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1 Public health

Council: conclusions on supporting people living with dementia: improving care policies and practices

In its conclusions, the Council calls for strengthened cooperation between Member States in the Government Expert Group on dementia, to facilitate the sharing of information on policy frameworks and good practices already in place, as well as to support countries in developing and implementing national strategies, plans and programmes on dementia.

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Council: lessons learnt for public health from the Ebola outbreak – Health Security in the European Union

These conclusions call for discussions to be held on improving coordination mechanisms in order to address incidents in the future.

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European Medical Corps launched to respond faster to emergencies

The European Union launched the European Medical Corps, to help mobilise medical and public health teams and equipment for emergencies within and outside the EU. So far, Belgium, the Czech Republic, Finland, France, Luxembourg, Germany, Spain, Sweden and the Netherlands have committed teams and equipment to the voluntary pool.

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Mapping of the use of European Structural and Investment Funds (ESIF) in health

This report provides an overview of the investments planned in health for 2014-2020, under the ESIF, as well as investments realised in the previous planning period 2007-2013. It consists of an analytical section; covering the whole of the EU, as well as individual country sheets.

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2 Medicines and medical devices

Council: conclusions on personalised medicine

Personalised medicine bases itself on an individual's characteristics to develop a specific therapeutic strategy for that person. This approach is gaining in importance due to a new generation of medicines specifically targeting the molecular basis of diseases. The Council conclusions call for, among other things, the development of common principles on the collection of patient data, to enable data-analysis on a larger scale.

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European Commission: safety features on the packaging of medicines

The Commission published a delegated regulation containing rules on safety features on the packaging of medicines, in the form of a unique identifier and an anti-tampering device, making it possible to check the authenticity of the medicine.

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European Commission: inventory of incentives to support research into and the development of orphan medicinal products

The Commission published an inventory of Union and Member State incentives to support research into and the development and availability of orphan medicinal products.

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European Commission: study on enhanced cross-country cooperation in the area of pharmaceutical product pricing

The study analyses the policy options of 'external price referencing' (EPR) and differential pricing (DP), in order to investigate possible benefits from improved cross-country policy coordination in the area of pharmaceutical pricing.

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Council: conclusions on the justification of medical imaging involving exposure to ionising radiation

The conclusions state that a significant share of the medical radiological imaging taking place may not be necessary, entailing an increased level of patient exposure and exposure of workers. In them, the Council invites the Commission to pay particular attention to the legal provisions relating to the proper justification of medical radiological imaging when reviewing the implementation of the legal framework, Directive 2013/59/Euratom.

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3 Healthcare services in the internal market

▶ **Belgium: transposition of the European directives on public procurement**

A legislative proposal on public contracts (Doc. parl., Kamer, 2015-2016, no. 54-1541/001), transposes the new European directives on public procurement (2014/24/EU) into Belgian law. The Directive sets out a more flexible regime for health and social services, since these are usually provided in a specific context which varies greatly from one Member State to another.

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▶ **European Professional Card introduced**

With the entry into force of the up-dated directive on the recognition of professional qualifications, the European Professional Card (EPC) has also been introduced. This electronic procedure enables professionals to have their professional qualifications recognised in another EU country. The professional card procedure can currently be used by general care nurses, pharmacists and physiotherapists.

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4 eHealth

▶ **eHealth network: guideline on the setting up of National Contact Points (NCP)**

The eHealth network, a voluntary Member State network set up under the EU directive on patients' rights in cross-border healthcare, adopted a guideline on an organisational framework for the setting up of eHealth National Contact Points. The NCPs are used for communicating with other Member States and as intermediaries in the provision of services.

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5 Social policy

▶ **European Commission: draft joint employment report**

This report is published together with the 2016 Annual Growth Survey. It analyses the employment and social situation in the EU and the policy measures taken by Member States. Quite some attention is paid to healthcare reforms. Figures are also published on unmet medical needs in the various Member States.

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▶ **European Commission: Employment and Social Developments in Europe 2015**

In its yearly analysis of employment and social developments in Europe, the Commission also examines social protection and healthcare (cf. from p. 280 onwards in chapter 3.2).

