

### 1 Public health

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- Two Commissioners nominated for public health and health crisis preparedness
- New standing committee on public health established at the European Parliament
- Council approved conclusions on cardiovascular health
- Council approved conclusions on organ donation and transplantation
- ECA assessed EU's response to the COVID-19 pandemic
- Evidence and advice published on the One Health governance in the EU
- Commission and OECD released report on European health systems

### 2 Medicines and medical devices

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- Critical medicines and countermeasures addressed by the new Commission
- Commission adopted new implementing acts and a guidance under the Health Technology Assessment Regulation
- Commission recommended opening negotiations for a new agreement on health emergencies with three EFTA countries
- Study examines the transparency of measures regulating the prices and reimbursement of medicinal products
- Commission published a report on progress in the safety of medical radiology practices
- European Shortages Monitoring Platform launched
- The French Senate published an information report on the revision of the EU pharmaceutical legislation

### 3 e-Health

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- Cybersecurity and artificial intelligence focused on by the new Commission
- The Commission launched a call for setting up AI Factories
- ECA published a report on the digitalisation of health care
- ENISA published a report on cybersecurity in the EU

### 4 Internal market

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- Provisional agreement reached on a new instrument for cross-border regions
- Commission is about to amend the Professional Qualifications Directive as regards the profession of veterinary surgeon

## **5 Social policy**

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- An Executive Vice-President is in charge of social and employment policy for the new Commission
- Commission published its proposal for the 2025 Joint Employment Report
- Council approved conclusions on labour and skills shortages
- Council conclusions focused on the promotion of social inclusion
- Council conclusions targeted women's mental health
- Guidance and evidence on independent living for persons with significant care needs

## **6 Economic policy**

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- Report looked at the future of EU competitiveness with implications for the health sector
- European Semester Autumn Package presented by the Commission
- Post-programme surveillance reports published for five Member States

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- Contribution agreement signed with WHO to address shortages of nurses
- Two HERA Invest agreements were signed
- Agreement signed under the InvestEU Initiative for innovation in cancer treatment
- The Commission announced a new EU Competitiveness Fund

## **8 Competition**

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- European Commission withdrew decisions related to Illumina/GRAIL case
- European Commission fined Teva linked to multiple sclerosis medicine
- European Commission and Swiss Competition Commission closed investigations into Novartis
- Commission assessed killer acquisitions in the pharma sector
- Commission approved Slovenian State aid to support production of biological drug substances
- Eight acquisitions related to the health sector approved by the Commission

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- Judgement annuls Commission's decision to examine the proposed acquisition of GRAIL by Illumina
- Judgement upholds the annulment of a Commission's decision related to Slovenia's aid to a public pharmacy
- Judgement provides a preliminary ruling on national tax legislation applied to a pharmaceutical company
- Judgement upholds Commission's decision on the marketing authorisation of medicinal products containing the active substance tobramycin
- Judgement annuls Commission's decision on the marketing authorisation granted to the medicinal product Dexmedetomidine Accord
- Two judgments provide a preliminary ruling on health data processed under the GDPR

## **10** Infringement procedures

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- Hungary asked to comply with EU rules for reproduction services
- France asked to comply with EU rules on freedom of establishment and free movement of workers in the EU
- Bulgaria and Cyprus failing to transpose the Proportionality Test Directive
- Spain urged to prevent abusive use of fixed-term contracts in public sector
- Spain referred to the Court of Justice for failing to correctly transpose the Public Procurement Directives
- Portugal referred to Court of Justice to improve rules on pollution from industrial activities
- 23 Member States called to fully transpose the NIS2 Directive
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- 10 Member States called to comply with the Data Governance Act

## **11** Miscellaneous

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- Life science research among the areas addressed by the new Commissioner for research and innovation
- Mid-term reviews published for strategies promoting equality across the EU
- EU Member States committed to step up action against AMR

## **12** Publications

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- A study investigates how the European Semester can support the Wellbeing Economy
- Article highlights the added value of the new EU-'SILC's method for measuring health unmet needs
- Article explores the implication for health of the EU Artificial Intelligence Act
- Articles suggests three ways to move forward with solidarity and trust in European Union health governance
- Report investigates company practices to tackle labour shortages
- Outcomes of the 2024 European Health Forum Gastein published
- Report assesses structural and institutional racism (also in health care) in 8 Member States
- Report examines the burnout economy

