European Health Care News

Newsletter No.33 - March 2015

Ose European Social Observatory

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1 Public health

Commission: progress report on implementation of the action plan against the rising threats from antimicrobial resistance

The Commission published a progress report on implementation of its five-year action plan on antimicrobial resistance (AMR).

DOC 1 EN PDF | DOC 2 EN HTML

EFSA and ECDC: EU Summary report on antimicrobial resistance

The European Food Safety Authority (EFSA) and the European Centre for Disease Prevention and Control (ECDC) published their annual joint EU summary report on antimicrobial resistance (AMR) in zoonotic indicator bacteria from humans, animals and food.

DOC EN PDF

EXPH: request for an opinion on cross-border cooperation in health care

The Commission asked the Expert Panel on effective ways of investing in health (EXPH) to identify areas which would potentially benefit from greater formal cross-border cooperation and collaboration in health care provision, particularly in border regions.

DOC EN PDF

EXPH: request for an opinion on the application of disruptive innovations in health care

Disruptive innovations enable a population of less-schooled people to do things in a more convenient or lower-cost way, which previously could only be done by specialists in less convenient settings. The EXPH has been asked to draft an opinion on application of the concept of disruptive innovation in EU health care systems.

DOC EN PDF

EXPH: request for an opinion on access to health care

The EXPH has been asked to give its opinion on options for actions to improve equity of access to health care in the EU.

DOC EN PDF

Commission and EXPH: opinion and public consultation on competition among health care providers

The EXPH brought out a provisional opinion investigating policy options in relation to competition between health care providers, as a way of improving efficiency in the use of health system resources. The Commission and the EXPH are organising a public consultation on this issue.

DOC EN HTML

EXPH: Francqui lecture on primary care in the European Union

Jan De Maeseneer, chair of the EXPH, held a Francqui lecture on primary care in the European Union, with an interactive exploration with members of the panel.

DOC EN HTML

Commission: study on continuous professional development and lifelong learning for health care providers

The Commission published a study containing an overview of the continuous professional development and lifelong learning situation for five health care professions (doctors, nurses, dentists, midwives and pharmacists) in the 31 countries of the EU/EEA/EFTA. It also published a summary of this study.

DOC 1 EN PDF | DOC 2 EN PDF

Commission: study on the impact of lifestyle habits on the efficiency of Europe's health systems

This study, led by RIVM at the request of the European Commission, investigated the impact of health behaviours in EU countries on the cost-effectiveness of health systems.

DOC EN HTML

2 Medicines and medical devices

Commission: Expert group on safe and timely access to medicines for patients (STAMP)

The expert group on safe and timely access to medicines for patients (STAMP), set up to provide advice and expertise to the Commission services in relation to EU policy in the field, met for the first time.

DOC EN HTML

EMA: public consultation on application of the transparency rules in the EU clinical trials regulation

The European Medicines Agency (EMA) organised a public consultation on its proposal for application of the transparency rules in the EU regulation on clinical trials.

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According to some NGOs, this proposal could jeopardise the progress obtained, in terms of the transparency of clinical trial databases, through the new regulation.

DOC EN PDF

EMA: suspension of authorisations for hundreds of generic medicines, due to flawed studies

EMA has recommended the suspension of marketing authorisations for a series of medicines, principally based on clinical studies carried out at GVK Biosciences in Hyderabad in India. Concerns were raised as to how GVK carried out studies on behalf of marketing authorisation holders. Medicines considered to be of critical importance for patients must, according to the EMA, remain available.

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Commission: withdrawal of the proposed revision to the directive relating to the transparency of measures regulating the prices and reimbursement of medicines

Following a 3 year political deadlock in the Council, the Commission decided to withdraw its proposal for a directive, to replace the existing transparency directive (COM/2012/0084), relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems.

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European Parliament: debate on access to innovative and affordable medicines

On 11 February, the European Parliament held a plenary debate on access to innovative and affordable medicines, in view of the high prices for new treatments such as that for Hepatitis C.

