European Health Care News

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Ose European Social Observatory

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1 Public health

Council: exchange of views on EU investments to reform health care systems

On the basis of a note drawn up by the Finnish presidency, the ministers of public health discussed how the use of the various EU financial instruments and funds could be optimised and adapted to the investment priorities in the health sector.

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European Commission: support for the setting-up of registries of patients affected by rare diseases for the European Reference Networks (ERNs)

The European Commission published a call for the European Reference Networks to set up registers of patients affected by rare diseases. These registers collect data on diseases such as : clinical data, characteristics and different manifestations, the family history of the patients and the evaluation of treatments.

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European Commission: new criteria for joining existing ERNs

The European Commission amended the criteria for the establishment and evaluation of ERNs and their members, and for facilitating the exchange of information and expertise. On this basis, a new call for candidates to join the ERNs will be launched.

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ERN Board of Member States: guidelines to frame collaboration between the ERNs and the industry

The guidelines aim to ensure transparency of collaboration and avoid conflicts of interest. The ERN Board acknowledges the importance of collaboration between the ERNs and the industry, especially in the field of research. Where public funding is not available, industry funding is allowed for specific activities.

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ERN Board of Member States: statement on the integration of ERNs into national health care systems

The Board also adopted a statement with recommendations and good practices to facilitate the integration of ERNs into national health care systems. The statement covers five areas of intervention: 1) national rare diseases plans or strategies and legal framework for ERN integration; 2) patient care pathways; 3) systems for referral to the ERNs; 4) support by member states to ERN coordinators, full members and affiliated partners; 5) information about ERNs provided at member state level.

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EXPH: opinion on defining value in "value-based health care"

The EXPH proposes to define "value-based health care (VBHC)" as a comprehensive concept built on four value-pillars: appropriate care to achieve patients' personal goals (personal value), achievement of best possible outcomes with available resources (technical value), equitable resource distribution across all patient groups (allocative value) and contribution of health care to social participation and connectedness (societal value).

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EXPH: opinion on task shifting in health care systems

The EXPH issued an opinion on task shifting in health care systems.

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2 Medicines and medical devices

Council: implementation of the new regulation on medical devices

The Irish and German delegations presented a note on the challenges for a timely implementation of Regulation (EU) 2017/745 on medical devices. Many delegations wondered whether enough progress had been made in order to implement the regulation from May 2020 onwards.

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Council: regulation on health technology assessment

The ministers received a state of play regarding the discussions in the Council's Working Party about the draft regulation on health technology assessment.

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European Ombudsman: decision on the scientific advice provided by the EMA to the medicine developers in the period leading up to marketing authorisation applications

The Ombudsman found that EMA should carefully manage the contacts its evaluators have with medicine developers during the pre-submission phase. She also found that EMA should provide greater transparency on its pre-submission activities.

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France and the Netherlands: push for an EU-wide approach to stopping drug shortages

An article in Politico on shortages in the supply of medicines reports that France and the Netherlands are pushing for an EU-wide approach to tackle shortages.

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EMA: guidance on medicine shortages

The task force set up by the EMA with representatives of the European Commission and the national competent authorities to address problems with medicines supply has published two documents:
- guidance for marketing authorisation holders on reporting of shortages in the EU
- good practice guidance for communication to the public on medicines' availability issues.

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EMA: consultation on draft guideline on quality requirements for medical devices in combination products

EMA launched a consultation on a draft guideline on quality requirements for medical devices in medicines that include a medical device.

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EMA: report on the challenges encountered during the development of medicines under early access programmes

EMA and the US Food and Drug Administration (FDA) have published a report on their joint workshop with stakeholders, discussing scientific and regulatory approaches to address quality and manufacturing challenges encountered during the development of medicines under early access programmes, such as the PRIority MEdicines scheme (PRIME) in the European Union.

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EMA: letter on transparency regarding results of clinical trials

The European Commission (EC), the European Medicines Agency (EMA) and the Heads of Medicines Agencies (HMA) have co-signed a letter reminding all sponsors of clinical trials conducted in the European Union of their obligation to make summaries of results of concluded trials publicly available in the EU Clinical Trials Database (EudraCT).

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EU-US trade talks: mutual recognition on pharmaceuticals

The US Food and Drug Administration (inspection of food and drugs, FDA) delivered its recognition of Slovakia, the last outstanding EU Member State, thus marking the full implementation of the EU-US Mutual Recognition Agreement (MRA) for inspections of manufacturing sites for human medicines in their respective territories.

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Germany: Act to ensure uniform prices for medicines

The Act to Strengthen Local Pharmacies is intended to ensure that pharmacy prices for prescription medicines remain fixed. This is the final reaction to an EU infringement procedure that has been ongoing since 2013 and a ruling of the European Court of Justice from 2016 (C-148/15). The judgment stated that requiring mail-order pharmacies located abroad to charge fixed prices was to be regarded as a quantitative restriction on imports and thus contravened the free movement of goods.

