directive on the application of patients' rights in cross-border healthcare was transposed into Belgian law in 2013, which led to a revision of the guidance on the application of the pre-existing domestic legal frameworks relating to prior authorization for programmed healthcare abroad. This research paper (in NL and FR) explores the application in practice of this revised guidance by the sickness funds and provides some policy recommendations.

DOC [FR - NL](#) HTML

Article: implementation of the cross-border healthcare directive in Poland

This article, entitled 'Implementation of the cross-border healthcare directive in Poland: How not to encourage patients to seek care abroad?' describes the process of implementing Directive 2011/24 / EU into Polish law, the content of the Polish legislation transposing the directive, and the implications for patients of this new law.

DOC [EN](#) HTML

ESPN: flash report on statutory health insurance in Liechtenstein

This flash report published by the European Social Policy Network (ESPN) refers to the people's initiative launched in Liechtenstein, asking for the introduction of income-linked premiums for statutory health insurance.

DOC [EN](#) HTML

ESPN: flash report on individual expenditure on health services in Iceland

This flash report published by the European Social Policy Network (ESPN) refers to the introduction of a maximum cap on individual expenditure on healthcare services in Iceland.

DOC [EN](#) HTML

Special issue: parallel trade in pharma

This special issue gives an insight into European case law on parallel trade in the pharmaceutical sector.

DOC [EN](#) HTML

Doctors of the World: access to high-quality healthcare increasingly problematic

According to a report from Doctors of the World, access to healthcare deteriorated once again in Europe in 2015, both for European nationals and for EU or third country migrants. The international network lists a series of recommendations to political decision-makers.

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11 Miscellaneous

Spain wants UK to foot the healthcare bill for British citizens

According to Euractiv, the Spanish government intends to broker a deal with the United Kingdom under which the outgoing Member State would cover the healthcare costs of the British diaspora living in Spain.

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Turkish private hospitals entice patients to Brussels

Two private Turkish hospitals wish to open an establishment in Brussels in the future. These hospitals are targeting an international public, but also the Turkish community in Belgium.

DOC [NL](#) HTML

European Health Forum Gastein 2016: webcast available

The overarching topic for the European Health Forum Gastein 2016, held in Bad Hofgastein from 28 to 30 September 2016, was 'Demographics and diversity in Europe - new solutions for health'. Videos of the event are available.

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Dublin ready to house two European agencies based in London after Brexit

Looking ahead to the United Kingdom's departure from the European Union, Ireland has launched a formal bid to house two European agencies currently based in London: the European Banking Authority (EBA) and the European Medicines Agency (EMA).

DOC [EN](#) HTML

OECD: online access to the 2016 Health System Characteristics Survey

For the third time, in 2016, the OECD has collected qualitative information on the key institutional characteristics of health systems in OECD countries and key partner and accession countries. These responses can be accessed online.

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The WHO and Greece expand collaboration on health reform priorities

The second phase of the 'Strengthening capacity for universal coverage' project supports Greece's move towards universal health coverage and will focus specifically on providing universal access to health services, establishing transparent, inclusive and modernised health governance and ensuring fair and sustainable health financing.

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Cohesion policy supports the integration of migrants in Brussels

At the request of the Belgian authorities, the European Commission has agreed to modify the 2014-2020 cohesion programme for Brussels and to redirect a portion of funding towards a social inclusion project. The centres receiving this support will help marginalised communities by providing healthcare and social services to those most in need in urban areas.

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