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1 Public health

Communication on the European Health Union

The European Commission highlighted progress made during the past 5 years to improve EU citizens' health and strengthen the resilience and accessibility of health systems. It recalled the three main pillars structuring the European Health Union: a new health crisis framework; security of medical supply; and modern and innovative health policies. It finally stressed the need for health to remain a political priority over the coming years.

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Reflection on strategic priorities for the health agenda of the next European Commission (2024-2029)

A high-level conference was organised at the end of March under the Belgian Presidency of the Council of the EU, to reflect on the future EU health agenda. Issues discussed include shortages of health workers, security of medicines supply, crisis preparedness, prevention of non-communicable diseases, and investing in health.

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Debate on the health workforce crisis and prevention of non-communicable diseases

The issues of health workforce and prevention of non-communicable diseases were the main points for consideration at the informal meeting of health ministers on 23 and 24 April. Ministers were notably invited to discuss the idea of a comprehensive EU health workforce strategy focusing on planning, training, and regulatory improvements to meet the evolving needs of health systems. Regarding the prevention of non-communicable diseases, ministers discussed areas to be targeted by EU legislation.

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New ECDC framework for prevention of communicable diseases

Based on its amended mandate, the European Centre for Disease Prevention and Control (ECDC) has launched a holistic framework which expands on traditional infectious disease prevention by examining social and behavioural aspects, including socioeconomic risk factors, health promotion and health literacy. To support its implementation, a Community of Practice on Prevention will be established.

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Cross-agency framework for action on One Health

The European Centre for Disease Prevention and Control (ECDC), the European Chemicals Agency (ECHA), the European Environment Agency (EEA), the European Food Safety Authority (EFSA), and the European Medicines Agency (EMA) published a joint framework to strengthen cooperation supporting the implementation of the One Health agenda in the European Union. A cross-agency task force will notably work on implementing the framework over the next three years (2024-2026).

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2 Medicines and medical devices

New measures for the management of medicine authorisations

The European Commission has proposed to adapt the current system for assessing variations to the initial marketing authorisation of medicines. The revisions aim to facilitate more efficient lifecycle management of medicines while awaiting the broader proposed reform of the EU's pharmaceutical legislation.

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New rules for joint clinical assessments of medicines

The European Commission adopted new rules defining the timelines and the steps for conducting EU joint clinical assessments. These rules are the first of six acts to be adopted this year under the Regulation on Health Technology Assessment. Joint clinical assessments will start as of January 2025 for medicinal products with new active substances for the treatment of cancer and for advanced therapy medicinal products.

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Initiatives to strengthen supply chains of critical medicines

The Medicines Shortages Steering Group (MSSG) of the European Medicines Agency (EMA) has published recommendations to address vulnerabilities in the production and delivery of medicines included in the Union list of critical medicines.

The MSSG will work closely with the Critical Medicines Alliance. This consultative mechanism was officially launched by the Health Emergency Preparedness and Response Authority (HERA) and the Belgian Presidency of the Council of the EU in the margins of the informal meeting of health ministers of 24 April. The Alliance will work over the next 5 years to enhance security of supply; strengthen availability of medicines; and reduce EU supply chain dependencies.

At the launch of the Alliance, France and eight other Member States presented a manifesto calling for a coordinated and inclusive EU-level investment plan to strengthen critical pharmaceutical production capacities.

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Targeted actions to boost biotechnology and biomanufacturing

The European Commission published a Communication on Building the future with nature, which identifies the challenges and barriers faced by the EU biotechnology and biomanufacturing sector and proposes a series of actions to tackle them. A thriving EU biotech ecosystem is considered of strategic importance for the effectiveness of health care and the resilience of health systems.

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Toolbox to combat counterfeiting and better protect intellectual property rights

The European Commission has adopted a resolution proposing key actions to increase companies' resilience and ability to combat counterfeiting, both offline and online, and to enhance the enforcement of intellectual property rights. Member States, in cooperation with consumer organisations, are encouraged to raise awareness of counterfeit pharmaceutical products advertised and sold online.

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Principles on limiting the most harmful chemicals to essential uses

The European Commission has adopted guiding criteria and principles for what would constitute 'essential uses' of the most harmful chemicals. Use of such chemicals should notably only be allowed if this is necessary for health or safety or is critical for the functioning of society, and if there are no acceptable alternatives. This may, for example, be to prevent, monitor or treat illness; to sustain basic conditions for human or animal life and health; or to manage health crises and emergencies.

