



## Dear colleagues

This edition of the Bulletin follows a highly productive General Assembly in Dubrovnik. Thank you to the Croatian Medical Chamber for hosting us so warmly and generously, and thank you to everyone who joined and contributed to the meetings.

I am delighted to welcome Dr Martin Balzan to our Board of Directors following his election. He will bring vast experience to the leadership our association, and we very much look forward to working together. He was highly involved in leading the drafting of the new Policy on Climate Change which was adopted during the meeting.

Another key milestone was the adoption of a new Policy on Antimicrobial Resistance, and we look forward discussing the topic further in the upcoming event co-hosted with the Swedish Medical Association on 27 April (see page 7).

We hope you enjoy reading about this and much more in this month's edition.

**Dr Christiaan Keijzer**

CPME President



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## BOARD OF DIRECTORS MEETING – 23 MARCH 2023

## Finances

### Final accounts and balance sheet 2022 and revised budget 2023

- ▶ The Board discussed the final accounts and balance sheet 2022 and revised budget 2023 to be presented to the General Assembly.

The reserve remains at over €700 000. The revised 2023 budget was prepared following the request by the General Assembly in October and proposes possible savings of €66 000. There are changes in the IMMUNION project income and expenses for 2022 which will be balanced in 2023. An increase in meeting expenses was discussed. It was noted that the reason for this was that meeting expenses were vastly decreased during the COVID-19 pandemic. The Board agreed to continue to be open to members to make proposals to host General Assemblies in their countries, pending a decision by the General Assembly.

### Simulated budgets 2024-2025-2026

- ▶ The Board discussed the Simulated budgets 2024-2025-2026, concluding that we will need to reconsider our ambitions in case of reductions to the budget.

The Board discussed the risk of raising fees resulting in members leaving the organisation, and we should consider all possible options for savings, noting that we are on a skeleton budget and in case of further reductions, we will need to seriously reconsider our ambitions.

## Internal Affairs

### Agendas of General Assembly and Policy Sessions

- ▶ The Board reviewed the draft agendas of the General Assembly and Policy Sessions to take place during the following days, noting tight timings on Friday 24 March.

## BOARD OF DIRECTORS MEETING – 23 MARCH 2023

## Policies

### Legal cases of the Turkish Medical Association, and response to the earthquake

- ▶ The Board took note that the trial against the Central Council of the TMA had been delayed, and the German Medical Association will share details of a fund to support medical students affected by the earthquake.

Ole Johan Bakke reported that he went to Ankara on 8 March for the trial of the TMA's Council. The TMA requested a new judge, which was not granted, and the hearing lasted only 4 minutes to allow a decision from a higher court.

The German Medical Association had a call with the TMA president on the response to the earthquake. They noted that many medical students have been affected, therefore they are working on a project to provide stipends to support the students and will spread the details to other associations who wish to contribute to the fund.

### European Health Data Space

- ▶ The Board took note of developments of the EHDS, and the meetings with the co-legislators, in particular the French, Italian, Bavarian, Danish and Spanish permanent representations.

The Board noted that a joint statement may be prepared with other professional associations (CED, PGEU and HOPE) on the administrative burdens, high costs, need for clarity on medical liability and requesting exemption of small practices and hospitals from providing data for secondary use. They also noted the lobby package on the EHDS prepared for CPME members and suggested that it is shared with countries outside of CPME, and to highlight this to the General Assembly, requesting members to meet with their national authorities on the topic.

### Revision of EU Pharmaceutical legislation

- ▶ The Board decided to prepare a letter to the European Commission sharing concerns about the delay in the publication of the legislation, and the lack of transparency of the process.

## BOARD OF DIRECTORS MEETING – 23 MARCH 2023

## UEMS Statement: Impact of the COVID-19 pandemic on the CME/CPD of European Specialist

- ▶ The Board decided to endorse a [UEMS Statement](#): Impact of the COVID-19 pandemic on the CME/CPD of European Specialist.

## EMOs statement on working conditions

- ▶ The Board decided to co-sign an EMOs statement on working conditions.

The statement resulted from a survey by UEMS on the effects of the pandemic on private practice which was then processed by a working group over the course of several meetings. Recent amendments underline the need to ensure decent conditions for work and training for all doctors.

## Hungarian Medical Chamber

- ▶ The Board decided to send a letter supporting the Hungarian Medical Chamber against government action threatening their autonomy.

The government has enacted an emergency procedure, withdrawing mandatory membership and certain oversight responsibilities.

## Childhood obesity

- ▶ The Board took note that, together with other organisations of the “Stop Unhealthy Food Marketing” group, CPME will comment on the European Economic and Social Committee’s (EESC) draft opinion on childhood obesity

## Antimicrobial resistance crisis urgently needs greater European action

CPME has updated its [policy](#) on antimicrobial resistance (AMR), calling for greater EU action for a deepening crisis which is leaving doctors short of effective treatments for life-threatening infections.

AMR is one of the greatest global health threats, causing 1.2 million deaths each year, more than 35 000 of which are in Europe. Bacteria have evolved ways to resist antibiotics, accelerated by overuse or misuse of medicines, including in agriculture.

Whilst the effectiveness of current antibiotics is decreasing, no novel class of antibiotics has been brought to market since the 1980s. In addition, this winter medicine shortages in most European countries left doctors and patients without access to critical antibiotics.

