European Health Care News

Newsletter No.39 - September 2016

Ose European Social Observatory

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1 Public health

European Commission: Eurobarometer survey on the use of and perception of antibiotics

As part of its broader strategy to combat antimicrobial resistance (AMR), the European Commission published a special Eurobarometer survey, which shows a 6% decrease in the consumption of antibiotics, but at the same time a persistent lack of awareness of their effects.

DOC EN/FR HTML

Council: conclusions on antimicrobial resistance

These Council conclusions call upon the Member States and the Commission to step up their efforts to combat antimicrobial resistance.

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European Commission: the state of healthcare in the EU

The Commission plans to develop a number of tools to support Member States in better evidence-based policy making.

DOC 1 EN PDF | DOC 2 EN HTML

European Commission: use of the European Fund for strategic investments in the field of healthcare

The Commission informed ministers as to the best way to use this fund for strategic investments in innovative financing in healthcare.

DOC EN PDF

European Commission: expert group on health systems performance assessment

The Commission informed ministers as to the work of the expert group on health systems performance assessment.

DOC EN PDF

EXPH: three opinions and a memorandum

The Commission's expert panel on 'effective ways of investing in health' (EXPH) has adopted three opinions and one memorandum The opinions concern:
- access to health services;
- a typology of health policy reforms and a framework for evaluating reform effects;
- best practices in public health sector commissioning from private providers.

The memorandum contains reflections on hospital reforms in the EU.

DOC EN HTML

2 Healthcare services in the internal market

CEN: work programme 2016

According to the European Committee for Standardization (CEN), there is increasing demand from stakeholders in relation to the standardisation of healthcare services. The increasing mobility of patients and healthcare professionals implies a greater need to measure quality and compare services (see p. 54).

DOC EN PDF

Council: standardisation of healthcare services

At the Council meeting of health ministers, Poland expressed its concern as to CEN's work programme for 2016. In the view of the Polish delegation, it is the organisations of the healthcare providers concerned which should set out principles regarding good practices. It calls upon the Member States and the Commission to prevent further actions from CEN in this area.

DOC EN PDF

ESIP: position on the standardisation of health and social services

The European Social Insurance Platform (ESIP) calls upon the European Commission and the standardisation institutions not to pursue their plans in relation to the standardisation of health and social services, in particular those services provided by statutory social insurance systems.

DOC EN PDF

European Commission: national action plans for the reform of access to regulated professions

On the basis of the amended EU directive on professional qualifications (2005/36/EC), the Member States carried out an evaluation of the proportionality of their legislation concerning access to and the exercise of the regulated professions, including healthcare professions. In their plan, Member States must state whether they see a need for reform of legislation.

DOC EN HTML

European Commission: public consultation on the proportionality of legislation on regulated professions

In this consultation, stakeholders may give their views on the national action plans.

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European Commission: sectoral reports on the regulated professions

The Commission has so far published sectoral reports on the following healthcare professions: dental hygienists, opticians, psychologists and related professions and physiotherapists.

DOC 1 EN HTML | DOC 2 EN PDF | DOC 3 EN PDF | DOC 4 EN HTML | DOC 5 EN PDF

European Commission: directive on a proportionality test for the regulation of professions

The Commission has announced that it will be issuing a directive containing an EU-wide methodology for assessing the proportionality of national legislation on the regulation of professions. It will also publish opinions if it is of the view that legislation in a Member State imposes unnecessary requirements for a particular profession compared to other Member States.

DOC EN PDF

Ecorys: definition of 'highly specialised and cost-intensive medical infrastructure or medical equipment'

The Commission published a report, drawn up by Ecorys, proposing criteria for defining 'highly specialised and cost-intensive medical infrastructure or medical equipment'. These criteria are designed to help assess the national implementation of the relevant provisions in EU Directive 2011/24/EU on patients' rights in cross-border healthcare.

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3 Medicines and medical devices

Council: conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States

Patients' access to important medicines is sometimes endangered by very high price levels or by market-withdrawal of products which are out-of-patent. The Council invites Member States to work together on a voluntary basis to tackle this problem, and asks the Commission to prepare an analysis of the impact of the existing EU pharmaceutical legislation on availability, accessibility and innovation.

