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1 Public health

➤ Council recommendation on vaccine-preventable cancers

The Council of the European Union (EU) adopted a recommendation that aims to combat vaccine-preventable cancers in the EU by boosting the uptake of vaccinations against Human papillomaviruses and the Hepatitis B virus.

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➤ Council conclusions on the future of the European Health Union

The Council of the EU stressed the urgent need to continue to build upon and improve the European Health Union, in the light of the systemic challenges faced by health systems today. It acknowledged the work already done to improve health policy coordination at EU level and set out the key areas of focus for strengthening the European Health Union.

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➤ European Council 2024-2029 strategic agenda concerning security, innovation and access to medicines

The strategic agenda adopted in June by the European Council provides guidance to EU institutions on the political priorities for the next 5 years. While health is not specifically prioritised, action in this sector is mentioned, with a view to strengthening EU security and defence against health emergencies, bolstering EU competitiveness by supporting innovation, and improving access to medicines across the Union.

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➤ Improving preventive health – among the political guidelines for the next European Commission

The Commission President Ursula von der Leyen presented the political guidelines that will guide her second term from 2024 to 2029. They notably focus on the resilience of the EU economy. In this regard, work on preventive health will be improved, based on the model of the Beating Cancer Plan, notably in relation to mental health, cardiovascular diseases, degenerative illness and autism. Other priorities relate to medicines (see next section) and digitalisation (see e-Health).

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2 Medicines and medical devices

➤ Council conclusions on radioisotopes for medical use

The Council of the EU approved conclusions to ensure the supply of medical radioisotopes, which are key to diagnosing cancer, cardiac conditions and other diseases, and are increasingly used for cancer treatment.

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➤ Guidance from the Commission on the clinical evaluation of orphan medical devices

The European Commission published guidance developed by the Medical Devices Coordination Group (MDCG), which provides manufacturers and notified bodies with criteria for determining when a medical device or an accessory for a medical device should be regarded as an 'orphan device' under the Medical Devices Regulation 2017/745.

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➤ Two pilot projects within the 'Accelerating Clinical Trials in the EU' initiative

The ACT EU initiative is a collaboration between the European Medicines Agency, the Heads of Medicines Agencies in the Member States and the European Commission. The two pilot projects offer advice on clinical trials and on requirements for marketing authorisation applications, on the one hand, and on pre-submission issues for clinical trial applications, on the other.

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Commission technical report on the supply of critical medicines

The European Commission's Health Emergency Preparedness and Response Authority (HERA) assessed the supply chain vulnerabilities of eleven medicines on the Union list of critical medicines. The findings will help the Critical Medicines Alliance to recommend further action to enhance security of supply of this first tranche of medicines.

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Two joint procurement framework contracts signed by HERA

The European Commission's Health Emergency Preparedness and Response Authority has signed a joint procurement framework contract for the supply of pre-pandemic vaccine doses for the prevention of avian flu. Another contract was signed for the supply of a medicine used to treat diphtheria. Fifteen Member States from the European Union and the European Economic Area are participating in the first voluntary procurement, while eight Member States are involved in the second one.

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A Critical Medicines Act announced in the political guidelines for the next European Commission

The political guidelines presented by the Commission President Ursula von der Leyen for her second term (2024-2029) focus particularly on the resilience of the health and pharmaceutical sector. A series of measures are proposed in this regard. A 'Critical Medicines Act' is announced to remedy shortages of medicines and medical devices; work in this area will be carried out as part of the European Health Union. A new strategy to support medical countermeasures against public health threats is also proposed. And a 'European Biotech Act' is planned for 2025 to boost the use of biotechnologies, also in the health sector.

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European mechanism activated to tackle shortages of medicines in France

The voluntary European solidarity mechanism created in October 2023 was activated by France for the first time, due to shortages of methotrexate-based drugs used to treat certain leukaemias and lymphomas. Via this mechanism, the European Medicines Agency (EMA) forwarded France's request to all EU countries, and Slovenia answered the call by sending boxes of medicines to France.

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3 e-Health

Second Commission report on the State of the Digital Decade

The European Commission assessed progress made towards the achievement of the objectives and targets set for 2030 in the Digital Decade Policy Programme. These include accessibility of electronic health records by European citizens. This year's report is accompanied by an analysis of the national strategic roadmaps presented by Member States, and includes country-specific as well as cross-cutting recommendations for every EU Member State.

