European Health Care News

Newsletter No.42 - June 2017

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1 Public health

European Commission: Strengthening of the EU cooperation on health technology assessment – Results of the public consultation

This report gives an overview of the responses received from all stakeholders on the EU cooperation on health technology assessment.

DOC EN PDF

European Reference Networks: 900 medical teams to connect across Europe

On 1 March, 24 thematic European Reference Networks (ERN) – bringing together over 900 highly specialised healthcare units from 26 countries – began to work together on a broad range of issues, from bone disorders to haematological diseases, from paediatric cancer to immunodeficiency.

DOC EN/FR/NL HTML

European Reference Networks: conference report

The report on the third conference on the European Reference Networks, held at Vilnius on 9 March, is available online.

DOC EN PDF

EU Ombudsman: the European Commission's initiative on the European Reference Networks for rare diseases receives the award for good administration 2017

The European Commission initiative on the ERN for rare diseases was the overall winner of the EU Ombudsman's Award for Good Administration 2017.

DOC EN HTML

Mapping of the use of European Structural and Investment Funds in health

This report presents the envisaged investments in health-related areas that have been planned for implementation in the 2014-2020 programming period with the support of European Structural and Investment Funds (ESIF).

DOC EN HTML

Benelux: tackling cross-border healthcare fraud

A study by the European Healthcare Fraud and Corruption Network (EHFCN) estimates the volume of healthcare fraud in Europe at millions of euros. The Belgian and Luxembourg Ministers of Public Health and the Dutch Secretary of State for Health announced their intention to work together to prevent and tackle cross-border healthcare fraud.

DOC 1 EN HTML | DOC 2 EN HTML

European Commission: analytical report on access to healthcare in cross-border situations

This report, prepared by a network of legal experts (FreSsco), provides an update of previous studies, taking account of recent developments in cross-border healthcare.

DOC EN PDF

EPSCO Council: Informal Health Ministers Council in Malta

At their meeting on 20 March, ministers discussed the possibility of a voluntary structured cooperation approach in order to facilitate access to expensive innovative health technologies, and to facilitate cross-border post-graduate medical training in innovative or highly specialised services.

DOC EN PDF

Expert Group on Health Systems Performance Assessment: tools and methodologies to assess integrated care

The most recent work done by the expert group concerns integrated care. Their report firstly focuses on identifying principles and factors that enable successful and effective integration of care, then looks for tailored ways to assess the performances of integrated care models.

DOC EN PDF

European Commission: report on the seminar on 'Strategic investments for the future of healthcare'

This event, organised by DG SANTE, together with DG ECFIN, DG RTD and the European Investment Bank (EIB), aimed to promote the Investment Plan for Europe and the European Fund for Strategic Investments in the health sector, and to encourage the community of stakeholders in health to design and implement new forms of healthcare.

DOC 1 EN PDF | DOC 2 EN HTML

European Parliament: petition on extending the scope of EU legislation in the area of patient law

The petitioner calls for the drafting of a law on the protection of patients in the context of extension to the scope of the regulation on social security coordination. He calls for an obligation to provide after-care and a new form of patient protection law.

DOC EN - FR - NL PDF

Expert Group on Social Determinants and Health Inequalities: presentations available

The presentations from the meeting of 14 and 15 March in Luxembourg are available online.

DOC EN PDF

2 Healthcare services in the internal market

European Parliament : draft opinion on the proposal for a directive on a proportionality test before adoption of new regulation of professions

The rapporteur, Gilles Lebreton, proposes exclusion of the healthcare sector from the scope of the proposal (amendment 25).

DOC EN - FR - NL PDF

National parliaments: opinions and contributions on the proposal for a directive on a proportionality test before adoption of new regulation of professions

In response to the proposal for a directive on a proportionality test before adoption of new regulation of professions, several national parliaments have issued reasoned opinions (AT, DE, FR) and contributions (PT, RO, ES, DE) concerning the non-respect of the principles of subsidiarity and proportionality.

DOC EN HTML

European Parliament : parliamentary question to the Commission on the recognition of professional qualifications

In response to a parliamentary question to the Commission, the latter confirmed that the revised directive on the recognition of professional qualifications does not prevent Member States from allowing their trainee doctors to complete part of their basic medical training, including its practical part, in other Member States.

DOC EN PDF

European Commission: public consultation on operation of the European Professional Card (EPC) and the accompanying 'Alert Mechanism'

The Commission has launched a public consultation to gather opinions on the first year of operation of the European Professional Card (EPC) and the accompanying 'Alert Mechanism'.