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➤ **Social Protection Committee (SPC): review of recent social policy reforms**

This report also looks at reforms to healthcare systems (chapter 4).

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➤ **European Commission: first policy debate on a European Pillar of Social Rights**

The Pillar of Social Rights is to become a legal reference document, setting out the most important principles and values shared within the EU. It should be used as a reference framework for screening the employment and social performance, including access to basic healthcare, of participating Member States.

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➤ **ESPN: flash report on healthcare reform in Cyprus**

A flash report produced by the European Social Policy Network (ESPN) provides information on a recent healthcare reform in Cyprus.

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➤ **Council: conclusions on social governance for an inclusive Europe**

These conclusions call for greater involvement, at EU level, of the social partners and civil society in the European Semester process.

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6 Economic policy

➤ **European Commission: fiscal sustainability report**

According to this report, significant challenges remain over the medium and long term. The report examines at length the impact of ageing on public expenditure on healthcare and long-term care.

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➤ **European Commission: new guidance on applying the Stability and Growth Pact (SGP)**

This guidance note gives a new interpretation of current SGP rules, in order to encourage structural reforms and investment. Temporary deviations from the path towards the medium-term budgetary objective are possible, in the case, for example, of major structural reforms in the field of healthcare, provided that these have verifiable long-term positive budgetary effects.

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➤ **European Commission: report on Greece's compliance with the second set of milestones**

Compliance with these milestones is a pre-condition for payment of the next instalment of funds from the European Stability Mechanism (ESM). The decision on this payment was postponed by a couple of weeks as insufficient progress had been made on three points, of which two referred to the health sector: a hospital claw-back system and a reduction in the prices of diagnostics from private sector providers.

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➤ **European Commission: statement following the conclusion of the fourth post-programme surveillance mission to Ireland**

According to this statement, further structural efforts are needed to improve cost effectiveness in the delivery of healthcare, especially in hospitals and public spending on pharmaceuticals.

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European Commission: Annual Growth Survey 2016 (AGS)

The AGS sets out the general economic and social priorities for the EU, and provides Member States with policy guidance for the following year. It marks the start of the 2016 European Semester. The AGS calls for continued reforms to care systems, to enhance their cost-effectiveness and ensure adequate access.

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European Commission: proposal to finance technical assistance for structural reforms

The aim of this proposal is to offer to all Member States, on request, the technical assistance made available to Cyprus and Greece to support their economic adjustment programmes. Support may also be granted for reforms in the health sector, more specifically in line with country-specific recommendations.

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European Fund for Strategic Investments (EFSI): projects in the health sector

The European Fund for Strategic Investments contributes to the funding of infrastructure and innovation projects. Of the 42 projects approved so far by the European Investment Bank, 4 were in the health sector: the building of primary care centres in Ireland, construction of hospital facilities in Austria and the UK, and medical research in Spain.

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European Commission: country reports published

These country reports contain an analysis of the economic and social challenges facing the EU Member States, including in the field of healthcare. They are a tool to monitor policy reforms under the European Semester and form the basis for the country-specific recommendations to be published in June. For 18 Member States, these reports also include an in-depth evaluation as part of the macroeconomic imbalance procedure.

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European Parliament: briefing paper on implementation of the Macroeconomic Imbalance Procedure (MIP)

This briefing paper describes the Member States' situation with regard to the macroeconomic imbalance procedure. References to healthcare are made in the cases of Bulgaria, Spain, Croatia, Slovenia and Romania.

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7 International trade agreements

European Commission: Statement following the conclusion of the 12th negotiation round of the Transatlantic Trade and Investment Partnership (TTIP)

According to the EU chief negotiator, important progress has been made in the field of regulatory cooperation in a number of sectors, including the medical devices and pharmaceuticals sectors. Discussions are also ongoing in the services sector, to facilitate, for example, the mutual recognition of professional qualifications.