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ESIP and AIM welcome the Council conclusions on strengthening the balance in the pharmaceutical systems in the EU

Social security organisations, represented by ESIP (European Social Insurance Platform) and the international association of mutuals and health insurance funds (AIM), welcome the Council's commitment towards a more balanced pharmaceutical system in the EU.

DOC EN PDF

European Commission: the impact of biosimilar competition

The Commission services responsible for the internal market published a report on the impact of competition between biosimilar medicinal products on the price, volume and market share of these medicines. A biosimilar medicinal product is a biological medicine which is similar to another biological medicine which has already been authorised for use (the so-called 'reference medicinal product').

DOC EN HTML

European Commission: public consultation on the concept of 'similar medicinal product' in the context of the legislation on orphan drugs

The Commission wishes to adjust the orphan legislation to technical progress, particularly in the area of biological medicines.

DOC EN HTML

European Commission: report on pharmacovigilance

This report describes the activities carried out by the Member States and the European Medicines Agency (EMA) to monitor the safety of medicinal products. It is accompanied by a detailed working document on the activities carried out by the EU system to monitor and survey the safety of medicines.

DOC 1 EN PDF | DOC 2 EN PDF

EMA: marketing authorisation for the preventive use of a medicinal product for people at high risk of HIV infection

Truvada is used to treat HIV-1. The European Medicines Agency (EMA) is recommending to the Commission that it should extend the marketing authorisation to use by people at high risk of HIV infection. If the Commission decides to authorise this extension, each Member State will have to take a decision on price and reimbursement.

DOC EN HTML

European Commission: study on the economic landscapes of human tissues and cells for transplantation

This study, financed by the European Commission's Health Programme, identifies key activities and costs, the key public and private sector players, legislative and reimbursement schemes across Member States, and finally emerging technological trends and associated ethical, legal and social issues.

DOC EN PDF

EMA: report on the ‘adaptive pathways’ pilot project

The EMA’s intention with the ‘adaptive pathways’ approach is to enable earlier and progressive market access to medicines. EMA published the final report on its pilot project, which investigates the practical implications of such an approach.

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IQWiG: ‘adaptive pathways’ provides insufficient reassurance as to the safety and effectiveness of drugs

The German ‘Institute for Quality and Efficiency in Healthcare’ (IQWiG) is of the view that the EMA’s ‘adaptive pathways’ plan fails to provide sufficient reassurance that the drugs to be approved via this fast-track procedure would be safe and effective. It is asking for this plan to be put on hold.

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Scientists criticise the ‘adaptive pathways’ approach

According to these academics, there is insufficient scientific evidence that the approach would benefit patients and public health.

DOC EN HTML

BEUC: position on ‘adaptive pathways’

The European consumer organisation BEUC is concerned that the fast-track procedure for approving new medicines could put patient safety at risk.

DOC EN PDF

European Commission: discussion with the pharmaceutical industry on EU cooperation in relative effectiveness assessment for medicines

The European Federation of pharmaceutical industries and associations (EFPIA) and its Norwegian member Novo-Nordisk met, at its request, with the Commission’s DG SANTE, to explain its views on EU cooperation on clinical assessment (REA).

DOC EN PDF

European Commission: public consultation on clinical trials

The Commission organised four consultations on different recommendations related to the clinical trials legislation.

DOC EN HTML

European Commission: consultation on a digital entrepreneurship scoreboard

The European Commission wishes to tackle bottlenecks to digitalisation in a number of sectors and to create an adequate environment to exploit its full potential. It is organising a consultation to this effect, including consultation of companies in the pharmaceutical sector.

DOC EN HTML

Austria joins the Benelux initiative on orphan drugs

Austria has become the fourth country to sign up to the Benelux cooperation on orphan drugs. The four countries will carry out joint negotiations with pharmaceutical companies, to keep down the prices of orphan drugs. They will also exchange information and cooperate on innovation.