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Measures for new air mobility concepts and services

The European Commission has adopted a set of measures to address challenges raising from the emergence of piloted air taxis and unmanned drone operations. The aim is to unify and streamline the regulatory landscape across Member States, improving oversight and operational safety standards. Specific rules are also introduced for the provision of emergency medical services and rescue operations.

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3 e-Health

Agreement on the creation of a European Health Data Space

The Council of the EU and the European Parliament reached a provisional agreement on the regulation establishing a European Health Data Space. Its aim is to facilitate the exchange of and access to health data at EU level. Approved by the European Parliament in April, this inter-institutional agreement is now awaiting approval by the Council.

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Agreement to strengthen cyber security capacity in the EU

The Council of the EU and the European Parliament reached a provisional agreement on the Cyber Solidarity Act, which is expected to strengthen the EU's and Member States' capabilities to prepare, prevent, respond, and recover from large-scale cyber threats or incidents. Preparedness actions include testing entities in highly critical sectors such as health care. This inter-institutional agreement was approved by the European Parliament in April, and is now awaiting approval by the Council.

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Expert advice on the uptake of artificial intelligence in science

The European Commission's Scientific Advice Mechanism published its scientific opinion on how the Commission can accelerate responsible uptake of artificial intelligence in science at EU level. Four overarching recommendations were made to support the integration of AI across a variety of areas, including health. They will inform the overall strategy for AI in research and innovation, to be developed by the European Commission.

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4 Internal market

Priorities for the future of the single market

Enrico Letta, President of the Jacques Delors Institute and former Prime Minister of Italy, presented an independent high-level report on the future of the single market. This was commissioned by the Spanish and the Belgian presidencies of the Council of the EU and provides concrete proposals to empower the single market and align it better with the current European and global context. The proposals include leveraging the single market to strengthen health resilience.

The Special European Council convened on 18 April invited the current and future Council Presidencies to take work forward on the recommendations included in the Letta report by the end of the year. Among other drivers, the focus should be on the cross-border provision of services, as well as cross-border movement of goods, including medicines.

On this same topic, the conclusions adopted by the Council of the EU in May draw up a roadmap to strengthen the single market and prepare it for future global challenges. The Commission is invited to prepare a strategy for a modernised single market before June 2025.

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5 Social policy

Measures to tackle labour and skills shortages

The European Commission published an action plan to tackle labour and skills shortages over the coming years, including in the health care and long-term care sectors. The plan sets out actions to be implemented at the EU, national, regional, and social-partner level. Progress in its implementation will be monitored as part of the European Semester.

Eurofound published a report assessing the effectiveness, efficiency and potential transferability of policy measures taken by the Member States to address labour shortages in sectors with long-standing structural shortages aggravated by the COVID-19 pandemic (health and long-term care, information and communication technology) and in sectors affected by the green and digital transitions.

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Declaration on the future of the European Pillar of Social Rights

The Declaration adopted at the end of a high-level conference in La Hulpe, Belgium, by the EU institutions, social partners, and civil society organisations, proposes initiatives for the EU's social agenda for 2024-2029. It reaffirms the Pillar as the guiding framework for EU social policies, including for the preservation of accessible health care.

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Conclusions on the fiscal sustainability challenges arising from ageing

The conclusions approved by the Council of the EU in May reaffirm the need to further address the economic and budgetary consequences of ageing, including by adapting pension, health care and long-term care systems to these challenges.

The conclusions draw on the main findings of the 2024 ageing report, which provides projections for age-related public expenditure, including on health care and long-term care.

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Country-specific analysis on social convergence for seven Member States

The European Commission has published a country analysis, considering the areas of employment, skills and social inclusion, for Bulgaria, Estonia, Spain, Italy, Lithuania, Hungary and Romania. The analysis is in line with the features of the social convergence framework and also covers aspects related to health care. Its findings will inform the forthcoming European Semester Spring Package.

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2024 edition of the EU regional Social Progress Index

The index published by the European Commission measures wellbeing and social progress across the EU by tracking 53 socio-economic and environmental indicators. It includes indicators related to health conditions and health care.

