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### Launch of the EU-US Health task force

This task force is part of the agreement signed between the European Commission and the US Department of Health and Human Services, to strengthen cooperation between the European Union and the United States in preparing for and responding to public health threats. The task force will focus on three areas: cancer priorities, global health threats, and global health architecture.

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### New infectious disease surveillance framework for 2021-2027

This framework, published by the European Centre for Disease Prevention and Control (ECDC), contributes to the implementation of the ECDC's strengthened mandate and the regulation on serious cross-border health threats. The objectives aim, among other things, to improve the relevance of the data collected and the coordination of surveillance systems in European countries.

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### Lessons and recommendations from the COVID-19 pandemic

The European Centre for Disease Prevention and Control (ECDC) presented the lessons identified by public health actors in four specific areas of the health crisis response: investing in the health workforce, preparing for future crises, risk communication and community engagement, as well as the collection and analysis of data.

For its part, the European Parliament's Special Committee on the COVID-19 pandemic has published its draft final report, on which a vote is scheduled for 12 June. The lessons and recommendations put forward cover four areas: health, a coordinated approach in favour of democracy and fundamental rights, the social and economic impact, and the global level.

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### Calls to promote mental health and access to care

Mental health was one of the themes addressed by one of the thematic networks organised in 2022 as part of the European Health Policy Platform, moderated by the European Commission. In its final declaration, the network called on the European Union and the Member States to take mental health into account in all policies. Member States are invited, among other things, to strengthen access to healthcare for vulnerable groups, as a first step towards access to mental health services.

The issue of mental health and well-being was also addressed by the Education, Youth, Culture and Sport Council in its conclusions on the social dimension of a sustainable Europe for young people. Member States are called upon, among other things, to strengthen mental health promotion and prevention, but also to promote access to high-quality, integrated, safe and person-centred health services.

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### Provisional agreement on the new European Drugs Agency

The European Parliament and the Council of the European Union have reached provisional agreement on a proposal for a regulation that aims to transform the current European Monitoring Centre for Drugs and Drug Addiction into a fully-fledged agency. The new Agency will continue to play a key role in collecting, analysing and disseminating data, but will also be given a stronger mandate to assess threats to health and safety, to cover poly-substance use, and to consolidate its cooperation with national players.

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### Proposed revision of the pharmaceutical legislation

The European Commission has adopted a proposal for a new directive and a new regulation to revise and replace existing pharmaceutical legislation, including legislation on paediatric medicines and orphan drugs. The aim is to improve the availability and accessibility of medicines, to make them more affordable, as well as to support innovation, competitiveness and attractiveness of the pharmaceutical industry while taking into account the environmental impact of the production of medicines.

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### Specific measures to combat antimicrobial resistance

The European Commission's proposal to revise pharmaceutical legislation (see above) foresees incentives for companies investing in new priority antimicrobials, in the form of transferable exclusivity vouchers. This incentive has already provoked a great deal of criticism (see Newsletters 64 and 65 and the "Publications" section).

To strengthen the fight against antimicrobial resistance, the Commission has also proposed a Council Recommendation. The latter aims to adapt the objectives to national circumstances and to promote the application of national action plans based on the "One Health" principle. The Council is expected to adopt this proposal in mid-June.

For its part, the European Parliament has adopted a resolution calling for greater EU coordination and increased action to combat antimicrobial resistance.

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### Proposals for regulations updating the existing framework on patents

Presented by the European Commission, these proposals aim to provide a better framework for granting standard essential patents; to create a European compulsory licence in the event of a crisis situation; as well as to harmonise the supplementary protection certificate system for medicinal products and plant protection products.

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### New measures under the PRiority MEDicines programme

The PRIME programme of the European Medicines Agency (EMA) was launched in 2016 with the aim of supporting the development of medicines that can meet unmet medical needs. Based on the experience gained, the EMA has strengthened existing measures and introduced new tools to better support drug developers and speed up the evaluation process.

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### Guidelines on exposure to hazardous medical products

These non-binding guidelines, published by the European Commission, offer advice to employers and workers on managing exposure to hazardous medical products. Medical staff are included in the groups of workers who may be exposed to these products.

