# **European Health Care News**



# Newsletter No.61 – Spring 2022

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# 1 Public health

### European Commission: Launch of EU network for comprehensive cancer centres

This EU network of cancer centres, one of the flagship actions of Europe's Beating Cancer Plan (EBCP), should be set up by 2025. It is intended to provide patients with access to high quality diagnostics and innovative treatments, bringing together national comprehensive cancer centres and networks from across the EU. At the same time, this EU network will support actions for improved training, research and clinical trials across the EU.

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### European Commission: Four new actions of the EU Cancer Plan

The Commission has launched four new actions in Europe's Beating Cancer Plan

- A cancer inequalities registry that will identify trends and differences between Member States and social groups. The registry will guide investment and interventions at EU, national and regional level.
- A cancer screening call for evidence.
- A joint action on HPV vaccination.
- An EU network of youth cancer survivors.

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### EOHSP: Results of consultations on the EU Cancer Plan

In early 2020, the European Commission launched a major consultation process on the Europe's Beating Cancer Plan (EBCP) that focuses on the future of cancer prevention, care and the wellbeing of people living with cancer. The European Observatory on Health Systems and Policies (EOHSP) published an overview report of the main findings of the three EBCP consultation strands (consultation on the Roadmap, open public consultation and targeted stakeholder consultation).

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### European Parliament: Report on strengthening Europe in the fight against cancer adopted

The European Parliament adopted the report advocating a stronger role for the EU in the fight against cancer, submitted by Véronique Trillet-Lenoir, by a large majority.

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### Council: State of play on the implementation of the EU Cancer Plan

The Presidency and the Commission briefed ministers in the Council on the implementation of the Europe's Beating Cancer Plan.

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### **European Commission: Country Health Profiles, 2021**

Experts from the Organisation for Economic Co-operation and Development (OECD) and the European Observatory on Health Systems and Policies (EOHSP) have prepared a set of country

health profiles of EU Member States. They provide insights into the latest health policy challenges and developments in each country. The country health profiles are accompanied by a Companion Report.

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### European Commission: 2022 EU4Health Work Programme

The 2022 work programme of the EU's health programme EU4Health (2021-2027) has been adopted by the Commission. The budget for 2022 is 835 million euros. It will contribute to the realisation of the European Health Union under four overarching themes: (1) crisis preparedness; (2) disease prevention; (3) health systems and healthcare workforce; and (4) digitalisation. Cancer prevention comes under several of these themes.

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### EXPH: Request for an opinion on managing antimicrobial resistance across the health system

The European Commission has asked the Expert Panel on Effective Ways of Investing in Health (EXPH) for an opinion on managing antimicrobial resistance across the health system.

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### EXPH: Opinion on European solidarity in public health emergencies

The EXPH has published its opinion on European solidarity in public health emergencies. DOC EN HTML

### European Reference Networks: 620 new members

Following approval by the ERN Board of Member States, 620 new members joined the European Reference Networks (ERNs). The ERNs system is an innovative model of virtual healthcare and collaboration. It brings together the most specialised centres (now almost 1,500 care units) across the EU to accelerate diagnosis, improve standards of care and generate expertise and new evidence for patients with rare or complex diseases.

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European Health Ministers met informally on Thursday, 10 February at the invitation of the French Presidency of the Council of the European Union. The main purpose of the meeting was to jointly draft proposals for a European public health strategy.

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### Council: Conclusions on strengthening the European Health Union

In its conclusions, the Council stresses the need for strategic investments in health systems and for better cooperation within and with other countries. The Council wants to create better conditions for responding to future challenges. The conclusions identify four main areas for strengthening the European Health Union: innovative solutions for resilient health systems, accessibility and availability of medicinal products and medical devices, global health, and beating cancer.

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#### Social Democrat ministers: Declaration promoting quality healthcare for all Europeans

The social democrat health ministers of eleven Member States have made a series of recommendations to improve Europeans' access to affordable and quality health care. In their joint declaration, they point out that the right to timely access to affordable, preventive and curative health care of good guality for all is included in the European Pillar of Social Rights and they want to put an end to cuts in the health sector.

