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10 Publications

- WHO/Europe: Report on mechanisms for improving transparency of markets for medicines, vaccines and health products
- Friends of Europe: EU health systems post-pandemic: delivering care to patients at the right place and time
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- Open letter initiated by the SheDecides movement on the right to abortion
- EP: Resolution 'An old continent growing older – possibilities and challenges related to ageing policy post-2020'
- Council of Europe's Commissioner for Human Rights: Urgent call for reform of mental health services
- Belgian Chamber of Representatives: Exemption from value-added tax (VAT) on medical care only for interventions and treatments with a therapeutic purpose
- MISSOC: Latest update of the database on national social protection systems
- EC: Proposal for reform of the Energy Efficiency Directive
- TO-REACH project: Final Conference
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- EU-US Summit Statement: 'Towards a renewed Transatlantic partnership'
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- EC: Market access offers of the EU-China investment agreement
- European Council: Condemnation of recent malicious cyber activities
- EC: Long-term vision for the EU's rural areas
- EC: Draft report on a social taxonomy by the Platform on Sustainable Finance
- Global Health Summit: Rome Declaration

Council: Progress report on strengthening the role of the ECDC

The regulatory package for the European Health Union presented by the European Commission on 11 November 2020 includes a proposal for a stronger mandate for the European Centre for Disease Prevention and Control (ECDC). The proposal foresees that the ECDC can better assist Member States and the European Commission with real-time monitoring of the epidemiological situation or with mobilising EU health task forces. Ministers were briefed on the progress of the talks at the meeting of the Council of the European Union (EU).

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EP: Report on the proposal for a regulation to strengthen the mandate of the ECDC

The Committee on the Environment, Public Health and Food Safety (ENVI) of the European Parliament (EP) has adopted its position on reinforcing the mandate of the ECDC. The report is expected to be voted on by Plenary in September.

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Council: Progress report on the proposal concerning serious cross-border threats to health

The Council of the EU has also issued a progress report on a second proposal in the regulatory package for the European Health Union, namely the proposal for a regulation on serious cross-border threats to health. The proposal requires, among other things, the development of an EU health crisis and pandemic preparedness plan and makes recommendations for the development of national plans, which will in turn be evaluated.

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EP: Report on the proposal concerning serious cross-border threats to health

The ENVI Committee of the European Parliament has adopted the draft report on the proposal for a regulation to strengthen the EU's preparedness for cross-border threats to health.

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EC: Public consultation on patients' rights in cross-border healthcare

The European Commission (EC) is organising this consultation to support its review of the EU Directive, ten years after its adoption. Stakeholders are invited to exchange views on how the Directive has improved patients' rights in respect of healthcare abroad and on its role in strengthening European cooperation in the field of rare and complex diseases.

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EC: Report on the application of the Directive on patients' rights in cross-border healthcare

Directive 2011/24/EU provides that when a European patient is treated in another Member State, the costs of healthcare may be reimbursed by the country of affiliation up to the level provided for by the healthcare system of that country. The latest report on the application of the Directive, with data from Member States on cross-border healthcare for the year 2019, reveals that medical tourism remains a limited phenomenon, mostly taking place between neighbouring countries. Twenty Member States and Iceland have introduced a system of prior authorisation for certain types of healthcare.

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EC: Report of the Expert Group on HSPA on methods to assess access to healthcare

The Commission has published a report by the EU Expert Group on Health Systems Performance Assessment (HSPA) titled: Improving access to healthcare through more powerful measurement tools.

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EXPH: Opinion on public procurement in healthcare systems

The Expert Panel on 'effective ways of investing in Health' has adopted its opinion on public procurement in healthcare systems. As part of this opinion, the Expert Panel examines the tendering of pharmaceuticals, health technology and e-Health. The recommendations emphasise the importance of public policy objectives and, in particular, the interests of patients.

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EC: Launch of a Knowledge Centre to fight cancer

The Commission is launching the Knowledge Centre on Cancer, the first flagship action delivered under Europe's Beating Cancer Plan. The Knowledge Centre is a new online platform to gather evidence and coordinate actions against cancer.

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EC: Communication 'Drawing the early lessons from the COVID-19 pandemic'

The European Commission has presented a communication on the lessons learnt from the COVID-19 pandemic in the last 18 months and on how to build on them to improve activities at EU and national level. Ten lessons focus on what can be done better in the future.

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EC: Results of the public consultation on the creation of a European Health Emergency Preparedness and Response Authority (HERA)

This consultation concerns the creation of a 'European BARDA – an agency for biomedical advanced research and development'. The agency should support EU capacity and readiness to respond to cross-border threats and emergencies, whether of natural or deliberate origin. The Commission has published a summary of the responses.