CPME President Dr Christiaan Keijzer said “Europe is facing a growing public health threat from AMR. It is crucial that we keep existing antibiotics working. We emphasise that prudent prescription of antibiotics is a responsibility of each practicing doctor in Europe and worldwide. We need to act in collaboration with many partners and are committed to the One Health approach bringing together the human health, veterinary and environmental sectors.

“The revision of the EU’s pharmaceutical legislation provides an opportunity that cannot be missed. We call for legislation that provides responsible incentives for innovation and equitable access to medicines, as well as facilitates prudent use of established antibiotics.

“Shortages of existing antibiotics pose a real challenge for doctors, and we need to ensure that the shortages that occurred in recent months do not happen again next winter. Antibiotics should be considered a public good and we urge decisive measures to be taken to ensure stable supply of antibiotics in the future.”

## Event: How to make progress on tackling AMR? Addressing Antimicrobial Resistance in Medical Practice

27 April, 13:00–16:15, Stockholm and online

Register here: <https://www.trippus.net/registration-startpage>

CPME and the Swedish Medical Association (SMA) [invite you](#) to participate in discussion on addressing antimicrobial resistance in medical practice.

Despite a decrease in total antibiotic consumption in healthcare in Europe, AMR remains an unsolved challenge. Tackling it is complex and requires a comprehensive One Health approach. CPME and SMA believe that medical profession has an important role to play in combating AMR.

The Swedish Presidency of the European Council has made AMR one of its political priorities. For a long time, Sweden has been a leader in the fight against AMR thanks to the effective implementation of antibiotic stewardship programs at national level. AMR is also a priority for European doctors.

Through this event we want to look for solutions to such issues as:

- doctors' role in combating antibiotic resistance;
- improving prudent use of antibiotics in healthcare;
- ensuring sustainable access to effective antibiotics.

In this event moderated by Dr Sofia Rydgren Stale (SMA President) and Dr Christiaan Keijzer (CPME President), key experts will consider how to address AMR in medical practice in the most effective way. Speakers will include Swedish Ambassador on AMR, European Centre for Disease Prevention and Control, Slovenian Medical Chamber, Strama, European Commission, Health Action International, ReAct Europe, Public Health Agency of Sweden, Health Emergency Preparedness and Response Authority.

## European doctors' recommendations to tackle climate change, the biggest global health threat in the 21st century

CPME has published a [new policy](#) on climate change and health, making key recommendations to policy-makers and the healthcare sector.

Climate change already has an impact on health, affecting factors such as heatwaves, clean air, drought, and sufficient food, as well as shifting the geographical distribution of diseases. It is a societal, political, scientific and economic imperative to mitigate the negative effects of climate change. Healthcare services have a key role to play in reducing their own carbon footprint and achieving net-zero emissions, as the health sector accounts for 4.4% of greenhouse gas emissions globally, and even more in certain European countries.

CPME President Dr Christiaan Keijzer said "We must meet the targets of the EU climate law, including Fit for 55. Reducing greenhouse gas emissions is vital to improve health, for example by making sustainable transport and food choices. Doctors should advocate for better climate protection, including in the healthcare sector. CPME is committed to work with policy-makers to make healthcare delivery more sustainable and climate neutral."

This year, the EU is revising the Ambient Air Quality Directives, providing a crucial opportunity to improve environmental standards for public health.

CPME Vice President Dr Martin Balzan said "Air pollution causes thousands of premature deaths and much ill health in Europe every year. It is indefensible to adopt new EU laws that continue to ignore the science on unsafe levels of pollution. The EU's ambient air quality laws need to fully align with the WHO guidelines and the latest scientific evidence by 2030 at the latest. We urge the EU to be ambitious in protecting the health of its citizens."

Earlier this year, the winter edition of our [magazine](#) focused on climate action as a necessary and immediate priority for the healthcare sector.



## IMMUNION Project Booklet

The two-year-long IMMUNION project to strengthen the Coalition for Vaccination ended on 31 March. The [IMMUNION booklet](#) brings together all the key outputs of the project. Although IMMUNION is finished, the Coalition remains active, using the [website](#) and social media channels, such as [Twitter](#), developed by the project, to share updates on its activities.

## Health organisations call on MEPs to improve air quality standards

**Seven health organisations have joined forces to [write](#) to Members of the European Parliament, urging them to increase the ambition of the proposal to revise the EU’s ambient air quality directives (AAQD) with science-based recommendations.**

The ENVI committee is currently considering the proposal to revise the EU’s ambient air quality directives (AAQD), a cornerstone for the protection of people’s health and the environment from air pollution.

European doctors have joined six other organisations representing the European health sector, including healthcare professionals, patients and health insurers, to urge MEPs to step up on the Commission’s proposal, to reduce ill-health and health costs swiftly and significantly.

Currently, the health burden of poor air quality remains unacceptably high. Leadership and political is crucial to put people’s health at the forefront of EU policy and prevent further ill health.

## Dr Martin Balzan elected Vice President of CPME

**We are pleased to announce that the CPME General Assembly today elected Dr Martin Balzan (Malta) as our Vice President.**

In line with our [statutes](#), Dr Balzan shall serve for the remainder of the current term of the Board of Directors until the end of 2024. He will oversee the policy areas of [professional practice and health systems](#).