DOC EN HTML

HPCB: results of the sanctions mapping survey, on fitness-to-practise of healthcare professionals

Healthcare Professionals Crossing Borders (HPCB) published the results of its survey on national sanction systems concerning the fitness-to-practise of healthcare professionals. This survey was carried out in connection with implementation of the alert mechanism set up at the time of the revision of the directive on professional qualifications (2013/55/EU).

DOC EN PDF

HPCB: recommendations to the Commission on the European Professional Card and the alert mechanism

Healthcare Professionals Crossing Borders (HPCB) put forward a number of recommendations to the European Commission on the European Professional Card (EPC) and the alert mechanism.

DOC 1 EN PDF | DOC 2 EN PDF

3 Medicines and medical devices

European Commission: assessment report on Directive 2001/83/EC on the Community code relating to medicinal products for human use

The report points to certain shortcomings in the summaries of product characteristics and package leaflets, and suggests ways of improving these to better meet the needs of patients and health professionals.

DOC EN - FR - NL PDF

European Commission: publication of guides on patient blood management

The Commission published two guides on patient blood management (PBM), one aimed at the authorities, and one for hospitals. It hopes that this will support the efforts being made by health authorities and professionals throughout the EU to obtain similar results for EU patients.

DOC 1 EN PDF | DOC 2 EN PDF

European Commission: scientific advice on breast implants

The European Commission and its Scientific Committee on Health Environmental and Emerging Risks have published two scientific opinions on breast implants and health. These examine new scientific knowledge on the safety of PIP breast implants and a possible connection between breast implants and anaplastic large cell lymphoma.

DOC 1 EN PDF | DOC 2 EN PDF

European Network of Official Medicines Control Laboratories: falsified medicines

The network has highlighted how new analytical techniques will support national authorities in the fight against falsified medicines in Europe and globally.

DOC EN PDF

European Commission: study on 'off-label' use of medicinal products in the EU

This study covers the public health aspects related to the prescription and use of medicinal products not in line with the marketing authorisation, and, in particular, investigates the balance between the benefits and risks of such use for patients and the regulatory framework for 'off-label' use of medicines.

DOC EN PDF

Coordinated opposition to the sofosbuvir patent filed with the European Patent Office

30 civil society organisations from 17 European countries have filed a coordinated patent opposition on sofosbuvir with the European Patent Office. This medicine is used to treat hepatitis C.

DOC EN HTML

European Parliament: resolution on access to medicines

This resolution concerns the difficulties for national health budgets caused by the high prices charged by pharmaceutical companies for medicines. It sets out a number of possible ways to address issues such as research and innovation, competition and transparency.

DOC EN/FR/NL HTML

European Parliament: adoption of regulations on in vitro diagnostic medical devices

The EP adopted two regulations on in vitro medical devices. These two texts are designed to help prevent cases such as the 2010 PIP defective breast implant scandal or the 2012 metal hip replacement scandal.

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

EMA: Task force asked to establish a roadmap and recommendations for the use of big data in assessment of medicines

This task force, set up by the European Medicines Agency (EMA) together with the national competent authorities of the European Economic Area (EEA), is to explore how medicines regulators in the EEA can use big data to support research, innovation and robust medicines development in order to benefit human and animal health.

DOC EN HTML

EMA: framework and action plan for closer interaction with the academic community

As a science-driven organisation, EMA has developed a framework to formalise, structure and further develop interactions with the academic community in the context of the European medicines regulatory network.

DOC EN HTML

EMA: notice to market authorisation holders – legal consequences of Brexit

Looking towards Brexit, EMA has informed holders of market authorisations that, for products authorised in the centralised procedure, EU legislation requires authorisation holders to be established in the EU or the EEA. Some of their activities, such as pharmacovigilance, must also be performed in the EU (or the EEA).

DOC EN PDF

EMA: discussions on the consequences of Brexit

EMA organised an information meeting with heads of the national competent authorities of the Member States of the EU/EEA to discuss how the work related to the evaluation and monitoring of medicines will be shared between Member States following Brexit.

DOC EN HTML

BEUC: calls on the Commission to investigate excessive pricing of pharmaceutical products

According to BEUC, the European Consumer Organisation, the practices of certain pharmaceutical groups such as Gilead, Roche Novartis and Aspen Pharma are undermining consumer access to essential medicines. It is asking the European Commission to investigate whether the practices in certain countries are in violation of the Treaty on the Functioning of the EU (TFEU).

DOC EN PDF

PIP implants: German safety certifier TÜV ordered to pay 60 million euros to victims

TÜV, the body which certified the faulty breast implants made by the manufacturer PIP, was ordered by the commercial court in Toulon to pay compensation of 3,000 euros each to 20,000 claimants.