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EC: Public consultation on the priorities, strategy and needs for the EU4Health annual work programme for 2022

The new EU4Health programme, the EU's ambitious response to COVID-19, goes beyond crisis response to address the resilience of health systems. The consultation seeks feedback from stakeholders on the priorities and strategic orientations and on the needs to be addressed through the annual work programmes, in particular for 2022.

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2 Medicines and medical devices

EP and Council: Political deal on health technology assessment (HTA)

The Council of the EU and the European Parliament have struck a political deal on a joint European framework for health technology assessment (HTA). The proposal harmonises the requirements for this procedure, which compares new medical interventions with existing ones or with the status quo. Under the agreed scheme, Member States must take due account of the published joint clinical reports at EU level, but are not obliged to use these joint reports at national level.

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Council: Agreement on reinforcing the role of the European Medicines Agency (EMA)

Health ministers in the Council of the EU have reached agreement on the general approach relating to the proposal for a regulation to reinforce the role of the European Medicines Agency (EMA). In particular, the intention is to reduce shortages of medicines and medical products, to ensure timely development of high-quality and efficacious medicines and to strengthen crisis preparedness and management in the field of medicines and medical devices. The draft is part of the broader regulatory package for a European Health Union.

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EP: Position on extending the mandate of the EMA

The Parliament has adopted its position for negotiations with the Council on extending the mandate of the EMA and strengthening its role. To enhance the agency's powers in crisis preparedness, management for medicinal products and medical devices, MEPs are calling for the creation of an interoperable digital EU database aimed at detecting, predicting and preventing shortages of medicinal products.

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Council: Conclusions on access to medicines and medical devices

The Council of the EU has adopted conclusions on access to medicines and medical devices. The conclusions address the triple challenge of accessibility, availability and affordability of medicines and medical devices.

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The Multilateral Working Group on pharmaceutical mergers launches a joint public consultation

The European Commission's Directorate General for Competition, the United States' Federal Trade Commission ('FTC'), the Canadian Competition Bureau and the UK's Competition and Markets Authority have launched a joint public consultation on mergers in the pharmaceutical sector.

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EC: Public consultation on medicines for children and rare diseases

The Commission has held a public consultation on the revision of the legislation on medicines for children and for rare diseases.

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EC: Roadmap for the revision of the general pharmaceuticals legislation

The European Commission has published a roadmap for the revision of the general pharmaceuticals legislation. The Commission wants to reach a common understanding of the notion of 'unmet medical needs' and revise the incentive system that complements market protection.

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EC and EMA: Pilot project 'Market launch of Centrally Authorised Medicinal Products'

The Commission is launching a pilot project with the EMA and EU countries, with the participation of future marketing authorisation holders, to better understand the root causes of deferred market launches for centrally authorised medicinal products. The EMA is inviting marketing authorisation applicants for orphan medicines and medicines to treat cancer to participate in the pilot project.

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EC: Structured dialogue on security of medicines supply

The structured dialogue initiative facilitates discussions with and between the actors in the pharmaceutical manufacturing value chain, public authorities, research community, health professionals and patient organisations. It is a two-phase process. The objective of phase 1 is to gain a better understanding of the functioning of global pharmaceutical supply chains and to identify the precise causes of different potential vulnerabilities. Phase 2 will result in concrete measures that will address the identified issues.

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AIM: Tool for calculating fair medicines prices in Europe

The International Association of Mutual Benefit Societies (AIM) has developed a tool for calculating fair medicines prices in Europe. The calculator transposes the fair pricing model developed previously by AIM into a policy tool that should help the public, specialists and non-

specialists alike, to evaluate fair medicines prices and compare them with those currently paid by healthcare systems.

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International Horizon Scanning Initiative (IHSI): Award of the contract to supply the International Horizon Scanning Database

IHSI provides data that enable political decision-makers and payer organisation negotiators to strive for better prices for medicines. It is a large-scale spin-off of the horizon scanning activities of Beneluxa. IHSI has signed a contract with ECRI to set up the International Horizon Scanning Database.

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EP: Resolution on the trade-related aspects and implications of the COVID-19 outbreak

This European Parliament resolution focuses, among other things, on lessons learnt from the COVID-19 crisis for trade policy for critical health products. The resolution calls for greater transparency in respect of available stocks, global supply networks, production capacities and the pricing of essential health products, the implementation and development of exceptions for public health security in the intellectual property rights framework and an increase in the global mobility of essential services.