## 1 Public health

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### Two Commissioners nominated for public health and health crisis preparedness

Within the new College of Commissioners, Olivér Várhelyi was nominated as Commissioner for health and animal welfare. His task is to complete the European Health Union and to build on the One Health approach. Specific to public health, he is responsible for stepping up the Commission's work on preventive health, by ensuring the implementation of the European Beating Cancer plan. Based on this model, Várhelyi announced a Plan for European Cardiovascular Health during his confirmation hearing at the European Parliament. His mandate was stripped of oversight over reproductive and sexual rights as well as health preparedness.

These competences are taken over by Hadja Lahbib, the new Commissioner for equality and for preparedness and crisis management. Lahbib will address discrimination in health and will supervise the Commission's Health Emergency Preparedness and Response Authority (HERA). She is expected to develop an EU preparedness Union strategy based on a cross-sectoral approach and to implement the Union health crisis and pandemic plan that is envisaged to be adopted in the first months of the new Commission.

Lahbib's work will take into account the findings and recommendations advanced in the report by the special adviser Niinistö on strengthening Europe's civilian and military preparedness and readiness.

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### New standing committee on public health established at the European Parliament

The European Parliament approved changes put forward by its Conference of Presidents, establishing two new standing and two special committees. These notably involve the upgrade of the subcommittee on public health as a full standing committee.

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### Council approved conclusions on cardiovascular health

The Council of the European Union (EU) put forward a series of measures aimed at improving cardiovascular health by focusing on prevention, early detection, treatment and rehabilitation.

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### Council approved conclusions on organ donation and transplantation

The Council of the EU called on the Commission to update the EU action plan on organ donation and transplantation in order to further improve practice in this field across Europe.

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### ECA assessed EU's response to the COVID-19 pandemic

The European Court of Auditors (ECA) assessed how the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA) responded to the COVID-19 pandemic, as well as the reforms implemented by the European Commission to address the weakness identified in the early stages of the pandemic. ECA highlighted some remaining challenges and made recommendations to better prepare for future health emergencies.

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### Evidence and advice published on the One Health governance in the EU

The Scientific Advice Mechanism (SAM) published a review of scientific evidence and an opinion on the One Health approach in the EU, at the request of the European Commission. A set of recommendations were advanced, including reinforced collaboration across policy areas and disciplines, increased education and training on One Health, greater promotion of research and innovation in this field, as well as more integrated preventive actions, surveillance and risk assessments.

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### Commission and OECD released report on European health systems

The 2024 edition of the report 'Health at a Glance: Europe' was published by the European Commission and the Organisation for Economic Cooperation and Development (OECD). The assessment of the state of health and health systems in the EU is accompanied by two thematic chapters, which focus on the health workforce crisis and the promotion of healthy ageing.

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## 2 Medicines and medical devices

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### Critical medicines and countermeasures addressed by the new Commission

One of the main tasks of the new Commissioner for health and animal welfare, Olivér Várhelyi, is to propose a Critical Medicines Act to address the severe shortages of medicines and medical devices and to reduce dependencies in their supply. He will also lead the work on a new European Biotech Act aimed at boosting innovation, for example in health technology assessment and clinical trials.

To support preparedness for and management of health crises, the new Commissioner for preparedness and crisis management, Hadja Lahbib, is charged with the development of a new strategy for medical countermeasures against public health threats, involving also a wider EU stockpiling strategy.

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### Commission adopted new implementing acts and a guidance under the Health Technology Assessment Regulation

The European Commission adopted three new implementing acts in view of the application of the Health Technology Assessment (HTA) Regulation as of 12 January 2025. The act adopted on 18 October establishes the rules for cooperation with EMA in the joint work under the HTA Regulation. The act adopted on 25 October concerns participants in joint clinical assessments and joint scientific consultations to manage conflicts of interest. The last act, adopted 18 December, defines rules for joint scientific consultations on medicinal products for human use.

In addition, the Commission published a guidance document on the validity of clinical studies for joint clinical assessments.

