European Health Care News



Newsletter No.31 - September 2014

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1 Health care services in the internal market

European Economic and Social Committee: study on the liberal professions

The European Economic and Social Committee presented the results of a study on the liberal professions, which essentially confirms the recommendations adopted by the Committee in March this year. Both documents pay particular attention to the importance and role of regulation in this sector.

Judgment of the Supreme Court of the Netherlands: reimbursements for noncontracted care

Dutch health insurance policy holders with contracted care policies can also be reimbursed subject to a ceiling - for care provided by a non-contracted care provider. In this way, the Netherlands applies the principles from European case law relating to the reimbursement of care provided abroad also to care providers based in the Netherlands. The health insurer CZ recently reduced the reimbursement rate for care provided by non-contracted providers from 75 to 50% of the average market rate. According to the Supreme Court ruling, health insurance companies may not calculate reimbursements to patients for treatments provided by non-contracted care providers at such a low rate as to restrict them in their free choice of care provider.

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Belgium: health care services provided abroad requiring prior authorisation

The Ministerial Decree setting out, for Belgium, the list of health care services for which, in application of the European Directive on patients' rights in cross-border health care, prior authorisation is required was published in the Belgian Official Gazette on 22 July 2014.

DOC NL/FR HTML

2 Medicines and medical devices

Council: exchange of information on prices of hepatitis C medicines

The French delegation drew the attention of the Council of health ministers to the high price of medicines for hepatitis C, which are unsustainable for Member States' health budgets. Many Member States supported the French suggestion to set up a network for information exchange on this subject.

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Council and Commission: implementation of the action plan concerning controls on medical devices

The European Commission published a working document on implementation of the Joint plan for immediate actions agreed upon by the Commission and the Member States in 2012, following the scandal relating to defective breast implants produced by the French company PIP. The aim of the plan was to tighten controls on medical devices under the current regulatory system.

The (EPSCO) Council discussed these joint actions.

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European Commission: logo for online pharmacies

The Commission adopted an implementing regulation under the Falsified Medicinal Products Directive (2011/62/EU) setting out the design for a common logo for online pharmacies. The regulation also contains technical requirements for ensuring its authenticity.

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European Investment Bank (EIB) and UCB: partnership to develop new medicines

The European Investment Bank (EIB) signed an agreement with the Belgian biopharmaceutical company UCB, committing itself to providing funding for UCB R&D projects to an amount of € 75 million.

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European Medicines Agency (EMA): scientific advice from EMA and the national HTA bodies to the pharmaceutical industry

The European Medicines Agency (EMA) issued a draft guidance paper on pilot parallel scientific advice procedures for advice from the EMA and the national Health Technology Assessment (HTA) bodies to the pharmaceutical industry.

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In a joint response to the consultation, a number of organisations working in the health sector (ISDB, MiEF, HAI Europe and AIM) warn that early, opaque trialogues between the EMA, the HTA bodies and pharmaceutical companies can lead to increased 'regulatory capture', and could threaten the independence of pricing and reimbursement decisions.

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EMA: access to clinical trial data

In response to criticism from the European ombudsman, researchers and experts from the health sector, the EMA has revised its policy on access to clinical trial data. It has removed from the policy the restrictions on sharing data for non-commercial research purposes.

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EMA: consultation on access to the EudraVigilance database

The European Medicines Agency is launching a public consultation on the updating of its policy to give scientists and industry access to data in its EudraVigilance database on suspected adverse reactions to medicines.

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3 Public Health

European Commission: documents on patient safety

The European Commission published a patient safety package, to be fed into the reflection process on future EU-level action on patient safety and quality of care.

The package consists of three documents:

- A report on the implementation of the 2009 Council recommendation on patient safety. The report puts forward a list of areas for action:
- A Eurobarometer survey on patient safety and quality of care;
- The results of the public consultation.

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European Commission: expert group on cancer control

The European Commission set up an expert group on cancer control. This group will assist the Commission in the drawing up of legal instruments and policy documents.