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Cybersecurity and innovation among the political guidelines for the next European Commission

The political guidelines presented by the Commission President Ursula von der Leyen for her second term focus on the resilience and the competitiveness of the EU economy. For the health sector, a 'European action plan on the cybersecurity of hospitals and healthcare providers' is announced for the first 100 days of the new mandate. An 'Apply AI strategy' is also proposed, the aims of which include improved delivery of public services such as health care.

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4 Internal market

▶ ECA report on the recognition of professional qualifications in the EU

The European Court of Auditors examined how effectively the European Commission has ensured the application of the directive on recognition of professional qualifications. This directive aims to protect the right of EU citizens working in regulated professions, including health professions, to move freely between Member States, for professional purposes or to establish businesses. The assessment concludes that this mechanism is essential but used sparsely and inconsistently.

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5 Social policy

▶ Commission guidelines for national employment policies

The European Commission provided policy guidance to Member States in the 2024 European Semester Spring Package. This sets common priorities for national employment and social policies. The Commission notably proposed an update of the 2023 guidelines to include actions that tackle skills and labour shortages, improve basic and digital skills, and address the impact of new technologies and artificial intelligence. It also recalls the need to ensure timely and equal access to affordable high-quality long-term care and health care services.

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▶ Council conclusions on the role of the labour market, skills and social policies for resilient economies

The Council of the EU approved conclusions which stress the mutually reinforcing nature of economic and social objectives. Member States are notably invited to strengthen their capacity to assess the impact of labour market, skills and social policies (including health care policies) on employment, skills and social outcomes, as well as on economic growth, competitiveness, and productivity. Voluntary guiding principles are available to help Member States conduct this evaluation.

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▶ Eurostat report monitoring progress towards the SDGs

Eurostat published the 2024 monitoring report assessing the progress made by the European Union towards the Sustainable Development Goals set for 2030 by the United Nations. The findings over the past five years show a moderate negative trend concerning the achievement of the third SDG on good health and well-being. In fact, the EU experienced setbacks in around half of the indicators analysed, and notably in relation to healthy life expectancy, self-perceived health, unmet needs for medical care, and avoidable mortality.

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6 Economic policy

▶ Commission communication on the 2024 European Semester Spring Package

The European Commission published the 2024 European Semester Spring Package, which provides policy guidance to Member States in relation to economic and social policies. The communication that accompanies the package highlights the EU aim to secure competitiveness and resilience, while maintaining sound fiscal policies. Regarding health and long-term care systems, it notably stresses the need to strengthen their cost-effectiveness while ensuring adequacy, quality, and good coverage.

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Country reports published under the European Semester

The country reports included in the 2024 European Semester Spring Package of the European Commission analyse economic, employment and social developments and challenges in each Member State. For the health sector, information is provided in relation to the health status of the population, labour shortages, health spending, digitalisation of services, access to health care, as well as the funding allocated under the Recovery and Resilience Facility and the Cohesion Policy.

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Country-specific recommendations agreed by the Council

The Council of the EU agreed on the country-specific recommendations (CSRs) proposed by the European Commission under the European Semester Spring Package. These provide guidance to Member States on how to tackle the key challenges that are only partially, or not at all, addressed in Member States' recovery and resilience plans. Six Member States received a recommendation specific to health care (Austria, Estonia, Finland, Ireland, Latvia, Lithuania), and seven countries received a recommendation specific to long-term care (Austria, Belgium, Croatia, Estonia, Italy, Netherlands, and Poland).

Regarding the recommendation on long-term care addressed to Belgium, the Commission notably calls on the country to make the long-term care system more cost-effective in view of the expected increase in age-related expenditure.

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Post-programme surveillance reports for five Member States

As part of the European Semester Spring Package, the Commission published post-programme surveillance reports for Cyprus, Greece, Ireland, Portugal and Spain, countries that have benefited from financial assistance programmes. These reports assess their economic, fiscal and financial situation, including for the health sector, and conclude that all five Member States retain the capacity to repay their debt.

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Excessive deficit procedures opened for seven Member States and maintained for Romania

The Council of the EU adopted decisions establishing the existence of excessive deficits for Belgium, France, Hungary, Italy, Malta, Poland and Slovakia. These are based on the European Commission's assessment of the situation of twelve Member States with regard to the deficit criterion of the Treaty on the Functioning of the European Union.

