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Provisional agreement on the revision of EU rules on substances of human origin

The European Parliament and the Council of the EU struck a provisional agreement on the proposal tabled by the European Commission in July 2022 aiming to update and expand EU legislation on the safety and quality of substances of human origin (SoHO), such as blood, tissues, and cells. Negotiations particularly revolved around the incentives possibly due to donors. According to the agreement reached, donations of SoHO should be voluntary and unpaid as a matter of principle, but compensation or reimbursement can be provided as appropriate in line with national legislation.

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New report and recommendation on cancer prevention and care

The report prepared by the European Commission, in collaboration with the Organisation for Economic Co-operation and Development (OECD), examines policies and actions to tackle inequalities in cancer care across the EU Member States, Norway, and Iceland. The focus is placed on addressing preventable risk factors, improving screening and early diagnosis, and ensuring the sustainability of high-quality cancer care systems.

The European Commission also published a recommendation to support Member States in their efforts to prevent cancer through vaccination. It notably includes a series of measures to improve the uptake of vaccinations against Human papillomavirus (HPV) and the Hepatitis B virus (HBV).

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Two new joint actions launched on AMR and NCDs

The first joint action launched by the European Commission, JAMRAI-II, focuses on antimicrobial resistance (AMR) and healthcare-associated infections. The second joint action, PreventNCD, focuses on prevention of cancer and other non-communicable diseases (NCDs), such as cardiovascular diseases, diabetes and mental health. Both actions are funded under the EU4Health programme.

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Resolution sets recommendations to combat non-communicable diseases

The European Parliament called on the European Commission and the Member States to step up their fight against non-communicable diseases. Specific recommendations were made on improving prevention, early diagnosis, and health care; on accelerating the development of effective, accessible, and affordable technology and medicines; and on sharing knowledge and cooperating more closely.

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Resolution makes recommendations on prioritising mental health

The European Parliament called on the European Commission to draw up a long-term, comprehensive, and integrated EU Mental Health Strategy, building on its communication of June 2023. It also called on the Member States to develop corresponding national strategies. Specific recommendations were made on addressing mental health determinants, strengthening mental health systems, promoting non-discrimination and integration, as well as in relation to EU support in this area.

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The 2021-2027 ECDC Strategy reviewed to reflect its strengthened mandate

The European Centre for Disease Prevention and Control (ECDC) presented its multi-annual programming for 2024-2026 and its 2024 work programme. These reflect the expectations set in the amended ECDC Founding Regulation of October 2022, which strengthened the ECDC's role in supporting the European Commission and the Member States in emergency preparedness and response. For 2024, priority will notably be given to digitalisation of the EU and national surveillance system and to the enhancing of strategic partnerships.

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Call to enhance training of health care professionals in pandemic preparation

The HERA Civil Society Forum of the European Commission's Health Emergency Preparedness and Response Authority (HERA) adopted a discussion paper on the importance of training health care professionals in health emergency preparedness. The paper outlines key challenges and proposes recommendations on the role that HERA can play to support work in this area.

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New reports highlight the performance and resilience of EU health systems

The European Commission published the State of Health Preparedness Report 2023, which maps EU actions taken since the COVID-19 pandemic to address cross-border health threats.

A set of 29 Country Health Profiles were also published as part of the State of Health in the European Union (EU) cycle, a joint project of the European Commission, the Organisation for Economic Co-operation and Development (OECD) and the European Observatory on Health Systems and Policies. They cover the latest health policy challenges and developments in all EU Member States, Iceland, and Norway.

A companion synthesis report underlines cross-cutting observations and highlights three areas in which more work is needed: mental health; health inequalities and unmet medical needs; and data collection and investment to prepare for future crises.

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2 Medicines and medical devices

Two initiatives launched on critical medicines

The first Union list of critical medicines was published by the European Commission, together with the European Medicines Agency (EMA) and the Member States' Heads of Medicines Agencies (HMA). It contains more than 200 human medicines and will be reviewed annually.

