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1 Public health

An advisory committee on public health emergencies has been set up

An independent committee was set up by the European Commission as part of the regulation on serious cross-border health threats. It will help the Commission and the Member States to formally identify public health emergencies. It will also provide advice on the measures to be taken. It will be made up of 51 experts from 16 different economic sectors and is due to start work in spring 2024.

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New Joint Action on non-communicable diseases

A new Joint Action called JACARDI, funded by the EU4Health programme, focuses on cardiovascular diseases and diabetes. It aims to reduce the burden of these two non-communicable diseases through the implementation of pilot projects across 21 Member States of the European Union. The projects cover the entire patient journey and address transversal aspects, such as equity and data availability.

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Conclusions support actions for a comprehensive approach to mental health

Drawing on the European Commission's communication published in June 2023 on mental health, the Council of the EU invited Member States to elaborate action plans or strategies with a cross-sectoral approach. Actions should aim to ensure access to timely, effective, and safe mental health care, but also to involve a wide spectrum of areas, including managing psychosocial risks at work, with special attention to health professionals.

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The European Union was urged to step up closer cooperation on rare diseases

During a conference on rare diseases held in October 2023 under the auspices of the Spanish Presidency of the Council of the EU, the European Economic and Social Committee urged the EU to launch a European action plan that further strengthens the cooperation between national health systems to fight rare diseases and give patients access to the best care wherever it is available in Europe.

For its part, the European Commission confirmed its commitment to support European patients and families affected by rare diseases. The upcoming Joint Action on integration of the European Reference Networks (ERN) into national health systems (JARDIN) will notably pave the way for ERN integration and sustainability.

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2 Medicines and medical devices

Initiatives taken to address shortages of medicines in the EU

The European Commission announced a series of actions to better prevent and mitigate critical medicine shortages in the EU. In the short term these include, for example, a European voluntary solidarity mechanism for medicines, a Union list of critical medicines, and the possibility for Member States to use regulatory flexibilities. In the mid- and long-term, a Critical Medicines Alliance will contribute to coordinate action at EU level and to address supply chain vulnerabilities.

Further details of the European voluntary solidarity mechanism were published by the European Medicines Agency (EMA), together with a toolkit of the Medicines Shortages Steering Group that lists a series of recommendations on tackling shortages of medicinal products.

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An Observatory on Patents and Technology opened its doors

The Observatory was created by the European Patent Office with the aim to provide up-to-date information on innovation and the role of patents in emerging technologies. The platform will initially focus on ten topics, including patents in the health sector. The two current outputs expected in this area are a study on innovation in the fight against cancer and an Espacenet platform that identifies the patents in this field.

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Strategic initiative carried out on EMA's policy regarding the publication of clinical trial data

The Ombudsman carried out a strategic initiative to seek more information about how the European Medicines Agency (EMA) will manage the gradual relaunch of its policy of proactively publishing clinical trial data for medicinal products submitted in the context of application for market authorisation in Europe.

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Cooperation with Japan strengthened on medical countermeasures

The Commission's Health Emergency and Preparedness Response Authority (HERA) and the Japan Agency for Medical Research and Development strengthened their cooperation on medical countermeasures to step up prevention, preparedness and response to serious cross border health threats.

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Provisional agreement reached on the European Medicines Agency's fees

The Council of the EU and the European Parliament reached a provisional agreement on a regulation aiming to modernise and simplify the structure of fees payable to the European Medicines Agency. Changes were introduced in the text proposed by the Commission in order to better reflect all associated costs and improve transparency on the amounts paid to the national authorities.

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Progress made and actions needed to address antimicrobial resistance

The European Centre for Disease Prevention and Control (ECDC) has monitored progress made towards the five targets to be reached by 2030, that were set by the Council recommendations adopted in June 2023, to combat antimicrobial resistance. Despite some progress, stronger interventions are still needed.

Several priorities for action were also highlighted by the Organisation for Economic Co-operation and Development (OECD) in its review of the policies implemented across the European Union / European Economic Area countries in this field.