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### Commission recommended opening negotiations for a new agreement on health emergencies with three EFTA countries

The Commission adopted a recommendation for a Council decision to begin negotiations with the European Economic Area (EEA) states of the European Free Trade Association (EFTA), Iceland, Liechtenstein, and Norway, on a new agreement on health emergencies regarding medical countermeasures. This agreement would foster closer cooperation with the EU on health preparedness and response.

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### Study examines the transparency of measures regulating the prices and reimbursement of medicinal products

The European Commission published a study requested to examine the functioning of Directive 89/205/EEC, which relates to the transparency of measures regulating the prices and reimbursement of medicinal products and their inclusion in national health insurance systems. The study highlights the benefits and challenges experienced by Member States, the pharmaceutical sector and other stakeholders, as well as potential recommendations to support the functioning of the Directive in its current form.

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### Commission published a report on progress in the safety of medical radiology practices

The European Commission published a report evaluating the progress of the last years on the quality and security of medical radiology practices. The study was conducted with radiological institutions in 7 EU countries, including Belgium, to assess the tendency of 'unjustified' exposure to medical radiation. The study offers an overview of scanner justification systems in each country and suggestions for how to continue to support the progress for imaging departments.

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### European Shortages Monitoring Platform launched

Thanks to the European Shortages Monitoring Platform (ESMP), marketing authorisation holders may now submit data to routinely report shortages of centrally authorised medicines. The transition period will end 2 February 2025, when the use of a second and complete version of the platform becomes mandatory. The Platform is part of EMA's extended mandate under Regulation 2022/123, aiming to facilitate information exchange to better prevent and manage shortages, and ensure medicine availability.

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### The French Senate published an information report on the revision of the EU pharmaceutical legislation

The Committee on European Affairs of the French Senate has authorised the publication of an information report reviewing the revision of the EU pharmaceutical legislation proposed by the European Commission. It also adopted a motion for a European resolution on this subject and the political opinion based on it.

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## 3 e-Health

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### Cybersecurity and artificial intelligence focused on by the new Commission

One of the first actions of the new Commissioner for health and animal welfare, Olivér Várhelyi, will be to prepare a European action plan on the cybersecurity of hospitals and health care providers. This is expected within the first 100 days of his mandate and will be defined in close collaboration with the Executive Vice-President for Tech Sovereignty, Security and Democracy, Henna Virkkunen.

Vice-President Virkkunen will also lead the work on boosting artificial intelligence (AI) innovation. This involves the development of an Apply AI Strategy, which will contribute to improving the delivery of public services, also in the health sector.

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### The Commission launched a call for setting up AI Factories

The call for proposals launched by the European Commission aims to boost European leadership in trustworthy artificial intelligence (AI). These Factories will support the development and validation of AI industrial and scientific uses in key sectors, such as health care.

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### ECA published a report on the digitalisation of health care

The European Court of Auditors (ECA) published a report on the digitalisation of healthcare, which has been a strong trend following the COVID-19 pandemic. The report notes that the Commission has helped Member States to progress on their digitalisation efforts despite the obstacles they still face. The Court of Auditors concludes recommending that the Commission should improve reporting on the progress made by Member States in health care digitalisation and the use of EU funds.

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#### **ENISA published a report on cybersecurity in the EU**

The European Union Agency for Cybersecurity (ENISA) published a report on the state of cybersecurity in the EU. The report offers an evidence-based overview of the cybersecurity landscape and capabilities at the EU, national, and societal levels on which its policy recommendations build on. Risks and management capacities in the health sector are also assessed.

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### **4 Internal market**

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#### **Provisional agreement reached on a new instrument for cross-border regions**

The Council of the EU and the European Parliament reached a provisional agreement on the Commission's amended proposal for a Regulation on facilitating cross-border solutions. This introduces a standard procedure to identify and resolve cross-border obstacles that affect the deployment of cross-border infrastructure or public services, such as access to health care and emergency services. According to the agreement, the instrument will cover the land border regions of neighbouring Member States, it remains voluntary based and can be initiated by public or private law entities only.

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#### **Commission is about to amend the Professional Qualifications Directive as regards the profession of veterinary surgeon**

The Commission opened a public consultation from 23 September to 21 October 2024 to gather feedback on a draft delegated directive amending the Professional Qualifications Directive. The Commission's initiative aims to update the minimum training conditions required for the automatic recognition of qualifications for cross-border access to the profession of veterinary surgeons in the EU.

