European Health Care News

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European
Social
Observatory

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1 Public health

European Parliament (EP): Regulation on serious cross-border threats to health

The Parliament adopted its position on the proposal for a Regulation on serious cross-border threats to health (COM(2020) 727 final). Among other things, it calls for greater cooperation and transparency in joint procurement for medical countermeasures.

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European Commission: EU health emergency preparedness and response authority (HERA)

The Commission launched its proposal for an EU Health Emergency Preparedness and Response Authority (HERA) to prevent, detect and respond rapidly to health emergencies.

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European Commission: pre-announcement of the EU FAB call, part of the HERA industrial dimension

The Commission has published the advance notice, giving vaccine and pharmaceutical manufacturers preliminary information on the EU FAB call, scheduled for early 2022. The aim of EU FAB is to establish a network of 'always warm' production capacities for vaccines and medicines that can be activated in case of future crises. EU FAB will be an important part of the industrial dimension of the European Health Emergency Preparedness and Response Authority (HERA)

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EP: Resolution on transparency in the EU on the development, purchase and distribution of COVID-19 vaccines and on HERA

Parliament expresses deep disappointment at the lack of transparency in the development, procurement and distribution of COVID-19 vaccines. Parliament calls for a legislative proposal on the future joint procurement of vaccines, COVID-19 treatments and treatments for orphan diseases, with clear provisions on transparency and the division of competences between the actors. Parliament also criticises the fact that the new European Health Emergency Preparedness and Response Authority (HERA) has not been established as a fully-fledged, independent agency, charged with protecting the public interest.

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MEPs from the Greens/EFA group are filing suit in the European Court of Justice to claim access to information on vaccine contracts

MEPs from the Greens/EFA group are filing suit in the European Court of Justice, in which they claim transparent access to information on vaccine contracts between the European Commission and vaccine manufacturers.

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19 Health NGOs: HERA must prioritise the public interest, be accountable to citizens, and ensure fair and affordable access to medical devices

19 organisations representing patients, consumers, health professionals and civil society have written a joint letter to the responsible European Commissioner, Kyriakides, and to the health attachés of the Member States' permanent representations on HERA. They urge HERA to put the public interest first, be accountable to citizens, and ensure fair and affordable access to medical devices.

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EPHA: HERA for public health or industrial policy in disguise?

According to this opinion from the European Public Health Alliance (EPHA), HERA must go beyond offering advances to corporations to ensure that it is not seen as cloaked industrial policy and to serve its public health mission. EU non-profit infrastructure should be given priority, according to the author.

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EXPH: advice on mental health support for health and other essential workers

The Independent Expert Panel on Effective Ways to Invest in Health (EXPH) has published its advice on supporting the mental health of health and other essential workers.

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Eurofound: COVID-19: a turning point for health and healthcare convergence in the EU?

The findings of this study show that from 2008 to 2019, the health of EU citizens generally improved and Member States started to converge on health outcomes, but differences in public spending and provision of health services continued to widen. The COVID-19 pandemic caused further divergence. The authors stress that a European health union would ideally also allow for convergence of health and health indicators in its member states.

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European Commission: Roadmap for implementation of the European cancer plan

The European Commission has published a roadmap for implementation and indicators of progress for the European cancer plan.

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2   Medicines and medical devices

Council: Green light for new rules on health technology assessment

The new rules provide for Member States to cooperate in carrying out joint clinical assessments and joint scientific consultations. They will also join forces when it comes to identifying emerging health technologies. In order to reduce the administrative burden, especially for smaller companies, health technology developers would only have to submit the information necessary for the joint clinical assessment once at EU level.

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European Commission: public consultation on the review of the pharmaceutical legislation

The Commission has launched a public consultation on the review of the EU's pharmaceutical legislation. This is the final step towards reform of this legislation.

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European Commission: phasing in of new regulation on in-vitro diagnostic medical devices

The European Commission proposes a gradual roll-out of the new regulation on in-vitro diagnostic medical devices to avoid disruption in the supply of these essential health products.

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EP: report on the pharmaceutical strategy for Europe

The Committee on the Environment, Public Health and Food Safety of the European Parliament has adopted an own-initiative report on the pharmaceutical strategy for Europe.

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Council and EP agree on strengthening the role of the European Medicines Agency (EMA)

The European Parliament and the Council reached a political agreement on an enhanced role for the EMA in preparing for, and responding to, health emergencies. With its revised mandate, the EMA will closely monitor and mitigate shortages of medicines and medical devices during major events and public health emergencies. In addition, it will play a key role in the development and more rapid approval of medicines capable of treating or preventing disease during a public health crisis.