DOC 1 FR HTML | DOC 2 EN HTML

Southern European Health Ministers: cooperation to improve access to medicinal products

The Maltese, Italian, Spanish, Portuguese, Greek and Cypriot Ministers of Health discussed strengthened cooperation to negotiate better prices for medicines and medicinal products with the pharmaceutical industry.

DOC EN HTML

The Euripid project on 'Statistical data for medicinal product pricing' reaches half-time

The Euripid database contains data on the official prices of publicly reimbursed medicines published in accordance with the transparency directive 89\105\EC.

DOC EN HTML

Belgian Healthcare Knowledge Centre: Horizon scanning for pharmaceuticals: proposal for BeNeLuxA collaboration

This study looks at the possibility of setting up a joint Horizon Scanning system for pharmaceuticals, for Belgium, the Netherlands, the Grand Duchy of Luxembourg and Austria.

DOC FR - NL - EN PDF

Eurostat: overview of European statistics on the use of medicines

This article gives an overview of European statistics on the use of medicines, including prescription medicines. All the data presented in the article come from the European health interview survey carried out between 2013 and 2015. The data are based on self-reported medicine use.

DOC EN HTML

European and US regulators agree on mutual recognition of inspections of medicines manufacturers

This agreement is in an annex to the EU-US Mutual Recognition Agreement (MRA,) signed in 1998, but not yet implemented. Many provisions of the agreement have already entered into force, and others will enter into force on 1 November 2017.

DOC 1 EN PDF | DOC 2 FR - EN PDF

European Commission: the impact of biosimilar competition on price, volume and market share – update 2017

This report, drawn up by QuintilesIMS, contains a set of key performance indicators (KPI) used to monitor the impact of biosimilars on the European markets, using data from 2016.

DOC EN HTML

4 e-Health

European Commission: the mid-term review of the digital market strategy includes digital health and care

This document assesses progress towards the implementation of the digital single market, identifying where more efforts are needed and where new action is called for at European level.

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

European Commission: task force set up to take health and digital policies further

The task force will make specific proposals on making greater use of data and technology to improve healthcare in Europe. It will focus on data protection and secure data exchange throughout Europe.

DOC EN HTML

European Commission: public consultation on the safety of apps and other non-embedded software – synopsis report

According to the respondents, the main category of apps which could cause safety risks are health and wellbeing apps.

DOC EN HTML

CEN: launch of two new work item proposals on the International Patient Summary

The Patient Summary is a standardised document which contains the most important medical information to ensure safe and secure cross-border care. The European Committee for Standardization (CEN) has launched two new work item proposals on the International Patient Summary. Stakeholders are asked to give their opinions.

DOC 1 EN HTML | DOC 2 EN PDF

European Commission: workshop on the state of play of the International Patient Summary

The presentations from this workshop are available online.

DOC EN HTML

Workshop on standardisation of the International Patient Summary

The European 'eStandards' and 'International Patient Summary (IPS)' projects organised, together with IHE Connectathon, two workshops to involve IHE members in the activities and results of the projects, which aim to contribute to the real implementation of standards. IHE International is an initiative of health professionals and the industry aiming to improve the way in which healthcare ICT systems share information.

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

European Commission: 2017 rolling plan for ICT standardisation

The plan identifies standardisation activities in the field of Information and Communication Technologies (ICT) which support EU policies, including health policy.

DOC EN HTML

5 Social policy

European Commission: clarification of some provisions of the working time directive

The European Commission has provided greater legal clarity on the provisions of the directive by publishing an interpretative communication, accompanied by an updated report on implementation of the directive. One section concerns the rules on on-call time.

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

European Commission: 2016 annual report on application of the European Charter of fundamental rights

The report outlines the initiatives taken by the EU in 2016 to strengthen fundamental rights to the benefit of people within the EU, and examines how these rights have been applied in EU policies and in the Member States. The working document accompanying the report describes the initiatives taken by the EU in 2016 to strengthen fundamental rights, including in the area of health (Article 35 of the Charter).

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

EPSCO Council: adoption of the 2017 Joint Employment Report

The EPSCO Council adopted the 2017 joint employment report, including the scoreboard of key employment and social indicators. According to the report, access to healthcare is still difficult for a significant share of the population in several Member States, particularly for low-income families.

DOC EN - FR - NL PDF

European Commission: reflection paper on the social dimension of Europe

This document raises questions as to how to support our standard of living, to create increasing numbers of jobs, to provide people with appropriate skills and to create more unity in our future society and work environment.