DOC EN HTML

3 Health care services in the internal market

European Commission: annual report on the application of EU law in Member States

The Commission published the annual report on its monitoring of the application of EU law in 2018. In this report the Commission also reports on infringements in the field of health policy.

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4 e-Health

European Commission: EU countries' digital performance

The European Commission released the results of the 2109 Digital Economy and Society Index (DESI), which monitors Europe's overall digital performance and tracks the progress of EU countries with respect to their digital competitiveness. With regards to the use of digital public services, including eHealth and eGovernment, Finland and Estonia registered the highest scores in the index.

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European Commission: study on eHealth adoption in primary health care

According to this study, eHealth adoption in primary health care in the EU has increased from 2013 to 2018, but there are large differences between the countries surveyed. Compared to 2013, the group of general practitioners who are enthusiastic about eHealth has doubled.

DOC EN HTML

European Commission: Guidance on the free flow of non-personal data in the EU

The European Commission published a new guidance on the interaction of free flow of non-personal data with the EU data protection rules. A framework text specifically deals with the processing of health data (p. 10).

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First electronic health records of patients exchanged between EU countries

As of now doctors in Luxembourg will be able to receive digital Patient Summaries of travellers coming from the Czech Republic.

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European Commission: policy and investment recommendations for trustworthy artificial intelligence (AI)

The High-Level Expert Group on Artificial Intelligence (AI) wrote a document for the European Commission containing policy and investment recommendations for trustworthy AI, addressed to EU institutions and Member States. These recommendations also apply to the health care sector. For specific sectors, such as health care, the group proposes to promote the creation of specific trusted data rooms.

DOC EN HTML

European Commission: €35 million to develop AI solutions in the fight against cancer

The European Commission has launched a call for proposals with €35 million available aimed to support the development of analysis of health images for cancer diagnostics based on AI, as well as other tools and analytics focused on the prevention, prediction and treatment of the most common forms of cancer. The call is part of the Horizon 2020 programme.

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5 Social policy

Council: the ministers held a steering debate on the Economy of Well-being

The ministers held a steering debate on the Economy of Well-being. The discussion was based on a Finnish presidency steering note. The Economy of Well-being is a broad concept covering social, employment, gender-equality, health and education-related policy measures.

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European Commission: Overview of Country Specific Recommendations (CSRs) related to health care

The Commission published an overview of the recommendations it made on health care in the context of the European Semester.

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Council: the ministers approved the opinions of the Social Protection Committee (SPC) on the Country Specific Recommendations (CSRs)

These provide an assessment of the employment and social protection challenges in the 2019 national reform programmes and examine the implementation of the 2018 CSRs. They also assessed health care reforms.

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6 Economic policy

European Commission: results of the investment plan for Europe (Juncker Plan)

The Commission published the results of the Juncker Plan, with funding from the European Fund for Strategic Investments (EFSI), by sector and country. This financing has been approved by the European Investment Bank (EIB) Group. In the health sector, too, a large number of investments have been financed, as reported under the social sector.

DOC EN/FR HTML

European Commission: third enhanced surveillance report on Greece

This report monitors the commitments made by the Greek government at the Eurogroup in 2018. It also discusses reforms in the fields of social protection and health care.

DOC EN HTML

European Commission: update of the country reports of the Joint Report on Health Care and Long-Term Care Systems

This joint report of the European Commission (DG Economic and Financial Affairs) and the Economic Policy Committee (EPC) describes the health care and long-term care systems of all EU Member States and presents the related policy challenges, in particular in terms of financial sustainability. The country reports have now been updated.

DOC EN HTML

European Investment Bank (EIB): European support for Dutch Noordwest Ziekenhuisgroep

The European Investment Bank lends €120 million to Noordwest Ziekenhuisgroep with support from the Investment Plan for Europe (Juncker Plan). The financing is meant, among other things, for Noordwest's renovation of the hospital in Den Helder, and for the new construction of a hospital in Alkmaar.

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EIB: loan for the development of new medication

The EIB provides the Spanish pharmaceutical company Almirall with €120m to develop new medication for dermatological problems currently lacking effective treatment.

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EIB: loan to a German pharmaceutical company

The EIB and the German pharmaceutical company PAION AG have signed a €20 million loan agreement for the development of medication.

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7 Court of Justice of the European Union

Judgment: application of European public procurement rules to non-urgent patient transport

According to the judgment in Case C-424/18, non-urgent patient transport carried out by emergency vehicles is not covered by the exceptions provided for in European public procurement legislation.