He replaces outgoing Vice President Dr Marily Passakiotou, who resigned following a change of rules by her national medical association. We wholeheartedly thank Dr Passakiotou for her many years of committed service to our association.

Dr Balzan said "It is an honour to be elected as Vice President of CPME and I look forward to joining the Board of Directors to serve and contribute to the needs and expectations of European doctors in policy-making."

Dr. Balzan has been head of the Maltese delegation to CPME since 2003 and has been rapporteur for the environment since 2014, representing CPME in the Lancet Countdown initiative. His most recent contribution being the development of new, updated policies on air quality and climate change. He has been a member of the Medical Association of Malta council since 1997, and is currently President. He also served as Secretary of the Commonwealth Medical Association (2008–2010), President UEMS section of Pneumology (2010–2022), and Secretary of the European board of Accreditation in pulmonology (2010–2014).

Dr. Balzan is the lead respiratory physician at Mater Dei Hospital. He is a Senior Lecturer at the University of Malta Medical School, and Queen Mary University of London Medical School (Barts) Malta Campus, with over 70 scientific contributions to his name, mainly on Asthma epidemiology and environmental issues.

## European Doctors deeply concerned by delay of the EU pharmaceutical reform

CPME has [written](#) to European Commission President Ursula von der Leyen to express concern about the latest delay of the much-anticipated publication of the revised pharmaceutical legislation. Moreover, CPME joined an [open letter](#) to the President of the European Commission alongside 23 other organisations condemning this further delay of the publication of the EU pharma reform.

Ensuring equitable access to medicines for all patients across Europe is a crucial aspect of this legislation. It is unacceptable for the proposal on such critical legislation to be delayed without any explanation.

The lack of justification for the delay raises questions about the transparency and accountability of the process. European doctors are concerned that industry influence may result in significant last-minute amendments to the proposal, risking that patients will not be at the centre of this legislative package. It is particularly worrisome that private interests may be given priority over democratic debate in the European Parliament and the Council, especially when vital measures for the well-being of all European citizens are at stake. We urgently call for the publication to be put and maintained on the agenda of the next meeting of the college of Commissioners in April.

CPME President Dr Christiaan Keijzer said “Patients and doctors cannot wait any longer for this revision. The European institutions must be serious about the responsibility they have for delivering a new framework for medicines. We are genuinely concerned about the behind the scenes commercial influence that jeopardises a fair and balanced proposal that prioritises patients. We call on the European Commission to allow the much needed democratic process to start as soon as possible.”

Our position on the revised pharmaceutical legislation is available [here](#).

## European medical organisations support better conditions for Croatian healthcare professionals

CPME, together with seven other European medical organisations, has published a [statement](#) supporting Croatian doctors in their calls for lawful and decent working conditions.

The Croatian Medical Chamber has shared worrying reports about the state of financing and organisation of the health system, which has created unsustainable conditions for doctors to provide patient care.

The statement expresses our support for our Croatian colleagues in their calls for lawful and decent working conditions. The medical profession's experiences during the COVID-19 pandemic leave no doubt as to the importance of doctors' conditions of practice both for the healthcare system and society as a whole.

Governments must ensure sustainable education and training conditions, adequate remuneration, and lawful working conditions as well as safe staffing levels. European medical organisations support their Croatian colleagues in their action to this end and call on the government of the Republic of Croatia to find a sustainable agreement with health professionals which enables the delivery of the highest quality of healthcare to every patient.

A joint protest "SOS for Health" took place on 18 March in Zagreb.

CPME also sent an open letter to the Croatian Prime Minister and Ministers of Health and Finance in support of the Croatian Medical Chamber.

## **Violence against healthcare professionals: a rising threat to the health workforce and patient care**

**Violence against healthcare professionals is increasing at an alarming rate across Europe. On Sunday 12 March we marked the 4th European Awareness Day of Violence Against Doctors and other Healthcare Professionals to raise attention and catalyse action.**

The World Health Organization [reports](#) that up to 38% of healthcare professionals suffer physical violence at some point in their careers, and many more are exposed to verbal and online abuse. Such aggression can have devastating consequences, including physical injuries, impacts on mental health, and in the most extreme cases even death.

Violence and abuse also coexist with burnout, a growing factor in professionals choosing to leave the health sector altogether. This interacts with unsafe working conditions, [health workforce](#) shortages and the effects of the ongoing COVID-19 pandemic.

CPME President Dr Christiaan Keijzer said “We need to recognise the impact of violence on healthcare professionals, which in the end affects not only the workforce but patient care. It is critical to promote a culture of respect for healthcare professionals, and provide resources to report and support incidences when violence occurs.

“The health workforce is already in crisis. We call for policymakers and the general public to help keep healthcare professionals safe.

“We also urge the European Commission to support governments by providing benchmarks for minimum workforce capacities and address healthcare professionals in the upcoming comprehensive approach to mental health.”

We are committed to continuing our work with European Medical Organisations and partners in the health community to raise awareness for this important topic.

## Turkish Medical Associations' Case Hearing Delayed Again

The hearing, which was expected to be held on 6 April, has been postponed again until 22 June, 2023. On 22 June, 11 members of the TMA's Central Council will appear before the 31st Civil Court of Law in the capital, Ankara. They risk being dismissed from their elective functions under TMA Law No. 6023. With over 110,000 members nationwide, the TMA is the country's largest association of physicians.