An open call for expressions of interest to join the Critical Medicines Alliance was also launched by the Health Emergency Preparedness and Response Authority (HERA). This multi-stakeholder network will develop recommendations and provide advice to the Commission, Member States, and other EU decision makers on how to address long-standing medicines shortages.

Both initiatives follow the Commission's Communication of October 2023 on addressing medicines shortages in the EU.

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Key updates and implementation of EU rules on medical devices

The European Commission proposed amendments to the EU regulations on medical devices and on in vitro diagnostic medical devices, with the aim to prevent shortages and enhance transparency. Manufacturers will have more time to apply the new rules, under certain conditions; they are required to flag potential shortages, and to provide information about their products via the European database on medical devices. The Council of the EU has already endorsed the proposal, and a positive vote in the European Parliament is expected without amendments in April 2024.

The European Commission also adopted an implementing act in the field of in vitro diagnostic medical devices, which designates five EU reference laboratories to be involved in conformity assessment of high-risk devices and to carry out advisory tasks.

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Legislative proposals to reform the assessment of chemicals

The European Commission proposed two regulations and one directive to: streamline assessments of chemicals across EU legislation; strengthen the knowledge base on chemicals; and ensure early detection

and action on emerging chemical risks. The aim is to promote more consistent and transparent safety assessments of chemicals, including those used in medical devices.

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Provisional agreement reached to phase out the use of dental amalgam

The Council of the EU and the European Parliament struck a deal on the revision of the mercury regulation. The co-legislators maintained the Commission's proposed date for the total phase-out, 1 January 2025, but introduced an eighteen-month derogation for those countries that have not yet adjusted their reimbursement system, to avoid negative repercussions for low-income individuals. The ban on the manufacturing, import and export of dental amalgam is also scheduled.

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New rules to phase down fluorinated gases also apply to health care

The Council of the EU adopted two regulations on fluorinated greenhouse gases (F-gases) and on ozone-depleting substances, which aim to further reduce their emissions into the atmosphere and to contribute to limiting global temperature rises. The rules on F-gases also cover medical applications, such as inhalation anaesthetics and metered-dose inhalers (MDIs) used to treat asthma and chronic obstructive pulmonary disease.

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Provisional agreement reached on urban wastewater treatment involves costs for the pharmaceutical industry

The Council of the EU and the European Parliament agreed on new rules for the collection, treatment, and discharge of urban wastewater. The text proposed by the European Commission in October 2022 introduced the 'polluter pays principle' for pharmaceuticals and cosmetics. The co-legislators agreed that at least 80% of the costs of removing micro-pollutants from urban wastewater will be covered by producers and topped up by national financing.

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Workplan for the use of artificial intelligence in medicines regulation

The European Medicines Agency (EMA) and the Heads of Medicines Agencies (HMA) published an artificial intelligence workplan for up to 2028, which will help the European medicines regulatory network to use artificial intelligence in medicines regulation.

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Declaration signed on the strategic importance of quantum technology

Fourteen Member States recognised the importance of quantum technology for the scientific and industrial competitiveness of the European Union. They committed to collaborate with each other and with the European Commission on the development of a world-class quantum technology ecosystem across Europe, enabling its application in a wide range of sectors, including health care.

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3 e-Health

Provisional agreement on rules for artificial intelligence

The Council of the EU and the European Parliament struck a deal on the proposal on harmonised rules on artificial intelligence (AI). Regulation of AI is based on the latter's capacity to cause harm to society, following a risk-based approach. Specific requirements and obligations were set for high-risk AI systems used in sectors such as health care. Clarifications and new provisions were added in relation to the use of regulatory sandboxes and real-world testing to support innovation.

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New measures to support innovation in artificial intelligence

The European Commission launched a package of measures to support the development of trustworthy AI. Two of them target AI models and systems that can also be applied in health care. The proposal amending the Regulation on European High-Performance Computing aims to include the setting up of AI factories within its scope. The EU Start-Up and Innovation Communication sets out a strategic framework for investment in trustworthy AI.

