



## Dear colleagues

We hope you had a fantastic holiday season and wish you a healthy new year. 2023 was a busy year for CPME, when we published new policies, held high-level events and our two General Assemblies in Dubrovnik and Tallinn provided the perfect occasions to advance our activities.

This first edition of 2024 follows the Board meeting held on 14 December, as we start to look forward to the upcoming General Assembly in Slovenia from 22-23 March 2024. We hope many of you will be able to join us in Ljubljana.

We were also pleased to hear the report of the successful webinar on the Quality of Basic Medical Education held on 13 December 2023, when over 50 participants discussed with the expert panelists. A survey will be distributed this month to provide further insights.

We invite you to read about all this and more in this month's edition.

**Dr Christiaan Keijzer**  
CPME President



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## Internal Affairs

### Planning for General Assembly in March 2024

- ▶ The Board took note of the planning for the next General Assembly and the preliminary planning for the morning of 22 March.

### Call for nominations for WG Chairs and Rapporteurs

- ▶ The Board took note of the open vacancies and agreed to consider suitable candidates.

## Policies

### Health Emergency Preparedness and Response Authority (HERA)

- ▶ The Board adopted a draft responses to a public consultation on the review of HERA, and a survey contributing to a study supporting the review of HERA with regard to its operations, structure, and governance.

The objective of the public consultation and survey is to assess the extent to which HERA's mandate and tools (legal basis, structure, governance, funding) have enabled it to effectively and efficiently contribute to the political objective of strengthening the EU's health emergency preparedness and response.

## BOARD OF DIRECTORS MEETING – 14 DECEMBER 2023

## CEmPaC Advisory Board

- ▶ The Board decided to end CPME's involvement in the Advisory Board of the Centre for Empowering Patients and Communities (CEmPaC).

Dr Katrín Fjeldsted, CPME Past President and Rapporteur on Health Literacy & Patient Empowerment, had represented CPME in the Advisory Board since 2018. CPME will continue to monitor developments on this topic.

## Medical devices

- ▶ The Board took note of CPME not submitting a response to the survey on the EU Regulation on medical devices and decided to monitor the outcomes of the survey and other elements of the review process with a view to providing future input.

## Interim evaluation of the 2021–2027 EU4Health Programme

- ▶ The Board adopted a response to a call for evidence on interim evaluation of the 2021–2027 EU4Health Programme and will monitor future funding calls.

The response highlights the need to ensure a policy framework and vision to guide funding to relevant projects, e.g. support for the implementation of the European Health Data Space, as well as the emphasis facilitating access to funding for stakeholders.

## Joint conference with PGEU

- ▶ The Board discussed the draft agenda of a joint conference with PGEU on shortages of medicines, medical devices and healthcare professionals.

## BOARD OF DIRECTORS MEETING – 14 DECEMBER 2023

## Turkish Medical Association

- ▶ The Board discussed the dismissal of the Central Council of the Turkish Medical Association (TMA), and a template letter for NMAs to write to the Turkish authorities will be considered.

The 11 members of the Central Council were dismissed from their elected positions by a civil court in Ankara on 30 November. The decision was unexpected and the TMA was still waiting for the reasoned decision from the court, after the publication of which they would have 15 days to appeal. An interim council of 5 members appointed by the court would oversee new elections.

## Quality of basic medical education

- ▶ The Board took note of the recent webinar (see page 6) and decided to initiate a survey on the Quality of Basic Medical Education.

## European Health Data Space

- ▶ The Board took note of the latest developments of the positions of the European Parliament and of the Council in view of guiding on the strategy and messages for the trilogues meetings.

The Board decided that CPME will write a letter to the Commission requesting information on how doctors could comply with the secondary use obligations with a “click of a button” and how “health data intermediaries” would intervene in practice.

The Board noted that CPME has contributed to several events related to the EHDS at EU level.

## Webinar on Quality of Basic Medical Education

The Webinar on Quality of Basic Medical Education held on December 13, 2023, witnessed active participation and discussion, engaging 58 participants alongside the valuable insights provided by expert panelists. A survey and report will be distributed among participants and NMAs in January 2024. The webinar recording is available [here](#).

## Reinstate Turkish Medical Association's Central Council

The unprecedented dismissal of 11 eminent Turkish physicians from their elected positions on the Central Council of the Turkish Medical Association (TMA), the country's largest professional medical group, is a flagrant violation of international human rights law and ethical standards, said a global coalition of medical professional organisations, including CPME.