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### **5 Social policy**

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#### **An Executive Vice-President is in charge of social and employment policy for the new Commission**

The new College of Commissioners includes an Executive Vice-Presidency for Social Rights and Skills, Quality Jobs and Preparedness, which was attributed to Roxana Mînzatu. She is responsible for guiding the work on the European Pillar of Social Rights to tackle the skills and labour gaps, focusing on training and education. In her confirmation hearing, she announced her wish to address the unequal distribution of health care workforce across Europe, through skills recognition, investment and by building European university alliances.

On the social side, Mînzatu's tasks include the strengthening of the EU Child Guarantee, the further integration of the social convergence framework in the EU Semester cycle, as well as the development of the first EU Anti-Poverty Strategy through a comprehensive approach focused also on health care and housing.

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#### **Commission published its proposal for the 2025 Joint Employment Report**

The European Commission published its proposal for the Joint Employment Report as part of the 2025 European Semester cycle. This maintains a strong country-specific focus on employment, skills and social aspects based on the principles of the Social Convergence Framework. For the health sector, Member States are notably invited to invest in the capacity of the health care system, reduce out-of-pocket payments and improve health care coverage, and promote better working conditions as well as upskilling and reskilling of health workers.

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### ➤ Council approved conclusions on labour and skills shortages

The Council of the EU called on Member States to address the shortages of labour and skills shortages by boosting support for training and education, particularly for people who are currently underrepresented in the labour market. This also involves addressing the specific needs of older workers through health promotion and investment in health care.

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### ➤ Council conclusions focused on the promotion of social inclusion

The Council of the EU proposed a set of measures to reduce territorial inequalities with the aim to improve access to enabling services, such as health care, and employment services for people at risk of poverty and social exclusion. These measures involve, for example, integrated cross-sectoral action and better identification and mapping of disadvantaged territories.

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### ➤ Council conclusions targeted women's mental health

The Council of the EU proposed a wide range of measures to promote gender equality with a view to strengthening women's and girls' mental health. These involve adopting a gender perspective when designing mental health policies, supporting prevention and health promotion, as well as improving access to medical, social and psychological support services.

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### ➤ Guidance and evidence on independent living for persons with significant care needs

The European Commission published practical recommendations on how Member States can use EU funding to accelerate the transition from institutional care to community-based services and independent living for persons with disabilities. Measures include ensuring access to health and mental health care, better integrating health and social services, mapping health and long-term care needs, and training health care and social services staff.

A report published on this issue by Eurofound presents evidence on changes in the extent of institutional living for people with significant care needs, as well as information on national deinstitutionalisation strategies and practices. The report emphasises supporting family- and community-based care and services, including health care, through a people-centred approach that ensures financing and staffing, as well as EU-wide data collection.

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## 6 Economic policy

### ➤ Report looked at the future of EU competitiveness with implications for the health sector

In September, Mario Draghi presented his report on the future of European Competitiveness, prepared at the request of the Commission. This will feed a new plan for Europe's sustainable prosperity and competitiveness. For the health sector, the report focused on digitalisation of health services and on the pharmaceuticals sector.

The Hungarian Presidency of the Council initiated a discussion among the health ministers on the synergies and gaps between the report and the priorities set out in the Council conclusions on the Future of the European Health Union approved in June 2024. While acknowledging the importance of pharmaceuticals, the steering note highlighted additional areas where Union-level action is needed to support patient access to health care and its sustainability.

In a comment published in the academic journal *The Lancet*, Martin Mckee, Aniek de Ruijter and Tamara Hervey also deplored the exclusive focus of Draghi's report on pharmaceuticals and electronic health data, at the blind spot represented by the health of the European population in general.

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### European Semester Autumn Package presented by the Commission

The European Commission published the Autumn Package of the European Semester, marking the launch of the 2025 cycle of socio-economic coordination under the new economic governance framework.

The first part published on 26 November 2024 relates to the fiscal aspects of the framework. The Commission notably assessed 21 national medium-term plans, which set out Member States's fiscal path as well as priority public investments and reforms, including for the health sector.