Informal Meeting of European Health Ministers

### WHO: Agreement to negotiate on an instrument to tackle pandemics

The 194 members of the World Health Organization (WHO) reached a consensus on the creation of an international instrument to strengthen prevention, preparedness and response to pandemics. An intergovernmental negotiating body will be formed to agree on practices and time scales. The European Union is pushing for a global deal, with a ban on wildlife markets and incentives for countries to report new viruses or variants.

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### European Commission: Member State data on cross-border healthcare for 2020

Directive 2011/24/EU on the application of patients' rights in cross-border healthcare sets out the conditions under which a patient may travel to another EU country to receive medical care and reimbursement. This statistical report provides data on the application of the Directive for 2020.

# European Commission: Study on enhancing implementation of the Cross-Border Healthcare Directive (2011/24/EU)

Some core findings of this study are:

- The way Prior Authorisation procedures are implemented differs greatly across Member States.
- Certain administrative procedures and requirements across Member States may be regarded as creating potentially unjustified obstacles for patients seeking cross-border healthcare.
- A limited number of Member States implement consultation arrangements between national contact points (NCPs) and relevant national stakeholders such as healthcare insurers, providers, and patient organisations.

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### European Commission: Cross-border patient mobility in selected EU regions

This study aims to provide an overview of cross-border patient mobility and the reimbursement system used for planned care treatments in selected EU regions.

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# Council and European Parliament: Provisional agreement on a stronger European Centre for Disease Prevention and Control (ECDC)

The ECDC is an EU agency tasked with supporting the EU in the fight against infectious diseases, including through information on epidemic diseases, scientific advice and training activities. The Council and the European Parliament have reached a political agreement to strengthen the ECDC's mandate in the areas of epidemic disease surveillance, early warning, preparedness, and response. The ECDC's new mandate is part of the broader European Health Union package.

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### 2 Medicinal products and medical devices

#### Council: Political agreement on emergency framework for medical countermeasures

The Council has reached a political agreement on a Council Regulation that is to facilitate the purchase of medicines, vaccines and raw materials, activate emergency funding and enable control of production facilities when a new health crisis strikes.

# European Commission: First annual work plan for HERA approved

The new European Health Emergency Preparedness and Response Authority (HERA) has presented its first annual work plan, with a budget of  $\in 1.3$  billion in 2022 to prevent, prepare for and rapidly respond to cross-border health emergencies.

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### European Commission: Responses to the public consultation on the revision of pharmaceutical legislation

The Commission has published the responses to the public consultation on the revision of general pharmaceutical legislation and a summary report.

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### European Commission: Study on medicine shortages in the EU

The study confirms that frequent medicine shortages mostly involve older, off-patent, and generic medicines. The causes are multifactorial, with bottlenecks along the entire pharmaceutical value chain, from manufacturing of raw materials to national pricing and procurement practices. A series of 16 policy measures are presented for action at EU and national level.

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### European Parliament: Resolution on the EU's new pharmaceutical strategy

The European Parliament has adopted the report by Dolors Montserrat (EPP, Spain) on a pharmaceutical strategy for Europe.

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### European Commission: Consultation on new framework for standard-essential patents

The Commission wants to reform EU patent law and will develop a package of three proposals to do so. These will cover supplementary protection certificates, compulsory licensing, and standard-essential patents (SEPs). The initiative focuses on patents on drugs.

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### Protocol on Provisional Application of the Unified Patent Court (UPC) Agreement has entered into force

The Protocol on the Unified Patent Court (UPC) has entered into force after being ratified by enough Member States. For companies, including drug manufacturers, the UPC, once operational, will result in a significant reduction in administrative costs and burdens.

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### The Innovative Medicines Initiative (IMI) will be succeeded by the Innovative Health Initiative (IHI)

The Innovative Medicines Initiative (IMI) started life in 2008 as a public-private partnership (PPP) between the European Union and the European pharmaceutical industry. The IMI1 and IMI2 programmes have resulted in almost 200 projects covering a wide range of disease areas. With the end of the IMI2 programme in sight and aware of the growing importance of cross-sectoral cooperation, the European Commission decided to launch a new PPP in the health sector: the Innovative Health Initiative (IHI).