## European Health Data Space must not push small medical practices into administrative burnout

Ahead of the final negotiations on the European Health Data Space (EHDS), European doctors called on the European Parliament and Council to exclude micro and small enterprises from the secondary data obligations.

## Health groups coalition calls on EU environment ministers to accelerate action for clean air for health

Health groups have sent a joint letter to EU environment ministers, calling to accelerate action for clean air for health.

## European Medicines Agency requests healthcare professionals organisations to monitor medicine shortages

EMA’s Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) recommended to continue close monitoring of the availability of several antibiotics and medicines used for treatment of fever in children. EMA is requesting patient and healthcare professional organisations to report any early signals of disruptions in supply for these medicines.

We invite you to report any such shortages to CPME [secretariat@cpme.eu](mailto:secretariat@cpme.eu) so they can be passed on to EMA.

Antibiotic	Situation
Amoxicillin/clavulanic acid	<e.g. Member states X, Y, Z: limited/no availability of paediatric formulations requiring HCPs to switch to <X > as alternative antibiotic treatment >
Azithromycin	
Clarithromycin	
Cefotaxime	
Ceftriaxone	
Piperacillin/tazobactam	
Paracetamol and ibuprofen in formulations such as syrup and suppositories	
Cough syrups for children	

## MONITORING

The Secretariat monitors the news and uploads [weekly monitoring reports](#) the members' section of the website. In the following pages we include a selection of the most relevant news items.

## EU Political Outlook

### The European Commission adopted the EU4Health 2024 Work Programme

The [EU4Health 2024 Work Program](#) consists of four overarching strands: crisis preparedness, health promotion and disease prevention, health systems and healthcare workforce, and digital health, with cancer considered as a transversal strand. With a budget of €750 million, the 2024 Work Program will address health-related issues relating to the Covid-19 pandemic and the war in Ukraine. It will also support emerging policy initiatives focusing on mental health, global health, digital health, medicinal products, cancer screening, and medicine shortages.

### United Kingdom joins Horizon Europe Program

As of 1 January 2024, the UK is officially an associated country to Horizon Europe. Its researchers are now able to participate in the EU's research and innovation program on the same terms as researchers from other associated countries and have access to funding.



## Professional Practice and Health Systems

### The Commission published two key reports on the EU's health systems

The [2023 State of Health Preparedness report](#) and the [State of Health in the EU: Synthesis Report 2023](#) examine EU health systems and show how the EU has responded to the need for more resilient, robust, and equitable health systems. The first report focuses on the steps taken by the EU to improve its capacity to face serious cross-border health threats, and the second outlines how health systems are performing across the EU in meeting the needs of European citizens, with dedicated country profiles.

### WHO report demonstrates that out-of-pocket payments for primary care are unaffordable for millions in Europe

On 12 December, the WHO celebrated International Universal Health Coverage Day 2023, notably publishing a report entitled "[Can people afford to pay for health care? Evidence on financial protection in 40 countries in Europe](#)". The report highlights that out-of-pocket payments push between 1 and 12% of households into poverty or make them poorer. The report proposes five policy choices that have improved financial protection in countries with a low incidence of financial hardship and unmet needs.

## MONITORING

## Pharmaceuticals and Healthcare

### The European Medicines Agency published the first version of the Union list of critical medicines

The list was [published on 12 December](#) and contains more than 200 active substances. A medicine is listed as critical when it is essential to ensure the provision and continuity of quality healthcare and guarantee a high level of public health in Europe. The list will be reviewed and updated annually.

### Health Emergency Preparedness and Response Authority (HERA) published its 2024 Work Plan

The [2024 Work Plan](#) outlines HERA's upcoming focus on medical countermeasures and on tackling medicine shortages. It links the authority to several other EU programmes, including EU4Health and Horizon Europe, as well as the proposal for a Critical Medicines Alliance recently presented by the Commission.

### WHO Europe roadmap to tackle antimicrobial resistance using behavioral and cultural insights

The Health ministers and delegates from WHO Europe have endorsed a new [roadmap](#) on applying behavioural and cultural insights to work on AMR. The WHO advocates for individual and contextual factors that influence health behaviours to be taken into consideration in policies to tackle AMR. These factors include hospital procedures, social norms, prescription habits among doctors, and fears of malpractice. These are recognised as high-impact, and therefore key to understand and address AMR.

## MONITORING

## The WHO Quadripartite Collaboration launched a guide to support countries implementing One Health policies

The "Guide to Implementing the One Health Joint Plan of Action at National Level" outlines three pathways (governance, sectoral integration, and evidence and knowledge) to achieve One Health Implementation. The guide also proposes a five-step approach to support implementation.