The second part was published on 18 December and includes a proposal for a recommendation on the 2025 economic policy of euro area Member States. The latter are invited to, among others, strengthen innovation in critical technologies, promote upskilling and reskilling of the workforce, and to strengthen public finances to ensure the sustainability of pensions, health care and long-term care systems.

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### Post-programme surveillance reports published for five Member States

As part of the European Semester Autumn Package, the European Commission also assessed the economic, fiscal and financial situation of Cyprus, Greece, Ireland, Portugal and Spain, which have benefited from financial assistance programmes. The assessment focus on the countries' capacity to repay their debt and examines also the sustainability of health care and long-term care spending.

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## 7 EU funding

### Contribution agreement signed with WHO to address shortages of nurses

The European Commission signed a contribution agreement with the World Health Organization (WHO) Regional Office for Europe to support Member States in retaining nurses in their health systems and making nursing a more attractive profession. The agreement is funded as part of the EU4Health programme.

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### Two HERA Invest agreements were signed

The Commission's Health Emergency Preparedness and Response Authority (HERA) and the European Investment Bank signed an agreement with the French biopharmaceutical company Fabentech to support the development and deployment of broad-spectrum therapeutics against biological threats to public health.

A second agreement was signed with the Danish biotech company SNIPR Biome with the aim to advance the development of innovative therapies that specifically target infections resistant to traditional antibiotics.

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### Agreement signed under the InvestEU Initiative for innovation in cancer treatment

The European Investment Bank and the Amsterdam-based company LUMICK signed a venture debt agreement to support research and development in cancer immunotherapy.

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### **The Commission announced a new EU Competitiveness Fund**

Within the new College of Commissioners, the Executive Vice-President for Prosperity and Industrial Strategy, Stéphane Séjourné, is responsible for the development of a European Competitiveness Fund for innovation and technologies investment. This could merge several existing funding instruments, including EU4Health, which has raised concerns within the health sector.

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## **8 Competition**

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### **European Commission withdrew decisions related to Illumina/GRAIL case**

The European Commission withdrew 6 referral decisions concerning the review of the acquisition of GRAIL by Illumina, both based in the US. GRAIL develops cancer tests and Illumina, genomic sequencing. This follows a judgement called by the Court of Justice of the European Union annulling the Commission's decisions (see section 9).

In view of this judgement, the Commission has also decided to withdraw its 2021 guidance on the application Article 22 of the EU Merger Regulation, meaning that the Member States can no longer refer a transaction to the Commission when not competent to do so under their national merger control rules.

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### **European Commission fined Teva linked to multiple sclerosis medicine**

The European Commission fined the global pharmaceutical company Teva €462.6 million for abuse of its dominant position in markets by preventing market entry of a competing product and misusing patent procedures for its blockbuster medicine Copaxone. Proceedings began in 2021 following unannounced inspections of Teva subsidiaries in 2019.

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### **European Commission and Swiss Competition Commission closed investigations into Novartis**

The European Commission and Swiss Competition Commission (COMCO) decided to close their investigation into Novartis for violation of antitrust law. The purpose of the investigation was to determine if Novartis was unlawfully protecting one of its dermatological medicines by filing patent infringement lawsuits, thereby breaking antitrust law. The investigation revealed that there was no unlawful action taken by Novartis.

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### **Commission assessed killer acquisitions in the pharma sector**

The Commission held a study with the goal of assessing the pervasiveness and characteristics of killer acquisitions in the pharmaceutical sector and conducting an ex-post evaluation of cases that may have involved killer acquisitions. These mergers and acquisitions of innovative competitors threaten innovation and competition by eliminating overlapping drug R&D projects.

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### **Commission approved Slovenian State aid to support production of biological drug substances**

The Commission has approved Slovenia's State aid of €52 million to support Lek Pharmaceuticals' construction of a new high-tech plant to produce biological drug substances. The plant is expected to contribute to EU's strategic objectives regarding job creation and regional development, as well as the Pharmaceutical Strategy for Europe's goal of ensuring affordable medicines.

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## ➤ **Eight acquisitions related to the health sector approved by the Commission**

The European Commission approved eight acquisitions. The first is the acquisition for the joint control of Eurobio (France) by IK Partners (Luxembourg) and NextStage (France). The merger concerns the pharmaceutical diagnostic products and services sector.