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### Regulation on health technology assessment (HTA) published

Regulation (EU) 2021/2282 on health technology assessment has been published in the Official Journal of the European Union. HTA is a research-based tool that supports decision-making in healthcare by assessing the added value of a particular health technology compared to others. The Regulation provides the basis for ongoing cooperation at the EU level in this area.

### European Commission: New Standardisation Strategy

The Commission has presented a new Standardisation Strategy outlining its approach to standards, both within the Single Market and globally. The Strategy proposes five key sets of actions. It identifies the production of vaccines and medicines for COVID-19 as one of the standardization urgencies.

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### PGEU: Position Paper on the revision of European pharmaceutical legislation

The Pharmaceutical Group of European Union (PGEU) is calling for greater access and availability of pharmaceuticals for patients. To this end, it proposes to expand the role and resources of the European Medicines Agency (EMA) in coordinating Member States' activities on the prevention and management of shortages and to create an EU monitoring system for (anticipated) shortages of medicines. It also calls for a European mechanism enabling fair redistribution of medicines among Member States.

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### EC, HMA, EMA: Accelerating Clinical Trials in the EU (ACT EU)

The European Commission (EC), the Heads of the Medicines Agencies (HMA) and the European Medicines Agency (EMA) have launched an initiative to accelerate how clinical trials are initiated, designed and run, referred to as Accelerating Clinical Trials in the EU (ACT EU). The ACT EU strategy paper lists ten priority actions for 2022/2023, including enabling innovative trial methods and establishing a multi-stakeholder platform.

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### Council: Agreement on a proposal to update EU rules on value added tax (VAT) rates

The Council has reached an agreement on a proposal to update EU rules on VAT rates. The Member States will have more flexibility to choose the products or services to which they will apply reduced rates. The Directive will allow for the gradual introduction of reduced rates for health-related goods.

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### 3 e-Health

### European Commission: Proposal for a Regulation on a fair and innovative data economy

The Commission has proposed new rules on the use of and access to data generated across all economic sectors of the EU. The scope of the proposal covers physical products that obtain, generate, or collect data about their performance, use, or environment by means of their components and that are able to communicate that data via a publicly available electronic communications service. Such products may include medical and healthcare devices.

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#### Council: Position on stronger cybersecurity in the EU

The Council has agreed on its position ("general approach") on measures for a high common level of cybersecurity across the EU. These are intended to improve the resilience and incident response capacities of the public and private sectors and the EU as a whole with regard to cyber-incidents. The new Directive, known as NIS2, will form the basis for risk management and reporting obligations across all the sectors that it covers, such as energy, transport, health, and digital infrastructure.

# 4 Social policy

# European Parliament: Motion for a resolution on a new EU strategic framework for health and safety at work post 2020

The report, prepared by Marianne Vind, was adopted by the Committee on Employment and Social Affairs. The report emphasises the need to pay particular attention to the mental health of healthcare workers and refers in this regard to the opinion of the Expert Panel on Effective Ways of Investing in Health (EXPH) on this topic. The Commission and Member States are called upon to ensure adequate follow-up and implementation of these recommendations.

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### ELA: Analysis of shortage and surplus occupations, 2021

The report, prepared by the European Labour Authority (ELA), provides insight into the impact of the COVID-19 pandemic on the labour market. By 2020, almost one in three workers in the EU was employed in a labour surplus or shortage occupation. Many of the most significant labour shortages have been increasing in recent years, and the pandemic has amplified the demand for several specific shortage occupations. The greatest impact is being observed in the demand for skills in the healthcare sector.

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### European Commission: Action Plan to boost the social economy and create jobs

Social economy organisations operate in many forms (from cooperatives, health insurance funds to social enterprises) and in many sectors (from care services to recycling). The Action Plan proposes a definition for the social economy and addresses three main areas: adapting policy and legal frameworks (in particular, on public procurement and state aid) to the needs of the social economy, improving access to finance, and recognising the social economy and therefore harnessing its potential.