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Concerns raised about EU rules on medical devices and in vitro diagnostics

France, supported by nine other Member States including Belgium, shared its concerns about the implementation of the regulations on medical devices and in vitro diagnostics. These notably relate to the risk of supply disruptions and to the lack of preparation of the system.

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Two studies explored the issue of access to medicines

A study requested by the European Parliament's Committee on Legal Affairs (JURI) explores the consequences of the European Commission's proposals that introduce a unitary supplementary protection certificate (SPC) and a centralised assessment procedure for granting SPCs for medicinal products. The study notably analyses the potential impact on access to medicines, as well as the administrative burden to applicants and the cost to national health systems.

Another study by the Panel for the Future of Science and Technology analyses the impact of different research and development incentive mechanisms and alternative frameworks for pharmaceutical innovation and public health. It places specific emphasis on their effects on innovation and patient access to medicines, in terms of both affordability and availability. A range of policy options are provided.

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The first electronic product information for human medicines harmonised across the EU

A one-year initiative by the Heads of Medicines Agencies (HMA), the European Medicines Agency (EMA), and the European Commission is dedicated to the creation and testing of electronic product information (ePI) for selected human medicines in real regulatory procedures. The information is published for medicines evaluated by EMA or by national authorities in Denmark, the Netherlands, Spain and Sweden.

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3 e-Health

First report published on the State of the Digital Decade

The report by the European Commission provides a comprehensive assessment of the EU's performance towards the digital targets set for 2030. It includes horizontal recommendations and country-specific recommendations. One of the targets is that all EU citizens have access to their electronic medical records.

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Provisional agreement reached on the Interoperable Europe Act

The Council of the EU and the European Parliament have laid down measures for improving public sector interoperability across the EU. Changes to the Commission's proposal were introduced to clarify the scope of the legislation as well as the objectives and conditions of the assessment required when investing in network and information systems. This act will apply to digital public services with trans-European relevance, including access to social security and health data such as pandemic and vaccination certifications.

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Provisional agreement reached on the EU-wide digital wallet

The Council of the EU and the European Parliament agreed on a new framework for a European digital identity. This will ensure universal access to secure and trustworthy electronic identification and authentication. It will be used to access digital services, including within the health sector. Ongoing pilot projects are testing the wallet in real-life scenarios such as claiming medical prescriptions and accessing social security benefits.

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Report explores the impact of digitalisation on the rights of older persons

The European Union Agency for Fundamental Rights (FRA) mapped the current legislation, policies and practices fostering digital inclusion and equal access to public services, both online and offline, for older persons. The information covers all EU Member States and the candidate countries of North Macedonia and Serbia. The issue of access to health-related services is also addressed.

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4 Internal market

Targeted amendment proposed for the Professional Qualifications Directive

The European Commission wants to facilitate the recognition process for nurses responsible for general care who have completed the upgrading programme that Romania set up for nurses whose qualifications did not meet the minimum training requirements upon the country's accession to the EU. Namely, the Commission proposes that these nurses should benefit from recognition under special acquired rights without the need to prove professional experience. The Commission's proposal is now being debated by the European Parliament and the Council of the EU.

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Revisions proposed for the Late Payment Directive

The proposal of the European Commission aims to address the shortcomings of Directive 2011/7/EU on combating late payments in commercial transactions. The revisions include stricter payment periods, which are limited to a maximum of 30 days. The exceptions for a maximum payment period of 60 days for health care and public authorities carrying out economic activities are removed.

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New online platform facilitates Member States' notification obligations

The Single Notification Window launched by the European Commission will provide a single-entry point for EU countries' notification obligations that are relevant for the single market. These are related to various areas and sub-areas, including for example, medical products, services and professions, or social security coordination.

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5 Social policy

Conclusions approved on digitalisation in social security coordination

The Council of the EU invited Member States and the European Commission to further work in the field of digitalisation in social security coordination to facilitate the exercise of social security rights in the EU and alleviate administrative burden.