In a [letter](#) issued on 4 April, four international medical and human rights organisations call on Turkish authorities to drop the baseless charges against the leadership of the Turkish Medical Association (TMA) at a time when doctors are urgently needed to tend to victims of the February 6 earthquake that has caused over 45,000 deaths in Turkey and Syria.

## European Commission webinar on their proposal for Council Recommendations on Vaccine Preventable Cancers

On 23 March 2023, the European Commission organised a webinar to hear stakeholders' views on their proposal for a Council Recommendation aimed at preventing vaccine-preventable cancers, as part of Europe's Beating Cancer Plan. It is anticipated to be adopted during the third quarter of 2023.

CPME welcomed the goal set in the Europe's Beating Cancer Plan to vaccinate at least 90% of the EU target population of girls against HPV by 2030 but highlighted that the target should be set also for boys. HPV vaccination should start early (9-12 years of age) and be free of charge as part of the national immunisation programmes. Moreover, the cost effectiveness of a nonavalent HPV vaccination should be studied and discussed in Europe. CPME also welcomed the proposal's call for measures to increase access to vaccination against Hepatitis B. The full report on this stakeholder consultation webinar can be found [here](#).

## MONITORING

## EU Political Outlook

### Parliament's Public Health Subcommittee begins work (SANT)

At the [constitutive meeting](#) on 23 March, the European Parliament's new subcommittee on public health (SANT) elected Bartosz Arukowicz as chair and the four vice-chairs (First Vice-Chair: Tudor Ciuhodaru (S&D, RO); Second Vice-Chair: Irena Joveva (Renew Europe, SI); Third Vice-Chair: Tilly Metz (Greens/EFA); Fourth Vice-Chair: – Joanna Kopcińska (ECR, PL)). As per its mandate, the subcommittee will be concerned with pharmaceutical and cosmetic products, and the health effects of bioterrorism, as well as the EMA and the ECDC. Members of the newly formed Subcommittee on Public Health (SANT) were announced in plenary on 14 February 2023. The subcommittee will have [30 members](#).

### Employment, Social Policy, Health and Consumer Affairs Council, 13–14 March 2023

- [Medicines Shortages](#): In addition to discussing what led to recent shortages of medicine in the EU, ministers discussed ways to prevent and prepare for similar situations. Medicine shortages will be on the agenda of the informal meeting of health ministers in Sweden in May. According to the Commissioner Kyriakides, the proposal to revise the general pharmaceutical legislation aims to alleviate medicine shortages by improving access to medicines and securing supplies.
- [Covid-19 Vaccine Procurement](#): Member States' needs regarding the future of Covid-19 vaccines procurement were discussed, particularly regarding the purchase of vaccines and related products at the EU level and the possible use of procurement tools. In the case of future joint procurements of Covid-19 vaccines, many ministers expressed support, if lessons learned from past pandemic procurement contracts are incorporated into the new contracts. Further, member states stressed the need to find ways to adapt existing contracts in the face of ongoing negotiations.

## MONITORING

## Employment, Social Policy, Health and Consumer Affairs Council, 13–14 March 2023 (continued)

- [Regulation on fees and charges payable to EMA](#): Ministers held a policy debate on a draft law, presented by the Commission on 13 December 2022, on fees and charges payable to the European Medicines Agency. Ministers agreed on a targeted approach to adjusting fees and remuneration, as well as on flexibility, transparency, and futureproofing. To put EMA's budget on a more sustainable footing, the proposal aims to ensure that the fees better reflect the underlying costs of its work. A stable funding source for the EMA was stressed during the debate by ministers. Several delegations also emphasised the crucial role member state bodies play in the authorisation processes of medicines.
- [Medical device Regulation](#): An update was provided the amendment to the medical devices' regulations by the Commission. Upon formal approval by the European Parliament and Council, the proposed amending Regulation was signed on 15 March 2023.
- [Long-term effects of Covid-19](#): A network of centres of expertise will be established for managing and treating long Covid, as well as €110 million in funds will be allocated to research into its causes and treatment.
- [European Union Global Health Strategy](#): In response to the Commission's presentation of the EU global health strategy on 30 November 2022, ministers held an exchange of views. According to the strategy, global health is one of the core pillars of EU external policy, which makes it a critical geopolitical issue. Several ministers acknowledged the importance of the strategy as part of the EU's response to current and future global health challenges, including COVID-19, antimicrobial resistance, and the Ukraine war-related health and humanitarian crisis, according to Acko Ankarberg Johansson. The Commissioner Stella Kyriakides mentioned that Council Conclusions are currently prepared that will endorse this strategy's priorities.



## MONITORING

## Professional Practice and Health Systems

### WHO Europe – The Bucharest Declaration on Health Workforce

On 22–23 March, representatives from 50 of the WHO European Region's 53 member states joined health workers, their unions and associations, and academics and experts, in adopting the [Bucharest Declaration](#), which urged political action and commitment to protect, support, and invest in health and care workers across Europe and Central Asia.

### Swedish doctors and nurses' battle for proper rest breaks

Swedish healthcare workers are fighting for their [right](#) to enough rest between shifts. After the European Commission criticised the country for not confirming the European Working Time Directive, they are awaiting a decision from the commission for the confirmation of the changes. Negotiations with the Swedish Medical Association, and other organisations, are still ongoing.

