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- A new comprehensive approach to mental health was proposed
- Report examines metrics on disease prevention and health promotion
- Progress assessed for the EU Missions in Horizon Europe, including the Cancer Mission

## 2 Medicines and medical devices

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- The Health Technology Assessment Stakeholder Network was created
- The COVID-19 regulatory flexibilities are being phased out
- The EU FAB Network was launched
- Action taken to prevent shortages of antibiotics for next winter
- Five Member States called for a needs-driven approach to pharmaceutical innovation
- Opinion published on the revision of EU rules regarding the exposure to radiofrequency electromagnetic fields

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- A new virtual world initiative launched to support clinical decisions and personal treatment

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- A new acquisition cleared involving services to pharmaceutical and biotechnology firms
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- Judgment regarding the participation of experts from university hospitals in EMA's activities
- Judgment regarding EMA's decision not to renew a scientific advisory group
- Judgment on compensations due to frontier workers in case of isolation due to COVID-19-related reasons
- Judgment on first aid administered following an accident that took place on board an aircraft
- Opinion on the marketing of medicinal products online

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- Three Member States fail to correctly transpose EU rules on recognition of professional qualifications
- Bulgaria fails to correctly transpose EU rules on public procurement
- Poland fails to correctly transpose EU rules on services with respect to pharmacies
- Czechia fails to correctly transpose EU rules on services of insurance undertakings
- Sweden fails to transpose EU rules on radiation protection

## **11** Miscellaneous

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- Voluntary review and resolution published on the implementation of the SDG
- New framework proposed for European statistics
- List of critical entities adopted, including for the health sector
- The Harnessing Talent Platform will include a working group on health

## **12** Publications

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- Report shows how to adapt European social services to new challenges
- Policy comment on the European Health Data Space
- Opinion raises concerns about the ongoing review of the new draft legislation on Substances of Human Origin
- Report presents solutions to promote socially just and inclusive growth

## 1 Public health

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### **A new comprehensive approach to mental health was proposed**

A communication published by the European Commission paves the way for a new cross sectoral approach to mental health, putting mental health on par with physical health. EU action will focus on three guiding principles: i) access to adequate and effective prevention; ii) access to high quality and affordable mental health care; and iii) reintegration into society after recovery. Twenty flagship initiatives are planned, including training for health care and other professionals, technical support for Member States to design and implement reforms on mental health services, and improvement of data collected on mental health.

An opinion published by the European Economic and Social Committee calls for the swift transposition of the Commission's communication into an EU Mental Health Strategy that has a timeframe, is sufficiently funded, defines responsibilities, and includes indicators to monitor progress across the EU and in Member States, as well as within the framework of the European Semester process.

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### **Report examines metrics on disease prevention and health promotion**

The report published by the EU Expert Group on Health Systems Performance Assessment (HSPA) explores how disease prevention and health promotion are monitored across Member States as part of their national health system performance assessment frameworks.

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### **Progress assessed for the EU Missions in Horizon Europe, including the Cancer Mission**

The European Commission published a communication on progress made implementing the EU Missions which were introduced two years ago as a new initiative of Horizon Europe. Achievements, challenges, and actions to address them are presented. One of the five current missions is on cancer. Notably it fostered a new dialogue with Member States on cancer and enabled the development of a data platform to support research in this area.

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## 2 Medicines and medical devices

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### **The Health Technology Assessment Stakeholder Network was created**

The Network is a formal stakeholder body created under the Health Technology Assessment Regulation and involves representatives from stakeholder organisations as well as Member States from the Health Technology Assessment Coordination Group. At the inaugural meeting held in June 2023, participants discussed the role of stakeholders in the implementation of the Regulation and the Terms of Reference of the network.

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### **The COVID-19 regulatory flexibilities are being phased out**

The European Medicines Agency (EMA), the European Commission, and the Heads of Medicines Agencies (HMA) are phasing out the COVID-19 regulatory flexibilities put in place during the pandemic, in line with the declared end of the COVID-19 public health emergency by the World Health Organization in May 2023. These regulatory flexibilities covered different areas, such as marketing authorisation, labelling and packaging requirements, or inspections of manufacturing facilities.

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### **The EU FAB Network was launched**

The network is part of the flagship initiatives planned by the European Health Emergency Preparedness and Response Authority (HERA) for 2023. It comprises vaccines producers from Belgium, Ireland, the Netherlands, and Spain and aims to ensure sufficient and agile manufacturing capacities for different vaccine types in the event of public health emergencies.