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Conclusions linked mental health and employment conditions

The Council of the EU called upon Member States, the European Commission and the social partners to take various actions to address the impact of precarious work on mental health. Health professionals are among the worker groups to be paid particular attention.

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Conclusions focused on the social protection for the self-employed

The Council of the EU called on the European Commission and the Member States to take actions to ensure and improve the social protection coverage of self-employed workers across Europe, with a focus on unemployment and sickness benefits.

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Resolutions and evidence published on the European Child Guarantee

The European Child Guarantee aims to ensure that all children have access to key services, including health care. Two years after its adoption, the European Parliament adopted a resolution urging all Member States to adopt their Child Guarantee national actions plans and to effectively implement them. In a second resolution, the Parliament also called for reduced inequalities and greater social inclusion for children and their families. This requires ensuring universal access to high-quality services, including health care.

The European Social Policy Analysis Network (ESPAN) examined the extent to which the six services targeted by the Child Guarantee are readily available, accessible as well as free or affordable to children in low-income households across the EU. The report draws on national reports and is intended to help the European Commission set a baseline for monitoring the implementation of the Child Guarantee.

Trends and disparities in accessing the services covered by the Child Guarantee were also analysed by Eurofound, with a focus on differences between urban and rural areas as well as between different socio-economic status.

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Debate kicked-off on social investment

The Council of the EU endorsed the opinion of the Employment Committee and the Social Protection Committee on the added value of social investment and the role of the Employment, Social Policy, Health and Consumer Affairs (EPSCO) Council in the governance of the European Semester.

To support the debate on this issue, the Spanish Presidency and the upcoming Belgian Presidency of the Council of the EU launched an Informal Working Group on Social Investment (IWGSI). This has notably worked on empirical evidence regarding the micro and macroeconomic returns on social investment, and on methodologies for monitoring and evaluating those returns. Social investments include health and long-term care.

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Country focus strengthened in this year's Joint Employment Report

In its proposal for a Joint Employment Report, the European Commission maintains a strong focus on the implementation of the European Pillar of Social Rights. Country-specific challenges are particularly analysed based on the Social Scoreboard headline indicators. These also monitor self-reported unmet needs for medical care. In this area, Member States are invited to invest in the capacity of the health care system to reduce out-of-pocket payments and improve health care coverage, as well as to promote the upskilling and reskilling of health workers.

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6 Economic policy

Priorities set out for the 2024 European Semester cycle

The European Commission published the Autumn package of the European Semester, thus launching the 2024 cycle of socio-economic policy coordination.

In this framework, the Annual Sustainable Development Growth Survey puts forward the policy agenda to enhance the EU's sustainable competitiveness. Tackling labour and skill shortages within the health care sector and ensuring adequate and sustainable social protection are addressed under the "fairness" priority.

The Commission also assessed the consistency of the draft budgetary plans for 2024 with the fiscal county-specific recommendations from July 2023. For some Member States, these included the sustainability of the health care sector.

In the recommendation proposed for the euro area economic policy, the Commission encouraged Member States to adopt coordinated and prudent fiscal policies. These include, where needed, measures to improve the sustainability and adequacy of the health care system. Particular focus is placed upon the synergies between the Recovery and Resilience Facility and the Cohesion Policy programmes. These funding instruments support investment in and reform of the health care sector.

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Health priorities linked to the EU's open strategic autonomy

The European Commission reiterated its priority to build the EU's open strategic autonomy. Actions taken towards a more resilient, competitive, and sustainable Europe include those aimed at enhancing the security of medicines supply and ensuring their availability across Europe.

The Spanish Presidency of the Council of the EU published a non-paper on how to strengthen EU long-term resilience. Several concrete strategic vulnerabilities are identified, together with nine lines of actions to tackle them in a systemic and realistic way. Health is one of the four critical sectors the non-paper focuses on.