DOC NL - FR HTML

4 eHealth

European Commission: proposal for a code of conduct on privacy for mHealth apps

On the basis of this proposal, which has been submitted for comments to the Data Protection Working Party, app developers can comply with the code of conduct on a voluntary basis.

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5 Social policy

Council: country-specific recommendations (CSRs) 2016

The EPSCO Council held a policy debate on the 2016 CSRs proposed by the Commission as part of the European Semester.

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Council: endorsement of the opinions of the Employment Committee and the Social Protection Committee on the 2016 CSRs

The Committees conclude that the focus of the health-related CSRs is still on cost-effectiveness, but that more attention is also paid to issues related to quality and/or access to care. The opinion underlines that cost-effectiveness of health services must be considered with reference to the objectives of health systems, not purely in terms of costs. The opinion also assesses the implementation of the 2015 (health-related) CSRs.

DOC EN PDF

European Commission: working time directive allows sufficient flexibility to guarantee the continuity of care

This was the answer given by the Commission to a question from an Italian MEP, who claimed that the working time directive, which limits the number of working hours for care-providers, combined with the savings which Italy is being required to make, have meant that some organ transplants have not been able to take place.

DOC EN HTML

ESPN: reform of the healthcare system in Finland

The European Commission published a report on the reform of the Finnish healthcare system, drawn up by experts from the European Social Policy Network (ESPN).

DOC EN HTML

European Commission: integrated ways to collect data for social statistics

The Commission is proposing a regulation on new, integrated ways to collect and use data from social surveys. This framework regulation concerns seven household surveys, including the European Health Interview Survey (EHIS).

DOC EN/FR/NL HTML

6 Economic policy

Council: country-specific recommendations adopted

The finance ministers meeting in the Council adopted the final versions of the country-specific recommendations. 12 Member States received a recommendation concerning healthcare.

DOC EN/FR/NL HTML

Finland: excessive deficit procedure concluded

In its report, which closes the procedure, the European Commission also discusses Finland's plans to achieve savings of € 3 billion (or 1.5% of GDP) in the health sector (see p. 7 under the heading 'Administrative Reform').

DOC EN HTML

7 International trade agreements

TiSA: report on the 18th and 19th negotiation rounds

The Commission published its report on the 18th and 19th negotiation rounds on a Trade in Services Agreement (TiSA). The discussions related to issues including individual service providers, professional services, e-commerce, state-owned enterprises and government procurement.

DOC 1 EN HTML | DOC 2 EN PDF | DOC 3 EN PDF

ITA: the Council endorses the agreement to end customs duties on high-tech IT products

The EU and 24 other countries have concluded this agreement (ITA), in the framework of the World Trade Organisation. The new agreement expands the coverage of the original 1996 agreement, adding 201 new products, including medical imaging apparatus such as magnetic resonance imaging scanners.

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Trade agreement between the EU and the Philippines: report on the first round

This round included discussions on trade in goods, the country of origin principle, sanitary and phytosanitary measures, services, intellectual property rights, competition and dispute settlement. For the EU, this agreement is in line with its long-term objective to conclude an EU-ASEAN free trade agreement.

DOC EN PDF

EU-Indonesia: negotiations for a free trade agreement launched

The ambition is to conclude an agreement which covers the following areas: tariff and non-tariff barriers to trade, trade in services and investment, public procurement, competition rules and intellectual property rights.

DOC EN HTML

TTIP: European Commission publishes further documents

One of the new texts deals with medical devices.

DOC EN HTML

TTIP: European Parliament adopts a resolution

The resolution asks, among other things, for recognition that in areas where the EU and the US have very different rules - such as public healthcare services - there will be no agreement.

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CETA: Health insurance funds and health mutuals ask for clarification of the current exemptions on public services and health services

Health insurance funds and health mutuals are urging clarification of the exclusion of public services and health services from the Canada - EU free trade agreement (CETA).