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6 Economic policy

Conclusions on the future of industrial policy

The Council of the EU has adopted conclusions pointing the way forward towards a new European competitiveness deal. The conclusions analyse the situation of the EU's industrial sector, explore ways to improve innovation, access to finance and the business environment for manufacturers, and propose the main principles underlying a future EU industrial policy. They recommend, among other things, giving priority to areas of technology that are critical for the EU's economic security and can reduce dependencies in sensitive sectors such as health.

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7 EU funding

Strategic orientations for research and innovation funding

The European Commission has adopted the second strategic plan for Horizon Europe. It sets out three strategic orientations for 2025-2027: the green transition; digital transition; and a more resilient, competitive, inclusive, and democratic Europe. The plan also includes objectives and the expected impacts for the health cluster.

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Assessment of the state of cohesion in the European Union

The European Commission published its 9th Cohesion report, which assesses the situation of economic, social, and territorial cohesion across the EU. The report presents progress made and lessons learned and invites reflection on how the design of Cohesion Policy could be further improved to address the remaining challenges. It also examines the accessibility of health care and the impact of the green, digital, and demographic transitions on health care.

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8 Competition

Conclusions on improving competition in public procurement

The Council of the EU has adopted conclusions on improving fair and effective competition for public procurement contracts awarded for works, goods and services in the EU. It proposes the launch of an EU-wide strategic action plan for public procurement as one of the priorities for the Commission's next mandate. In so doing, the Council is responding to the report of the European Court of Auditors, which had criticised the decreasing competition in public procurement over the last decade in several sectors, including health services and medical equipment.

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First Important Project of Common European Interest in the health sector

The European Commission has approved, under EU State aid rules, the first Important Project of Common European Interest to support research, innovation and the first industrial deployment of health care products, as well as innovative production processes for pharmaceuticals. The project was notified by six Member States: Belgium, France, Hungary, Italy, Slovakia and Spain.

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Amendment to the Guidelines on regional state aid

The European Commission has adopted an amendment to the Regional Aid Guidelines to allow Member States to grant higher amounts of regional aid for investment projects covered by the Strategic Technologies for Europe Platform (STEP). This is expected to support the development and manufacturing of digital technologies and deep-tech innovation, clean technologies, and biotechnologies.

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Four acquisitions approved in the health care sector

The European Commission has approved four acquisitions. The first is the acquisition of joint control of Cotiviti by KKR and Veritas, all of the United States. The transaction relates primarily to the provision of data analytics services, including in health care.

The second is the acquisition of joint control of Byggfakta (Sweden) by TA Associates (United States), Stirling Square Capital Partners (United Kingdom), and Macquarie European Investment Holdings Limited (Australia). The transaction relates primarily to the provision of integrated market data and software

intelligence services to companies in various industries, including health care.

The third is the acquisition of joint control of Smart Clinic by Generali, Gruppo San Donato, and GK Holding, all of Italy. The transaction relates primarily to the provision of outpatient health care and diagnostic examinations.

The fourth is the acquisition of joint control of Resonetics by Carlyle and GTCR, all of the US. The transaction relates primarily to the development and manufacturing of medical instruments.

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Illumina's plan to divest Grail approved in relation to the market of cancer screening tests

The European Commission has approved the divestment plan submitted by Illumina for the disposal of GRAIL. In line with the restorative measures that the Commission adopted in October 2023, the plan is expected to restore competition in the market for the development of early cancer detection tests.

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9 Court of Justice of the European Union

Opinion on the appeals brought by Illumina and Grail against the European Commission

In the joint cases C-611/22 P and C-625/22 P, the Advocate General suggests that the Court of Justice should set aside the judgment of the General Court of 13 July 2022 (T/227/21) and annul the Commission decisions accepting 1) the request of the French competition authority to examine the concentration relating to the acquisition by Illumina of sole control over Grail, and 2) the requests of the Belgian, Dutch, Greek, Icelandic and Norwegian competition authorities to join that referral request. The concentration relates to the marketing of blood-based early cancer detection tests.

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Judgments on two appeals against decisions regarding the marketing authorisation of medicinal product

In case T-416/22, the General Court dismissed the action for annulment brought by Fresenius Kabi Austria GmbH and other applicants against the European Commission's decision requiring the Member States concerned to suspend the national marketing authorisation for medicinal products containing hydroxyethyl starch (HES) as an active substance.

In case C-291/22 P, the Court of Justice set aside part of the judgment of the General Court of the EU which dismissed the action for annulment brought by Debrégeas et associés Pharma against the European Commission, and annulled the Commission decision refusing the marketing authorisation application for the medicinal product Hopveus – sodium oxybate, intended to combat dependence on alcohol.