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Risk assessments recommended for four critical technology areas

Drawing on the joint communication on the European economic security strategy of June 2023, the European Commission elaborated a list of ten critical technology areas to be assessed in terms of technology security and technology leakage. Member States are invited to start by assessing the following four critical technology areas: advanced semiconductors, artificial intelligence, quantum, and biotechnologies.

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7 EU funding

EU Invest programme supports the development of medical products in three Member States

The European Investment Bank signed agreements with private partners to support the following projects: the development and commercialisation of new medical technology and devices for reducing cross-infection risks for patients in France; the development and commercialisation of a cutting-edge cancer detection technology in Poland; and the creation of advanced pharmaceutical manufacturing capacity in Romania.

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Principles and request set out for the future of the Cohesion policy

Conclusions approved by the Council of the EU define guiding principles for the future development of cohesion policy. They will serve as a basis for the Commission's work on the legislative framework for cohesion policy after 2027. One of the goals of Cohesion policy is to support improvement to citizens' quality of life, such as by financing investment and reform in the health care sector.

The opinion adopted by the European Committee of the Regions (CoR) put forward a series of requests on how to make Cohesion policy more flexible, robust and for all territories. Among other things, the CoR calls for macroeconomic conditionality to be abolished after 2027, as well as excluding the investments in Cohesion Policy co-funded projects from spending calculations within EU fiscal rules.

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8 Competition

New platform supports Important Projects of Common European Interest

The European Commission launched a Joint European Forum for Important Projects of Common European Interest with the aim of increasing the effectiveness of these projects and identifying relevant strategic technologies for the EU economy. These projects enable Member States to pool resources and cooperate to support innovations and large-scale infrastructure projects in key sectors, including health.

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Pharma companies fined in antitrust cartel settlement

The European Commission found six companies to have participated in a cartel involving an important pharmaceutical ingredient used to produce the abdominal antispasmodic drug Buscopan and its generic versions. This is the first time that the Commission sanctions a cartel in the pharmaceutical sector.

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Danish scheme approved to support pharmaceutical wholesalers

The scheme was approved by the European Commission under the State aid Temporary Crisis and Transition Framework. It supports pharmaceutical wholesalers supplying Danish pharmacies that are affected by Russia's war against Ukraine.

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Series of acquisitions approved by the European Commission

The first is the acquisition of sole control of Chacrim Directorship of Spain by Apax Partners and Fremman Partners, both of the UK. The transaction relates primarily to the sector of medical supplies' distribution in Spain, Italy, and Portugal.

The second is the acquisition of sole control of Oticon Medical's cochlear implant business of Denmark by Cochlear Limited of Australia. The transaction relates to the hearing care sector, in particular to the market for cochlear implants.

The third is the acquisition of Seagen by Pfizer and is related to the production of oncology therapies.

The fourth is the acquisition of joint control of Everise of Canada by Warburg of the US and Brookfield of Canada. The transaction relates primarily to the sector of business process outsourcing in the health care and insurance fields.

The last acquisition is that of SYNLAB of Germany by Cinven of Guernsey and relates primarily to the sector of human medicines, in particular the provision of medical diagnostic services.

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9 Court of Justice of the European Union

Judgement on jurisdiction related to VAT exemption for medical and paramedical services

Case C-355/22 relates to proceedings between an osteopathy company and the Belgian state concerning a report and a collection and recovery notice for value added tax (VAT) due for the period from 2013 to 2019, a fine and interest. The Court ruled that a national court may not make use of a national provision empowering it to maintain certain effects of national provisions which it has found to be incompatible with Council Directive 2006/112/EC on the common system of VAT.

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Judgement dismisses action brought against the Commission by two pharmaceutical companies

In case T-74/21, Teva Pharmaceutical Industries Ltd and Cephalon Inc. sought annulment of a decision taken by the European Commission in 2020. The latter imposed a fine on the two companies for agreeing to delay the market entry of a generic version of Cephalon's drug for sleep disorders, modafinil, after Cephalon's main patent had expired. The General Court fully upheld the Commission's assessment and decision and dismissed the action.