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### Call from nineteen Member States to secure the supply of medicines in the European Union

Led by Belgium, these States have called for stronger rules to tackle drug shortages within the EU. Three areas in particular are being considered: the introduction of a voluntary solidarity mechanism; the rapid development of a European list of critical medicines; and a law on critical medicines to reduce dependence on countries outside of the EU.

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### **Good practices for the pharmaceutical industry on how to prevent shortages of medicines for human use**

The European Medicines Agency (EMA) recommended best practices that marketing authorisation holders, wholesalers, distributors, and manufacturers can adopt to ensure continuity of supply of medicines and reduce the impact of shortages on patient care. These guidelines are in addition to those published last year on the same subject for patients and healthcare professionals.

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### **New measures to improve access to medicines in Northern Ireland**

The Council of the European Union has adopted three regulations that aim to implement the Windsor framework. This framework, concluded by the European Commission and the United Kingdom government, sets out the new arrangements for implementing the Protocol on Ireland and Northern Ireland established when the United Kingdom withdrew from the European Union. One of the three regulations specifically concerns medicinal products and contains additional guarantees concerning access to them for Northern Ireland citizens.

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## **3 e-Health**

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### **Proposal to strengthen the EU's cybersecurity capabilities**

The European Commission has proposed a regulation on cyber solidarity with multiple objectives: to support the detection of cybersecurity threats and incidents; to prepare entities operating in critical sectors, including healthcare; and to strengthen European solidarity and coordinated management and response capabilities. Preparedness measures include the testing of critical entities for potential vulnerabilities.

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### **Proposal for a European public procurement data area**

The European Commission aims to integrate and improve the quality of public procurement data, including data on the preparation of calls for tender and their results. To this end, the creation of a European platform and the use of modern analysis technologies are planned. The objectives include better targeting and execution of public spending, greater transparency and accessibility of calls for tender. The health sector is also concerned, and possible links with the European Health Data Space will be examined.

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### **Call to speed up the digitalisation of public services**

In a resolution adopted by the European Parliament, the MEPs stress the importance of digitalising public services to make them more accessible and transparent, citing electronic medical records as an example. However, they call for the greatest possible protection of individual data, including medical data, and for interoperability of the various European data areas, including health and public procurement.

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### **A call to combat the inequalities and inequities in healthcare that can result from artificial intelligence**

One of the thematic networks organised in 2022 as part of the European Platform on Health Policy, moderated by the European Commission, worked on the potential impact of the use of artificial intelligence (AI) in healthcare. In its final declaration, the network called on the European Union, the Member States, and the other concerned stakeholders to better coordinate their efforts within existing European strategies. This includes protecting vulnerable groups to prevent AI from increasing health inequalities and inequities.

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### **Analysis of the relationship between social security coordination and cross-border healthcare**

The European Commission has studied the issue of cross-border healthcare, analysing three aspects: the relationship between the social security coordination regulations and the directive on cross-border healthcare; how patients are informed of their rights in this area; as well as the challenges posed by cross-border telemedicine services.

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### **Informal meeting and reports on labour shortages in the European Union**

At the beginning of May, the Employment, Social Policy, Health, and Consumer Affairs Council (EPSCO) met for an informal meeting organised by the Swedish Presidency and devoted to labour shortages in the European Union and the adequacy and sustainability of social protection systems.

The debate on labour shortages has been fuelled in particular by a Eurofound document which highlights the main challenges facing the labour market and sets out the factors which could improve the match between skills and jobs, including in the health and care sectors.

In another report, Eurofound has also studied the measures taken by EU countries to remedy to labour shortages. For the health and long-term care sectors, the conclusions show in particular that these measures must not focus solely on pay but must also intervene in the living and working conditions that can make these sectors more attractive.

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### **Open letter on the implementation of the European Pillar of Social Rights**

This letter was signed at the end of the Social Forum organised in Porto at the end of May by 37 European leaders, including representatives of the European institutions as well as labour and social affairs ministers from several Member States, including Belgium. They reaffirmed the role of a social Europe and renewed the commitments made at the Porto Social Summit in 2021 to promote employment, training, and the reduction of poverty.

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### **Roadmap for a Social Europe**

In the roadmap adopted by the European Parliament, MEPs restated the importance of the objectives set at the Porto Social Summit in May 2021 and called on the European Commission to transform the commitments made into legislative instruments, for example by adopting a European social security passport or a European disability card.