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### European Commission and Council: Proposal for a Joint Employment Report

Published as part of the European Semester process, the proposal for a Joint Employment Report for 2022 invites Member States to, among other things:

- provide all children at risk of poverty or social exclusion with free and effective access to healthcare;
- invest in healthcare capacity, including primary care, coordination of care, healthcare staff, and e-Health;
- reduce out-of-pocket payments, improve healthcare coverage, and promote up-skilling and re-skilling of health workers.

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### **SPC: Annual Report**

The Annual Report of the Social Protection Committee (SPC) provides an overview of the impact of measures taken by Member States to protect employment, income, and access to services in response to the pandemic. The report also addresses reforms in healthcare systems.

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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 Group to study the future of the welfare state in the light of mega-trends such as: demographic changes, labour market transformations, globalisation and the emergence of new risks. The group will make recommendations on how to make social security systems fit for the future. In doing so, the Group will consider the interaction between social protection systems and other welfare policies, including healthcare and long-term care.

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# 5 Economic policy

# European Commission: 2022 European Semester cycle of economic policy coordination launched

The European Commission has launched the 2022 European Semester cycle of economic policy coordination. The European Semester Autumn Package includes the Annual Sustainable Growth Survey, Opinions on euro area Draft Budgetary Plans for 2022, policy recommendations for the euro area, and the Commission's proposal for a Joint Employment Report. The Semester process also encourages reforms in healthcare systems.

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### Cyprus and Portugal: Post-Programme Surveillance Reports

The European Commission's Autumn Package includes post-programme surveillance reports for Member States under enhanced surveillance by European institutions due to their financial situation in the wake of the financial and economic crisis. The reports on Portugal and Cyprus also evaluate healthcare reforms in these Member States.

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#### Greece: 13th enhanced surveillance report in Greece

The Commission has issued a favourable opinion on the measures taken by Greece to meet its fiscal, financial and reform commitments as part of the enhanced surveillance process launched after the completion of the last rescue package for Greece. The healthcare reforms that Greece undertook to make were also evaluated.

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# 6 EU funding

#### European Commission: Recovery and Resilience Scoreboard launched

This scoreboard is a public online platform to reflect progress made in the implementation of the Recovery and Resilience Facility (RRF) as a whole and of individual national recovery and resilience plans. The Scoreboard includes, among other items, data on expenditure by policy area. Through thematic analyses, the Scoreboard also provides qualitative information on implementation of plans in specific policy areas, including healthcare (see next news item).

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# European Commission: Recovery and Resilience Scoreboard: thematic analysis of health care

All 22 plans currently covered by the Scoreboard include healthcare measures. Expenditure on care-related measures represents 8% of the plans' total spending. The plans include measures to improve primary care, to support the transition from hospital care to outpatient care, to reorganise hospital networks, to scale up prevention, to increase the quality of diagnosis and treatment of patients, to strengthen the healthcare workforce, and to modernise healthcare institutions.

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# Belgium: NIHDI receives 29 million euros from European recovery plan for investments up to 2025

These funds received by the Belgian National Institute for Health and Disability Insurance (NIHDI) from the European Recovery Plan to finance investment and reform projects will be used to introduce the integrated, electronic and interprofessional patient record and to set up a Health Data Authority. In collaboration with its partners, NIHDI aims to create a system to make data findable, accessible, interoperable and reusable for scientific and policy support work.

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# 7 Competition

# European Commission: Communication on state aid to promote the execution of important projects of common European interest

Important projects of common European interest are strategic projects in different sectors that require joint investments by public authorities and industries from different EU countries. The purpose of the Communication is to provide guidance on how to assess public funding for such projects under the Union's State aid rules. Infrastructure projects in the healthcare sector that are of important interest to the Union may also be covered if they meet the criteria.

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### European Commission: Fines for pharmaceutical companies Teva and Cephalon for 'payfor-delay' agreements

The Commission has fined the pharmaceutical companies Teva and Cephalon a total of 60 million euros. They agreed to delay the market entry of Teva's cheaper generic version of Cephalon's sleep disorder drug, modafinil. Such agreements are called 'pay-for-delay' agreements. They stand in the way of competition and are illegal under EU antitrust rules.