### Junior doctors in England hold 72-hours strike

Around 50,000 junior doctors in England held a 72-hours [strike](#) in demonstration of their continuing salary and work conditions. The BMA endorsed a proposal for an industrial action while the Government has remained unwilling to engage in negotiations. A second round of strikes takes place from 11–14 April.

### Three Policy Briefs for WHO Fifth Global Forum on Human Resources for Health

The European Health Observatory on Health Systems and Policies prepared three policy briefs to inform high-level roundtable dialogues during the World Health Organization's Fifth Global Forum on Human Resources for Health. One of the key pillars of these policy briefs is lessons [learned from COVID-19](#), [intersectoral governance](#) roles, and [efficient financing](#) to recruit, retain, reskill, and support health workers.

## MONITORING

## WHO Europe Policy brief: Making Health for All Policies

The European Observatory on Health Systems and Policies and the WHO Regional Office for Europe have released a [policy brief](#) that reveals win-win solutions for multiple sectors, encouraging policymakers to invest in health. The brief highlights that without a shift in narrative, health actors will not achieve their Sustainable Development Goals. Despite its importance in making that change, Health in All Policies is often overlooked as being 'too health sector-focused'. The key to achieving the SDGs is to convince other sectors that health contributes to their goals and to achieving goals across sectors by demonstrating the co-benefits of working intersectorally.

## WHO Europe: New evidence on financial protection in Belgium

Several country-based studies have been conducted to develop new evidence on the financial protection of European health systems. In order for a health system to perform optimally, financial protection is central to universal health coverage. [Belgium](#) has a higher incidence of catastrophic health spending than most western European countries. This problem is primarily concentrated among the poorest fifth of the population and among families headed by unemployed or inactive individuals. The unmet need for healthcare and dental care in Belgium is similar to that in the European Union, but there is a significant gap between the richest and the poorest. Health coverage gaps in all three dimensions (population coverage, service coverage, and user charges) and administrative barriers undermine financial protection in Belgium.

## Pharmaceuticals and Healthcare

### New date for the publication of the pharmaceutical package: 26 April

Under the latest version of the College of Commissioners agenda published on 28 March, the revision of the EU's general legislation on pharmaceutical products will be presented on 26 April. CPME joined an open letter to the President of the European Commission alongside 23 other organisations condemning this further delay of the publication of the EU pharma reform.

### Eight EU countries sign a letter criticising delays in the pharma reform

Eight countries of the EU sent the European Commission an official letter expressing their concerns over sliding dates for the proposed revision of the bloc's pharmaceutical regulations. It was first set for December last year. The letter is signed by ambassador Marten Kokk, the deputy permanent representative of Estonia to the EU, on behalf of Croatia, Cyprus, Lithuania, Malta, the Netherlands, Romania and Slovenia, as well as Estonia. The eight countries additionally support cutting the market protection period for new drugs and only restoring it if the drugs are made available in all 27 of the union's member states one of the more radical changes that were outlined in a leaked draft of the legislation. They state that shortening the data protection term would help in decreasing the cost of medicines.

### Four countries called for regulation on Pfizer Contract

During an EU Council meeting on 14 March, the health ministers of Bulgaria, Poland, Lithuania, and Hungary filed a joint proposal demanding that the European Commission renegotiate the terms for the delivery of COVID vaccines supplied by Pfizer. As [stated](#) by the Bulgarian government, the contract should meet the demands of particular nations, identify specified amounts with an expiration date, and allow for payment after delivery.

## MONITORING

## Council adopted the Medical Device Regulation extension

The Council of the European Union has adopted the Commission's [proposal](#) to give notified bodies and manufacturers more time to certify medical devices and thereby mitigate the risk of shortages. The legislative proposal provides a longer transition period to adapt to new rules foreseen under the Medical Devices Regulation, ensuring continued access to medical devices for patients in need.

The European Commission [published](#) a Q&A on practical aspects related to the implementation of the extension.

## EMA pilots scientific advice for certain high-risk medical devices

For certain high-risk medical devices (all class III devices and class IIb active devices intended to administer and/or remove medicinal products), EMA has launched a [pilot study](#) to offer scientific advice on the intended clinical development strategy and clinical investigation proposals. From 27 February 2023, manufacturers can apply to join a pilot programme on scientific advice provided by medical device expert panels as part of the scientific advice pilot.

## HERA signs agreement with ECDC and with EMA to strengthen cooperation on health emergency preparedness and response

There have been [agreements](#) between the Commission's Health Emergency Preparedness and Response Authority (HERA) and the European Centre for Disease Prevention and Control (ECDC), as well as HERA and the European Medicines Agency (EMA) to strengthen cooperation and coordinate their efforts to prepare for and respond to health emergencies in the area of medical countermeasures. By agreeing to the working arrangements, resources will be used more efficiently, and no unnecessary overlap will occur.

## MONITORING

## Council of Europe's Recommendation on equitable access to medicinal products and medical equipment in a situation of shortage

The Council of Europe has adopted a [Recommendation](#) on access to medicines and medical devices in situations of shortage, both in the context of health emergencies and beyond. The recommendation highlights the principles of non-discrimination and promotes prioritisation based on medical criteria, while also respecting accountability, transparency and inclusiveness, by carrying out individual medical assessment, with the aim of minimising the risk of mortality and, subsequently, morbidity. It calls for the creation of national policies to react to shortages, and for health professionals to be involved in their development. Alongside the policies on medicine shortages and health inequalities, CPME contributed the [CPME survey on triage protocols in the context of COVID-19](#) coordinated by the WG on Ethics and COVID-19 to the drafting process.