Following another assessment by the Commission, the Council also concluded that Romania, which has been under the excessive deficit procedure since 2020, has not taken effective action to correct its deficit, and that therefore the procedure should remain open.

The deficit-based excessive deficit procedure aims to ensure that all Member States return to or maintain discipline in their governments' budgets, including in relation to health care spending, and avoid running excessive deficits.

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7 Competition

Statement of Objections sent to Alchem over first pharmaceutical cartel case in the EU

The European Commission has informed Alchem of its preliminary view that the company participated in a long-lasting cartel involving an important pharmaceutical ingredient used to produce the abdominal antispasmodic Buscopan and its generic versions.

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Vifor's commitments to remedy anti-competitive practices

The European Commission accepted commitments by Vifor to address possible anti-competitive disparagement of Monofer, the closest competitor of Vifor's flagship intravenous iron medicine in Europe, Ferinject. The Commission had opened a formal antitrust investigation into Vifor's behaviour in June 2022, following a complaint filed with the Commission by Pharmacosmos.

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Approval of Dutch support for the production of medical radioisotopes

The European Commission has approved, under EU State aid rules, a €2 billion Dutch measure to support the PALLAS project aimed at producing medical radioisotopes for cancer diagnosis and treatment. A new reactor will replace the one operating since 1961 in Petten, and a nuclear health centre will be built to notably conduct research in the field of nuclear medicine.

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Eleven acquisitions related to the health sector approved by the Commission

The European Commission approved 11 acquisitions. The first is the acquisition of joint control of Advanz Pharma by Nordic Capital, both of Jersey, and by Ontario Teachers' Pension Plan Board of Canada. The transaction relates primarily to the supply of pharmaceutical products.

The second is the acquisition of the European over-the-counter business of Viatrix (United States), which includes pharmaceutical products for personal hygiene, by Cooper (France). Cooper distributes consumer health products and over-the-counter self-medication products. The approval is conditional upon full compliance with the commitments offered by the parties.

The third is the acquisition of sole control of the Aenova group of companies (Germany) by Kühne Holding (Switzerland). The transaction relates primarily to the pharmaceutical industry.

The fourth is the acquisition of joint control of Uriach (Spain) and Ineldea (France) by ICG (United Kingdom) and Holding Uriach (Spain). The transaction relates primarily to consumer health care products, including over-the-counter finished dosage pharmaceuticals and natural food supplements.

The fifth is the acquisition of sole control of Evonik Superabsorber (Germany) and Evonik Superabsorber Companies (United States) by ICIG (Germany). The transaction relates primarily to the chemical markets of phenothiazine, acrylic acid and superabsorbent polymers used in the manufacture of hygiene articles and medical products.

The sixth is the acquisition of sole control of Bubbles BidCo (Italy) by TDR Capital (United Kingdom). The transaction relates notably to the retail sale of health products.

The seventh is the acquisition of joint control of Kona Topco and its subsidiaries, including RedSail, by Leonard Green & Partners and Francisco Partners, all of the US. The transaction relates primarily to the sector of business management software and services for pharmacies.

The eighth is the acquisition of sole control of HFO Group (Germany) par PAI Partners (Luxembourg). The transaction relates primarily to the operation of health care facilities offering inpatient and outpatient rehabilitation services, as well as preventive medicine and nursing services.

The ninth is the acquisition of sole control of Nexeye (Netherlands) by KKR (United States). The transaction relates primarily to the retail of optical and hearing aid products in the European Economic Area.

The tenth is the acquisition of sole control of Sunrise Medical (Germany) by Platinum Equity Group (United States). The transaction relates primarily to the supply of medical aid solutions.

The eleventh is the acquisition of joint control of Immedica Pharma by Impilo, both of Sweden, and KKR of the United States. The transaction relates primarily to the commercialization of medicines for rare diseases and specialty care products.

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Judgment upholding a Commission decision from 2014 on anti-competitive behaviour in the perindopril market

The Court of Justice dismissed the appeals brought by six generic manufacturers, confirming that the agreements concluded by the Servier group regarding the market for perindopril, a medicine intended for the treatment of certain heart diseases, constituted market-exclusion agreements and restricted competition. The Court also found that the General Court had relied on incorrect grounds when it invalidated the Commission's definition of the relevant market and that it made a number of errors of law.