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3   e-Health

EP: proposed directive for a high common level of cyber security across the Union

According to the report on the legislative proposal for a high common level of cybersecurity in the Union, adopted in the European Parliament's Industry Committee, EU countries would have to comply with more stringent monitoring and enforcement measures and harmonise their penalty regimes. The healthcare and medical device manufacturing sectors and digital providers are included in the scope. All medium and large companies in selected sectors would be covered by the legislation.

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EU Council: general approach to the Data Governance Act (DGA) adopted

The DGA is a framework for sharing industrial data. The initiative is designed to be able to aggregate data to provide the critical mass needed for big data analytics and artificial intelligence. The DGA also introduces the idea of data altruism, which relates to individuals and organisations collecting and sharing data on a non-profit basis for the public good, for example in health research. EU countries proposed to introduce self-regulatory codes of conduct for this purpose. The general approach provides the Council with a mandate that forms the basis for negotiations with the European Commission and the Parliament.

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EuroHPC: new supercomputer inaugurated

The High Performance Computing Joint Undertaking (EuroHPC) has inaugurated a new EU-funded supercomputer, which will be among the top 100 most powerful in the world, in Bulgaria. The computer is designed to be part of a continental supercomputing network that can be used to accelerate research in various sectors. It will stimulate highly data-intensive research in fields such as medicine, industry or security.

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EP: study on the exchange of personal data after the Schrems II Decision

This study examines reforms to the legal framework for the exchange of personal and other data between the EU and the US that would be necessary to ensure that the requirements of EU law are met and that the rights of EU citizens are respected, following the Schrems II

Decision of the Court of Justice of the EU. The differences in the regulations concerning the exchange of health data are also discussed.

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EP: draft report on artificial intelligence in a digital age

Artificial intelligence (AI) regulation should focus on the level of risk associated with specific uses, the draft report says. According to the text, the public debate should shift to the enormous potential of AI, which offers humanity the unique opportunity to improve almost every area of our lives. AI can help combat climate change, pandemics and global hunger, and improve quality of life through personalised medicine, the draft report said.

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4 Social policy

European Commission: study on the impact of the COVID-19 pandemic on the outermost regions

This study provides a first snapshot of the socio-economic impact of the COVID-19 crisis on the outermost regions of the European Union and makes recommendations. It analyses the impact on important economic sectors, on society, the labour market and healthcare.

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Council: annual report of the Social Protection Committee (SPC) adopted

The report provides an overview of the social policies of the Member States during the COVID-19 pandemic, offers a first analysis of the impact of the crisis on social protection and proposes guidelines for social protection measures in the aftermath of the crisis. According to the report, more efforts should be made to protect minimum income, linked to access to quality social services and inclusive labour markets. It is, therefore, necessary to invest in the social, long-term care and health sectors.

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EP: Resolution on the employment and social policy of the euro area, 2021

The resolution stresses that social policy is essential for Europe's economic recovery. According to MEPs, budgetary policy must take account of social objectives such as sustainable public investment and prosperity, in addition to traditional macro-economic indicators. The resolution calls for a European legal framework for universal access to social security and stresses the importance of increasing investment in public health and social care, including wages and worker training.

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Belgium and Spain: proposal for a warning mechanism for social imbalances under the 'European Semester

According to Agence Europe, Spain and Belgium have presented a proposal in the EU Council of Ministers of Social Affairs (EPSCO) to introduce an alert mechanism for social imbalances as part of the 'European Semester' budget process. The Social Imbalance Procedure (SIP) is a system for the annual monitoring of social indicators designed to identify possible imbalances in the social sphere, with regard to employment, education, social protection and social rights.

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EP: resolution on the introduction of a European Social Security Pass (ESSP) to improve the digital enforcement of social security rights and equitable mobility

Parliament calls on the Commission to present a legislative proposal for an ESSP. The pass should ensure effective identification, traceability, aggregation and portability of social security rights. The resolution is accompanied by a parliamentary question on the subject, addressed to the Commission on behalf of the European Parliament's Committee on Employment and Social Affairs.

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European Commission: High-Level Group on the future of social protection and the welfare state

The European Commission has set up a high-level expert group on the future of social protection and the welfare state in the EU. It will examine the future of the welfare state, its funding and links to the changing world of work and, by the end of 2022, will present a report and recommendations on how to make social protection and social security systems fit for the future.

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5 Economic policy

European Commission: Eleventh report on the enhanced surveillance of economic developments and policies in Greece

This eleventh report on enhanced monitoring of the commitments made by the Greek Government in the Eurogroup of 22 June 2018 also assesses the reforms in the healthcare system to which Greece has committed.