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Opinion on the protection of personal data and the concept of data concerning health

In Case C-21/23, the Advocate General makes proposals regarding the interpretation of a number of provisions of the General Data Protection Regulation (GDPR) in relation to the system of remedies established by that regulation and the category of 'data concerning health'. The request for a preliminary ruling involved an action for an injunction brought by an undertaking with a view to putting an end to the online marketing of non-prescription medicines by one of its competitors, due to unfair competition, and notably its failure to comply with the requirements arising from the GDPR with regard to the processing of 'data concerning health'.

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10 Infringement procedures

Hungary failing to comply with EU rules on freedom of establishment for reproduction services

The European Commission sent a letter of formal notice to Hungary regarding restrictions on medically assisted reproduction services to State-owned or State controlled providers only. This measure violates article 49 of the Treaty on the Functioning of the European Union (TFEU) concerning the freedom of establishment.

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France failing to comply with EU rules on freedom of movement for veterinary companies and veterinarians

The European Commission sent a letter of formal notice to France regarding its national rules concerning veterinary companies and veterinarians. These requirements are found to breach the EU rules on freedom of establishment and free provision of services set out in the TFEU and in the Services Directive.

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Czechia and Greece failing to correctly transpose EU rules on proportionality of professional regulations

The European Commission referred Czechia and Greece to the Court of Justice of the EU for their failure to ensure the correct transposition of the 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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Greece and Romania failing to correctly apply EU rules on late payments in the health sector

The European Commission sent a letter of formal notice to Romania and referred Greece to the Court of Justice of the EU for not correctly applying Directive 2011/7/EU. In the case of Romania, the public health authorities are found to be paying independent pharmacies with an excessive delay for medicines dispensed to patients through the national health insurance system. In Greece, the Commission wishes to address the incorrect payment practices of public hospitals towards their suppliers.

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Three Member States failing to comply with the public procurement legislation

The European Commission sent a letter of formal notice to Bulgaria, Romania, and Spain for failing to comply with EU rules covering public contracts and concession contracts. In the case of Bulgaria, the letter notably addresses the exclusion of private hospitals from EU public procurement rules, even when these hospitals are partly financed through public funds.

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Eleven Member States failing to fully transpose EU rules regarding the exposure to carcinogens, mutagens and reprotoxic substances at work

The European Commission sent a letter of formal notice to eleven Member States that have yet to fully transpose Directive (EU) 2022/431 into national law and notify their measures to the Commission. The Directive aims to broaden the protection of workers, including health care workers exposed to carcinogens, mutagens and reprotoxic substances contained in certain hazardous medicinal products.

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Three Member States failing to transpose EU rules regarding the use of hazardous substances in electrical and electronic equipment

The European Commission sent a letter of formal notice to Belgium, Malta, and Slovakia for failing to transpose Directives (EU) 2023/1526 and (EU) 2023/1437 into their national legislation. The two directives set out exceptions allowing the use of lead in in vitro diagnostic medical devices and of mercury in rheometers respectively.

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Ireland failing to correctly transpose EU legislation on industrial emissions

The European Commission sent a reasoned opinion to Ireland for failing to address shortcomings in the transposition of Directive 2010/75/EU. The Directive lays down rules designed to prevent and reduce harmful industrial emissions into air, water, and land, as well as to prevent the generation of waste, including in the production of pharmaceutical products.

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Eighteen Member States failing to comply with the EU Data Governance Act

The European Commission sent a letter of formal notice to 18 Member States, including Belgium, which have not designated the authorities responsible for implementing Regulation (EU) 2022/868, or which have failed to prove that the latter are empowered to perform the tasks required by the Regulation. These authorities are in charge of the registration of data altruism organisations, and of monitoring the compliance of data intermediation service providers. Data altruism allows citizens to give their consent to use their data for the common good, for example for medical research projects.

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11 **Miscellaneous**

Evidence and recommendations on managing climate risks in the health sector

The European Commission has published a Communication on managing climate risks in Europe, which sets out how the EU and its Member States can better anticipate, understand, and address growing climate risks. Specific suggestions for action are put forward, including for the health sector.

The Communication is a response to the first ever European Climate Risk Assessment published by the European Environment Agency (EEA). This scientific report provides evidence to support strategic policymaking. It examines major climate risks and policy priorities, including for the health sector.