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4 Internal market

Provisional agreement on a new crisis coordination framework

The Council of the EU and the European Parliament struck a provisional deal on the regulation for a single market emergency instrument (SMEI), which was renamed Internal Market Emergency and Resilience Act (IMERA). This is intended to anticipate, prepare for, and respond to the impact of future crises. Three alert levels with specific tasks and measures were established to ensure the free movement of crisis-relevant goods, services and persons, including, for example, masks and vaccines, doctors and nurses in case of a public health crisis.

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Mechanism proposed to resolve obstacles in cross-border contexts

The European Commission adopted an amended proposal for a Regulation on facilitating cross-border solutions. Its aim is to tackle obstacles that negatively impact citizens, business, and public administrations in Europe's cross-border regions. These are obstacles such as technical standards or national administrative and legal provisions, including in relation to health care services.

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Call for contributions on the recognition of health professional qualifications

The European Commission held a public consultation on its proposal for a delegated act amending the Professional Qualifications Directive by updating the minimum training requirements for nurses responsible for general care, dental practitioners, and pharmacists. Professionals from EU countries complying with these requirements can have their qualifications automatically recognised and practice their profession in another EU country.

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Position paper on the revision of the late payment directive

According to the German Social Insurance (DSV), the regulation proposed by the European Commission to repeal Directive 2011/17 on combating late payment in commercial transactions does not take into account the reality of business and accounting operations in the social insurance sector.

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5 Social policy

New monitoring framework for the European Child Guarantee

The European Commission, together with the Social Protection Committee's Indicators Sub-Group, prepared a framework to better monitor children's access to the key services covered by the European Child Guarantee, including health care. EU countries are encouraged to use this framework when drafting their progress reports, and the Commission will use it during the European Semester.

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Working paper on workforce relevant for the European Child Guarantee

Eurofound provided categories and definitions of workforce related to the key areas of the European Child Guarantee, including health care. It also mapped international data sources relevant to the workforce categories identified. The paper acknowledges the vital role that the workforce plays in delivering accessible and high-quality services.

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Ongoing work on the health care workforce

The Belgian Presidency of the Council of the EU is paying special attention to the multiple problems faced by the health care workforce. The issue is on the agenda of the conference about the future of the EU Health Union, which will be held on 26-27 March. The results are expected to inform the following ministerial debates and to pave the way for a future EU health workforce strategy.

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Tripartite declaration to strengthen social dialogue at EU level

The European Commission, the Belgian Presidency of the Council of the EU and European social partners gathered at the Val Duchesse Social Partners Summit, where they committed to join forces to address key challenges in the EU economy and labour market, including labour and skills shortages. This is also a key challenge for the health care sector.

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6 Economic policy

Provisional agreement on the reform of the EU economic governance

The Council of the EU and the European Parliament reached a political agreement on the proposed reform of the EU's economic governance framework. The agreement retained the reform's overall objective of reducing debt ratios and deficits, while supporting structural reforms and public investment to achieve priorities such as social and economic resilience. The monitoring of the implementation of the European Pillar of Social Rights and the assessment of the risks to social convergence were confirmed within the European Semester cycle. Principle 16 of the Pillar aims to ensure timely access to quality health care.

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Post-Programme Surveillance Reports published for five Member States

The European Commission published the Post-Programme Surveillance Reports for Cyprus, Greece, Ireland, Portugal, and Spain. These aim to assess the economic, fiscal, and financial situation of these Member States and to ensure they maintain their capacity to service their debt. The sustainability of health care and long-term care spending is also assessed.

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Communication setting out a European strategy for advanced materials

The European Commission outlined its strategy to ensure industrial leadership in advanced materials. These include new technologies that are highly relevant for the green and digital transition and can be used in several key sectors, including pharmaceuticals and health care. The strategy lays the groundwork for further action.