DOC EN HTML

8 Court of Justice of the European Union

Judgment: payment of royalties, even when the licensed patents are not infringed by the licensee's product

Case C 567/14, Genentech Inc. v. Hoechst GmbH, Sanofi-Aventis Deutschland GmbH, concerns a licence agreement requiring the licensee to pay royalties for the use of a patented technology. The Court found that EU competition law does not preclude the application of such an agreement even when the licensed patent has been revoked, provided that the licensee was able freely to terminate that agreement by giving reasonable notice.

DOC EN/NL/FR HTML

Judgment: concept of 'public contract' applied to contracts between a statutory health insurance fund and suppliers of medicinal products

Case C 410/14 concerns the procedure followed by the German health insurance fund DAK-Gesundheit to conclude rebate contracts with undertakings marketing a particular medicinal product. The Court found that the concept 'public contract', within the meaning of EU directive 2004/18/EC, cannot be applied to a contract scheme in which a public entity intends, throughout the period of validity of that scheme, to contract with any economic operator who undertakes to provide the goods concerned in accordance with predetermined conditions, without choosing between the interested operators, and allows them to accede to that scheme throughout its validity.

DOC EN/NL/FR HTML

Order: criterion for assessing the need to open a new pharmacy

Case C 634/15 concerns application of a previous judgment of the Court in the case Sokoll-Seebacher (C 367/12). In the view of the Court, when assessing the need to open a new pharmacy, the Austrian criterion strictly limiting the number of 'persons who continue to be served' is not to be applied in a general manner in every specific situation which will be the subject of an assessment.

DOC EN/NL/FR HTML

Opinion of the Advocate General: a system of price-fixing for prescription-only medicinal products is contrary to the free movement of goods

In case C 148/15, the Advocate General concludes that a price-fixing system for prescription-only medicines, as set out in German legislation, is contrary to the principles of free movement of goods set out in the TFEU, and is not justified on grounds of protecting public health. He suggests that a system of maximum prices, rather than fixed prices, could be a less restrictive measure.

DOC EN/NL/FR HTML

9 Competition

Commission approves public compensation for Brussels IRIS hospitals

The European Commission has concluded that the public financing granted to the Brussels public IRIS hospitals since 1996 is in line with EU state aid rules. This financing was granted to compensate for deficits incurred through the provision of health and social services of general economic interest.

DOC EN/FR/NL HTML

Netherlands: recommendations from the Landelijke Huisartsen Vereniging (LVH - Dutch association of GPs) on the establishment of new doctors

In 2008, the LHV posted recommendations on its website concerning how to regulate the establishment of (new) general practitioners in a region. The Dutch competition authority (ACM) found that these recommendations restricted competition on the general practice care market. The court of Rotterdam annulled this ruling. It found that GPs are not in a strong enough position to impose their will on health insurers with respect to deciding whether or not to contract new GPs.

DOC NL HTML

Germany: price restriction for the sale of a diet product is not an appreciable restriction of competition

The manufacturer of A-Vitalkost offered pharmacies a one-off 30% reduction on a specific diet product, on the condition that they sell this product at a minimum retail price. The German Higher Regional Court of Celle held that this vertical price-setting does not infringe competition law.

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UK: pharmaceutical companies fined for financial deals to delay the entry of generic products onto the market

GlaxoSmithKline plc (GSK), the supplier of a branded product, concluded financial agreements with the producers of generic versions of the product in order to delay the potential entry of generic competitors onto the UK market. The competition authority CMA fined the companies for anti-competitive conduct.

DOC EN HTML

Sweden: three healthcare providers fined for collusion in a procurement process

The Stockholm District Court fined the healthcare providers Aleris, Capio and Hjärtkärlgruppen for unlawful collusion in a procurement of clinical physiology services. They had concluded an agreement under which the party which lost the procurement would still have the right to carry out services as a sub-contractor if the other party won.

DOC EN HTML

Bulgaria: regulation on patients' co-payment of medicines restricts competition

The Bulgarian competition authority (CPC) is asking for the repeal of legislation limiting patients' co-payment for partly reimbursed medicines to 60% above the price of the cheapest medicine in the group. According to the CPC, the doctor, together with the patient, should have the maximum possible choice of medicines.