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### **Action taken to prevent shortages of antibiotics for next winter**

The European Commission, the Heads of Medicines Agencies (HMA) and the European Medicines Agency (EMA) published recommendations aimed at avoiding shortages of antibiotics used to treat respiratory infections during winter. These were developed by the EMA's Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) and include actions to increase the production of key antibiotics, monitoring of supply and demand, and fostering public awareness on antibiotics use.

This topic was addressed by the European Health Emergency Preparedness and Response Authority (HERA) during a meeting with representatives of the Member States and industry. In particular, perspectives and potential strategies to implement the recommendations were discussed.

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### **Five Member States called for a needs-driven approach to pharmaceutical innovation**

At the Employment, Social Policy, Health, and Consumer Affairs (EPSCO) Council of June 2023, the delegations of Austria, Belgium, Ireland, Luxembourg, and the Netherlands presented an information note on the application of a needs-driven approach to pharmaceutical innovation. This involves a new business model focused on patient and societal needs rather than on supply.

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### **Opinion published on the revision of EU rules regarding the exposure to radiofrequency electromagnetic fields**

The final opinion published by the European Commission and its Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) calls for a revision of the annexes in the Council Recommendation 1999/519/EC and Directive 2013/35/EU based on the latest scientific evidence available regarding radiofrequency. The assessment includes a study on worker exposure to radiofrequency due to medical devices used in hospitals.

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## **3 e-Health**

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### **Transition to a global digital health certificate is on its way**

The Council of the European Union adopted a recommendation inviting Member States to join, follow and participate in the further development of the WHO Global Digital Health Certification Network. This global certification will build upon the existing EU system of digital certificates issued for COVID vaccination, test, and recovery. It will only cover COVID-19 initially but could be expanded to other diseases at a later stage. The European Commission and WHO have launched a partnership on digital health, which involves close collaboration in the development, management, and implementation of the WHO system.

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### **A new virtual world initiative launched to support clinical decisions and personal treatment**

The new strategy of the European Commission on Web 4.0 and virtual worlds includes the development of a new public flagship initiative: the European Virtual Human Twin. This will digitally replicate the human body, by bringing together cutting-edge digital technologies, access to high-performance computing and access to research and health care data. It will serve clinical decision support systems, personal health forecasting tools and personalised medicine approaches.

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## **4 Internal market**

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### **Proposals to facilitate cross-border activities of non-profit associations**

The European Commission proposed a directive that introduces in each Member State a new legal form for non-profit associations acting across borders: the 'European cross-border association' (ECBA). It will reduce legal and administrative barriers for non-profit associations engaging in more than one Member States in sectors such as health, care, and social services. The Commission also adopted a regulation amending the Internal Market Information System and the Single Digital Gateway regulations, with the aim to allow cooperation and exchange of information about the ECBA.

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## **5 Social policy**

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### **Measures proposed to support the social economy**

Following up on the 2021 Social Economy Action Plan, the European Commission presented a proposal for a Council recommendation for Member States to develop comprehensive strategies enabling the social economy to grow. It also launched a one-stop shop website - the social economy gateway - to provide information on EU funding, training, and other initiatives on this area. The social economy spans a diverse range of sectors, including the social and health care sectors, and it includes private not-for-profit entities such as mutuals and cooperatives.

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### **Proposals for a more digital social security coordination**

The European Commission published a communication proposing concrete steps for Member States to further digitalise the coordination of social security systems and thus make access to social security quicker and simpler across borders in Europe.

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### **A European social dialogue committee for social services set up**

The Committee was established by the European Commission as part of the follow-up to the 2022 Care Strategy and the 2023 Social Dialogue Initiative. It will bring together European employers and trade union organisations of social services and will focus on areas such as working conditions, job evaluation, skills and attractiveness of the social services sector, which also includes long-term care.

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### **Report published on employment and social developments in Europe**

The 2023 annual report provides evidence on persistent labour shortages and changing skill needs in the European Union, considers the implication of skills demands in the context of the green and digital transitions, and highlights challenges and proposes measures to address them. The analysis covers different sectors, including health care.

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### **Discussions ongoing on a Social Convergence Framework**

The Employment, Social Policy, Health and Consumer Affairs (EPSCO) Council of June 2023 discussed key messages from the Employment Committee and the Social Protection Committee on the introduction of a Social Convergence Framework in the European Semester. This framework aims to support the implementation of the European Pillar of Social Rights by establishing a more structured and deeper analysis of employment and social developments at national and EU levels within the annual Semester cycle. Principle 16 of the Pillar focuses on access to health care.

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## **6 Economic policy**

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### **Strategy proposed to achieve economic security includes the health sector**

The strategy jointly proposed by the European Commission and the High Representative is based on three priorities: i) promoting the EU's competitiveness; ii) protecting against risks; and iii) partnering with other countries. A methodology for risk assessment is proposed in four areas, including the resilience of supply chains (e.g., for pharmaceutical products), and the physical and cyber security of critical infrastructures (e.g., health infrastructures).