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TV programme: market authorisation for a fictional internal medical device

An edition of the Dutch TV series Radar showed how an internal medical device can easily be brought onto the European market. Radar thought up a pelvic floor mesh (a device used to help women suffering from a prolapse) made up of an orange-net.

DOC NL/EN HTML

3 Social policy

Commission: annual review of employment and social developments in Europe

The Commission published the fourth edition of its annual review of employment and social developments in Europe. This report also examines the impact of the crisis on health and access to health care.

DOC EN/NL/FR HTML

Commission: quarterly review of the employment and social situation in the EU

A supplement to the "Employment and Social Situation Quarterly Review" looks at health care and social services from an employment and economic perspective.

DOC EN HTML

SPC: recent social policy reforms

The Social Protection Committee (SPC) published a review of recent social policy reforms for a fair and competitive Europe - 2014.

DOC EN HTML

European Commission and SPC: financing arrangements for social protection systems in the EU

The SPC and the European Commission published a joint report on the effectiveness and efficiency of the financing mechanisms for social protection in the EU.

DOC EN HTML

EPSCO Council: key messages on the financing arrangements for social protection systems

The Council took note of the joint report from the European Commission and the SPC on the financing arrangements and resource allocation in social protection systems, and endorsed the key messages.

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SPC: 2014 annual report on the social situation in the EU

The SPC published its 2014 annual report on the social situation in the EU, providing an analysis of recent trends in the social situation in the EU Member States. According to the report, there has been little improvement in the overall situation in the EU, and the situation is worsening in several Member States. To carry out its analysis, the report made use of the indicators from the Social Protection Performance Monitor (SSPM).

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EPSCO Council: conclusions on the 2015 annual growth survey and joint employment report

The Council of social affairs ministers adopted conclusions on the 2015 annual growth survey and joint employment report. These conclusions also address the modernisation of social protection systems and innovation in health care and long-term care. The Council calls upon the Social Protection Committee to cooperate with the Working Party on Public Health at Senior Level (WPPHSL) on issues related to health policies.

DOC 1 EN - FR - NL PDF | DOC 2 EN HTML

European Parliament: resolution on the social and employment aspects in the 2015 annual growth survey

According to this resolution, some Member States, as a consequence of the crisis, have not been able to ensure full coverage of health care. It calls on the Commission to issue concrete recommendations to correct this situation, and calls for further reform efforts to ensure that the quality and financial accessibility of health infrastructure is not put at risk. The resolution also invites the Commission to report on progress in developing initiatives for investment in

the health and social care sectors with regard to quality employment.

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Council: amendment to the mandates of the SPC and the EMCO with regard to their role in the European Semester

The Council reached agreement on two decisions revising the mandate of the Employment Committee (EMCO) and the SPC. The aim of the decisions is to enhance the efficiency of the committees and improve cooperation between them, as well as adjusting their mandate to the role they play in the European Semester.

DOC 1 EN PDF | DOC 2 EN - FR - NL PDF

4 eHealth

Commission: summary of the responses to the public consultation on mHealth

The Commission published a summary of the responses to the public consultation on the use of apps on mobile devices for health applications (mHealth).

DOC EN HTML

National data protection authorities: consent required for the processing of data in mHealth applications

The "Article 29 WP", a working party made up of representatives of the national data processing authorities, sent a letter concerning mHealth to the European Commission's DG CONNECT. In it, they state that individuals should give their explicit consent for the processing of their medical data in mHealth applications, both under the current data protection directive and according to the text being discussed in Council. They claim that 'health data' is a far broader concept than 'medical data'.

DOC 1 EN PDF | DOC 2 EN PDF

5 Economic policy

Commission: guidance on applying the rules of the Stability and Growth Pact

The Commission published new guidance on how it will apply the existing rules of the Stability and Growth Pact to strengthen the link between structural reforms, investments and fiscal responsibility. The Commission will take account of the effect of structural reforms if they i) are major, ii) have verifiable positive long-term budgetary effects, and iii) are implemented. As regards long-term budgetary effects, the Communication refers explicitly to savings resulting from reforms in the health care sector.