The second is the acquisition of Famar's holding company, Luxembourg-based MPILO, by Guernsey-based MidEuropa Partners, concerning the pharmaceutical sector.

The third is the acquisition for the joint control of R1 RCM Inc. by TowerBrook Capital Partners and Clayton, Dubilier & Rice, all US-based firms. The merger relates to the provision of technology-driven solutions to hospitals, health systems, and physician groups in the US.

The fourth is the acquisition for the joint control of Orisha (France) by Francisco Partners Management and TA Associates Management, both based in the US. The merger concerns the software publishing sector for companies operating in various sectors, including health care.

The fifth is the acquisition for the sole control of Vantive, the kidney care division of Baxter International, by the Carlyle Group. All groups are US-based. The acquisition concerns the supply of renal replacement therapy products.

The sixth is the acquisition for the sole control of Catalent, headquartered in the US, by Novo Holdings, headquartered in Denmark, and relates to the supply of pre-filled syringes and orally disintegrating tablets.

The seventh is the acquisition for the joint control of SRK Kliniken Beteiligungs by STRABAG and Haselsteiner Familien-Privatstiftung, all of Austria. The transaction relates primarily to the management consultancy and hospital activities sectors.

The eighth acquisition is the creation of a joint venture, CorroHealth, by Patient Square and Carlyle Group. All the companies are US-based. The venture concerns the provision of solutions to optimise the revenue cycle management for health care systems in the US.

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

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### ➤ **Judgement annuls Commission's decision to examine the proposed acquisition of GRAIL by Illumina**

In joined cases C-611/22 P and C-625/22 P, the Court of Justice set aside the judgement of the General Court of the European Union of 13 July 2022 and annuls the decision of the European Commission of 19 April 2021 to accept the request of the French Competition Authority to examine the concentration relating to the acquisition by Illumina of sole control over GRAIL, as well as its decision to accept the request of the Belgian, Dutch, Greek, Icelandic and Norwegian competition authorities to join the referral request. GRAIL develops cancer tests and Illumina, genomic sequencing.

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### ➤ **Judgement upholds the annulment of a Commission's decision related to Slovenia's aid to a public pharmacy**

In case C-447/22 P, the Court of Justice dismissed the appeal brought by the Republic of Slovenia against the judgment of the General Court of the European Union of 27 April 2022, which annulled a Commission decision to close the examination of measures concerning the municipal network of dispensing pharmacies Lekarna Ljubljana in the light of EU State aid rules.

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➤ **Judgement provides a preliminary ruling on national tax legislation applied to a pharmaceutical company**

In case C-248/23, the Court of Justice interpreted article 90(1) of the Council Directive 2006/112/EC on the common system of value added tax (VAT) in relation to the decision of the Hungarian appeals directorate to refuse to permit Novo Nordisk to deduct ex lege payments made to the National Health Insurance Fund Management Agency from the taxable amount for VAT purposes.

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➤ **Judgement upholds Commission's decision on the marketing authorisation of medicinal products containing the active substance tobramycin**

In case C-237/22 P, the Court of Justice dismissed the appeal brought by Mylan IRE Health Ltd, based in Dublin (Ireland), against the judgment of the General Court of the European Union of 26 January 2022 and thus upheld the Commission's implementing decision concerning the marketing authorisation for 'Tobramycin VVB and associated names', medicinal products for human use which contain the active substance 'tobramycin'.

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➤ **Judgement annuls Commission's decision on the marketing authorisation granted to the medicinal product Dexmedetomidine Accord**

In case T-223/20, the General Court accepted the request from Orion Oyj, based in Espoo (Finland), to annul the Commission implementing decision granting marketing authorisation for 'Dexmedetomidine Accord', a generic medicinal product for human use.

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➤ **Two judgments provide a preliminary ruling on health data processed under the GDPR**

In case C-21/23, the Court of Justice interpreted several provisions of the General Data Protection Regulation (GDPR) in the context of the marketing of pharmacy-only medicinal products on online platforms. The Court notably ruled that the information which the customers enter when ordering the medicinal products online constitutes data concerning health, even where the sale of those medicinal products does not require a prescription. Consequently, the processing of these data requires the explicit consent of the customer.