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### **2023 Strategic Foresight Report focuses on sustainability and wellbeing**

The report presented by the European Commission analyses how to put sustainability and people's wellbeing at the heart of Europe's Open Strategic Autonomy. It describes key social and economic challenges and suggests ten areas for action. These include ensuring a new European social contract with renewed welfare policies and a focus on high-quality social services, as well as developing tools to assess future dependencies across strategic sectors such as health.

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## **7 EU funding**

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### **The Strategic Technologies for Europe Platform ('STEP') was proposed**

The European Commission wants to reinforce and leverage existing EU instruments to direct funding towards technology fields that can enable the green and digital transition and strengthen the EU's economic security (see section: Economic policy). STEP will support the uptake and scaling up of development and manufacturing of digital and deep technologies, clean technologies, and biotechnologies.

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### **HERA Invest was created to support research and development in pressing cross-border health threats**

This is part of the flagship initiatives of the European Health Emergency Preparedness and Response Authority (HERA). By complementing the Invest EU programme, HERA Invest will support research and development conducted through the EU4Health programme on health emergency prevention and preparedness.

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## 8 Competition

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### **Austrian support to Sandoz's penicillin production approved**

The Austrian measure to support the modernisation of Sandoz GmbH penicillin production site in Tyrol was approved by the European Commission under the EU State aid rules. This measure will contribute to maintain the last fully integrated production of amoxicillin in the EU.

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### **A new acquisition cleared involving services to pharmaceutical and biotechnology firms**

The European Commission has approved the acquisition of joint control of Syneos Health by Veritas Capital Fund Management, Elliott Investment Management, and Patient Square Capital, all based in the United States. Syneos Health is a global contract research and outsourced commercialisation organisation providing services to pharmaceutical and biotechnology firms.

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### **A joint venture approved by the European Commission in the insurance sector**

The joint venture involves Vittoria Assicurazioni of Italy and MAPFRE Asistencia of Spain, which are both active in the insurance sector. Its aim is to offer assistance services in Italy in the area of car glass repair and services for pets, but it may extend its operations to assistance services in the areas of home and health.

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## 9 Court of Justice of the European Union

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### **Judgment regarding the participation of experts from university hospitals in EMA's activities**

In joined cases C-6/21 P and C-16/21 P, the Court annulled the decision of the General Court of the European Union which had found that the experts of the European Medicines Agency (EMA) could have been impartial in the negative opinion issued on the marketing authorisation application by Pharma Mar for the orphan drug 'Aplidin'. The Court found that all the staff of a university hospital cannot be considered as employed by a pharmaceutical company and be subject to an overall exclusion from participation in medicines assessment activities for EMA.

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### **Judgment regarding EMA's decision not to renew a scientific advisory group**

In case C-136/22 P, the Court dismissed the appeal brought by 'Debrégeas et associés Pharma SAS' against the order of the General Court of the European Union which considered as being inadmissible its action for annulment of the decision of the European Medicines Agency (EMA) not to renew the scientific advisory group on psychiatry of the Committee for Medicinal Products for Human Use.

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### **Judgment on compensations due to frontier workers in case of isolation due to COVID-19-related reasons**

In case C-411/22, the Court stated that public compensation due to workers for the pecuniary disadvantages caused by the impediment to their employment during their isolation as persons infected with (or suspected of being infected with) COVID-19 does not constitute a 'sickness benefit' as referred to in regulation 883/2004 on the coordination of social security systems. Moreover, European rules preclude legislation of a Member State under which the granting of compensation for loss of earnings suffered by frontier workers because of this isolation is subject to the condition that the imposition of the isolation measure be ordered by an authority of that Member State under that legislation.

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### **Judgment on first aid administered following an accident that took place on board an aircraft**

In case C-510/21, the Court stated that the inadequate first aid administered on board an aircraft to a passenger, which aggravated the bodily injuries caused by an 'accident' must be regarded as forming part of that accident.

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### **Opinion on the marketing of medicinal products online**

Case C-606/21 concerns the activity carried out by Doctipharma SAS on its French website to connect pharmacists and customers for the sale of medicinal products not subject to medical prescription. The Advocate General analysed whether this activity constitutes an 'information society service', and whether the prohibition of certain activities imposed on the provider of such a service falls within the scope of Directive 2001/83/EC on the Community code relating to medicinal products for human use.