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3 e-Health

EC: Proposal for a regulatory framework for artificial intelligence (AI) and a new coordinated plan by the Union and the Member States

The Commission has presented new rules and actions for trustworthy artificial intelligence (AI). The proposal distinguishes between AI applications with an unacceptable risk, a high risk, a limited risk and a minimal risk. The plan calls for funding through the various European programmes. The plan focuses, among other things, on the contribution of AI to healthcare by expanding the cross-border exchange of information.

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EC: Digital transformation of Europe by 2030

The Commission has presented a vision, targets and avenues for a successful digital transformation of Europe by 2030. The communication proposes to agree on a set of digital principles, to launch projects and to prepare a legislative proposal setting out a robust governance framework to monitor progress. The Commission is proposing a Digital Compass to translate the EU's digital ambitions for 2030 into concrete terms. One of the ambitions is for all citizens to have access to their e-medical records.

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ENISA: Procurement guidelines for cybersecurity in hospitals

The European Union Agency for Cybersecurity (ENISA) has published procurement guidelines for cybersecurity in hospitals. The new tool aims to help healthcare organisations identify best practices in order to meet cybersecurity needs when procuring products or services.

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Regulation establishing the Digital Europe Programme published

The Regulation establishing the Digital Europe Programme has been published in the Official Journal of the European Union. The general objectives of the programme are to support and accelerate the digital transformation of the economy, industry and society in the EU. Applications in healthcare are one of the spearheads of the programme. The financial envelope for the implementation of the programme for the 2021-2027 period is EUR 7.5 billion.

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TEHDAS project: Health data need dedicated EU regulation

The TEHDAS project is being implemented by 25 European countries with the involvement of various partners and stakeholders from all over Europe.

According to a TEHDAS analysis, the unique specificities of health data require dedicated EU legislation to regulate their cross-border use and exchange. The first TEHDAS output examines why regulating the secondary use of health data is a specific case in data governance that cannot be regulated only by horizontal legislation, such as the proposed Data Governance Act.

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eHealth Network: Release 3 of the Guideline on Patient Summary

The eHealth Network has adopted release 3 of the guideline on patient summary, following the contributions and consultation of an extended range of stakeholders.

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EC: Public consultation on the European Health Data Space

The European Commission has organised a public consultation on the European Health Data Space. The European Health Data Space will be built on 3 main pillars: a strong system of data governance and rules for data exchange, data quality, and strong infrastructure and interoperability.

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4 Social policy

EC: EU Strategy on the Rights of the Child and proposal for a Council Recommendation establishing a European Child Guarantee

The proposal for a Council Recommendation establishing a European Child Guarantee aims to promote equal opportunities for children at risk of poverty or social exclusion.

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EC: Study on the economic implementing framework of a possible EU Child Guarantee Scheme, including its financial foundation

The Commission has published a study on the economic implementing framework of a possible EU Child Guarantee Scheme, including its financial foundation, as well as a summary of this report. The study, which was coordinated by LISER and Applica, also includes an evaluation of the feasibility of providing routine health examinations and follow-up treatments free of charge.

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EP: Resolution on the European Child Guarantee adopted

The Resolution stresses that Member States should mainstream the European Child Guarantee across all policy sectors, allocate at least 5% of the ESF+ resources under shared management to supporting activities under the scheme, consider making the scheme a permanent instrument to prevent and tackle child poverty in a structural manner, and examine the possibility of establishing a European Authority for Children to support the implementation of the recommendation by Member States.

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Council: Recommendation for a European Child Guarantee adopted

The Council of the EU has adopted the recommendation establishing a European Child Guarantee. In particular, it is recommended that Member States guarantee effective and free access to early childhood education, school education, at least one healthy meal each school day, healthcare, healthy nutrition and adequate housing. Each Member State must nominate a national Child Guarantee coordinator who will submit an action plan to the Commission for the implementation of this recommendation.

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EP and Council: Green light for ESF+

The EP and the Council of the EU have approved the European Social Fund Plus (ESF+) Regulation, worth EUR 99.3 billion. Countries where children's risk of poverty or social exclusion is above the EU average must use at least 5% of their ESF+ resources to tackle this issue.

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Porto Social Summit

EU leaders, European institutions, social partners and civil society representatives met in Porto to reinforce their commitment to the implementation of the European Pillar of Social Rights. They discussed the European social policy agenda for the next decade and how to tackle existing and future challenges. There were 3 main themes, including the welfare state and social protection. At the end of the conference, the Porto Social Commitment was co-signed.

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European Council: The Porto declaration

In the Porto declaration, government leaders committed to deepening the implementation of the European Pillar of Social Rights and welcomed the 2030 Action Plan's headline targets on jobs, skills and poverty reduction.