DOC FR - EN - NL PDF

European Parliament: vote on the new European structural reform support programme

The European Parliament has given the go-ahead to the structural reform support programme set up by the Union to provide technical support to Member States. It will be managed by the Commission's Structural Reform Support Service, which provides technical expertise, to make the healthcare sector, for example, more efficient.

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

Future of the EU: the Southern European countries call for greater economic and social convergence

The leaders of seven Southern European countries have called for a Europe of 27 which respects national employment and social protection laws. They asked for progress towards completion of the EMU, in the economic and budgetary domain, and rapid finalisation of the banking union in the eurozone.

DOC EN HTML

European Commission: European Pillar of Social Rights

The pillar of social rights aims to deliver new and more effective rights to citizens. It states that every person is entitled to timely access to affordable, preventive and curative healthcare of good quality.

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

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6 Economic policy

European Commission: Spring 2017 'European Semester': the Commission publishes the country-specific recommendations

The European Commission has presented its country-specific recommendations for 2017, in which it describes the economic guidance it wishes to give Member States for the next 12 to 18 months. According to the Commission, progress in healthcare and long-term care has been slow. Nine Member States received a recommendation on health and long-term care.

DOC 1 EN HTML | DOC 2 EN/NL/FR HTML | DOC 3 EN PDF | DOC 4 EN PDF

European Commission: post-programme surveillance report - Portugal

This report identifies the challenges remaining for the Portuguese economy. The quality of and access to healthcare have improved, but the financial sustainability of the health system remains a problem.

DOC EN PDF

European Commission and ECB: statement following the post-programme mission to Cyprus

The statement emphasises that the draft legislation on reforms, including the healthcare reform, should be accompanied by a thorough fiscal impact analysis, to ensure consistency with the existing fiscal space.

DOC EN HTML

European Commission: post-programme surveillance report - Ireland

The report underlines the need to step up monitoring of public expenditure, including in the health sector, in the light of the pressure on the budget. Health reforms are underway, but concerns as to its cost-efficiency remain.

DOC EN PDF

7 | Court of Justice of the European Union

Opinion of the AG: proof of a causal link between the hepatitis B vaccine and multiple sclerosis

A French court asked the Court of Justice if it was sufficient to establish a causal link between the hepatitis B vaccine and multiple sclerosis solely on the basis of serious, specific and consistent presumptions, in the absence of scientific certainty (case C-621/15). In the view of the AG, a judge may consider that this disease is a consequence of the vaccine purely on the basis of serious, specific and consistent presumptions, if there is no scientific consensus.

DOC EN/FR/NL HTML

Judgment: Belgian law prohibiting advertising is not in compliance with EU law

The ban on advertising of dental services in Belgian law is not in compliance with the directive on electronic commerce and the free provision of services (case C-339/15). In the view of the Court, a ban on advertising a certain activity is liable to restrict the possibility, for the persons carrying on that activity, of making themselves known to their potential clientele and of promoting the services which they offer to that clientele.

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

8 | Competition

European Commission: formal investigation into Aspen Pharma's pricing practices for cancer medicines

The European Commission has opened a formal investigation into concerns that Aspen Pharma has engaged in excessive pricing concerning five life-saving cancer medicines. The Commission will investigate whether Aspen has abused a dominant market position, in breach of EU anti-trust rules.

DOC EN/FR HTML

State aid: the Commission concludes that the sale of a Slovak healthcare centre in Turzovka involves no aid

The European Commission concluded that the sale below market price of a public healthcare centre in Turzovka did not constitute state aid, since it is unlikely to affect competition and trade between Member States.

DOC EN HTML

Spanish competition authority: dual pricing system for the distribution of pharmaceutical products

The 'National Commission for Markets and Competition', the Spanish competition authority, opened an investigation into a number of pharmaceutical companies (including Eli Lilly,

Janssen-Cilag, Merck Sharp & Dohme, Novartis, Pfizer and Sanofi-Aventis), for allegedly establishing a system of dual pricing for the distribution of pharmaceutical products in Spain.

DOC EN HTML

Spanish competition authority: merger authorised between Quirónsalud and Fresenius Helios

Quirónsalud's network comprises 43 hospitals, 39 out-patient centres and around 300 occupational risk prevention centres. With this acquisition, Fresenius Helios is strengthening its position as Europe's largest private hospital operator.

DOC EN HTML

A Belgian company is bringing legal action against the Dutch State for the granting of illegal state aid by subsidising non-invasive pre-natal tests

From 1st April, hospitals in the Netherlands can offer non-invasive pre-natal tests to all pregnant women. The Belgian company Gendia, which also offers this kind of test, is taking the Dutch State to court, accusing it of granting illegal aid by subsidising the test.