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Revision of the EU's long-term budget raises concerns about funding of health and social programmes

The Council of the EU adopted three legislative acts related to the revision of the EU multiannual financial framework 2021-2027, which amended the EU's long-term budget and established the Ukraine Facility and the Strategic Technologies for Europe Platform (STEP). Budgetary redeployments were made, resulting in cuts to the EU4Health programme and Cohesion funds, instruments that support health and social priorities.

The European Parliament expressed some regret at the various cuts and adopted a non-legislative resolution containing recommendations on this subject.

Concerns about the negative impact the cuts will have on EU health and social policies were also raised by civil society organisations, such as the EU4Health Civil Society Alliance and EuroHealthNet, together with the Social Platform.

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Funding to boost preparedness for chemical, biological, radiological, and nuclear emergencies

The European Commission allocated funds to Czechia, Finland, France, Lithuania, Poland, Portugal, and Romania to further develop the rescEU strategic reserves of medical and chemical, biological, radiological, and nuclear (CBRN) items. EU funds were also granted to Italy, Poland, and Romania to develop the rescEU detection capabilities.

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Two InvestEU projects support health care services and medicines innovation

A loan agreement was signed between the European Investment Bank and Vitalia under the InvestEU programme, to improve the availability of and access to social and health care services for the elderly in seven Spanish regions.

A second loan agreement supports the Danish biotechnology company Zealand Pharma A/S by financing its research and development pipeline of clinical-stage product candidates targeting obesity, rare diseases, and chronic inflammation.

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Funding to improve access to health care for Ukrainian refugees

The European Commission launched a project backed by €4 million from the EU4Health programme, to help improve access to health care for Ukrainian refugees and displaced persons benefitting from temporary protection in Bulgaria, Czechia, Estonia, Hungary, Latvia, Lithuania, Moldova, Poland, Romania, and Slovakia.

The Commission also made available over €65 million from the Asylum Migration and Integration Fund (AMIF) to support Bulgaria, Czechia, Poland, and Romania in hosting people fleeing the war in Ukraine. This additional funding can be used to help them with access to social and health services.

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Reports assess the Cohesion policy and the Recovery and Resilience Facility

The final report of the independent Group of High-Level Specialists on the Future of Cohesion Policy assesses the functioning of Cohesion policy and includes recommendations on how to ensure that the policy continues to promote prosperity and social and economic convergence across the EU. Disparities across the EU in access to health care services are among the challenges addressed by the Cohesion funds.

The European Commission presented the mid-term evaluation of the Recovery and Resilience Facility (RRF). It assesses progress made so far, identifies the key lessons learned, and points to some areas for improvement. Health is among the policy areas targeted by the RRF.

Eurofound reviewed the quality of the social partners' involvement in 2023 in the ongoing implementation of reforms and investment funded by the RFF. It also examined the quality of their involvement in the preparation of the 2023 national reform programmes as part of the European Semester. The report includes analyses of social partners' involvement in health-related reforms and investments.

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8 Competition

Report on competition enforcement in the pharmaceutical sector

The report was drafted by the European Commission in collaboration with the national competition authorities of the EU Member States. It provides an overview of the enforcement of EU antitrust and merger rules in the pharmaceutical sector during the period 2018-2022.

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New rules for services of general economic interest

The European Commission adopted a regulation amending the general rules for small amounts of aid for Services of General Economic Interest (SGEI), such as health care. The main changes include an increase in the ceiling per company and the obligation for Member States to register de minimis aid in a central register at national or EU level.

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Approval of a merger and acquisitions related to health care services

The European Commission approved the proposed merger between Novzymes and Christian Hansen. The proposal is conditional upon full compliance with the commitments offered by the parties. Chr. Hansen develops natural ingredient solutions for the pharmaceutical and other industries.

The European Commission also approved three acquisitions. The first is the acquisition of joint control of Agilio by Five Arrows, both from the UK, and TA Associates from the Cayman Islands. The transaction relates primarily to the development of software for the health care sector.

The second is the acquisition of Dedalus Healthcare Systems Group (Italy) by Ardian (France). The transaction relates primarily to the medical software sector.