Another report by the EEA specifically addresses the impact of floods, droughts, and water quality on human health and health care systems. It urges accelerated action to better prepare the health sector to deal with climate-related problems in the future. This includes adapting health care infrastructure and building the health workforce capacity to anticipate, recognise and deal with the consequences of climate change.

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Calls for action to preserve the right for everyone to access health care

The European Parliament adopted a new Resolution urging the Council to enshrine, in the EU Charter of Fundamental Rights, the right for everyone to free, informed, full and universal access to sexual and reproductive health and rights, and to all related health care services without discrimination, including access to safe and legal abortion. It also urges Member States to fully decriminalise abortion.

At the high-level conference organised by the Belgian Presidency of the Council of the EU to mark the International Day against Homophobia, Biphobia, Transphobia and Intersexophobia, 18 Member States signed a declaration in which they commit to advancing the rights of LGBTIQ persons in Europe. This involves ensuring them equal access to health care services, taking into account their specific needs.

The declaration draws on the report presented by the European Union Agency for Fundamental Rights on progress made since 2019 and remaining challenges in relation to the rights of LGBTIQ persons, including the right to access health care.

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Proposals to improve working conditions for all trainees

The European Commission proposed a directive, as well as revision of the 2014 Council Recommendation on a Quality framework for traineeships, with the aim to improve working conditions for trainees – including, for example, by ensuring fair pay and access to social protection – and to

prevent employment relationships disguised as internships. The revision extends the scope of the quality framework to also cover traineeships that are part of formal education and training curricula and those required for accessing specific professions such as medicine.

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Agreement on the revised International Health Regulations

A package of amendments improving the International Health Regulations was agreed by the World Health Assembly, which brings together over 190 countries, including all EU Member States. The aim is to strengthen global preparedness, surveillance and responses to public health emergencies. Commitments were also made to complete the negotiations on a global pandemic agreement within a year.

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12 Publications

Policy brief on making the digital transition in health more inclusive

The Belgian National Intermutualistic College (NIC) presented a policy brief on how European citizens' rights can be safeguarded in a digital health system. It provides an overview of challenges across Europe and makes recommendations to the EU and its Member States, to actors in the health system and to citizens. The topic of digital health literacy was addressed during an event organised by the NIC under the auspices of the Belgian presidency of the Council of the EU, in cooperation with the National Institute for Health and Disability Insurance (NIHDI).

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Position paper on the health and care workforce crisis

The European Public Health Alliance (EPHA) published its position paper on health and care workforce challenges and ways forward to address them. The paper tackles the issues of shortages, difficult working conditions, growing skills needs and cross-cutting problems such as the lack of long-term planning. It focuses on solutions to be found with a cross-sectoral approach, stronger political governance, and improved funding. Recommendations are made to the EU institutions, Member States, and key stakeholders in the sector.

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Working paper on the use of private health insurance in the context of intra-EU mobility

HIVA - Research Institute for Work and Society (KU Leuven) published a paper exploring the extent to which private health insurance is needed and used by mobile EU citizens. The results are intended to stimulate debate and research on a topic that has received little attention from legal experts to date, and to prompt policymakers to take action to fill some of the gaps identified in transnational social protection.

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Article on how to strengthen the European Semester to achieve economies of wellbeing

EuroHealthNet published an article in the 'International Journal of Environmental Research and Public Health' which sets out what a wellbeing economy means and how it can be achieved in the context of the EU and the European Semester process. The article shows how, despite progress, the continuing emphasis on economic aspects, over other policy areas, contrasts with what could be considered a 'wellbeing strategy'. It sets out recommendations for reform and progress towards an overarching EU-level strategy that places everyone's health and wellbeing at its centre.

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2024 Europe report on health and climate change

The report published by Lancet Countdown tracks 42 indicators highlighting the negative impacts of climate change on human health, the delayed climate action of European countries, and the missed opportunities to protect or improve health with health-responsive climate action. New indicators have been added, covering also health care emissions.

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Handbook on testing the resilience of health systems

The Organisation for Economic Co-operation and Development (OECD) and the European Observatory on Health Systems and Policies has developed a comprehensive methodology to assess and enhance the resilience of national health systems. This work was supported by the European Commission and is designed to enable Member States to improve their preparedness for future crises and emerging structural challenges.

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