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Commission: results of the in-depth reviews of countries experiencing macro-economic imbalances in the framework of the European Semester

The Commission published a series of reports containing in-depth reviews of economic policy in the 16 countries assessed, in November, as experiencing macroeconomic imbalances. These reports were summarised in a communication. According to this communication, the significant fiscal efforts undertaken by most Member States since 2010 are starting to bear fruit. It concludes, however, that there has been limited progress in improving the efficiency of the health care and long-term care systems.

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ECOFIN Council: European fund for strategic investments

The Council discussed the proposal to create a European fund for strategic investments, which is expected to mobilise at least € 315 billion in private and public investment. The fund can also be used for investments in the health sector.

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6 International trade agreements

Commission: TTIP negotiating texts published

As part of its initiative to increase transparency concerning the negotiations on a Transatlantic Trade and Investment Partnership (TTIP), the Commission published its negotiating texts, including its position on pharmaceutical products.

DOC 1 EN PDF | DOC 2 EN HTML

Commission: TTIP factsheets

The Commission published factsheets on the areas subject to TTIP negotiations. These include factsheets on pharmaceuticals, medical devices and services. According to the factsheet on services, the EU will not enter into any commitments on publicly funded health care. There is also a separate web page on public services, including health care.

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Commission: results of the public consultation on the investor-to-state dispute settlement (ISDS) mechanism in the TTIP

On the basis of the ISDS, US companies would acquire a legal right to challenge government decisions which could affect their investments in Europe. The 150,000 responses to the consultation showed widespread scepticism as to the ISDS mechanism, and particular concern as to how it would apply to the health sector. Fears were expressed, for example, that the ISDS would make it impossible to re-nationalise investments in public services, such as the NHS, once they were privatised. Questions were also asked about the inclusion of intellectual property rights in the ISDS, since this would enable investors to challenge legislation on the pricing of medicines.

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ESIP: consequences of applying ISDS to the health sector

The European Social Insurance Platform (ESIP) published a paper giving examples of the consequences of applying the ISDS to the social and health sectors.

DOC EN PDF

Council: negotiating mandate for an international Trade in Services Agreement (TiSA) published

The Council decided to make public its negotiating mandate to the Commission for an international Trade in Services Agreement (TiSA).

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Committee of the Regions: opinion on the TTIP

The Committee of the Regions (CotR) underlined, in its opinion on the TTIP, that the EU must preserve sufficient regulatory room for manoeuvre, especially for services of general interest. It calls for a horizontal exemption clause for liberalisation measures in public services, including in the health care sector.

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NGOs warn of the consequences of the TTIP

375 NGOs from all over Europe are calling upon European policymakers to protect citizens, workers and the environment against the threat posed by the TTIP. In a letter, they warn against, for example, deregulation and privatisation in the field of public services, including health care.

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Belgian health insurance funds: position concerning the impact of TTIP on health care

The Belgian health insurance funds have also expressed concern as to the possible impact of TTIP on the quality and accessibility of health care.

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7 Judgments of the EU Court of Justice

CJEU Judgment: obligation to state reasons for the reimbursement of medicines

Pursuant to the directive relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems (89/105/EEC), reasons must be given for a decision not to reimburse a medicinal product. According to the Court in case C--691/13, this obligation to state reasons also applies to a decision which limits the reimbursement of a product to a particular category of patients.

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CJEU Judgment: liability for defective products

In the joined cases C-503/13 and C-504/1, the Court interprets directive 85/374/EEC on liability for defective products. According to the Court, a product may be classified as defective without there being a need to establish that an individual product has a defect, where it is found that products belonging to the same group or forming part of the same production series, such as pacemakers and implantable cardioverter defibrillators, have a potential defect. The producer is liable for any damage caused by a surgical operation for the replacement of a defective product.