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ESM: Assessment report on financial assistance provided to Greece

The independent assessment report "Lessons from Financial Assistance to Greece" published by the European Stability Mechanism (ESM) assesses financial assistance to Greece in terms of relevance, effectiveness, sustainability, efficiency and cooperation. It focuses mainly on the ESM programme from 2015 to 2018. The impact of the healthcare reforms is also examined.

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6 Competition

European Commission: interim measures to prevent damage to competition following the premature takeover of GRAIL by Illumina

The aim of the Commission is to restore and maintain conditions of effective competition following the premature acquisition of GRAIL by Illumina, which is in breach of the standstill obligation under the EU Merger Regulation. This is the first time that the Commission has taken interim measures following a merger at an unprecedented early stage. Illumina and GRAIL are both based in the US and active in the genomic sequencing market in Europe. For example, both are developing products in the field of tests to detect cancer.

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- **European Commission: Study on market trends in healthcare and social housing and the implications for the application of EU state aid rules**

  As part of the evaluation of the state aid rules for health and social services of general economic interest (SGEI), DG COMP of the European Commission has published an external study on market trends in health and social housing and the implications of EU state aid.

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7 EU funding

- **European Commission: recovery assistance to cohesion and Europe's regions (REACT-EU)**

  The Commission granted recovery assistance for Cohesion and Regions of Europe (React-EU) to several countries, on the basis of an amendment to their respective Operational Programmes (OP) for the European Regional Development Fund (EFRD) and the European Social Fund (ESF). In most countries, the programmes also include health initiatives.

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- **European Commission: support for the treatment of COVID-19 patients in Romania**

  Following a request for assistance from Romania, the EU is mobilising assistance to treat the large number of acute COVID-19 patients in the country. Through the EU Civil Protection Mechanism, the EU has provided, inter alia, oxygen concentrators and respirators.

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- **European Commission: Recovery and resilience plans adopted**

  The European Commission approved the Recovery and Resilience Plan of Finland, Estonia, Romania and Malta, opening the way for the EU to disburse grants under the Recovery and Resilience Facility (RRF). The plans in each of these countries include measures to reform and strengthen the health sector.

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8 Infringement proceedings

- **Belgium, Cyprus and Ireland: proportionality test prior to the adoption of new professional regulations**

  The Commission is sending reasoned opinions to Belgium, Cyprus and Ireland because they have not yet adopted national measures transposing Directive 2018/0958 on proportionality assessment prior to a new regulation of professions. This Directive aims to strengthen the internal market for services by preventing the introduction of new discriminatory, unjustified or disproportionate restrictions to professional services. Regulated health professions are included in the scope.

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9 Court of Justice of the European Union

Ruling: application of the Working Time Directive to an employee engaged in a self-employed activity while on call

In its ruling in Case C-214/20, the Court clarifies that a period of on-call duty performed by a fire-fighter on call, during which period he carries out a self-employed activity with the consent of his employer, but must be permanently available and at his barracks within 10 minutes or less in the event of an emergency call, does not constitute 'working time' within the meaning of Directive 2003/88/EC concerning certain aspects of the organisation of working time, if the obligations imposed do not substantially limit the worker's freedom to organise his time during that period.

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Ruling: the application of the concept of "insured person" in the Cross-border Healthcare Directive (2011/24/EU) to a pensioner who does not reside in the Member State that pays his pension

Case C-636/19 concerns a person who is entitled to a pension under the legislation of a Member State and who, under Article 24 of the Regulation for the coordination of social security systems ((EC) No 883/2004), is entitled to benefits in kind provided by the Member State of residence on behalf of the Member State which pays his pension. According to the Court, that person must be regarded as an "insured person", within the meaning of the Directive on the application of patients' rights in cross-border healthcare (2011/24/EU), who can claim reimbursement of the costs of cross-border healthcare received in a third Member State without being affiliated to the compulsory healthcare insurance scheme of the Member State which pays his pension.

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Conclusion of the Advocate General: obligation to have sickness insurance for persons exercising their right to freedom of movement

In his Opinion in Case C-247/20, the Advocate General states that:

- A child who is a national of a Member State of the European Economic Area (EEA) and who has acquired a permanent right of residence does not have to have health insurance covering the full cost of medical expenses in order to maintain the permanent right of residence.
- Economically inactive EU citizens staying in the host Member State for more than three months and less than five years must have comprehensive sickness insurance cover for themselves and their family members.

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10 Publications

EOHSP: Resilience of health systems during COVID-19: lessons for better rebuilding them

This publication from the European Observatory on Health Systems and Policies (EOHSP) identifies 20 key strategies, grouped by health system functions, that have been found to improve health system resilience in light of COVID-19.