The third is the acquisition of joint control of PLG (France) by Oakley Capital (UK) and 21 Invest Group (Italy). The transaction mainly concerns the provision of outsourcing services to pharmaceutical companies.

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9 Court of Justice of the European Union

Judgment on the online selling of non-prescription medicinal products

In case C-606/21, the Court of Justice concluded that a service provided on a website consisting in connecting pharmacists and customers for the sale, via the websites of pharmacies which have subscribed to that service, of medicinal products not subject to medical prescription falls within the concept of an 'information society service'. It also clarified the possibility for Member States to prohibit such a service.

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Opinion on the automatic recognition of medical qualifications

Case C-8/23 regards the interpretation of Directive 2005/36/EC on the recognition of professional qualifications. In its conclusion, the advocate general addresses the issue of the automatic recognition in the European Union of a diploma as a specialised doctor, and the allocation among the Member States of responsibility for the assessment of specialist medical training and for the control of access to that profession, where the basic medical training was completed outside the European Union.

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10 Infringement procedures

Three Member States failing to transpose the Industrial Emissions Directive

The European Commission sent a letter of formal notice to Estonia and Poland, as well as a reasoned opinion to Austria, for failing to correctly transpose certain provisions of the Industrial Emissions Directive. This Directive lays down rules on integrated prevention and control of pollution arising from industrial activities, including the production of pharmaceutical products.

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11 Miscellaneous

Conclusions on people suffering from both drug use and other mental health disorders

The Council of the EU invited Member States to consider drug use disorders that co-occur with other mental health disorders as an important challenge for drug and mental health services and policies, requiring a multidisciplinary and comprehensive response to the needs of people with these disorders. Particular attention should be paid to the availability and accessibility of adequate and effective treatment.

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Provisional agreement on the energy efficiency of buildings, including hospitals

The Council of the EU and the European Parliament reached a deal on the revision of the Energy Performance of Buildings Directive. The revision aims to help reduce energy consumption and greenhouse-gas emissions from the EU buildings sector by 2030 and make it climate neutral by 2050. Hospitals are among the building categories considered for the calculation of energy performance.

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Provisional agreement on combating violence against women

The Council of the EU and the European Parliament reached a deal on new rules to combat violence against women and domestic violence. The new legislation sets improved procedures for victims' safety and health, promoting immediate access to comprehensive and long-term medical care, including sexual and reproductive health care services.

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Call to further promote equality for LGBTIQ+ people

The European Parliament adopted a resolution on the implementation of the EU LGBTIQ+ Equality Strategy 2020-2025. The text highlights the discrimination that LGBTIQ+ people still face in accessing health care and social protection. Member States are urged to take measures to combat this discrimination and to expand coverage of health care services, including sexual and reproductive health and technologies.

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Evaluation and demands regarding EU-funded research programmes

The European Commission published the final report of Horizon 2020, the EU framework programme for research and innovation running from 2014 to 2020. This ex-post evaluation presents the scientific, societal, and economic impact of the programme, and identifies the areas for improvement. Health research notably contributed to emergency responses and innovation regarding rare diseases.

The European Research Council (ERC) published a statement recalling its achievements and calling on the EU to strengthen it in the next framework programme for research by supporting its funding and operating model. ERC-funded projects have addressed various societal challenges, including challenges related to health.

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12 Publications

Key health priorities analysed to mark the Belgian Presidency of the Council of the EU

A special issue of the EuroHealth journal was published to mark the 2024 Belgian Presidency of the Council of the EU. The aim is to feed into the policy debate during the Belgian Presidency and inspire reflection on the Commission's health agenda for the next five years (2024-2029). The papers address a selection of priorities including health system resilience, the health and care workforce, access to health care (see next item), needs-driven health care, and EU instruments such as technical support and the joint action mechanism.

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Analysis and recommendations on the affordability of health care in Europe

Experts from the European Social Observatory (OSE), the WHO Barcelona Office for Health Systems Financing, and the Belgian Health Care Knowledge Centre (KCE) highlighted gaps remaining in affordable access to health care, looked at how access to health care has been addressed through the EU's socio-economic governance and funding instruments, and suggested ways in which the EU can further support national progress towards universal health coverage.