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Opinion upholds the action for annulment brought against the Commission by Debregeas et associés Pharma

In case C-291/22P, Debregeas et associés Pharma sought the annulment of a judgement by the General Court of 2022 upholding the European Commission decision to refuse the marketing authorisation for Hopveus - sodium oxybate, a medicinal product for human use intended to combat dependence on alcohol. The Advocate General now proposes to set aside the judgment. In doing so, he clarifies the discretion available to the European Medicines Agency to convene scientific advisory groups or ad hoc groups of experts during the procedure for re-examining an application for marketing authorisation. He also discusses the conditions of objective impartiality applicable to the members of groups involved in this procedure.

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Judgement on the processing of personal data contained in EU Digital COVID Certificates

In case C-659/22, the Court ruled that the concept of 'processing' personal data referred to in the General Data Protection Regulation (Regulation (EU) 2016/679) must be interpreted as including the verification - using a national mobile application - of the validity of interoperable COVID-19 vaccination, test, and recovery certificates, used by a Member State for national purposes in the context of the COVID-19 pandemic.

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Judgment regarding the right to obtain a first copy of one's medical records

Case C-307/22 concerns the interpretation of the General Data Protection Regulation (GDPR) in the case of personal data contained in a medical file. According to the Court, a patient has the right to receive a first copy of his or her medical records free of charge, including for purposes unrelated to data protection. This right entails the right to obtain a full copy of the documents included in the medical records.

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10 Infringement procedures

Two Member States fail to comply with EU rules on professional qualifications

The European Commission sent a letter of formal notice to Ireland and an additional reasoned opinion to Slovakia for imposing excessive restrictions on linguistic controls for health care professionals. This fails to comply with the Directive 2005/36/EC on the recognition of professional qualifications, which aims to facilitate the professional mobility and recognition of qualifications across the borders within the EU.

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Nine Member States fail to comply with EU legislation on proportionality test

The European Commission sent a letter of formal notice to Belgium and a reasoned opinion to Bulgaria, Czechia, Greece, Croatia, Cyprus, Hungary, the Netherlands, and Slovakia for not having correctly transposed the EU Directive 2018/958. This requires that any new or amended national rules affecting professionals 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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Denmark fails to correctly transpose EU rules on radiation protection

The European Commission sent a letter of formal notice to Denmark for failing to correctly transpose the Council Directive 2013/59/Euratom. This lays down basic safety standards for protection of workers, patients and the public against the danger arising from exposure to ionising radiation.

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Greece fails to comply with EU rules on late payments

The European Commission referred Greece to the Court of Justice of the European Union due to excessive payment delays by public hospitals to their suppliers. This breaches the Directive 2011/7/EU, which fights against late payments in commercial transactions. The Commission also sent a reasoned opinion to Greece due to waivers signed by hospital contractors, agreeing to waive their rights under the directive against promises of immediate payments.

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11 Miscellaneous

Comprehensive approach to mental health supported for young people

The Council of the EU approved conclusions on a comprehensive approach to the mental health of young people in the EU. Member States are invited to promote cross-sectoral preventive measures improving the living and working conditions of young people, as well as to promote affordable access to mental health care services, and to raise awareness and destigmatise mental health issues.

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Temporary protection extended for Ukrainian refugees

The Council of the EU agreed to extend, to March 2025, the temporary protection for people fleeing from Russia's war of aggression against Ukraine that was activated in March 2022. This allows displaced persons to enjoy harmonised rights, including medical assistance, across Europe.

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Call reiterated to amend the EU Treaties

In line with the proposals of the Conference on the Future of Europe, the European Parliament adopted a resolution with a series of reforms aimed at enhancing the effectiveness and democracy of the EU. Part of these reforms are intended to strengthen EU powers in several areas currently within the Member States' exclusive remit, including public health.