DOC 1 EN HTML | DOC 2 NL HTML

9 Infringement proceedings

Free movement of students: the Commission closes the infringement case against Austria

The Commission has authorised Austria to maintain its quota system for students from other Member States, applying to medical studies, insofar as it is necessary to protect the Austrian healthcare system. It has asked the country, however, to end the quota imposed on dental studies.

DOC FR/EN HTML

10 Publications

ECDC: healthcare-associated infections pose a major public health threat in long-term care facilities in Europe

An EU-wide survey carried out by the European Centre for Disease Prevention and Control (ECDC) estimated that 4.2 million healthcare-associated infections occur each year in European long-term care facilities.

DOC EN HTML

Article: the Directorate-General for health and consumers 1999-2014: an assessment of its functional capacities

The authors conclude that improvements to the effectiveness of DG SANTE (successor to DG SANCO)'s policies can be made within the existing mandate.

DOC EN HTML

EuroHealth: What does Brexit mean for health in the UK?

In the field of health, Brexit is giving rise to many concerns: uncertainty for healthcare staff as to their professional future, patients' rights in the UK and elsewhere, regulatory challenges linked to the development of new licensing systems, etc.

DOC EN PDF

European Political Strategy Centre: strategic note on the social dimension of EMU

This document raises a number of questions, among them whether competitiveness might entail reduced access to healthcare for the most vulnerable members of society.

DOC EN PDF

OBS: How can voluntary cross-border collaboration in public procurement improve access to health technologies in Europe?

This document from the European Observatory on Health Systems and Policies (OBS) examines the European legal framework put in place to foster voluntary cross-border collaboration in the field of public procurement of health technologies, and describes recent developments in this field in Europe.

DOC EN HTML

OBS: How can structured cooperation between countries address health workforce challenges related to highly specialized healthcare?

This document identifies the factors that can enable or block structured cooperation, describes the institutional framework in place, and examines the policy implications for supporting structured cooperation in the European Union.

DOC EN HTML

OBS: Health system review – Malta

This report identifies the main challenges to be met, particularly adaptation of the health system to a diverse population, strengthening of the mental health sector, and access to new, high-cost medicines.

DOC EN PDF

OBS: Health system review – Portugal

While the overall health indicators for Portugal have improved considerably over recent years, they still hide significant health inequalities, principally in relation to health determinants, such as child poverty, mental health, and quality of life.

DOC EN PDF

ESPN report: Access to social protection for people working on non-standard contracts and as self-employed in Europe

This report describes the situation of these categories of workers in 35 European countries, looking at access to social protection, including access to health.

DOC EN HTML

OSE: Was the exclusion of health care from the Services Directive a pyrrhic victory? A proportionality test on regulation of health professions

This opinion paper analyses the background to the proposal for a directive on a proportionality test before adoption of new regulation of professions, and shows that a particular approach is needed to apply the rules on free movement to national regulation of health professions.

DOC EN PDF

Article: Conditional approval of medicines by the EMA

According to the authors of this article, the EMA should require stronger evidence of safety and efficacy as part of the conditional approval procedure, and should insist on even more convincing data before full approval is granted.

DOC EN HTML

OECD: Review of healthcare quality

This report reviews the quality of healthcare in 15 national health systems, and aims to determine what is meant by quality care in a modern health system, identifying those

policies and approaches which are best suited to improve the quality of healthcare.

DOC EN PDF

Friends of Europe: discussion paper on disruptive models of healthcare

This paper sets out seven key recommendations to reform Europe's healthcare systems and extend the number of years Europeans enjoy good health.

DOC EN PDF

11 Miscellaneous

EIB: EUR 4 billion of investment for urban development, hospitals, energy and small businesses

This sum includes investment to improve sustainable transport, healthcare, education and corporate research, as well as support for lending to small companies by the Bank's local financial partners across Europe and around the world.

DOC FR/EN HTML

'French Healthcare', the new brand to help export health services 'Made in France'

The 'French Healthcare' brand is intended to promote French health expertise abroad. This 'label' can be adopted by any, private or public, French bodies active in the field of healthcare which apply to use it: hospitals, universities, research or training institutes, laboratories, manufacturers of medical equipment, etc.

DOC FR HTML

NHS Confederation: statement on Brexit with a view to the 2017 elections

The NHS Confederation, which represents the health and care sector, launched an appeal to the political parties concerning Brexit, with a view to the 2017 elections.

DOC EN PDF