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Judgment: differences in VAT rate between health care providers and between medicines in Belgium

Case C-597/17 concerns VAT rules in Belgium and is twofold:
1) According to the Court, the exemption from VAT for medical and paramedical professions provided for by European legislation also applies to unregulated professions such as chiropractors and osteopaths.
2) A reduced VAT rate on medicinal products and medical devices supplied in the context of a therapeutic treatment but not applied to products supplied in the context of an aesthetic treatment, is in conformity with European legislation.

DOC FR/NL HTML

Judgment: refusal of a parallel import license for a generic medicinal product into Poland

According to the Court in Case C-387/18, European law precludes national legislation which prohibits any authorisation for parallel imports of a medicinal product in the case of a generic medicinal product, whereas the medicinal product which has already been granted a marketing authorisation in that Member State, is a reference medicinal product.

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Judgment: transposition of the European directive relating to the control of tissues and cells in Italy

In its judgment in Case C-481/18, Italy was condemned for failing to transpose the European Directive on the control of tissues and cells of human origin on time and for failing to communicate the text of the measures to the European Commission.

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8 Competition

European Commission: evaluation of EU rules on state aid for health and social services of general economic interest

Compensation measures for health and social services are subject to EU state aid rules and, in particular, to the texts of the 2012 SGEI (Services of General Economic Interest) package. The evaluation will assess whether public funding for such services does not unduly distort competition in the internal market; whether the existing rules have achieved their objectives and whether they are still appropriate in the light of developments in the sector and the case law of the Court of Justice of the EU.

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United Kingdom: suppliers of antidepressants accused of illegal anti-competitive conduct

The Competition and Markets Authority (CMA) in the UK has found that four pharmaceutical companies broke competition law in relation to the supply of an anti-depressant drug.

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European Commission: GlaxoSmithKline's acquisition of Pfizer's Consumer Health Business, approved subject to conditions

The European Commission has approved the acquisition of Pfizer's Consumer Health Business by GlaxoSmithKline. The decision is conditional upon the global divestment of Pfizer's topical pain management business carried out under the ThermaCare brand.

DOC EN/FR HTML

European Commission: fine on Canon for its acquisition of Toshiba Medical Systems Corporation (TMSC) before notification to and approval by the Commission

The European Commission has fined Canon, the Japan-based imaging and optical products manufacturer, €28 million for implementing its acquisition of Toshiba Medical Systems Corporation (TMSC) before notification to and approval by the Commission, in breach of EU Merger control rules.

DOC EN/FR HTML

Belgium: Order of Pharmacists fined for distorting competition

The Belgian Competition Authority (BCA) fined the Association of Pharmacists for trying to prevent new competitors from entering the market. In particular, according to the BCA, the anti-competitive practices were aimed at excluding MediCare-Market from the pharmacy market.

DOC FR PDF

Belgium: Test-Aankoops' complaint to the Belgian Competition Authority against Biogen for abuse of its monopoly position

According to the consumer organisation Test-Aankoop, the asking price of Spinraza, an orphan drug used for the treatment of the rare disease spinal muscular atrophy (SMA), is disproportionate to the investments made. Because the latter considers that the producer Biogen is abusing its monopoly position, it has lodged a complaint with the Belgian Competition Authority.

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9 Infringement proceedings

Germany: prohibition on the use of public procurement procedures for medical devices

A new provision of German law obliges statutory health insurance funds to negotiate their contracts for medical devices with interested providers, forbidding them to use the specific procedures defined in the public procurement directives. The European Commission considers that this is contrary to the EU directives on public procurement.

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Malta: establishment requirements for psychotherapists

Malta has introduced new shareholding requirements and restrictions on company forms for the establishment of psychotherapists. The Commission deems that the requirements in Malta disproportionately restrict access to these professions and should have been communicated to the Commission under the Directive on the recognition of professional qualifications.

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10 Publications

Bertelsmann Stiftung: international comparison of digital strategies for healthcare systems

In the #SmartHealthSystems study, the Bertelsmann Stiftung compared and analysed 17 countries, among these were 14 EU Member States. Each of these 17 countries was benchmarked and then evaluated with a new Digital Health Index developed specifically for the study.

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Eurofound: Quality of health and care services in the EU

This report reveals citizens' perceptions of quality in healthcare, long-term care and childcare, and compares them between countries, groups in society and the receivers of care and indirect service users.

DOC EN HTML

OECD Health Statistics 2019

The online database OECD Health Statistics 2019 has been released.

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11 Miscellaneous

Supercomputers at eight sites in EU countries

Eight computing centres have been selected across the EU to host the first European supercomputers. These computers will support European researchers and businesses in developing new applications in a wide range of areas, from designing medicines and new materials to fighting climate change.

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European Commission: preparations for a "No deal" Brexit

A Commission's Communication provides details on the extensive preparations in the EU27 in areas such as citizens' residence and social security entitlements, customs and taxation, transport, fishing, financial services as well as medicinal products, medical devices and chemical substances.

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