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### **Proposal of guidelines for national employment policies**

These proposed guidelines, published by the European Commission as part of the European Semester spring package (see next section), set out common priorities for Member States' employment and social policies, with a view to making them more inclusive and equitable. For 2023, the European Commission is proposing to carry over the current guidelines and stresses the importance of monitoring the progress made in implementing the European Pillar of Social Rights. It mentions, among other things, the importance of ensuring timely access for all to affordable, high-quality healthcare and long-term care.

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### Publication of the 2023 European Semester Spring Package

The European Commission is providing Member States with guidelines for building a strong economy capable of responding to current challenges and for implementing the Recovery and Resilience Facility and the Cohesion policy. In the communication accompanying the package, the Commission stresses the need to improve access to affordable, high-quality, and sustainable healthcare and long-term care. The issues of the digitalisation of healthcare services and the shortage of healthcare staff are also addressed.

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### Country reports as part of the European Semester

The spring package also includes country reports analysing the socio-economic challenges specific to each Member State and their capacity to address them. These reports take stock of the implementation of previous country recommendations and the measures included in national recovery and resilience plans to address the challenges identified. The challenges and measures taken in the health sector are also presented.

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### Country-specific recommendations

In its spring package, the European Commission also proposed country-specific recommendations to guide Member States on how to address key socio-economic challenges that are partially or not addressed in national recovery and resilience plans. This year, six Member States (Austria, Estonia, Greece, Latvia, Lithuania, and Slovenia) received a specific recommendation on healthcare reform. Three of them (Austria, Estonia, Slovenia) received a recommendation on long-term care reform, as did Belgium.

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### Proposed recommendations on Belgium's reform and stability programmes

Among the specific recommendations proposed for Belgium, the European Commission calls for greater efforts to improve the efficiency of long-term care. According to the Commission, the reforms implemented since 2019 are not sufficiently focused on resolving the problem of budgetary sustainability. The high level of public spending in this sector is explained in particular by excessive recourse to residential care and unnecessary or premature institutionalisation of the elderly.

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### Publication of post-programme monitoring reports

These reports, published by the European Commission as part of the European Semester's spring package, concern Cyprus, Greece, Ireland, Portugal and Spain. They conclude that these Member States remain in a position to repay their debt. For all five, the financial sustainability of their healthcare systems is also analysed.

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### Report on the progress towards the Sustainable Development Goals in Europe

This report by the Statistical Office of the European Union (Eurostat) was published at the same time as the European Semester spring package, to highlight its importance for national policymaking and to achieve the integration of these objectives into the economic coordination cycle. The results show that the EU has made progress in achieving most of the Sustainable Development Goals (SDGs) over the last five years. In particular, positive progress has been made on health and well-being (SDG 3).

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### Legislative proposals for new economic governance

The European Commission aims to strengthen the sustainability of public debt and to promote sustainable and inclusive growth. In particular, the Member States will have to draw up medium-term budgetary and structural plans incorporating their budgetary objectives, measures to remedy



macroeconomic imbalances and reforms as well as investments in favour of the EU's common priorities, including those defined in the European Pillar of Social Rights. While the Member States will have greater control over their plans, a stricter system is planned for monitoring the application of the rules.

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## 6 EU funding

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### **Results of the cohesion policy programming 2021-2027**

The European Commission has set out in a report the investments envisaged under the cohesion policy for the period 2021-2027. With the aim of promoting a more social and inclusive Europe, funding is planned to support the accessibility, efficiency and resilience of health systems, as well as to support health infrastructure and healthcare equipment. The annexes provide more detailed information on the programmes financed, including by country.

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### **Interactive map of projects supported by the Recovery and Resilience Facility**

This map, published online by the European Commission, identifies the reform and investment projects currently being implemented as part of the national recovery and resilience plans financed by the Facility. These projects also concern the healthcare sector.

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### **Assessment of funding allocated to respond to the COVID-19 crisis**

This preliminary evaluation looks in particular at the response to the crisis provided by the European Social Fund (ESF) and the Fund for European Aid to the Most Deprived (FEAD) under the two Coronavirus Response Investment Initiatives (CRII and CRII+) adopted in March and April 2020. It examines whether the process put in place has enabled Member States to respond to the crisis, targeting various areas including healthcare.