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EOHSP: European support for the improvement of health and care systems

This policy paper, addressed to decision makers, aims to maximise the EU's potential to support health systems by providing a map of the different forms of support available. According to the policy paper, access to EU assistance has become increasingly important, especially for the Member States that have joined since 2004, and will become even more so in the coming years.

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EOHSP: Use of digital health tools in Europe: before, during and after COVID-19

This policy brief, addressed to decision makers, takes stock of how digital health tools were used before and during the pandemic. The authors call for active strategies to build on the current momentum to increase use of digital health tools post-pandemic.

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Eurohealth: COVID-19 and the possibility of strengthening health system governance

This special issue of Eurohealth aims to contribute to strengthening the resilience of public health and health systems by addressing governance issues that arose during the pandemic.

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OSE: Eliminate inequalities in financial access to healthcare. Analysis of a survey of experts and stakeholders

The OSE-European Social Observatory has submitted to experts and stakeholders a series of proposals to improve financial access to healthcare in Belgium. This study was commissioned by the Belgian National Institute for Health and Disability Insurance (RIZIV/INAMI). The report containing the results of the consultation was handed over to the Belgian Minister for Health and Social Affairs, Frank Vandenbroucke.

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ESPN: Social protection and inclusion: an analysis of policy responses to the COVID-19 crisis in 35 countries

This report by the European Social Policy Network (ESPN) examines (sub)national policy responses in the field of social protection and inclusion to the COVID-19 crisis in 35 European countries, including the 27 EU Member States. In the area of healthcare, the report notes that coverage improved with ad hoc expansion of coverage to COVID-19 related treatments and vaccinations, but gaps remain.

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FoE: Defining a pathway for rare diseases in the European health data area

This report, prepared by Friends of Europe (FoE), outlines principles that cannot only optimise the use of rare disease data, but can be used more broadly for sharing medical data within the proposed European Health Data Space (EHDS). According to the authors, rare diseases can serve as a model case for the governance framework for health data in the European Union.

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WHO/Europe: can people pay for healthcare? New evidence on financial protection in Spain (2021)

This WHO/Europe report finds that people in Spain are less likely to experience financial hardship due to healthcare costs than people in most other European countries.

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Transfer: Integrating transnational processes into the analysis of the emerging European healthcare system

According to the authors in this article, a number of EU-wide processes have contributed to the construction of a European healthcare system that is unequal in terms of the distribution of access to services for patients and the wages and working conditions of healthcare workers, but very similar in terms of pressure from EU economic and financial governance on healthcare in EU Member States.

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Book: The interplay of global standards and EU drug regulation: The International Council on Harmonisation

Global standards increasingly determine risk regulation. Legislation and regulations in the pharmaceutical sector in the European Union are no exception. This book analyses the implementation of global pharmaceutical standards in the European regulatory framework for medicines and questions their legitimacy.

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OECD: Health at a Glance 2021

Health at a Glance provides a comprehensive set of indicators on population health and health system performance in OECD members and key emerging economies. These relate to health status, risk factors for health, access to and quality of healthcare and health resources.

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11 Miscellaneous

EHFG 2021: Rise like a phoenix - Health at the heart of a resilient future for Europe

The European Health Forum Gastein (EHFG) 2021 took place as a virtual event under the main theme Rise like a phoenix - Health at the heart of a resilient future for Europe. The session recordings are available online.

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European Commission: Work Programme 2022

The European Commission has presented its annual work programme 2022. A review of the general pharmaceutical legislation and a review of the regulation of orphan drugs and paediatric drugs is announced by the end of 2022. The work programme also announces a European strategy on care, from childcare to long-term care for the elderly, and a revision of the recommendation on cancer screening.

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WHO-Europe: recommendations of the Pan-European Commission on Health and Sustainable Development

18 European political, academic and scientific heavyweights and international leaders, led by Professor Mario Monti, were commissioned by WHO-Europe to issue recommendations to rethink health and policy in the light of pandemics. They published their findings in the report "Drawing light from the pandemic: a new strategy for health and sustainable development (2021)".

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EP: Resolution with a view to the twelfth Ministerial Conference of the World Trade Organisation (WTO)

In the preliminary draft resolution following a Commission declaration in view of the 12th WTO Ministerial Conference from 30 November to 3 December 2021, the European Parliament calls for the creation of a new committee on trade and health and asks WTO members to review the TRIPS Agreement in order to improve affordable access to health products.

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Joint communiqué of G20 finance and health ministers

Ministers commit to working for a healthy and sustainable recovery by strengthening national health systems, making them more inclusive and resilient and ensuring universal access to health services, with a focus on primary healthcare and achieving Universal Health Coverage (UHC).

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