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### European Commission: Acquisition of Nuance by Microsoft approved

The European Commission has unconditionally approved the proposed acquisition of Nuance Communications, Inc. ('Nuance') by Microsoft Corporation ('Microsoft') under the EU Merger Regulation. The Commission concluded that the transaction would not raise competition concerns in the European Economic Area. Nuance is a transcription software company with a strong focus on the healthcare sector and customer engagement solutions. Microsoft is a global technology company offering productivity and business software, cloud computing, and personal computing.

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### 8 Infringement proceedings

#### EU rules for assessing proportionality before adoption of new regulation of professions

The Commission has launched infringement proceedings against 20 Member States for failing to properly implement EU rules for assessing proportionality before adoption of new regulation of professions (Regulation (EU) 2018/958). The Regulation requires Member States to ensure that any requirements for professions that they introduce are necessary and balanced. Regulated healthcare professions are included in the scope.

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#### Belgium: qualification of general dental practitioner

The Commission has decided to open infringement proceedings against Belgium for failing to comply with EU rules on freedom of establishment and the recognition of professional qualifications (Directive 2005/36/EC). Belgium has introduced a specific qualification of general dental practitioner required to practice dentistry under the Belgian public healthcare system. This title requires additional training, but does not give access to activities other than those of a dental practitioner recognised by the Directive.

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### Spain: transposition of EU radiation protection legislation

The Commission has referred Spain to the Court of Justice of the European Union for failing to fully transpose the revised Basic Safety Standards Directive (Council Directive 2013/59/Euratom). The Directive, which modernises and consolidates EU radiation protection legislation, lays down basic safety standards to protect the general public, workers and patients against the dangers of exposure to ionising radiation.

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### 9 Court of Justice of the European Union

# Judgment: Parallel import licence for a drug after expiry of the marketing authorisation for the reference medicinal product

EU law precludes national legislation under which a parallel import licence for a medicinal product automatically expires one year after the expiry of the marketing authorisation for the reference medicinal product, without an examination of whether there is a risk to the health and life of humans. In the Court's view in Case C-488/20, this automatic expiry date goes beyond what is necessary to protect the health and life of humans.

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### Judgment: Exemption from VAT on the transaction for opening a medical file

In its judgment in Case C-513/20, the Court stated that the transaction consisting of the compilation of an individual file that includes the user's clinical history and entitles the user to purchase medical care at a spa, may, under certain conditions, be covered by the exemption from value added tax (VAT) as a transaction that is closely related to medical care.

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# European Journal of Risk Regulation: Towards a European Health Union: What Role for Member States?

e-Competitions Bulletin: Healthcare and competition law: an overview of EU and national

e-Competitions has published a special issue providing an overview of EU and national case law

Article 168(7) of the Treaty on the Functioning of the European Union (TFEU) is the legal basis of any European Health Union. This opinion piece assesses this Article and argues that a Treaty change to redress the balance between EU and Member State competence regarding national healthcare systems may be uncalled for, given both the flexibility afforded by the provision and the complexity and diversity of Member State healthcare systems.

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### Health politics in Europe: a handbook

on competition law and healthcare.

This reference work provides historical background and current information and analyses on healthcare policies and systems across Europe. In particular, it covers the developments that have taken place since the early 1990s. This was a turning point for many European healthcare systems, with most post-communist countries privatising their state-run health systems, and many Western European health systems experimenting with new public management and other market-based healthcare reforms.

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### Health Policy: How resilient is health financing policy in Europe to economic shocks?

This article explores the resilience of health financing policy to economic shocks by reviewing policy responses to the 2008 global financial crisis and the COVID-19 pandemic in Europe. It finds that some health systems were weakened by responses to the economic crisis in 2008. Responses to the pandemic show evidence of lessons learnt from the earlier crisis, but also persistent weaknesses in health financing policy that limit national preparedness to face economic shocks, particularly in countries with social health insurance schemes.

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### Health Policy: Rehabilitation Policies in Europe

Health Policy published a special issue on how to strengthen policies for rehabilitation programmes in Europe.

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#### ETUI: Embedding the Recovery and Resilience Facility into the European Semester

According to this policy brief, published by the European Trade Union Institute of research (ETUI), the new Recovery and Resilience Facility (RRF), which provides grants and loans, marks a reversal in the distribution of EU funds among EU Member States. According to the authors, the embedding of the RRF in the European Semester represents an opportunity to rethink the European Semester and to turn it into the policy coordination device that it has not been to date.