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Council: Follow-up to the Porto Social Summit

At the meeting of the Council of the EU, ministers discussed the target setting and monitoring of progress achieved in implementing the principles of the European Pillar of Social Rights at national level through the European Semester.

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Council: Assessment of the implementation of the 2020 and 2019 country-specific recommendations approved

The country-specific recommendations are provided in the context of the European Semester, the EU's framework for economic policy coordination in the European Union. The Council of the EU has approved the assessment of the implementation of the country-specific recommendations in the social sector for 2020 and 2019. Healthcare reforms were part of the recommendations for most EU Member States.

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Council: Opinion on the revision of the Social Scoreboard

The Council of the EU has adopted an opinion for a revised Social Scoreboard, with new headline indicators. This Scoreboard is used as an evaluation tool within the framework of the European Semester. Discussions on proposed new secondary indicators relating to the health sector, including health and long-term care expenditure as a share of GDP, coverage of long-term care needs, and preventable and treatable mortality have been paused for now.

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EC and the Social Protection Committee (SPC): 2021 joint long-term care report

The report provides the state of play in long-term care provision and the key challenges across the EU. It also offers a first analysis of the impact of the COVID 19 pandemic. The country reports provide a more detailed description of the long-term care in each of the 27 Member States.

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Council of the EU: Key conclusions of the 2021 long-term care report adopted

Ministers have approved the key conclusions on the 2021 long-term care report prepared by the SPC and the European Commission.

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EC: Feasibility study for a European Social Security Pass

The Commission, in cooperation with the Italian social security institution Istituto Nazionale della Previdenza Sociale (INPS), has launched a pilot project to explore by 2023 the feasibility of introducing a European Social Security Pass. The aim is to enable digital verification of citizens' social security coverage and entitlements by competent actors and institutions across borders. In 2023, the evaluation could also cover the integration and digitalisation of the European Health Insurance Card.

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EC: The review of employment and social developments in Europe

The Commission has published the 2021 edition of the Employment and Social Developments in Europe review. The report shows the uneven and diverse impact of the COVID-19 crisis. Developments in the field of healthcare are also discussed.

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EC: Second-stage consultation of social partners on better protection for people working through platforms

On the basis of the responses in the first stage, the Commission has concluded that the EU should take more action to improve the working conditions and social protection of people working through digital labour platforms.

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Council: Conclusions on the socio-economic impact of COVID-19 on gender equality

The Council of the EU has approved conclusions on the socio-economic impact of COVID-19 on gender equality. According to the Council, women are disproportionately affected by the COVID-19 pandemic and the containment measures. For example, they are at greater risk of contracting COVID-19 because they are over-represented among healthcare workers. The Member States and the Commission are invited to take steps to mitigate the long-term disadvantages experienced by women as a result of the COVID-19 crisis and to make gender equality a driver for recovery.

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5 Economic policy

EC: European Semester Spring Package

This package contains the fiscal guidance for Member States. The European Semester will from now on be linked to the Member States' recovery and resilience plans, which set out the investments and reforms that the Recovery and Resilience Facility will finance. The Commission has also announced that the general escape clause of the Stability and Growth Pact will continue to be applied in 2022 and that no action will be taken regarding Member States with excessive budget deficits.

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EC: Proposal on guidelines for the employment policies of the Member States

The European Semester Spring Package also contains a proposal on guidelines for the employment policies of the Member States, including healthcare policies. These guidelines provide that timely and equal access to affordable long-term care and healthcare services, including prevention and healthcare promotion, is particularly relevant in light of the COVID-19 crisis and in a context of ageing societies.

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EC: Proposals for country-specific recommendations within the framework of the European Semester

The European Semester Spring Package also contains recommendations to the Council for an opinion on the 2021 stability programme of each of the Member States. These country-specific recommendations also include recommendations for reforms in the healthcare sector.

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EC: Tenth report on enhanced surveillance for Greece

The report assesses Greece's progress with the policy commitments made to the Eurogroup in June 2018. In the area of healthcare, the report states, for example, that the authorities have reached the 30% target on centralised procurement of healthcare expenditure, that steps have been taken for the collection of clawback from healthcare providers and that the primary healthcare reform has been relaunched.

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EC: Post-Programme Surveillance Report – Portugal, Spring 2021

This report presents the findings of the thirteenth post-programme surveillance mission in Portugal and identifies remaining challenges. Expenditure control and improvements in cost efficiency in the healthcare sector are also on the radar here.