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CJEU Judgment: supplementary protection certificate for medicinal products for human use

In case C-631/13, the Court responds to a number of questions referred for a preliminary ruling in relation to the implementation of regulation (EC) 469/2009 concerning the supplementary protection certificate for medicinal products, where the active ingredient is covalently bound to other active ingredients which are part of a medicinal product, and for an active ingredient whose effect does not fall within the therapeutic indications covered by the wording of the marketing authorisation.

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CJEU Judgment: medicinal product cannot be categorised as a drug precursor as such

In joined cases C-627/13 and C-2/14, the Court rules that a medicinal product cannot be categorised as a ‘scheduled substance’ as such, in the meaning of regulation 273/2004 on drug precursors, even if it contains a substance referred to in the annex to this regulation, which can be easily used or extracted by readily applicable or economically viable means.

DOC EN/NL/FR HTML

CJEU Judgment: application of VAT exemptions to the acquisition and importation of dental prostheses

In joined cases C-144/13, C-154/13 and C-160/13, the Court deals with a number of questions for preliminary rulings concerning the application of exemption measures from the VAT directive (2006/112/EC) to the acquisition and importation of dental prostheses.

DOC EN/NL/FR HTML

CJEU Judgment: supplementary protection certificate for medicinal products

According to the Court, where a basic patent contains a claim to a product with an active ingredient which constitutes the sole subject matter of the invention, for which the holder of the patent has already obtained a supplementary protection certificate, as well as a subsequent claim to a product comprising a combination of that active ingredient and another substance, the holder may not obtain a second supplementary protection certificate for that combination.

DOC EN/NL/FR HTML

CJEU Judgment: concept of 'bodies recognised as being devoted to social wellbeing' in the VAT directive

The Court ruled that neither State-examined care workers who provide their services directly to persons in need of care, nor a temporary-work agency which supplies such workers to establishments recognised as being devoted to social wellbeing, come within the scope of 'bodies [...] recognised as being devoted to social wellbeing' in the meaning of the European VAT directive (2006/112/EC).

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8 Competition

Slovakia: investigation into bid-rigging in the care sector

The Slovak competition authority (AMO) initiated administrative proceedings against three undertakings for their suspected participation in a cartel agreement relating to public procurement regarding the construction of a health facility.

DOC EN HTML

Italy: provisions of code of conduct for doctors and dentists limiting advertising restrict competition

The Italian competition authority (ICA) adopted a decision against the code of conduct and guidelines of the National Federation of the Associations of Doctors and Dentists (FNOMCEO) limiting the possibility for doctors and dentists to advertise their services.

DOC EN HTML

Bulgaria: opinion on the legal framework regulating the activities of general practitioners

The Bulgarian Commission on the protection of competition (CPC) considers that the restriction on GPs who are specialised only in 'general medicine', which does not allow them to provide specialised ambulatory care or manage medical centres, is objectively justified.

DOC EN HTML

Italy: abuse of dominant position in the cancer drugs market

The Italian competition authority is investigating a possible abuse of dominant position in the cancer drugs market (Aspen).

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Italy: decision in the Roche / Novartis case upheld

An Italian administrative court has upheld the decision of the Italian competition authority in the Roche / Novartis case. Roche and Novartis discouraged the off-label use of Avastin in favour of the much more expensive Lucentis by alleging that such use of Avastin was risky.

DOC EN HTML

Denmark: price agreements between wholesale distributors of medicines

The Danish Competition and Consumer Authority (DCC) found that the two largest wholesale distributors of pharmaceutical products on the Danish market, Nomeco A / S (Nomeco) and Tjellesen Max Jenne A / S (TMJ), entered into an anti-competitive agreement in which they coordinated their prices and other trading conditions.

DOC EN HTML

Commission: acquisition of certain activities of Abbott Laboratories by Mylan approved, subject to conditions

The Commission cleared, subject to conditions, the acquisition of Abbott Laboratories' non-US developed markets speciality and branded generics business by Mylan.