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### **10** Publications

case law

# EuroHealthNet: Recovery and Resilience Plans: drivers to promote health and well-being in the European Union?

Ahead of the launch of the next annual cycle of EU economic and social policy coordination, known as the European Semester, EuroHealthNet has presented its latest assessment report 'Recovery and Resilience Plans: drivers to promote health and well-being in the European Union?'. According to the experts, the opportunities provided by the funds are not being sufficiently utilised to reduce inequalities and strengthen public health. They argue for better collaboration both across sectors, and between policy levels.

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# Eurohealth: Health system resilience post-COVID: Moving towards more European cooperation

This special issue of Eurohealth was published on the occasion of the French Presidency of the Council of the European Union, with the aim of gaining a better understanding of how health systems have responded to the health crisis and to draw lessons for improving the resilience of health systems.

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### KCE: More comparative studies for medical innovations needed

The Belgian Health Care Knowledge Centre (KCE) argues that companies producing pharmaceutical products or medical devices should plan clinical trials from the outset to generate not only the information needed for market authorisation, but also the comparative data needed for HTA evaluations by national agencies. The KCE is addressing these recommendations to the European Commission and the governments of the Member States.

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### **EPF: Contraception Policy Atlas Europe**

The European Parliamentary Forum for Sexual and Reproductive Rights (EPF) has published a Contraception Policy Atlas for European countries in 2022. The Atlas provides an overview of access to modern contraception, including reimbursement, access to counselling, and availability of online information.

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### Politico: Strong lobbying for EU health budget

The EU health budget has increased sharply in response to the COVID-19 pandemic. It amounts to 5.1 billion euros over the next seven years. Politico reports on how this is leading to a stampede of lobby groups who want to capture some of that money for their causes. According to Politico, the health lobby is being driven by actors who want more support for non-communicable diseases.

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# Politico: Disparity between EU citizens based in the UK according to their health insurance status

Under the EU Settlement Scheme (EUSS), EU citizens who settled in the United Kingdom (UK) before Brexit and lived in the country for less than five years can be granted pre-settled status, which allows them to retain their rights to live, work and access UK public services. According to the European Commission, the UK is splitting these EU citizens into two groups depending on whether or not they had private health insurance during periods of their residence when they were economically inactive.

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### DSV: Digitising social security: Necessary evil or overdue blessing?

This special issue from the umbrella organisations of German Social Insurance (DSV) discusses the digital initiatives of the European Commission in relation to social security systems such as: the European Exchange of Social Security Information (EESSI), the European Social Security Number (ESSN), the European Digital Identity (EU-ID) and the pilot project for a European Social Security Pass (ESSP).

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# 11 Miscellaneous

### Council: General approach on the draft directive on the resilience of critical entities

The draft directive aims to reduce the vulnerabilities of critical entities. These entities comprise physical infrastructures that provide vital services on which the livelihoods of EU citizens and the proper functioning of the internal market depend. The Council's negotiating mandate covers critical entities in nine sectors, including the health sector. These entities need to be able to prevent emergencies such as COVID-19 and to protect against, respond to, resist, and recover from emergencies.

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#### Conference on the Future of Europe: citizens' recommendations debated in Plenary

The Conference Plenary took stock of the recommendations made by the Citizens' Panel on Climate Change, Environment/Health and of related recommendations from national citizens' panels. The panel also made recommendations for strengthening healthcare systems and equal access to healthcare.

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# EHMA and EUPHA: Strengthening the EU's competitiveness in health requires an increased investment in the workforce and governance

Seeing that the health workforce takes centre stage in the discussion on the EU's preparedness for future challenges, EHMA and EUPHA have launched a joint statement to underline that increased investment in the health workforce and governance are essential for strengthening the EU's competitiveness in health.

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### "European Health Care News"

is an electronic newsletter published by the European Social Observatory (OSE), commissioned by the National Institute for Health and Disability Insurance (NIHDI).

Editors: Rita Baeten E-mail: <u>baeten@ose.be</u> Website: <u>http://www.ose.be</u>

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