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Council: Green light for EU Recovery and Resilience Facility disbursements for 16 Member States

At the meeting of the Council of the EU, the EU economic and finance ministers approved 16 national recovery and resilience plans, allowing the Member States concerned to make use of the EU recovery funds. The plans take into account the country-specific recommendations formulated in the context of the European Semester and focus on six policy areas, including digital transition, inclusive growth, and social and territorial cohesion. For most countries, the plans contain reforms in the healthcare sector, including initiatives for digitalisation.

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EC: The 2021 Ageing Report: Economic and Budgetary Projections for the EU Member States (2019-2070)

This report predicts that ageing-related expenditure (pensions, healthcare and long-term care) will increase.

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Council: Conclusions on the sustainability of public finances in light of an ageing population

The conclusions are based on the 2021 Ageing Report. The Council of the EU is calling on Member States to address the economic and budgetary consequences of ageing, including by reforming (long-term) care systems. The conclusions provide that they should take advantage of the reform and investment opportunities offered by the Recovery and Resilience Facility and the other components of NextGenerationEU.

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European Court of Auditors: EU funding for cross-border regions needs better focus

The European Territorial Cooperation (Interreg) programme is aimed at encouraging economic growth in border areas. According to a report from the European Court of Auditors (ECA), the cooperation programmes financed through Interreg contain clear strategies for tackling cross-border challenges, but there are several weaknesses in the implementation and monitoring of the programmes. The report finds that some of the challenges, for example in the field of cross-border healthcare, should be addressed at national level, by the Member States.

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Euractiv: The European Court of Auditors is looking into the contracts with large auditing firms to provide technical assistance to Member States for structural reforms

According to Euractiv, the European Court of Auditors is examining contracts worth hundreds of millions that the European Commission has concluded with external consultants. Since the start of the Commission's Structural Reform Support Programme, the funds spent on the big auditing firms to provide technical assistance to Member States for reforms in the fields of justice, health and the labour market have risen sharply.

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Euractiv: Big consultants advise on structural reforms in the Member States

According to Euractiv, the European Commission spent over EUR 462 million on contracts with PWC, KPMG, Deloitte and EY between 2016 and 2019. The role of consultants in EU and Member State policy-making is increasing through the technical advice they provide for structural reforms, funded by the Commission through the Structural Reform Support Programme. In a letter, MEPs from across the political divide have questioned the involvement of these consultants in the Structural Reform Support Programme, in particular in sensitive areas covered by projects financed, including healthcare.

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EC: Additional resources in cohesion policy for healthcare

The Commission is allocating additional cohesion policy funding as part of a modification of the Operational Programmes (OPs) for funding from the European structural funds, within the framework of the Recovery Assistance for Cohesion and the Territories of Europe (REACT-EU) initiative. In several Member States, the additional resources will be used in particular for healthcare and long-term care.

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REACT-EU: Financial resources for healthcare systems

'REACT-EU', financed by the EU Recovery Plan, is providing EUR 50.6 billion of fresh resources to existing cohesion policy programmes for the years 2021 and 2022. As of 19 August 2021, a total of EUR 24.8 billion has been allocated through the ERDF and ESF, of which EUR 4 billion to support healthcare systems. Resources for the digital economy and social inclusion may also include support for initiatives in the healthcare sector.

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EuroHealthNet: Seizing the opportunities for a healthy recovery – Multiannual Financial Framework 2021-2027 and NextGenerationEU

EuroHealthNet, the not-for-profit European partnership of public health bodies, has published a comprehensive overview of funds and programmes in the new EU budget and their relevance for health. The analysis explains how different areas of the budget can be used to improve health, tackle health inequalities and build resilience to future health crises while enabling a sustainable recovery.

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EC: Support for transport of COVID-19 medical supplies

The Commission is providing financial support to 6 Member States, amounting to over EUR 14 million, for the transport of COVID-19 vaccination-related equipment and COVID-19 therapeutics. The resources are available through the Mobility Package of the Emergency Support Instrument. The support includes, for example, the transport of intensive-care drugs to Belgium and of syringes and needles to Italy.

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7 Competition

EC: Green light for the acquisition of GrandVision by EssilorLuxottica, subject to conditions

The Commission has approved the proposed acquisition of GrandVision by EssilorLuxottica. This approval has been granted subject to full compliance by EssilorLuxottica with the commitments it has made in this regard. EssilorLuxottica is the largest supplier of ophthalmic lenses and eyewear, both worldwide and in Europe. In addition, EssilorLuxottica is active in the retail sale of optical products. GrandVision is a globally active eyewear retailer and operates some of the largest optical chains throughout Europe.

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EC: Sigma-Aldrich fined for providing misleading information during Merck takeover investigation

The European Commission has fined Sigma-Aldrich EUR 7.5 million for providing incorrect or misleading information during the Commission's investigation into Merck's acquisition of Sigma-Aldrich.