In case C-169/23, the Court of Justice interpreted provisions of the GDPR in the context of the issuance of COVID-19 certificates. The interpretation notably concerns the existence of an obligation to provide information on the part of the data controller to the data subject.

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## 10 Infringement procedures

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➤ **Hungary asked to comply with EU rules for reproduction services**

The European Commission sent a reasoned opinion to Hungary regarding restrictions on medical assisted reproduction services to State-owned or State controlled providers only. This measure violates the freedom of establishment defined by Article 49 of the Treaty on the Functioning of the EU.

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### ➤ **France asked to comply with EU rules on freedom of establishment and free movement of workers in the EU**

France received a letter of formal notice from the Commission for failing to comply to the free movement of workers and the freedom of establishment enshrined in Articles 45 and 49 of the Treaty on the Functioning of the EU. The Commission considers that French rules prevent EU doctors, dentists, and midwives qualified to practice within the EU from working in France if they are registered to practice in a non-EU country.

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### ➤ **Bulgaria and Cyprus failing to transpose the Proportionality Test Directive**

The European Commission referred Bulgaria and Cyprus to the Court of Justice of the EU for failing to ensure the correct transposition of the Directive (EU) 2018/958 into national legislation. This requires that any new or amended national rules affecting professions must be subject to a thorough analysis of proportionality before their adoption. Regulated health care professions are covered by this Directive.

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### ➤ **Spain urged to prevent abusive use of fixed-term contracts in public sector**

Spain received an additional letter of formal notice from the Commission for failing to sufficiently protect public sector workers against the abuse of successive fixed-term contracts, as required by the Council Directive 1999/70/EC. This letter follows the view that revisions to the national law are still inadequate to address this issue, particularly regarding the effectiveness of penalty measures. This also affects health care professionals working in the public sector.

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### ➤ **Spain referred to the Court of Justice for failing to correctly transpose the Public Procurement Directives**

The European Commission referred Spain to the Court of Justice of the EU for failing to correctly transpose three directives related to public procurement: Directive 2014/24/EU on public procurement, Directive 2014/25/EU on procurement in the utilities sectors, and Directive 2014/23/EU on the award of concession contracts. These rules govern the way public authorities and certain public utility operators purchase goods, works and services, also in the health and social protection sectors.

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### ➤ **Portugal referred to Court of Justice to improve rules on pollution from industrial activities**

Portugal was referred to the Court of Justice of the EU for failure to align national legislation with the Industrial Emissions Directive (Directive 2010/75/EU). The Directive establishes rules including the prevention and reduction of emissions in the air, water, and soil as a result of industrial activity, as well as the prevention of waste generation. This also concerns the manufacturing of pharmaceutical products.

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### ➤ **23 Member States called to fully transpose the NIS2 Directive**

The European Commission opened infringement procedures against 23 Member States for failure to transpose Directive 2022/2555. The Directive aims to ensure a high level of cybersecurity across the EU, covering entities operating in the health sector and other critical sectors.

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### ➤ **24 Member States called to transpose rules ensuring the protection of critical infrastructure and resilience of critical entities**

The European Commission sent a letter of formal notice to 24 Member States, including Belgium, for failure to notify national measures transposing the Directive 2022/2557. The Directive ensures the provision of vital services in the health sector and many other key sectors. The Member States had until 17 October 2024, to transpose the Directive.

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## 10 Member States called to comply with the Data Governance Act

The European Commission sent a reasoned opinion to 10 Member States, as they did not designate the responsible authorities to implement the Data Governance Act or have failed to prove that the latter are sufficiently empowered to perform their tasks. The Act aims to facilitate the re-use of certain categories of data held by public sector bodies. The competent authorities are notably in charge of the registration of data altruism organisations. Data altruism allows citizens and businesses to give their consent/permission to make available the data that they generate for objectives of general interest, such as medical research projects.

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## 11 Miscellaneous

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### Life science research among the areas addressed by the new Commissioner for research and innovation

The new Commissioner for Startups, Research and Innovation, Ekaterina Zaharieva, has a mandate to boost investment and cooperation in research and innovation. One of her tasks is to propose a Strategy for European Life Sciences in 2025, covering also biotechnology, with the aim of unlocking high-value technologies to support the green and digital transitions.