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### **RescEU funding for the first pan-European field hospital**

This funding has been allocated by the European Commission to Belgium, France, Germany, Italy, Luxembourg, Portugal, Romania, and Turkey to develop the new RescEU EMT (Emergency Medical Team) capability. Three emergency medical teams and 17 specialised care teams will be set up, to intervene in the event of large-scale disasters, either autonomously or in support of national healthcare establishments. This capability will become progressively operational from 2024.

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## 7 Competition

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### **Communication on the long-term competitiveness of the European Union**

This Communication, published by the European Commission, aims to boost the EU's competitiveness beyond 2030 in a sustainable perspective based on productivity growth, environmental sustainability, macroeconomic stability, and equity. Efforts in this direction include public investment, including in healthcare. The Communication stresses that high-quality healthcare systems are essential to the resilience of our economies. For the pharmaceutical sector, a regulatory sandbox is envisaged.

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## Two new acquisitions approved by the European Commission

The first acquisition was that of April S.A.S., a French-based insurance broker specialising in personal insurance, including health and personal protection, by KKR & Co Inc, a US-based global investment firm.

The second acquisition is that of ServiceCo, based in the Netherlands, by Ebert HERA Esser Holding GmbH, based in Germany. ServiceCo will provide engineering, procurement, subcontracting and maintenance services to existing chemical plants at the Chemelot Campus Park in Geleen, in the Netherlands. Ebert HERA provides industrial and mechanical subcontracting services for heavy industry such as chemical and pharmaceutical plants in the Benelux and Germany.

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## 8 Court of Justice of the European Union

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### Judgment concerning State aid granted to public hospitals

In Case C-492/21 P, the Court dismissed the appeal brought by Casa Regina Apostolorum della Pia Società delle Figlie di San Paolo against a judgment of the General Court of the European Union of June 2021. In its ruling, the Court confirmed that the activities of the national healthcare system are not economic in nature, as the system is based on the principle of solidarity and universality. The health services provided within this framework do not therefore involve State aid within the meaning of Article 107(1) of the Treaty on the Functioning of the EU.

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### Judgment concerning the marketing authorisation for a generic medicinal product

In cases C-438/21 P to C-440/21 P, the Court allowed three appeals brought respectively by the European Commission, Biogen Netherlands BV, and the European Medicines Agency (EMA) against a judgment of the General Court of the European Union of May 2021. The Court ruled that, when assessing if two medicinal products are part of the same global authorisation, it is not necessary to verify the existence of a therapeutic contribution by the active substance present in the first medicinal product authorised at national level but absent from the composition of the subsequently authorised medicinal product.

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### Conclusions concerning the right to obtain copies 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 Advocate General's Opinion, a patient has the right to receive a copy of his or her medical records, including for purposes unrelated to data protection; costs may be charged provided that the reimbursement requested is limited to the costs actually incurred; and finally, the data provided must be intelligible, complete, and accurate.

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### Conclusions concerning the processing of personal data by the medical department of a health insurance fund

Case C-667/721 concerns the interpretation of the General Data Protection Regulation (GDPR) with regard to the processing of personal data concerning the health of employees. According to one of the Advocate General's conclusions, the regulation does not prohibit the medical service of a health insurance fund from processing data relating to the health of one of its employees, where those data are a prerequisite for assessing that employee's working capacity.

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### Seven Member States given formal notice regarding the use of lead in certain magnetic resonance imaging devices

Belgium, Czechia, Latvia, Malta, Portugal, Slovakia, and Spain will receive a letter of formal notice from the European Commission for failing to communicate national measures fully transposing the Delegated Directive (EU) 2022/1632. This directive grants a temporary exemption from the provisions restricting the use of certain substances but limits the scope of this exemption to the use of lead in magnetic resonance imaging devices.

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### Five Member States given formal notice regarding radiation protection

Cyprus, France, Ireland, Lithuania, and Luxembourg have received a letter of formal notice from the European Commission for failing to correctly transpose the revised Basic Safety Standards Directive (Directive 2013/59/Euratom). These standards aim to ensure the highest level of radiation protection for workers, patients and the general public throughout the European Union.