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EC: Italian scheme to support self-employed and certain healthcare professionals approved

The European Commission has approved a EUR 2.5 billion Italian scheme to support self-employed individuals and certain healthcare professionals in the context of the coronavirus outbreak, by partially exempting them from social security contributions. The scheme was approved under the State aid Temporary Framework.

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EC: In-depth investigation into proposed acquisition of GRAIL by Illumina

The European Commission has opened an in-depth investigation to assess the proposed acquisition of GRAIL by Illumina. The Commission is concerned that the proposed acquisition may reduce competition and innovation in the emerging market for the development and commercialisation of cancer detection tests based on sequencing technologies.

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EC: Investigation into possible breach of the standstill obligation in the Illumina/GRAIL transaction

The European Commission is opening an investigation to assess whether Illumina's decision to complete its acquisition of GRAIL, while the Commission's in-depth investigation into the proposed transaction is still ongoing, constitutes a breach of the 'standstill obligation' of the Merger Regulation. This investigation is separate from the Commission's in-depth investigation into the substance of the case.

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EC: Acquisition of Willis Towers Watson by Aon approved

The European Commission has approved the acquisition of Willis Towers Watson by Aon. The approval is conditional on compliance with a set of commitments made by Aon. Both companies are global leading players in the markets for commercial risk brokerage services, reinsurance brokerage and the provision of retirement, health and welfare, and investment services to commercial customers.

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8 **Infringement proceedings**

Czech Republic: Failure to comply with EU rules on professional qualifications

The Commission is referring the Czech Republic to the Court of Justice of the European Union for non-compliance with EU rules on professional qualifications (Directive 2005/36/EC). The identified breaches concern various sector-specific issues affecting doctors, nurses, pharmacists, veterinary surgeons and architects, in addition to procedural formalities and guarantees for professionals.

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Belgium: Independence of the Data Protection Authority

The Commission is opening an infringement procedure against Belgium on the independence of its Data Protection Authority. According to the Commission, Belgium is violating the provisions of the General Data Protection Regulation (GDPR) (Regulation (EU) 2016/679) because some members of the authority report to a management committee that is dependent on the Belgian government, participate in governmental COVID-19 contact tracing projects or are members of the Information Security Committee.

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9 **Court of Justice of the European Union**

Judgment: Economically inactive EU citizens residing in another Member State have the right to be affiliated to the public sickness insurance system of the host Member State

In its judgment in Case C-535/19, the Court confirmed the right of economically inactive Union citizens residing in a Member State other than their Member State of origin to be affiliated to the public sickness insurance system of the host Member State in order to benefit from healthcare services financed by that State. Though the Court stated that EU law does not impose an obligation to affiliate such inactive citizens to that system free of charge. However, the required contribution must not be 'disproportionate'.

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Judgment: Stand-by time during which the employee must be permanently available is working time under certain conditions

In its judgment in Cases C-344/19 (D.J. v Radiotelevizija Slovenija) and C-580/19 (RJ v Stadt Offenbach am Main), the Court stated that a period of stand-by time during which the employee must be permanently available can only be regarded, in its entirety, as working time if the obligations imposed on the worker significantly affect his or her ability to manage his or her free time during that period. The organisational difficulties that a period of stand-by time may entail for the worker and which are the result of natural factors or the free choice of that worker are not relevant.

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Judgment: The public support to public hospitals in Italy does not constitute State aid

In Case T-223/18, the General Court upheld the conclusions of the European Commission in the 2017 decision that the Italian healthcare system (SSN) was not economic in nature and therefore the public support to public hospitals operating under the SSN did not constitute State aid within the meaning of EU law.

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Judgments: Appeals dismissed against fines imposed on manufacturers of medicines for delaying the marketing of a generic medicine

In its judgments in Cases C-586/16 P, C-588/16 P, C-591/16 P, C-601/16 P, C-611/16 and C-614/16 P, the Court of Justice dismissed appeals brought by a number of manufacturers of medicines involved in an agreement seeking to delay the marketing of the generic antidepressant citalopram. The European Commission had imposed on them fines of almost EUR 150 million.

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Judgment: Conditions governing the marketing of a medicinal product not subject to medical prescription in a Member State

In its judgment in Case C-178/20 (Pharma Expressz), the Court stated that a medicinal product that is not subject to medical prescription in one Member State cannot be placed on the market in another Member State unless it has also been granted marketing authorisation in that Member State. In the absence of such authorisation, it may nevertheless be possible to supply that medicinal product where its use meets special medical needs, in accordance with EU law.