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European Commission: provisions on medicine pricing and reimbursement in the TTIP

Responding to a question from the European Parliament, the European Commission has said that the US has signalled interest in adding provisions to the TTIP on the pricing and reimbursement of medicinal products. In the Commission's view, this would be inappropriate

in light of the significant differences in EU and US healthcare systems.

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EU-Vietnam free trade agreement

This agreement contains provisions on trade in goods and services, investment, government procurement, intellectual property, non-tariff barriers, health protection measures and technical barriers to trade. It also includes a chapter on investment protection. There is an annex on pharmaceutical products and medical devices. The text is still to be ratified by the Parliament and Council.

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European Commission: statement at the start of the 15th round of talks for a Trade in Services Agreement (TiSA)

In this statement, the Commission declares that it does not want the TiSA to go beyond real trade issues. It does not wish to include, for example, publicly-funded health services or insurance portability. The EU does not wish to jeopardise the quality of public healthcare or other public services.

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European Parliament: recommendations for the TiSA negotiations

In its resolution, the Parliament asks the Commission to exclude services of general (economic) interest, including healthcare, social services and social security systems, from the scope of application of the agreement. It also asks for countries to be able to decide to re-nationalise services, after these have been opened up to competition from private sector parties.

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European Parliament: analysis of the TiSA

The European Parliament also published an analysis of the negotiations for a trade in services agreement.

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8 Court of Justice of the European Union

Judgment: the Greek legislation on standby duties is in breach of the EU working time directive

In case C-180/14, the Court rules that the Greek legislation allowing doctors to work 24 or more continuous hours is in breach of EU law. By stating that the 24-hour rest period granted to doctors following an 'active standby' period may be postponed until up to a week after completion of that standby, the Greek legislation does not comply with the EU working time directive.

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Judgment: entrusting the provision of medical transport services to voluntary organisations

The Court found in case C-50/14 that national legislation may allow local authorities to entrust the provision of medical transport services by direct award, without any form of advertising, to voluntary associations, provided that the legal and contractual framework in which the activity of those associations is carried out actually contributes to the social purpose and the pursuit of the objectives of the good of the community and budgetary efficiency.

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• **Judgment: VAT exemption for services closely linked to welfare and social security**

The judgment in case C-335/14 states that the services provided by serviced residences to make specially adapted dwellings available to elderly people, as well as the care and assistance services for the elderly which such residences are obliged to provide, may be exempted from VAT, provided they are of a social nature. It is irrelevant in this respect whether or not the operator of a serviced residence is receiving a subsidy or any other form of advantage or financial support from the public authorities.

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• **Opinion of the Advocate General: scope of application of the European regulation on nutrition and health claims made on foods**

In case C 19/15, the Court is asked to give its opinion on whether the provisions of this regulation apply when such claims are made for a foodstuff to be supplied directly to consumers, but in commercial communications addressed exclusively to the health professionals. In the view of the Advocate General, these provisions apply if the purpose of the communication or advertisement is to reach consumers indirectly via the professionals.

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• **Request for a preliminary ruling: VAT exemption for osteopathy**

The question put in case C-531/15 regards whether alternative therapies, particularly osteopathy, may or may not be regarded as a paramedical activity for the purposes of the VAT directive.

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9 Competition

• **Hungary: fine for restricting competition in the sale of contact lenses**

The Hungarian competition authority (GVH) ruled that by setting up a rebate system to the detriment of the online retailers of contact lenses and care products, the two companies in question were restricting competition.

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• **France: pricing of hospital services tested against the criteria for provision of services of general economic interest**

In a case brought by the Private Hospitals Federation, the State Council assessed hospital pricing in France against the criteria for state aid in the form of compensation for the provision of services of general economic interest, as set out in the European Commission decision of 20 December 2011 (the so-called Altmark criteria).

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• **Analysis: merger in the medical implants sector**

This article analyses the Commission's investigation prior to the decision to clear a merger in the medical implants sector (Zimmer-Biomet). In this sector, the geographic markets are national markets because of the procurement characteristics and national registries, but the manufacturing needs to be done on a scale which goes beyond the needs of individual countries.