## European Medicines Agency – Shortage discussions with HERA

The European Medicines Agency's Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) has [encouraged](#) EU Member States to examine national regulatory flexibilities to allow the distribution of medicines that may not be authorised in their respective countries. In collaboration with DG HERA, the EMA will meet with key manufacturers to review manufacturing capacity and demand estimates for a select group of essential antibiotics.

## Germany tries to solve drug shortages

A [draft](#) law aimed at addressing drug shortages in Germany has been passed by the German cabinet, with Health Minister Karl Lauterbach saying the government has overdone it with cost savings on pharmaceutical supplies, and the draft law aims at correcting this to attract the generics industry to Germany. For children's medicines, fixed prices and discount agreements are being abolished, leaving pharmaceutical companies with the option to increase their prices by up to 50 percent. Additional costs will be covered by health insurance companies. Pharmaceutical companies will also be rewarded for developing new antibiotics. The draft law is facing substantial criticism by the National Association of Statutory Health Insurance Funds and the opposition.

## MONITORING

## Study requested by the COVI Committee on long-term public and private investments in Covid-19 vaccines

The European Parliament Research Service published a [study](#) mapping the funding contributions for research and development and the expansion of COVID-19 vaccine production capacity made by different actors. The study found that given the total EC purchase expenditure of EUR 71 billion reported by the European Court of Auditors (ECA) at EUR 15 average price per dose, and investors could earn an income of tens of billions in less than two years obtained from European taxpayers. The study concludes that the most important question is how this support can be provided to maximise returns on investments for governments and taxpayers but does not suggest operational proposals on how this can be implemented.

## COVI Public Hearing – One Health

The COVI Special Committee met with experts to discuss "[One Health](#)". The experts highlighted the need for proper disposal of human waste, minimisation of contact between humans and wildlife, active engagement of the public, and a long-term ecosystem of partnerships between the European Union, Member States, and stakeholders. Furthermore, the hearing addressed how the EU can effectively implement the one health approach in the future and provided insight into how the Pandemic Treaty will incorporate it.

## HERA study on “bringing AMR medical countermeasures to market”

HERA published two reports on bringing AMR medical countermeasures to the market. [The interim report](#) includes a mapping of existing AMR MCM & those in development, a gap analysis, and a methodology for prioritising AMR MCM in development. The [final report](#) includes (i) the results of a survey on needs and priorities, challenges and potential roles of HERA and (ii) an analysis of options for HERA to support development of and access to AMR MCM.

## MONITORING

## New features further strengthen Priority Medicines scheme (PRIME)

EMA is introducing a number of new features to the [Priority Medicines \(PRIME\)](#) scheme to strengthen its support for the development of medicines in areas of unmet medical needs. Through PRIME, the Agency offers early and proactive support to medicine developers for the generation of data on a medicine's benefits and risks and enable accelerated assessment of medicines applications. By the end of 2022, 26 medicines that benefited from PRIME support had received a positive recommendation for approval in the European Union (EU) Starting as a 12-month pilot until March 2024, expedited scientific advice can now be provided specifically for PRIME developments in case of issues with a specific development programme that has already received comprehensive initial advice.

## MONITORING

## Public Health and Disease Prevention

### ENVI Committee's draft report on the revision of the EU air quality directives

On 7 March, MEP Javi Lopez (S&D, Spain), the European Parliament's rapporteur on their report on the European Commission's proposal for the revised air quality standards, organised an event to present his [first draft of the report](#). It contains many amendments proposed by CPME and other health groups. Most importantly, he supports and proposes a full alignment of EU limit values with the 2021 WHO Air Quality Guidelines by 2030. He also wants to limit values for ozone instead of target values. Moreover, he highlights that it is important to protect sensitive populations and vulnerable groups. Next, the Parliament's ENVI Committee will discuss the draft report in their meetings on 22–23 March. The MEPs could table their amendments by 29 March.

### EU Drugs Agency: Council presidency and European Parliament agree to strengthen the agency's role

[Provisional agreements](#) have been reached between the Council presidency and the European Parliament regarding a proposed regulation on the EU Drugs Agency, which will turn the existing European Monitoring Centre for Drugs and Drug Addiction into an independent agency, strengthening its role. The provisional agreement is subject to approval by the Council and the European Parliament before formal adoption.

### Tuberculosis deaths increasing in the European Region

Tuberculosis (TB) deaths in Europe [increased](#) in 2021 for the first time in nearly two decades due to the pandemic's disruption on treatment and diagnostic services. The situation in Europe is detailed in a [report](#) on TB surveillance and monitoring in Europe.