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10 Publications

WHO/Europe: Report on mechanisms for improving transparency of markets for medicines, vaccines and health products

WHO/Europe has released a report identifying and summarising the current evidence on the implementation of the transparency measures of markets for medicines, vaccines and other health products in the WHO European Region. The review highlights the importance of transparency, among other recommendations such as price and cost monitoring.

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Friends of Europe: EU health systems post-pandemic: delivering care to patients at the right place and time

This report, published in cooperation with Baxter, on the future of healthcare in Europe breaks down three overarching recommendations into actions at EU, national and local levels to support the transformation of EU healthcare: 1) Make the patient the point of care, 2) Promote integrated care pathways through community and home-based care, 3) Make the architecture of healthcare digital by default to support integrated care.

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Health in the National Recovery and Resilience Plans: State of Play

This article by Dr Eleanor Brooks on the EU Health Governance Network (EUHealthGov) blog makes an initial analysis of health reforms in the national recovery and resilience plans. According to the author, the vast majority of plans dedicate a specific component or sub-component to health.

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SEPEN: Summary of the health workforce planning systems and policies in the 28 EU Member States

The 'Support for the Health Workforce Planning and Forecasting Expert Network' (SEPEN) joint tender is a new action in the area of European health workforce planning supported by the EU Health Programme. The study report on the national plans and policies relating to the health workforce in the EU-28 is now available. The report has been published with an online repository containing a summary of the national planning systems and an overview of data sources and challenges.

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11 **Miscellaneous**

Health in Europe: Virtual discussion forum

Health in Europe is a virtual discussion forum between experts and policy-makers on the effects of EU legislation and policies on the healthcare systems of Member States and other countries. It is organised by the Centre for Law and Society, Lancaster Law School (UK) and covers a wide range of topics from cross-border healthcare, pharmaceutical regulation, fiscal policy and COVID-19 to Brexit. Participation is free, and the 2020-21 discussions are available online.

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EUHealthGov: platform for the exchange of ideas and information on EU health governance

The EU Health Governance Network (EUHealthGov) is a network of academics, practitioners, researchers, policy-makers and other professionals interested in EU health law and policy. Through its website, blog and Twitter account, the network aims to provide a hub for the exchange of ideas and information on all things EU health governance.

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Open letter: Proposal to the Heads of National Medicines Agencies to improve harmonisation of access to Clinical Study Reports across National Competent Authorities.

Dr K. Boesen, from the Berlin Institute of Health at Charité, and colleagues call on the Heads of Medicines Agencies in an open letter to improve harmonisation of access to clinical studies across National Competent Authorities.

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EP: Resolution on the situation of sexual and reproductive health and rights in the EU, in the frame of women's health

This resolution highlights a range of different matters, including the provision of social security systems and universal healthcare. The report also focuses on the controversial issue of legal and safe abortions.

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EP: Resolution '25th anniversary of the International Conference on Population and Development (ICPD25) (Nairobi Summit)'

This resolution points out that sexual and reproductive health and rights are grounded in human rights and calls for the EU and Member States to recognise the rights of women and girls to bodily integrity and autonomous decision-making. It advocates support for victims and survivors of gender-based violence, including counselling, health services and psychosocial support, and calls for the strengthening of the health and education systems to prevent and respond to gender-based violence.

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Open letter initiated by the SheDecides movement on the right to abortion

An open letter, initiated by the SheDecides movement and signed by politicians, including Belgian, Swedish, Dutch and French ministers, aims to affirm the protection of the right to abortion. Among other things, the signatories call for a 'global campaign of factual and unbiased information' on abortion, the reopening of abortion services that were closed during the pandemic as they were deemed non-essential, and an end to policies such as mandatory counselling.

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EP: Resolution 'An old continent growing older – possibilities and challenges related to ageing policy post-2020'

The European Parliament has adopted a resolution with recommendations for addressing the ageing EU population. The report stresses the importance of increasing efforts to combat all forms of discrimination against older people and points out that care services should be developed further so as to enhance the continuity of care, preventive healthcare, rehabilitation and independent living.

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Council of Europe's Commissioner for Human Rights: Urgent call for reform of mental health services

In a 'Human Rights Comment', Dunja Mijatović, the Council of Europe's Commissioner for Human Rights, points out the devastating impact of the COVID-19 crisis on mental health. He therefore advocates an urgent reform of mental health services and policies.

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Belgian Chamber of Representatives: Exemption from value-added tax (VAT) on medical care only for interventions and treatments with a therapeutic purpose

From now on, the exemption from value-added tax (VAT) on medical care in Belgium will only apply to interventions and treatments with a therapeutic purpose. The law has been amended in accordance with European case-law on the subject.