DOC EN/FR HTML

Commission: acquisition of GSK's oncology business by Novartis approved, subject to conditions

The Commission approved, subject to conditions, the acquisition of GSK's oncology business by Novartis.

DOC EN/FR HTML

Commission: joint venture between GSK and Novartis approved, subject to conditions

The Commission approved, subject to conditions, both GSK's acquisition of Novartis' vaccination business and a consumer health care joint venture (concerning, for example, health products to help stop smoking and pain-management products) between GSK and Novartis.

DOC EN/FR HTML

9 Infringement proceedings

Germany: limitation of VAT shared services exemption to the health sector

The European Commission has decided to refer Germany to the Court of Justice of the European Union in relation to its VAT legislation on exemptions for shared services. German VAT legislation only exempts groups from the health and medical sector. The Commission is of the opinion that this is in conflict with EU law.

DOC EN/FR HTML

Italy, Estonia and Slovenia: information procedures for the exchange of human organs between Member States

The Commission is urging Italy, Estonia and Slovenia to notify the transposition measures of the information procedures for the exchange of human organs between the Member States, as set out in Directive 2012/25/EU.

DOC EN/NL/FR HTML

Denmark, Estonia and Italy: transposition of the rules on certain technical requirements on testing of human tissues and cells

The Commission is urging Denmark, Estonia and Italy to notify the transposition measures of the rules on certain technical requirements on the testing of human tissues and cells, as set out in Directive 2012/39/EU.

DOC EN/NL/FR HTML

Poland: transposition of EU directives on quality and safety standards for human blood

The Commission is urging Poland to transpose the EU directive on quality and safety standards for human blood.

DOC EN/NL/FR HTML

10 Publications

OSE Research paper: economic crisis and austerity in Southern Europe: threat or opportunity for building a sustainable welfare state?

On the occasion of a seminar on "Economic Crisis and Austerity in Southern Europe: Threat or Opportunity for building a sustainable Welfare State?", the OSE published a research paper on the topic. This also contained a detailed look at health care reforms in the Southern European Member States.

DOC EN HTML

ETUI: study on health care reforms and the crisis

The European Trade Union Institute (ETUI) published a study on health care reforms and the economic crisis, on the basis of case-studies of 10 EU Member States. A policy brief summarising the findings was also published.

DOC EN HTML

Friends of Europe: adapting EU health policy to an evolving Europe

A working group convened by Friends of Europe, representing policymakers at EU and national level, international organisations, academia, health-related industries and non-governmental organisations, published a report on the changes necessary to European health systems. The final report outlines 21 concrete recommendations to the EU.

DOC EN HTML

Friends of Europe: unequal Europe: recommendations for a more caring EU

A group of 25 well-known figures, under the chairmanship of the former Belgian Deputy Prime Minister and Minister of Social Affairs Frank Vandenbroucke, drew up a report containing recommendations to the new leaders of the EU institutions. It recommends actions to reaffirm Europe’s social principles, while at the same time addressing competitiveness issues.

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11 Miscellaneous

Doctors of the World: opposition to the granting of a patent for the Hepatitis C drug 'Sofosbuvir'

Doctors of the World has filed a European patent challenge with the European Patent Office against the granting of a patent for the Hepatitis C drug 'Sofosbuvir'.

DOC EN/FR HTML

Coalition of health NGOs warn against a new EU directive on trade secrets

A coalition of NGOs from the health sector are warning against a new EU directive on trade secrets which is currently being discussed in the Council of Ministers and the European Parliament. According to the signatories, the very broad definition of 'trade secrets' in the directive will hinder access to biomedical research data, particularly data on drug efficacy and adverse drug reactions.

DOC 1 EN PDF | DOC 2 EN/NL/FR HTML

Council: data protection regulation

The Council discussed a document from the Presidency giving the state of negotiations on Chapter II of the draft data protection regulation. This chapter also covers the protection of health data.

European Digital Rights (EDRi) published a comparative table showing the (most recently available) positions of the Council and European Parliament on the draft data protection regulation.

DOC 1 EN PDF | DOC 2 EN PDF

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