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## **10 Infringement procedures**

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### **Three Member States fail to correctly transpose EU rules on recognition of professional qualifications**

The European Commission sent a letter of formal notice to Germany, a reasoned opinion to Romania and referred Malta to the Court of Justice of the European Union for incorrect transposition of the Professional Qualifications Directive 2005/36/EC. These infringement procedures address obstacles to the recognition of the professional qualifications of midwives in Germany, of veterinarians in Romania, and of medical and para-medical professions, as well as of veterinarians in Malta.

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### **Bulgaria fails to correctly transpose EU rules on public procurement**

The European Commission sent a reasoned opinion to Bulgaria for having introduced two exclusions from the application of Directive 2014/24/EU on public procurement. One of these two exclusions concerns certain medical products.

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### **Poland fails to correctly transpose EU rules on services with respect to pharmacies**

The European Commission referred Poland to the Court of Justice of the European Union regarding the prohibition of advertising of pharmacies and their activities. Polish pharmaceutical law is indeed considered to breach the E-commerce Directive 2000/31/EC, as well as article 49 and 56 of the Treaty on the Functioning of the EU on free movement of persons, services, and capital.

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### **Czechia fails to correctly transpose EU rules on services of insurance undertakings**

The European Commission sent a letter of formal notice to Czechia for failing to correctly apply the Directive 2009/138/EC (known as 'Solvency II') on the taking-up and pursuit of the business of insurance and reinsurance with respect to private health insurance.

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### **Sweden fails to transpose EU rules on radiation protection**

The European Commission sent a letter of formal notice to Sweden for failing to correctly transpose certain parts of the Council Directive 2013/59/Euratom laying 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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## 11 Miscellaneous

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### **Voluntary review and resolution published on the implementation of the SDG**

The European Union presented its first voluntary review of progress made towards the Sustainable Development Goals (SDGs) to the United Nations in New York in mid-July. The review assesses how EU internal and external actions are contributing to delivering on the 17 SDGs both within the EU and in partner countries. One chapter is dedicated to the challenges, initiatives taken, and actions planned to achieve the SDG 3 on health and well-being.

For its part, the European Parliament adopted, in June, a resolution calling for the EU to adopt a more comprehensive strategy for achieving the SDGs, with clear goals and timetables for implementation. This also involves improving the quality and use of data collected for monitoring progress.

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### **New framework proposed for European statistics**

The European Commission has proposed to amend the existing regulation on European statistics in order to make the European Statistical System more efficient and effective by enabling the production of more relevant, more timely and more detailed information. This involves the strengthening of data sharing among key authorities and the possibility to initiate statistical actions at European level in times of crises, including health emergencies.

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### **List of critical entities adopted, including for the health sector**

Following the entry into force of the Critical Entities Resilience Directive, the European Commission has adopted a non-exhaustive list of services that are crucial for the maintenance of key societal functions. For the health sector, these include entities distributing, manufacturing, and providing health care, pharmaceutical products, and medical devices, as well as research centres and EU reference laboratories. Based on the list, Member States will have until July 2026 to carry out risk assessments and identify the national entities that need to enhance their resilience.

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### **The Harnessing Talent Platform will include a working group on health**

The Platform was launched by the European Commission to provide regions affected by the decline of their working age population with the guidance, information, and knowledge they need to train, attract, and retain talent. Dedicated working groups will enable strategic exchange on how sectors, such as health, can influence a region's ability to be competitive and attractive for a young and highly skilled workforce.

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## 12 Publications

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### **Report shows how to adapt European social services to new challenges**

The report published by Eurofound draws on lessons learned from the COVID-19 pandemic to assess how social services, including health care services, can be adapted in response to new challenges and social risks. It highlights the need to address structural issues such as staff shortages, poor working conditions and lack of digitalisation, but also the need to develop clear contingency plans and ensure funding.

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### **Policy comment on the European Health Data Space**

An international consortium of experts from health policy, law, ethics, and the social sciences raises concerns over the capacity of the European Health Data Space, as currently proposed, to achieve its stated aims. The authors identify shortcomings related to patient control over data, health data use and re-use by health professionals and researchers, as well as the public value generated through health data sharing. Recommendations to address these shortcomings are advanced.

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### **Opinion raises concerns about the ongoing review of the new draft legislation on Substances of Human Origin**

This opinion by Catherine Hartmann, published by the European Public Health Alliance (EPHA), discusses ethical and pragmatic questions that arise from the proposal by several EU national policymakers of supporting donations of plasma by introducing the possibility of payments to the donors in the new rules governing the use of substances of human origin (SoHO).

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### **Report presents solutions to promote socially just and inclusive growth**

The report published by the World Health Organization Regional Office for Europe explores the interactions between health, the economy and social capital and examines how social cohesion can be built to improve resilience. It explores the drivers of health inequities and suggests areas for action. These include developing responsive and integrated social and health protection systems.

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