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Council: conclusions on the economic crisis and health care

The Council of ministers of public health adopted conclusions on the economic crisis and health care. The conclusions address in more detail the impact of the crisis on health systems and on access to health care. They suggest ways to make the systems more resilient.

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Expert panel on effective ways of investing in health (EXPH): opinion on primary care

The EXPH adopted its final opinion on a frame of reference for primary care. The opinion focuses on financing and referral systems.

European Commission and EXPH: public consultation on an EU agenda on the quality of health care

The European Commission and EXPH are organising a public consultation on a preliminary opinion on the future EU agenda on quality of health care, with a special emphasis on patient safety.

DOC EN HTML

Belgium: peer review on Health System Performance Assessment (HSPA) within the FU

HSPA allows decision-makers to measure the performance of their health system. Belgium hosted a peer review which focused on the methods and tools needed to further develop HSPA in the EU.

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4 Social policy

Council: debate on the employment and social aspects of the 2014 country-specific recommendations (CSRs)

The EPSCO Council held a political debate on the 2014 European Semester, and approved its contribution to the European Council on the employment and social aspects of the CSRs, and the outcome of the multilateral surveillance exercise.

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Social Protection Committee (SPC): conclusions on the implementation of the 2013 CSRs

The SPC adopted conclusions on implementation by the Member States of the 2013 CSRs in the areas of social protection and inclusion policies. These conclusions will inform the preparation of the Council decision on the 2014 CSRs, and are the outcome of multilateral surveillance. The conclusions on health care were adopted jointly with the Council Working Party on Public Health at Senior Level.

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SPC and Council: assessment of cross-cutting issues in relation to the 2014 European Semester

The SPC carried out an assessment of the 2014 package of Council recommendations on cross-cutting issues, and of implementation of the 2013 CSRs. One request from the Committee was to limit the range of social policy CSRs - including health care - taken under the macro-economic imbalances procedure. The SPC also maintains that the CSRs on health and long-term care should be discussed by the ministers in charge.

The Council of Social Affairs Ministers endorsed the key messages of this assessment.

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SPC and Council: report on adequate social protection for long-term care needs

The Council endorsed an SPC report on adequate social protection for long-term care needs in an ageing society. The report investigates how adequate protection for long-term care can be organised in a sustainable manner.

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SPC: report on the feasibility of ex-ante coordination of social policy

The SPC presented a report on the outcome of a feasibility test concerning ex-ante coordination of major social policy reforms. This coordination is organised in a similar way to the ex-ante coordination of major economic reforms, under the leadership of the Economic Policy Committee (EPC). The intention is to discuss significant national reforms at EU level before the final decision is taken, in order to take account, early in the decision-making process, of possible spill-overs from reforms in other Eurozone countries.

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5 e-Health

늌 e-health network: multi-annual work plan

The e-health network adopted its multi-annual work plan for 2015-2018.

The activities proposed relate to:

- Interoperability and standardisation
- Exchange of knowledge
- Monitoring and assessment of implementation
- Global cooperation and positioning

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European Commission: technical standards for RFID users

The European Commission adopted new technical standards that will help users of Radio Frequency Identification (RFID) smart chips and systems to comply with EU data protection rules. The use of RFID is increasing rapidly, including in the health sector.

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6 Economic policy

European Commission: proposed Country-Specific Recommendations (CSRs)

In the framework of the European Semester for economic policy coordination, the European Commission has issued country-specific recommendations, based on its analysis of the situation in each country. Fifteen Member States received a CSR to reform their health care system, in order to help reduce public debt. Three of these countries were also urged to improve access to care.

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European Council: endorses the CSRs

The EU Heads of State and Government, meeting in the European Council, endorsed the CSRs proposed by the Commission, with some changes.

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Council: CSRs adopted

The Council of Ministers of Finance officially adopted the final, and sometimes amended, versions of the CSRs. To amend the Commission proposal, the Council must explain its position and must adopt the amendment with a qualified majority.

The Member States are expected to implement these measures when drawing up their budgets and planning structural reforms. The Council and the European Commission will monitor implementation and take action if necessary.