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MISSOC: Latest update of the database on national social protection systems

MISSOC (Mutual Information System on Social Protection) is an online source of up-to-date comparable information on social security systems in European countries. The information comes from a network of national authorities and institutions responsible for the management of social protection. Updated information on social protection systems in all EU Member States, Iceland, Liechtenstein, Norway and Switzerland (including brief descriptions of their organisation and information on the social protection of the self-employed) is now available on the MISSOC website.

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EC: Proposal for reform of the Energy Efficiency Directive

The proposal aims to further stimulate EU efforts to promote energy efficiency and achieve energy savings in the fight against climate change. It introduces specific energy-saving measures for the public sector, including healthcare. These include the obligation to reduce annual energy consumption, an enhanced obligation for renovation and the requirement to include energy efficiency requirements more systematically in public procurement procedures.

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TO-REACH project: Final Conference

The TO-REACH project has held its final conference: 'Implementing and transferring innovations across health systems'. During the conference, the main results of the TO-REACH project were presented: the Strategic Research Agenda and the Policy Briefs, which concluded the work of the past five years.

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Conference on the Future of Europe

The conference is an opportunity for European citizens to exchange views on Europe's challenges and priorities. Governments and organisations can organise events and contribute ideas. Citizens can share their ideas on a digital platform. European citizens' panels will discuss different topics and put forward proposals. Recommendations from the national and European citizens' panels will be debated in conference plenaries. Health, including healthcare, is one of the topics of the conference.

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WHO: Pan-European Commission on Health and Sustainable Development

The Pan-European Commission on Health and Sustainable Development is an independent and interdisciplinary group of leaders convened by the WHO Regional Office for Europe to rethink policy priorities in the light of pandemics. It seeks to elevate health and social care as societal and political priorities, recognised as being critical to both sustainable development and social cohesion. The Commission's work will culminate in a report with recommendations on investments and reforms to improve health and social care systems.

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EU-US Summit Statement: 'Towards a renewed Transatlantic partnership'

The leaders of the European Union and the United States have proposed a Joint Transatlantic Agenda for the post-pandemic era. This includes the goal of working together to end the COVID-19 pandemic and prepare for future global health challenges. A Joint EU-US COVID Manufacturing and Supply Chain Taskforce should deepen cooperation and resolve issues around expanding vaccine and therapeutics production capacity. The EU and the US will also cooperate more closely on the reform of the World Health Organisation.

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Switzerland: Discontinuation of negotiations on a framework agreement with the EU

Switzerland has halted the long-drawn-out negotiations on a framework agreement to govern relations between the EU and Switzerland. Currently, these relations are governed by a patchwork of bilateral treaties. These include numerous treaties relating to the health sector, such as the mutual recognition of professional qualifications and medical devices. The cessation of talks threatens to make it difficult to update existing arrangements in the future.

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EC: Market access offers of the EU-China investment agreement

The Commission has published the schedules of commitments agreed under the EU-China Comprehensive Agreement on Investment (CAI), concluded in principle on 30 December 2020. The CAI's objective is to rebalance the asymmetry in terms of market access and investment between the EU and China. China's new commitments in the services sector also include investment in private healthcare.

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European Council: Condemnation of recent malicious cyber activities

The European Council has condemned the recent malicious cyber activities against Member States. This is partly in response to the cyber attack on the Irish health service in May this year. The Council was asked to explore appropriate measures within the framework of the cyber diplomacy toolbox.

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EC: Long-term vision for the EU's rural areas

The European Commission is developing a long-term vision for more prosperous rural areas in the EU. A communication is the first step in a process that, through a Rural Pact and the rolling EU action plan for rural development, should eventually lead to the realisation of the long-term goals of the Vision for the EU's Rural Areas in 2040. Effective access to essential services of sufficient quality, including healthcare, is also part of the long-term vision.

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EC: Draft report on a social taxonomy by the Platform on Sustainable Finance

The draft report on a social taxonomy aims to identify economic activities that contribute to advancing social objectives. Built on the foundation of international norms and principles, the draft report argues that a social taxonomy would help investors to identify opportunities to finance solutions around ensuring decent work, inclusive and sustainable communities, and affordable healthcare and housing.

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Global Health Summit: Rome Declaration

The Global Health Summit was an opportunity for the G20 and leaders, heads of international and regional organisations, and representatives of global health bodies to share lessons learnt from the COVID-19 pandemic. The leaders adopted a 'Rome Declaration', committing to common principles to overcome COVID-19 and to prevent and prepare for future pandemics.

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Editors: Rita Baeten

E-mail: baeten@ose.be

Website: <http://www.ose.be>

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