## MONITORING

## ENVI Committee Meeting Updates

- [New Carbon Sink Targets](#): Land use and forestry sectors, as part of the new law, will have to reduce greenhouse gases by 57% by 2030 compared to 1990 to achieve the EU carbon sink target. The law aims to increase EU carbon sinks by 15% by 2030 is a new EU target. Moreover, all EU countries must set 2030 targets that are nationally binding. There are plans to improve monitoring and governance, including penalties for noncompliance
- [New Effort Sharing regulation](#): As a result of the new Effort Sharing Regulation, the maximum allowed level of greenhouse gas emissions from transport, buildings, and agriculture in member states will be reduced until 2030. All EU countries must reduce emissions by 2030 compared to 2005. The reduction targets for each member state are based on the GDP per capita and the cost-effectiveness of the program. A limited number of opportunities will exist for trading, borrowing, and reducing emissions, while a greater amount of transparency will be achieved as information on national actions is made publicly available.
- [Fluorinated Gas Emission Reduction](#): With 64 votes in favour, 8 against, and 7 abstentions, members of the ENVI Committee adopted their position on amending the EU's regulatory framework for fluorinated gases (F-gases) emissions.
- [Ozone-depleting substances](#): With 74 votes in favour, 0 against, and 2 abstentions, the ENVI Committee endorsed a report on the revision of the measures addressing ozone-depleting substances (ODS).
- [Carbon Removals](#): The ENVI Committee adopted the report on Sustainable Carbon Cycles with 64 votes in favour, 6 against, and 8 abstentions. In the report, MEPs highlight that carbon removals should never take the place of legally required emissions reductions and acknowledge the potential of the sustainable carbon cycles program to help the EU reach its net carbon removal target of at least net 310 megatons (Mt) by 2030.

## MONITORING

## MEPs support stricter sanctions for environmental crimes

The Legal Affairs Committee endorsed its [position](#) on an update to EU environmental crime rules, calling for new offence definitions and stricter punishments. The updated list would now include illegal timber trade, illegal depletion of water resources, pollution caused by ships, breaches of EU chemicals legislation, cultivation of genetically modified organisms, conduct causing forest fires, and infringements contributing to illegal, unreported, and unregulated fishing.

## Europe experienced second-warmest winter on record

Europe is emerging from its second-warmest winter on record, European Union [scientists](#) said on Wednesday (8 March), as climate change continues to intensify. That ranks as Europe's joint-second warmest winter on record, exceeded only by the winter of 2019–2020. High temperatures pose risks to wildlife and agriculture. Winter temperature spikes can cause plants to start growing or coax animals out of hibernation prematurely, making them vulnerable to being killed off by later cold snaps.

## Fluorinated gases and ozone depleting substances: member states ready to negotiate with Parliament

The European Parliament agreed on 30 March on its position on negotiations with EU governments regarding measures to cut down emissions of [substances that damage the ozone layer](#) and [to reduce fluorinated gas emissions](#). On 5 April, member states agreed to give the presidency a [mandate for negotiations](#) with the European Parliament on the two regulation proposals. With the proposals, the goal is to limit global temperature rises in line with the Paris Agreement. F-gases also have medical uses, such as in inhalation anaesthetics and metered-dose inhalers (MDIs). After the discussions on their limited replacements and stressing the need to maintain uninterrupted patient access to critical medicines, MEPs managed to pass some [amendments](#) to the European Commission proposal. The set of amendments agreed upon by the MEPs will be discussed with the EU ministers as soon as they approve their position on the dossier.

## MONITORING

## Council adopts regulation on CO2 emissions for new cars and vans

On 28 March 2023, the Council [adopted](#) a regulation setting stricter CO2 emission performance standards for new cars and vans. This new regulation aims to reduce emissions from road transport – the largest contributor to transportation emissions – and push the automobile industry towards zero-emission mobility while ensuring additional innovation. Compared to 2021 levels, the new rules set CO2 emission reduction targets of 55% for new cars and 50% for new vans from 2030 to 2034. The CO2 emissions of new cars and vans will be reduced by 100% by 2035. In the regulation, there is a reference to e-fuels, whereby the Commission will propose, after consultation with stakeholders, to still register vehicles solely powered by CO2-neutral fuels after 2035, in accordance with EU law, outside the scope of fleet standards, and in compliance with the EU's climate neutrality goal.

## Council reaches agreement on amendments to industrial emissions directive

On 16 March 2023, the Council adopted its [negotiating position](#) ('general approach') on a proposal to review the industrial emissions directive. Through the new rules, industrial installations and intensive livestock farms will reduce harmful emissions into the air, water, and waste stream that can harm human health and the environment. As a general approach, member states amended the Commission's proposal to extend the directive's scope to intensive livestock farms with more Live Stock Units (LSUs) than 350 LSUs for cattle and pigs, 280 LSUs for poultry, and 350 LSUs for mixed farms. There would be an exclusion for extensive farms. Initially, the new rules would apply to the largest farms.

## European Investment Bank Climate Survey

People's views on climate change in a rapidly changing world are explored in the second part of the [2022–2023 European Investment Bank Climate Survey](#). Specifically, the results examine the behaviours and actions people are taking to combat climate change. One finding was that 76% of young Europeans say the climate impact of prospective employers is an important factor when job hunting.

## MONITORING

## First meeting of the PHEG sub-group on vaccination

The Public Health Expert Group ("PHEG") sub-group on vaccination held its [first online meeting](#) under DG SANTE. A total of 26 Member States, Iceland and Norway, as well as the European Centre for Disease Prevention and Control, attended the meeting. The PHEG Rules of Procedure as well as the mandate for the subgroup on vaccination were presented. In support of Europe's Beating Cancer Plan, the subgroup on vaccination will emphasize human papillomaviruses (HPV) and hepatitis B virus (HBV) vaccination. Moreover, DG SANTE presented the Commission Proposal for a Council Recommendation on vaccine-preventable cancers. It is set to be adopted in the third quarter of 2023.