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European Parliament: poor implementation of CSRs

A study by the European Parliament shows that the Member States made little effort to implement the 2011 and 2012 CSRs.

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European Commission: fourth review of the economic adjustment programme for Cyprus

This report evaluates, among other things, implementation of the reforms of the health care system which Cyprus undertook, vis-a-vis the Troika, to carry out.

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Task force for Greece: seventh activity report

The European Commission's task force for Greece published its seventh report on the reforms to be carried out by Greece. Health care reform is a crucial component of this strategy.

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7 Court of Justice of the European Union

Judgment: concepts of 'residence' and 'stay' in the Regulation on the coordination of social security systems

Case C-255/13 deals with questions relating to the concepts of 'residence' and 'stay' in Regulation (EC) No. 883/2004 on the coordination of social security systems. The judgment states that where a European Union national who was resident in one Member State suffers a sudden serious illness when on holiday in a second Member State and is compelled to remain in the latter State for eleven years as a result of that illness and the fact that specialist medical care is available close to the place where he lives, such a person must be regarded as 'staying' in the second Member State if the habitual centre of his interests is in the first Member State.

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Judgment: products based on herbs and cannabinoids are not medicinal products

The Court has ruled in the joined cases C-358/13 and C-181/14 that substances which produce effects that merely modify physiological functions but do not have any direct or indirect beneficial effects on human health, and which are consumed solely to produce a state of intoxication, and are, as such, harmful for human health, do not fall under the European legislation on medicinal products.

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Judgment: in-house exception to the application of EU public procurement rules

Where the contractor selected for a public contract is a non-profit association which, at the time of the award of the contract, has as partners not only public sector entities but also private social solidarity institutions carrying out non-profit activities, the requirements established in order that the award of a public contract may be regarded as an in-house operation are not met, so that the relevant directive on public contracts applies.

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Judgment: application of the directive on unfair commercial practices to the professions, dentists and physiotherapists

In judgment C-421/12, the Court finds that Belgium has not correctly implemented the European directive on unfair commercial practices (2005/29/EC) into Belgian law, by excluding members of a profession, dentists and physiotherapists from the scope of the Law of 14 July 1991 on commercial practices, consumer information and consumer protection.

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Opinion of the Advocate General: liability rules for medicinal products

In case C-310/13, questions were put to the Court as to whether a national liability scheme for medicinal products complies with the special liability provisions set out in the European directive concerning liability for defective products (85/374/EEC). According to the Advocate General, victims' rights which go beyond the level of protection afforded by the provisions of the directive may be maintained, as long as these rights already existed at the time of notification of the directive. The right to information concerning adverse effects of medicines, included in a national liability regime with a view to simplifying the acquisition of evidence by the disadvantaged party, is not in conflict with the aforementioned directive.

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Opinion of the Advocate General: right to receive care services abroad which are part of the benefit package but which are not currently available domestically

According to the Advocate General in Case C-268/13 (Petru), pursuant to Regulation 1408/71, a Member State must agree to a medical service being provided in another EU Member State if the service in question is provided for under its own legislation, but can not be carried out on its own territory because of a momentary and temporary lack of equipment in its hospitals.

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Opinion of the Advocate General: notion of 'human embryos'

According to the Advocate General in case C-364/13, unfertilised human ova whose division and further development have been stimulated are not included in the term 'human embryos', as long as they are not capable of developing into a human being.

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Opinion of the Advocate General: ban on homosexual men giving blood

According to the Advocate General in case C-528/13, the fact that a man has sexual relations with another man does not in itself constitute conduct which involves a high risk of contracting severe infectious diseases which can be transmitted by blood. By permanently excluding homosexual men from giving blood, France has been guilty of unjustified discrimination.

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8 Competition

European Commission: fine for Servier and five generic companies

The Commission imposed fines totalling €427.7 million on these manufacturers, for concluding a series of deals aimed at delaying the entry onto the market of cheaper generic versions of a cardiovascular drug.

European Commission: investigation into price coordination between producers of generic medicines

The European Commission closed its investigation into suspected distortion of competition among generic companies in France. The investigation focused on suspected coordination between producers prior to negotiating with the French pricing authority.