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New skills partnership launched for the European health industry

The large-scale partnership supported by the European Commission brings together all stakeholders in the health care sector to increase training in this field. It focuses on the industrial aspects of health care by covering the manufacturing of pharmaceuticals, medical devices, and personal protective equipment. It complements the existing partnerships on the health ecosystem and long-term care.

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Measures proposed to attract and retain talent from outside EU

The European Commission proposed a series of new initiatives with the aim of attracting talent from outside the EU and thus help address critical labour shortages. The EU Talent Pool aims to facilitate the recruitment of jobseekers from non-EU countries by employers in the EU. Other measures are intended to promote the recognition of qualifications gained in third countries as well as to boost learner's mobility in all areas of education and training. Health care and long-term care are among the sectors that are most affected by labour shortages.

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Five EU agencies jointly committed to a One Health approach

The European Centre for Disease Prevention and Control (ECDC), European Chemicals Agency (ECHA), European Environment Agency (EEA), European Food Safety Authority (EFSA) and European Medicines Agency (EMA) published a joint statement expressing their commitment to fully support the One Health agenda in Europe. The benefits of this approach are recognised in several areas, including zoonotic and (re-)emerging infectious diseases and antimicrobial resistance.

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International declaration on climate and health endorsed

The declaration was officially endorsed by the Commission, on behalf of the EU, during the climate-health ministerial held in the context of the United Nations Climate Change Conference (COP28) in Dubai. Ministers discussed ways to address the burden of climate change on health and health systems, both through policy and investment.

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12 Publications

Best practices and recommendations to link health and environment

A paper published by the European Policy Centre calls for implementing a planetary health approach across all levels of governance to encourage transdisciplinary action. EU initiatives in this field are reviewed and ten recommendations are put forward. These include measures for health systems to be at the fore of planetary health promotion.

The European Representation of the German Social Insurance (DSV) dedicated the second issue of its ed* Magazine to the changes that climate change, together with digitalisation, are bringing in social security. EU and Member States initiatives in this area are analysed, with a focus on how social and health care systems can contribute to mitigate the effects of climate change.

The International Association of Mutual Benefit Societies (AIM) contributed to this debate by gathering recommendations based on the latest evidence on how to move towards climate-resilient health care and social protection systems at EU level.

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Evidence and recommendations related to working conditions in health and long-term care

A policy brief published by Eurofound examines the job quality of the workers who maintained access to health care, long-term care and other essential goods and services during the COVID-19 pandemic. It highlights imminent challenges to the sustainability of their work.

A report published by the Organisation for Economic Co-operation and Development (OECD) focuses more particularly on long-term care workers. It presents in-depth cross-country analysis and describes what measures can be taken to improve wages and working conditions for long-term care workers.

The Standing Committee of European Doctors (CPME) has published recommendations to enhance the well-being of doctors across Europe, with the aim of improving patient care, professional excellence, and overall job satisfaction.

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Study focused on innovation and access to effective antibiotics

The policy brief published by the European Observatory on Health Systems and Policies maps the challenges faced in securing access to new and pre-existing antibiotics and considers what policy options exist for action at the EU level.

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Two publications reflect upon the European Health Union

A paper published by the European Policy Centre assesses the initiatives undertaken by the European Health Union, identifies challenges and shortcomings, and outlines nine recommendations to address them.

A book published by the Foundation for European Progressive Studies (FEPS) and the European Institute of Health and Sustainable Development (EIHSD) is a compilation of essays that explore the origins and legal background of the concept of a European Health Union, analyse the main avenues for pan-European cooperation for health and describe future scenarios of European health policy development.

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Documents released for the 2023 European Health Forum Gastein

On the occasion of this year's forum, the European Observatory on Health Systems and Policies dedicated a special issue of its journal Eurohealth to how crises can help catalyse the development of new approaches to health system problems.

A public debate was also launched on EU health priorities to inform the mission of the next Commissioner for health ahead of the European elections in 2024. Nine briefing papers were published to frame the discussion on topics such as health security, health and care workforce, and universal health coverage.

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