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Opinion regarding national tax legislation, for a pharmaceutical company

In case C-248/23, the Advocate General makes suggestions on how to interpret article 90(1) of the VAT directive, and particularly whether certain payments imposed by Hungarian law and calculated based on the price of subsidised medicinal products should be treated as a price reduction or as a tax. In fact, if it is a price reduction, the taxable amount should be reduced, according to the VAT Directive.

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Rulings on the conditions for granting a supplementary protection certificate for medicinal products

In joined cases C-119/22 and C-149/22, the Advocate General proposes, in his opinion, how to interpret Article 3 of Regulation (EC) N°469/2009, which sets out the conditions for granting a supplementary protection certificate (SPC), for a combination of active ingredients used in a medicinal product, where a previous SPC has already been granted for one of those ingredients.

Case C-181/24 concerns the interpretation of this same article. The Court of Justice ordered that it should be interpreted as precluding the marketing authorisation submitted in support of an application for a SPC for a product from being regarded as the first marketing authorisation, if a prior marketing authorisation was granted for that same product but was withdrawn before the application for the SPC was submitted.

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Opinion on the marketing authorization of two orphan medical products

In case C-237/22 P, the Advocate General proposes to reject the first ground of the appeal brought by Mylan against the decision of the General Court, which upheld the marketing authorization granted by the European Commission to an orphan medical product (OMP), Tobramycin VVB, and its consequent derogation from the market exclusivity previously granted to another OMP, Tobi Podhaler. The two OMPs are indicated for the treatment of pulmonary infection in cystic fibrosis patients aged six years and older.

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Judgment regarding public access to agreements on COVID-19 vaccines concluded between the European Commission and pharmaceutical companies

In joined cases T-689/21 and T-761/21, the General Court partially upheld two pleas brought by five Members of the European Parliament and by individuals against two decisions taken by the Commission in 2022, which granted them only partial access to COVID-19 vaccine contracts. The Court notably annulled the parts of these two decisions containing irregularities. The Commission stated that it will study the Court's judgments and their implications.

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▶ **Judgment on the working conditions of part-time health workers**

In joined cases C-184/22 and C-185/22, the Court of Justice ruled on the interpretation of EU rules regarding equal opportunities and equal treatment in matters of employment and occupation, as well as part-time work. The case notably concerns the payment of additional pay for overtime worked in excess of the normal working hours agreed in the employment contracts, for two part-time care assistants working for a provider of out-patient dialysis services in Germany.

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▶ **Opinion on the application of the GDPR in relation to COVID-19 certificates**

In case C-169/23, the Advocate General makes proposals on how to interpret the derogation from the obligation on the data controller to provide information to the data subject, as laid down in Article 14(5)(c) of the EU General Data Protection Regulation. The case arose in the context of the issuance of COVID 19 certificates.

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▶ **Judgment on social security, social assistance and social protection measures for third-country nationals**

In joined cases C-112/22 and C-223/22, the Court of Justice ruled that access by third-country nationals who are long-term residents to a social security, social assistance or social protection measure of a Member State may not be conditional on the requirement of having resided in that Member State for at least 10 years, the last two of which continuously. In fact, standards on the eligibility of third-country nationals who are long-term residents are defined in Council Directive 2003/109/EC. According to the latter, social assistance should cover at least some core benefits, such as assistance in case of illness and pregnancy, and long-term care.

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9 Infringement procedures

▶ **Belgium and Bulgaria failing to correctly transpose EU rules on proportionality of professional regulations**

The European Commission sent a reasoned opinion to Belgium and a complementary reasoned opinion to Bulgaria for their failure to ensure the correct transposition of the Proportionality Test Directive (EU) 2018/958. This Directive governs the proportionality assessment of new or amended rules restricting access to, or pursuit of, regulated professions. Regulated health care professions are covered by this Directive.

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▶ **Bulgaria failing to correctly apply EU rules on the provision of services**

The European Commission referred Bulgaria to the Court of Justice of the EU for limiting the maximum duration of the provision of temporary cross-border social services, such as therapy and rehabilitation, and care services, to six months per year. The Bulgarian law on Social Services infringes the Services Directive 2006/123/EC and the Treaty on the Functioning of the EU.