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European Commission: acquisition of the company Het Gastenhuis by Amvest Vastgoed B.V.

The European Commission cleared the acquisition of joint control over Het Gastenhuis, a company providing nursing care for the elderly, by Amvest Vastgoed B.V., ultimately controlled by PGGM and AEGON, and by NPM Capital, ultimately controlled by SHV Holdings, a Dutch family company. All companies involved are based in the Netherlands.

DOC EN HTML

European Commission: acquisition of Independent Clinical Services Group Limited ('ICS') by TowerBrook Investors Limited

The European Commission cleared the acquisition of Independent Clinical Services Group Limited ('ICS') of the United Kingdom by TowerBrook Investors Limited of the Cayman Islands. ICS provides health, life sciences and social care staffing and services in the UK.

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European Commission: joint venture between Allergopharma, Stallergenes and LETI

The European Commission approved the creation of a joint venture between Allergopharma GmbH & Co. KG of Germany, Stallergenes S.A. of France and Laboratorios LETI, S.L. Unipersonal of Spain. All of these companies are active in the field of diagnosis and treatment of allergies.

DOC EN HTML

European Commission: joint venture between Fresenius SE & Co. KGaA and Sistema JSFC

The Commission approved a joint venture between Fresenius SE & Co. KGaA of Germany and Sistema JSFC of the Russian Federation. The joint venture will manufacture and distribute pharmaceutical products.

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European Commission: acquisition of GHD by Nordic Capital

The Commission cleared the acquisition of GHD Verwaltung GesundHeits GmbH Deutschland ('GHD') of Germany by Nordic Capital Fund VIII of Jersey, part of Nordic Capital Funds ('Nordic Capital'). GHD is active on the market for medicines and medical devices; Nordic Capital is a private equity fund.

DOC EN HTML

European Commission: acquisition of EdRCP by Bridgepoint

The Commission cleared the acquisition of Edmond de Rothschild Capital Partners (EdRCP) of France by Bridgepoint Advisers Group Limited of the United Kingdom. Both companies are private equity funds active in several sectors, including dentistry.

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Estonia: transparency in the funding of medical treatments

The Estonian Competition Authority made a recommendation to the Ministry of Social Affairs to amend the Health Insurance Act. It proposed clear and transparent criteria for allocating financing to health care institutions.

DOC EN PDF

Ireland: undertakings from the Irish Medical Organisation (IMO) to the High Court

The IMO has provided undertakings to the Irish High Court not to organise or recommend the collective withdrawal of services or boycotts by its members and to advise its members that they should decide individually, not collectively, whether to participate in publicly funded GP health services.

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United Kingdom: more competition in the private health care sector

The United Kingdom's Competition and Markets Authority (CMA) published a report on measures to increase competition in the private health care market. One point made by the authority was that the incentives offered to doctors to encourage them to refer their patients to private providers can lead to referrals being driven by considerations other than price or quality.

DOC EN PDF

Cyprus: investigation into sales of equipment for monitoring blood glucose to distributors and government services

The Cyprus Commission for the Protection of Competition conducted a dawn raid at the premises of Panicos Theo Hadjigeorgiou & Co Ltd, following the decision to conduct an ex officio investigation into the terms and prices for supplying equipment and strips for monitoring glucose to pharmaceutical distributors and public bodies.

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United Kingdom: acquisition of hospitals approved

The UK competition authority cleared the acquisition by Frimley Park Hospital NHS Foundation Trust of Heatherwood and Wexham Park Hospitals NHS Foundation Trust.

DOC EN HTML

9 Infringement proceedings

ireland: carer's allowance when resident in another Member State

The European Commission has requested Ireland to ensure that people who qualify for a carer's allowance under Irish social security law can obtain it even if they reside in another Member State.