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### Five Member States failing to transpose the rules on late payment

The European Commission has opened several infringement proceedings against Belgium, Greece, Italy, Portugal, and Slovakia for the incorrect transposition of Directive 2011/7/EU on combating late payment in commercial transactions. This obliges public authorities to pay invoices for the supply of goods and services within a limited period, notably 60 days for public hospitals.

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### Italy fails to transpose the directive on working conditions in the public sector

Italy has received a reasoned opinion from the European Commission for failing to correctly transpose Directive 1999/70/EC on fixed-term work. In particular, the Commission is calling for appropriate measures to be taken to prevent the abuse of fixed-term contracts and to avoid discrimination against fixed-term workers in several public sector categories, including healthcare professionals.

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### Proposal for a regulation on critical raw materials

This proposal, presented by the European Commission, aims to strengthen the supply chain for critical materials, diversify imports, improve the capacity to monitor and respond to supply risks, as well as to increase the circularity and sustainability of critical materials within the European Union. These materials are often essential resources for several strategic sectors, including healthcare.

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### Launch of a skills partnership for long-term care

This partnership was set up as part of the Pact for Skills supported by the European Commission, and brings together long-term care service providers, the social partners, as well as education and training providers. It aims to increase the attractiveness of the sector by improving career paths and the quality of long-term care.

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### **Progress made in improving the integration of Ukrainian refugees**

In a communication, the European Commission has taken stock of the implementation of the directive adopted in March 2022 on temporary protection for people fleeing the war in Ukraine. One chapter deals specifically with their access to healthcare and social benefits.

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### **Proposition for new rules to guarantee the rights of adults in need of protection or support**

The new rules proposed by the European Commission aim to ensure the protection of adults who, due to an impairment or insufficiency of their personal faculties, are not in a position to look after their own interests in the context of cross-border mobility, for example when seeking healthcare abroad. The aim is to rationalise and harmonise the rules that apply within the European Union.

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### **Criminal complaint lodged in Belgium against Ursula von der Leyen**

A Belgian citizen has filed a criminal complaint against the President of the European Commission for having acted in place of the federal government during the COVID-19 pandemic in the context of the negotiation of vaccine contracts with the Pfizer laboratory. The charges include "usurpation of functions and title", "destruction of public documents" and "illegal taking of interests and corruption".

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## **11 Publications**

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### **Analysis of gender-based segregation in healthcare**

The European Commission's quarterly review of social and labour market developments devotes a thematic section to the issue of gender-based segregation in the Member States of the European Union. The fields of science, technology, engineering and mathematics (STEM), and health care are examined.

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### **Study on the attractiveness of primary care in European countries**

A policy brief published by the European Observatory on Health Systems and Policies presents the results of a literature review on the strategies that can help to make primary care more attractive to medical students and primary care physicians.

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### **Publication of the 2022 "Living and working in Europe" report**

In this annual report, Eurofound analyses the impact that the events of 2022 have had on the economy and well-being of the European population. Among the subjects analysed are working conditions, including in the health sector; access to health care, including mental health care and more specifically for people with disabilities; public confidence in institutions, including health systems.

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### **Expert opinion on the use of transferable exclusivity vouchers to encourage innovation in antibiotics**

In a commentary published in the journal *The Lancet*, several experts highlighted the problems that can arise from providing an incentive to produce new antibiotics through the mechanism of transferable exclusivity vouchers, such as that which the European Commission has included in its proposal to revise European pharmaceutical legislation (see "Medicinal products" section).

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### **Reflection on the tasks of the European Commission's health emergency preparedness and response authority**

In an article published in the journal Health Policy, Olivier Wouters and colleagues analyse the reform process that led to the creation of the Health Emergency Response and Preparedness Authority (HERA). They describe the structure and responsibilities of this authority, exploring the implications of its creation, and suggest possibilities for collaboration with other institutions at the European level and beyond.

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### **Study on the coherence and effectiveness of health research at European level**

A study published by the European Parliament's STOA Panel (Panel for the Future of Science and Technology) analyses whether the organisation of health research funding at EU level is adequate to meet future challenges, such as preparing for new epidemics, the increase in chronic diseases, demographic changes and health problems linked to climate change.

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#### **“European Health Care News”**

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