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• **Acquisition of a dental equipment supplier approved, subject to conditions**

The European Commission approved the proposed acquisition of the dental equipment

supplier Sirona by Dentsply, both of the US, subject to conditions.

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Commission approves diabetes joint venture between Sanofi and Google

The European Commission has approved the setting up of a joint venture between Aventis Inc., a subsidiary of Sanofi SA of France, and Verily Life Sciences LLC, a subsidiary of Alphabet Inc. of the United States, the holding company of Google Inc. The joint venture will offer services for the management and treatment of diabetes.

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Novartis acquires the rights on auto-immune indications of a drug developed by GSK.

The Commission cleared the acquisition by Novartis of the rights for the development and marketing of the auto-immune indications - such as multiple sclerosis - of the drug 'ofatumumab' from the British pharmaceutical company GlaxoSmithKline (GSK).

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10 **Infringement proceedings**

Poland: transposition of the rules governing quality and safety standards for human blood

The Commission is referring Poland to the Court of Justice of the EU for failing to fully transpose quality and safety rules for human blood.

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Italy: investigation into the tender procedures for oxygen-therapy and ventilo-therapy services at home

The Italian competition authority is opening an investigation into the tender procedures for oxygen-therapy and ventilo-therapy at home (Gare ossigenoterapia e ventiloterapia).

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UK: fine for an association of ophthalmologists

The UK competition authority, CMA, issued an infringement decision against Consultant Eye Surgeons Partnership (CESP) Ltd, an association of ophthalmologists.

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11 **Publications**

OECD: Health at a glance

This new edition of 'Health at a Glance' presents the most recent comparable data on the performance of health systems in the OECD countries.

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How can countries address the efficiency and equity implications of health professional mobility in Europe?

This policy brief assesses how countries can address the efficiency and equity implications of

the mobility of health professionals, and how they can adjust their policies with reference to the WHO Code of Practice and in a context of free movement within the EU.

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▶ **Patient mobility in the context of austerity and an enlarged EU: the European Court of Justice's ruling in the Petru case**

This article analyses the Petru ruling against the background of the enlarged EU and austerity measures in the field of healthcare.

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12 Miscellaneous

▶ **European Parliament: Directive on the protection of trade secrets**

The European Parliament's Legal Affairs Committee voted on the Directive on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure. The text is based on a compromise reached with the Council, and still needs to be approved by the EP plenary and the Council.

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▶ **NGOs: call for the rejection of the draft directive on the protection of trade secrets**

The day before the vote on the directive, a number of civil society organisations, including health sector organisations, called for the proposal to be rejected. They warned of its consequences, including the potential impact on public interest disclosures, such as information on the safety and efficacy of medicines and data on clinical trials.

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▶ **WHO: support for the reform of the healthcare system in Greece**

The European division of the World Health Organisation (WHO) renewed its cooperation with the Greek Ministry of Health. The initiative, entitled 'Strengthening capacity for universal coverage' aims to support the medium-term reform priorities of the health sector.

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▶ **IMF: preliminary findings of the mission to Belgium**

This statement describes the preliminary findings of an official visit of IMF (International Monetary Fund) staff to Belgium. According to the statement, health spending could be made much more efficient, including by better enforcing budget ceilings and by further reducing medication and hospitalisation costs.

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▶ **Conference: Health systems and EU law and policy**

The conference on "Health systems and EU law and policy, the state of the art and direction of travel", organised by the NIHDI, the OSE and the University of Sheffield, addressed three topics: (1) mobility of patients and professionals in the EU; (2) healthcare in the EU economic governance and (3) healthcare in international trade agreements. The presentations and audio-clips are now available.

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▶ **BMJ: UK exit from the EU would be a serious threat to science and healthcare**

Experts warn that a UK exit from the EU would be a serious threat to science and healthcare.

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 **Greece: health insurance for vulnerable citizens approved**

The Greek Parliament approved a bill providing health insurance to vulnerable citizens, to mitigate the impact of bailout austerity measures on the poor.

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Editors: Rita Baeten and Dalila Ghailani

E-mail : baeten@ose.be

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

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