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Twelve Member States: implementation of the directive on patients' rights in crossborder health care

The European Commission has formally requested that Belgium, Bulgaria, Germany, Estonia, Ireland, Greece, France, Luxembourg, Austria, Poland, Finland and the United Kingdom notify full implementation of the directive on patients' rights in cross-border health care. Ireland and Luxembourg have not notified any measures to implement the directive, and the other Member States have partially implemented the directive, according to the Commission.

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Belgium, Ireland, Luxembourg and Portugal: cross-border recognition of medical prescriptions

The European Commission has sent a formal request to Belgium, Ireland, Luxembourg and Portugal to ensure full implementation of the provisions in the Directive on cross-border health care related to the cross-border recognition of medical prescriptions.

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10 Miscellaneous

European structural and investment funds (ESIF): partnership agreements

For the first time, the European Commission and the Member States are concluding partnership agreements on the use of ESIF funds. For some Member States, the agreements include health sector reforms, more specifically measures to encourage de-institutionalisation.

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Belgium: annual report of the Observatory for patient mobility

The Observatory for patient mobility, which monitors the influx of foreign patients into Belgian hospitals, has published its 2013 annual report.

Between 2009 and 2011, 1.5% of hospitalised patients were not resident in Belgium - a percentage which remains stable in comparison with previous years.

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European Commission: health services within the scope of the Transatlantic Trade and Investment Partnership (TTIP):

In a letter addressed to the British Parliamentary Group on the Transatlantic Trade and Investment Partnership (TTIP), the principal European negotiator, Ignacio Garcia Bercero, states that in principle health services fall within the scope of the TTIP, but that the rights of EU Member States to manage their health systems can be fully safeguarded. Among other things, he provided assurances that the proposals for dispute settlement between the state and investors would not affect the right of governments to regulate public health care.

DOC EN PDF

European Commission: State of play of TTIP negotiations

The European Commission published a document describing the current situation with respect to the TTIP, following the 6th round of negotiations. On the point of market access, various liberalisation measures were discussed, including public procurement and investment in services. Exploratory talks were also carried out on the liberalisation of professional services. With regard to regulation, there were discussions on medicines, medical devices and e-health.

DOC EN PDF

TTIP: activist groups warn that privatisation of the British NHS would be irreversible

British trade unions and activist groups are launching a national campaign to warn against the risks posed by the TTIP to the heath sector. They are warning that the planned privatisation of the NHS would be irreversible as a result of the TTIP.

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TTIP: coalition of health sector NGOs ask for the investor-to-state dispute settlement mechanism (ISDS) to be excluded from the negotiations

A coalition of European and American NGOs active in the health sector are asking for the ISDS mechanism to be excluded from the TTIP negotiations. They are warning that pharmaceutical companies could bring proceedings against EU Member States if these took measures to improve access to medicines, or excluded less effective treatments from the reimbursement scheme.

International Trade in Services Agreement (TISA): Greens warn of the consequences for public services

A new round of negotiations towards a TISA agreement began recently. On the basis of leaked documents, the Green party in the European Parliament is warning of the possible consequences of such an agreement in terms of liberalisation of public services, including health services.

DOC EN HTML

DREES (France): report on social protection spending in Europe

This report from DREES, the research and studies directorate of the French Social Affairs Ministry, shows a drop in social security spending during the crisis. According to the report health expenditure has been most severely affected.

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EU Data protection regulation: European Society for Medical Oncology concerned about cancer research

The European Society for Medical Oncology (ESMO) has expressed concern that the proposed European data protection regulation, and more specifically the provision requiring 'explicit and specific patient consent' to the use of data, could make cancer research impossible.

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OECD: Health Statistics 2014

The OECD Health Statistics 2014 show that health spending is rising again, after stagnating or even falling in several OECD countries. But the pace of growth remains slower than before the crisis, especially in Europe.

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Council of Europe Commissioner for Human Rights: universal access to health care undermined by the crisis

According to the Commissioner for Human Rights of the Council of Europe, Mr Nils Muižnieks, universal access to health care in Europe is being undermined by the crisis, despite the fact that the right to health care is guaranteed by international and European human rights instruments. In his view, the extreme effects of austerity measures on the accessibility of health care could be open to contestation in the Court.

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