Further evidence on the gaps remaining in affordable access to health care was published by the WHO Barcelona Office for Health Systems Financing in a new report covering 40 countries in Europe. The report also highlights aspects of coverage policy that undermine financial protection, and proposes a checklist for policymakers wanting to move closer to universal health coverage.

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Policy study on the European Pillar of Social Rights

The study analyses progress made in the implementation of the European Pillar of Social Rights, at both national and European levels. It underscores the importance of insights from social partners and civil society organisations, identifies key areas requiring intervention, including health care and social protection, and highlights new areas where reflection is necessary. The study was co-published by the Foundation for European Progressive Studies (FEPS), Social Platform, the Austrian Federal Chamber of Labour (AK), Solidar, and the European Policy Centre (EPC).

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Report on the state of children in the European Union

A report by UNICEF summarises findings on child wellbeing and progress for children in the European Union during the period of the current EU legislature, 2019-2024. Evidence on children's physical and mental health is provided, together with analyses of mental health services provision. Recommendations are formulated for the next political cycle.

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Civil society inputs for the next EU health policy

As we approach the European elections of June 2024, several papers and declarations from experts and civil society organisations have been published on health priorities to be pursued during the period 2024-2029. They include the following:

The European Policy Centre (CPE) analysed remaining challenges in the current EU health policy and proposed solutions to strengthen the supply of critical medicines in the EU.

The Standing Committee of European Doctors (CPME) pointed out five areas where the European Health Union can be further strengthened: the health workforce crisis; digitalisation of health care; determinants of health; accessibility and effectiveness of medicines; and climate change.

The manifesto published by the EU Health Coalition highlights the need for a robust and integrated strategy for EU health policy, building on a 'One health' approach. Recommendations include making health systems more integrated and people-centred; investing in upskilling the health workforce; reframing health care expenditure as an investment, not a cost; and supporting research and innovation.

The EU4Health Civil Society Alliance gathered a set of 10 priorities that focus on strengthening EU policymaking in public health, delivering stronger policies improving public health, and breaking policy silos.

The European Public Health Alliance (EPHA) put forward a series of recommendations to achieve the following five priorities: keeping health high on the political agenda; providing the means for an ambitious health policy; ensuring equal access to health and care; enhancing civil society participation in health policymaking; and securing a healthy planet for healthy people.

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Proposals for a European Health Union which is more than the sum of its parts

In a viewpoint published in The Lancet Regional Health - Europe, Martin McKee and Aniek de Ruijter discuss how national governments can take advantage of the opportunities provided by the European Health Union, and propose a path forward in terms of content and process.

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Analysis of the EU's economic governance prescriptions in health care

A paper in the Socio-Economic Review by Sabina Stan and Roland Erne assesses the new economic governance introduced by the EU after the 2008 financial crisis. It notably focuses on the policy orientation of the health care prescriptions addressed to Germany, Ireland, Italy, and Romania from 2009 to 2019. The analysis reveals that the various country-specific prescriptions followed an overarching message on commodification, which especially targeted the countries that lagged behind in health service commodification.

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Follow-up study on the lack of transparency in the pharmaceutical industry

In January 2023, two NGOs, Global Health Advocates (GHA) and StopAids, published a report on how the pharmaceutical industry disproportionately influenced EU institutions during the COVID-19 pandemic. One year later, a follow-up study concludes that little has changed in terms of transparency and access to medicines and health products.

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Trust and transformation at the heart of the 15th anniversary of the Tallinn Charter

On the 15th anniversary of the Tallinn Charter in December 2023, the conference organised by the World Health Organization Regional Office for Europe, the Ministry of Social Affairs of Estonia, and the European Observatory on Health Systems and Policies focused on how trust and transformation can make health systems more resilient and sustainable for the future. This was outlined in the outcome statement signed by the participants.

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