## Second meeting of the PHEG sub-group on mental health

The [second meeting](#) of the new Public Health Expert Group (PHEG) subgroup on mental health took place online on 28 March 2023. Members were informed of the current status of the Commission's mental health initiative, including some preliminary findings from a WHO survey of mental health capacity-building needs and the results of stakeholder consultations and calls for evidence. As part of the consultation, member states were invited to share their national priorities and challenges related to mental health, including mental health promotion and prevention, access to care, and early detection.

## MONITORING

## WHO Europe: New guidelines aim to protect children from unhealthy food marketing

A newly released [set of WHO nutrition criteria](#) aims to protect children from marketing promoting unhealthy foods and non-alcoholic beverages. The WHO Regional Office for Europe's Nutrient Profile Model (NPM) classifies foods to determine if they are healthy enough to be advertised to children. Decision makers can use it to develop strategies to improve overall dietary quality and support surveillance initiatives.

## What next for European action on childhood obesity?

A [public hearing](#) on "What next for European action on children's obesity?" was held by the European Economic and Social Committee on 23 March, with the purpose of contributing to the exploratory opinion requested by the incoming Spanish Presidency of the Council of the European Union. It is stressed that the future European Health Union must provide a healthy living life in accordance with SDG 3, as well as establish community efforts against obesity. This [exploratory opinion](#) aims to provide a chance to elaborate on the EESC's work on sustainable food systems, address the causes of obesity as a social determinant of health, and provide recommendations for promoting healthier and sustainable diets, healthy lifestyle habits, and the protection of vulnerable children to feed into the Spanish presidency's work.

According to the COSI (European Childhood Obesity Surveillance Initiative) study, obesity was prevalent in 13% of boys and 9% of girls in Europe. In addition, southern European countries such as Cyprus, Greece, Italy, and Spain had even higher rates of obesity, with more than 40% of children overweight.

## MONITORING

## Digital Health

### Data act: member states agree common position on fair access to and use of data

To ensure that the EU becomes a leader in a data-driven society, representatives of member states (Coreper) reached a [common position](#) ("negotiating mandate"), allowing the Council to engage in negotiations with the European Parliament regarding the proposed legislation regarding harmonised rules on access to and use of data (data act). Individuals and businesses will have more control over their data through the Data Act thanks to a strengthened portability right, which allows copying or transferring data across different services, with data generated through smart objects, machines, and devices. Through this new legislation, consumers and companies will have greater control over the use of data generated by their connected products.

### The European Commission has adopted the Digital Europe Programme Work Programme for 2023–2024

The Digital Europe Programme has been divided into two multiannual work programmes, outlining the objectives and specific topic areas that will receive [€1.284 billion in funding](#), of which €553 million will be available in 2023. There are two work programmes, the [Main DEP Work Programme](#) and the [Cybersecurity Program](#). Strategic investments will be made that will play a key role in making this Europe's Digital Decade. Digital Europe aims to strengthen Europe's technological sovereignty and bring digital solutions to the market for citizens, public administrations, and businesses while contributing to the European Green Deal's objectives.

## MONITORING

## Artificial intelligence: the EU needs to act as a global standard-setter

Taking the final step in 18 months of inquiries, Parliament's Special Committee on Artificial Intelligence in a Digital Age (AIDA) adopted its [final recommendations](#) on 22 March. In the adopted text, it is stated that the public debate should focus on the enormous potential of artificial intelligence (AI) to complement humans. According to the text, the EU has fallen behind in the global race for tech leadership. Consequently, standards may be developed elsewhere in the future, often by non-democratic actors, whereas the EU should serve as a global standard-setter in artificial intelligence. Artificial intelligence has been identified as a potential tool in health, the environment, and climate change, as well as in combating pandemics and global hunger and improving the quality of life of people through personalised medicine. In addition to increased capital and labour productivity, AI can also increase innovation, sustainable development, and job creation if it is paired with the necessary support infrastructure, education, and training.

## European Medicines Agency DARWIN EU®:

The Data Analysis and Real-World Interrogation Network, has accomplished its [first year](#) of establishment, and is calling for new data partners. The network launched its first four research, which used real-world data (RWD) from throughout Europe to better understand diseases, populations, and the uses and effects of medicines and is taking part in a pilot project for the European Health Data Space (EHDS) to investigate the network's potential as a research and data point.

## MONITORING

## Looking ahead

17–20 April	European Parliament plenary
18–19 April	Informal meeting of environment ministers
26 April	Pharmaceutical revision expected
3–4 May	Informal meeting of employment and social affairs ministers
4–5 May	Informal meeting of health ministers
12–13 June	Employment, Social Policy, Health and Consumer Affairs Council



# How to make progress on tackling AMR?

## Addressing Antimicrobial Resistance in Medical Practice

27 April 2023 | 13:00 – 16:15 CEST | Stockholm | In person and online



### Speakers will include:

Swedish Ambassador on AMR

Slovenian Medical Chamber

Health Action International

Public Health Agency of Sweden

European Commission | Strama

Health Action International | ReAct Europe

European Centre for Disease Prevention and Control

Health Emergency Preparedness and Response Authority

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