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### Mid-term reviews published for strategies promoting equality across the EU

The European Commission published the mid-term evaluation reports of three strategies promoting equality and combatting discrimination: the EU Anti-racism action plan; the EU Roma strategic framework for equality, inclusion and participation; and the LGBTIQ equality strategy. The reports assess progress made and make recommendations to address remaining challenges, including related to access to health services and discrimination in the health care sector.

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### EU Member States committed to step up action against AMR

A new political declaration was endorsed by the United Nations General Assembly to step up action against antimicrobial resistance (AMR). Its members, including EU Member States, committed to concrete actions to address AMR across all sectors and through a One Health approach.

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## 12 Publications

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### A study investigates how the European Semester can support the Wellbeing Economy

EuroHealthNet has analysed the 2024 European Semester and especially the Country-Specific Recommendations. The analysis highlights how the Semester can help support the Wellbeing Economy and the EU agenda of reducing social and health inequalities. The analysis shows that, while some progress has been made, improvement is still needed to put social, health and environmental goals on equal footing with fiscal and economic objectives.

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➤ **Article highlights the added value of the new EU-SILC's method for measuring health unmet needs**

In an article published by the European Journal of Public Health, David Ingleby and Caterina Guidi highlight the significance of a 2015 change in the methodology of the EU-SILC questionnaire on health needs distinguishing the probability of a person saying they needed care from the probability that they received it. They urge for more and better research into health inequalities in Europe and that Eurostat prioritise publishing more datasets.

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➤ **Article explores the implication for health of the EU Artificial Intelligence Act**

In an article for Health Policy, Hannah van Kolfschooten and Janneke van Oirschot explored the implications of the 2024 AI Act for the health care sector. They paid attention to legal obligations for health care stakeholders. The article emphasises the need for further AI guidelines for the unique needs of the health sector and makes recommendations for the upcoming implementation and standardisation phase.

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➤ **Articles suggests three ways to move forward with solidarity and trust in European Union health governance**

Writing for The Lancet Regional Health: Europe, Anniek de Ruijter, Tamara Hervey, and Barbara Prainsack explore the European Health Union since the COVID-19 pandemic, emphasising the EU's role in shaping governance and norms that affect trust and solidarity in health. Three strategies are proposed to ensure solidarity and public trust: the strengthening of solidarity mechanisms at the national and European levels, boosting resilience and stability of national health care systems through risk-sharing mechanisms, and ensuring a more equal baseline of public health through prevention and other public health policies.

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➤ **Report investigates company practices to tackle labour shortages**

A report by Eurofound finds updated evidence on the persistence of labour shortages despite declining levels of labour market slack in the EU and at the Member State level. It focuses on organisational policies aimed at attracting workers to occupations in which shortages are common, including health care. The report identifies five priority areas for action: activation of underrepresented people in the labour market, providing support for skills, training, and education, improving working conditions in certain sectors, improving mobility for workers and learners, and attracting talent from outside the EU.

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➤ **Outcomes of the 2024 European Health Forum Gastein published**

The 2024 European Health Forum Gastein tackled the evolving health landscape shaped by demographic changes, digital advancements, and the national and international political climate. The conference outcomes highlighted the need for improved understanding of commercial and environmental determinants of health, health equity, digital transformation, and a strategic EU vision for health to foster synergies across all levels.

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➤ **Report assesses structural and institutional racism (also in health care) in 8 Member States**

A report from the Migration Policy Group analysed structural and institutional racism in 8 EU Member States. Health care is among the sectors where patterns of racism are most evident in the different countries. The results also showed that the lack of racial and ethnic data fails to highlight how structural and institutional racism may drive inequalities in health care, but also other crucial areas. The authors note that embedded racism needs to be addressed by updating laws and policies at the national and EU level, but also engaging members of society unaware of the effects of racism and discrimination.

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### Report examines the burnout economy

In this year's report on extreme poverty and human rights, UN Special Rapporteur Olivier De Schutter examines mechanisms that expose people in poverty to an increased risk of mental health conditions. Considering the higher levels of depression and anxiety at a global level, he highlights how more should be done to fight poverty and inequality, and to address economic insecurity. He recommends increasing investments in mental health care as well as addressing psychosocial risks, strengthening social protection, and destigmatising mental health conditions.

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