DOC EN HTML

Acquisition of the consumer health business of Germany's Boehringer Ingelheim by Sanofi of France

The European Commission has approved the proposed acquisition of the consumer health business of Germany's Boehringer Ingelheim by Sanofi of France, subject to conditions. Both companies are active in the pharmaceutical industry.

DOC EN/FR HTML

Commission clears acquisition of Meda by Mylan subject to conditions

The European Commission cleared the proposed acquisition of Meda AB of Sweden by Mylan N.V. of the Netherlands, subject to conditions. Both companies are active in the pharmaceutical sector.

DOC EN/FR/NL HTML

10 Publications

Health system review: the Netherlands

The new review of the Dutch system, published by the European Observatory on Health Systems and Policies in the series 'Health systems in transition' (HIT), analyses the reforms in the Dutch system and discusses future challenges.

DOC EN HTML

Health system review: Slovenia

The analysis of the Slovenian healthcare system in the series 'Health systems in transition' was also updated.

DOC EN HTML

OECD health statistics 2016

The OECD released the online database on health statistics for 2016.

DOC EN/FR HTML

Healthcare coverage in 2012

The OECD published a report on healthcare coverage in OECD countries in 2012.

DOC EN HTML

Report: pharmaceutical expenditure - trends and challenges

The OECD published a report entitled 'Pharmaceutical Expenditure and Policies: Past Trends and Future Challenges'.

DOC EN HTML

The role of voluntary health insurance in Europe

The book 'Voluntary health insurance in Europe: role and regulation', published by the European Observatory on Health Systems and Policies, analyses the contribution of voluntary health insurance to health spending, and its role in 34 European countries in relation to publicly financed coverage.

DOC EN HTML

OECD: better ways to pay for healthcare

This publication presents the most important trends in innovative payment systems, as well as the policy impact of these.

DOC EN HTML

Article: consequences of the Trans-Pacific Partnership (TTP) on health

In this article, the authors warn, among other things, of the possible implications of intellectual property rights provisions on price-setting for medicines and on market access for generic medicines. The investor-state dispute settlement system (ISDS) could also represent a risk for the regulation of medicinal products.

DOC EN PDF

Article: is the EU offering a better alternative to the ISDS?

This article is a response to the above article on the TTP. The authors share the concern voiced in the previous article. They argue, however, that the system for settling disputes between investors and states proposed by the EU in the negotiations on the Transatlantic Trade and Investment Partnership offers a number of advantages compared to the ISDS. Under the EU proposal, the dispute settlement procedure would be overseen by judges.

DOC EN PDF

Article: Policy challenges and reforms in small EU Member State health systems

On the basis of a literature search, this article investigates the policy challenges faced by health systems in small EU Member States and the role played by the EU in supporting these Member States.

DOC EN HTML

Article: Potential for health system collaboration via the European Union Joint Procurement Agreement

This article investigates the potential impact of the EU Joint Procurement Agreement against cross-border health threats on collaboration between Member States. According to the authors, the agreement has the potential to increase health system collaboration and efficiency at EU level, provided that the incentives for sustained commitment of larger Member States are sufficiently attractive.

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11 Miscellaneous

NHS Confederation: Brexit could make staff shortages in the British healthcare system worse

The NHS Confederation has warned that staff shortages in the British healthcare system could increase following Brexit.

DOC EN HTML

European Commission: financing for primary healthcare for refugees in Greece

The Commission has awarded EUR 24.2 million in emergency funding to Greece for increasing the capacity to provide primary health care to migrants and refugees.

DOC 1 EN HTML | DOC 2 EN PDF

WHO: study visit to the Portuguese HTA agency with Greek policymakers

The European office of the World Health Organisation (WHO) organised a study visit to Portugal for Greek policymakers. The purpose was to study the functioning of a HTA agency in a European country of similar size and with similar economic, social and cultural circumstances.

DOC EN HTML

«European Health Care News»
is an electronic newsletter published by the European Social Observatory (OSE),
commissioned by the National Institute for Health and Disability Insurance (NIHDI).

Editors: Rita Baeten and Dalila Ghailani
E-mail : baeten@ose.be
Website: http://www.ose.be

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