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▶ **Spain failing to correctly transpose EU rules on fixed-term work**

The European Commission sent a second additional letter of formal notice to Spain for failing to correctly transpose Council Directive 1999/70/EC, which prohibits discrimination against fixed-term workers. Spanish law contains less favourable employment conditions for fixed-term employees working in the public sector than for permanent employees. This also affects health care professionals.

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▶ Ireland failing to comply with data governance legislation

The European Commission sent a letter of formal notice to Ireland because it has not designated the competent authorities to implement the Data Governance Act. This Act aims to facilitate data sharing across sectors and EU countries. 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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10 Miscellaneous

▶ Council recommendation on a coordinated response to disruptions to critical infrastructure

The Council of the EU adopted a Recommendation on a Blueprint to coordinate a response at EU level in the event of disruptions to critical infrastructure with significant cross-border relevance, including in the health sector. All relevant actors are encouraged to practise and test the functioning of the EU Critical Infrastructure Blueprint at national, regional and EU level.

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▶ 2024 edition of the Science, Research and Innovation performance report

The Commission has published the fifth edition of the biennial publication on the performance of science, research and innovation, which analyses the key determinants of research and innovation (R&I) in Europe. The report provides extensive coverage of topics including high-tech health, global health risks addressed by R&I, and the future of the health care sector.

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▶ Medical evacuation of sixteen Palestinian children from Egypt to Spain

This first EU-coordinated medical evacuation was held in July and was coordinated and financed by the EU Civil Protection Mechanism, in close coordination with the World Health Organization, the Palestine Children's Relief Fund and authorities of all countries involved. Other evacuations have followed since then. Belgium, Italy, Luxembourg, Malta, Romania, Slovakia and Spain have notably offered assistance with medical evacuations, including treatment for patients as well as transportation.

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11 Publications

▶ Analysis and recommendations on border region patient mobility in the EU

In an article published in the journal Health Policy, Markus Frischhut and Rosella Levaggi examine, with the use of a spatial competition model, EU cross-border health care in border regions. They look at the options used to regulate this patient flow and their welfare implications, both for patients and for governments. Suggestions are made for joint implementation of EU directives by neighbouring Member States.

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▶ Case study on EU resources for investing in and strengthening health systems

A report by the European Observatory on Health Systems and Policies presents the key findings from a mapping exercise of existing EU instruments. The findings on three Member States (Austria, Belgium and Slovenia) are reviewed, and tailored options are presented to address the common challenge of making the case for investing in health. The report's aim is to help Member States access relevant EU funding instruments.

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➤ **Call for progress on the implementation of the European Child Guarantee**

The EU Alliance for Investing in Children published a joint statement calling for progress in the implementation of the European Child Guarantee. It emphasises the need for innovative National Action Plans that go beyond superficial measures, in order to tackle child poverty effectively. Signatories also call for adequate and transparent funding from both EU and national sources.

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➤ **Outcomes of a public debate on the future health priorities of the EU**

A report published by the European Observatory on Health Systems and Policies, and commissioned by the European Commission's DG SANTE, outlines the key health priorities and actions that emerged from a seven-month public debate with citizens and stakeholders from a wide range of sectors. The findings highlight a collective call for the EU to play a more significant role in health.

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➤ **Study on the ethical principles and values guiding health care in Europe**

In an article published in the journal *Medicine*, Markus Frischhut and Gabriele Werner-Felmayer explore medical ethics principles in relation to health values in the European context and as reflected in EU law. The article focuses on solidarity and how it is understood in Europe, and some challenges for its realisation, particularly when using artificial intelligence in health care.

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➤ **Report on social protection of self-employed people**

A report by Eurofound examines the working conditions of different groups of self-employed people. It highlights the vulnerability of economically dependent self-employed individuals, who were more likely to suffer from health problems during the COVID-19 pandemic. The conclusions stress the need to ensure not only formal but also effective and adequate access to social protection for the self-employed.

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➤ **Evaluation of two catastrophic health spending indicators used in Europe**

In an article published in the journal *Health Policy*, Jonathan Cylus and colleagues examine the results produced by two indicators used to monitor the progress towards universal health coverage (UHC). The first is used in relation to Sustainable Development Goal 3 on health, and opts for a budget share approach, while the second chooses a capacity-to-pay approach and has been developed by WHO/Europe. The authors argue that the latter is more sensitive to medicines co-payment policies than the former, making it a better indicator for monitoring health system equity and progress towards UHC in Europe.

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