## EU medicines agencies reflect on lessons learnt from Covid-19

A joint report issued by the European Medicines Agency (EMA) and the Heads of Medicines Agencies (HMA) reviews the European Medicines Regulatory Network (EMRN) response and highlights the main learnings for any future health crises. It notably concludes that more can be done to set up large clinical studies rapidly and highlights the need for a larger pool of experts for scientific assessments in crisis situations.

## MONITORING

## Public Health and Disease Prevention

### More than 40 million health professionals demand bold health and climate action at COP28

For the first time ever, COP28 included a day dedicated to discussions on health. On this occasion, more than 40 million health professionals from around the globe joined the call to action by the WHO and civil society to prioritise health in climate negotiations.

### The WHO published a report on tools to support action on climate change and non-communicable diseases

The [report](#) acknowledges that policies which mitigate climate change and reduce air pollution can have major benefits for non-communicable diseases such as cardiovascular and respiratory diseases. Several impactful policy options are presented, including regulatory approaches to improve diets, capacity building to protect health during climate-change emergencies, and investment in transport planning to increase daily physical activity.

### Council and Parliament strike a deal on substances of human origin

The co-legislators reached a provisional agreement to improve the safety and quality of blood, tissues and cells used in healthcare and facilitate cross-border circulation of these substances in the EU. The agreement notably states that the donations of substances of human origin should be voluntary and unpaid as a matter of principle, and donors must not be provided with financial incentives to donate.

## MONITORING

## The Council published conclusions on drug use disorders that co-occur with other mental health disorders

These Council conclusions are part of a wider cluster of conclusions on mental health put forward by the Spanish Presidency. Suggestions put forward include more interconnection between health, mental health and drug policies, which should all develop responses tailored to people suffering from dual disorders. The conclusions also urge for more data collection on dual disorders, and for the association between drug use and other mental health disorders to be assumed as standard instead of exceptional.

## MEPs call for a long-term European strategy on mental health

The Parliament adopted in plenary its recommendations on prioritising mental health in European and national policies. These include the promotion of mental health for all with a focus on vulnerable groups, improved access to mental health services, addressing the mental health workforce shortage, and better awareness and communication to destigmatise mental health.

## WHO calls on countries to increase taxes on alcohol and sugary sweetened beverages

The WHO recently released data showing a low global rate of taxes on alcohol and sugar sweetened drinks. Findings indicate that most countries are not using taxes to incentivise healthier behaviours.

## Respiratory infectious diseases are on the rise across the WHO Europe region

Approximately half of the countries in the region are experiencing higher levels of fever and cough, and some countries are reporting a sharp increase in respiratory infectious diseases, including among young children.

## MONITORING

## WHO Europe calls for urgent action on measles

941 cases of measles were reported in 2022, while between January and October 2023, over 30 000 cases were reported by 40 of the region's 53 countries. The rise in measles cases has accelerated in recent months, and the trend is expected to continue if urgent measures are not taken. The resurgence is largely attributed to backsliding in vaccination coverage between 2020 and 2022.

## EU study recommends banning nicotine pouches

The EU recently banned "snus", a novel nicotine product, based on the EU Tobacco Products Directive. New [analysis](#) now shows that the market for nicotine pouches has doubled between 2020 and 2021 in 5 European countries, and a study carried out for the Commission suggests that extending the snus ban to nicotine pouches would significantly improve both the functioning of the internal market and health protection in the EU.

## WHO Europe and WHO Eastern Mediterranean collaborate on violence against women

The regional offices have launched a joint initiative to improve the skills of healthcare professionals who care for women survivors of physical and/or sexual violence. This training aims to provide practical, hands-on skills to health facility managers, ministry of health officials, civil society representatives, and non-profit organisations responsible for training healthcare staff.

## MONITORING

## Digital Health

### Council and Parliament make progress on the negotiations for the European Health Data Space

MEPs voted in favour of the EHDS proposal on 12 December. The Parliament stands in favour of an opt-out approach for the primary use of health data but does not support the exemption of small enterprises from the secondary use regime. The Council agreed on its position on 6 December, revising certain aspects of the initial proposal including greater clarity on the alignment with the GDPR, the possibility to have separate national and cross-border profiles in the European electronic health record exchange format, and the discretion of Member States to allow patients to opt out of the new data-sharing system.

The CPME Secretariat is continuing to work on these points, the exemption for small enterprises specifically, during the triilogue negotiations between the co-legislators.

### The Council configuration on Competitiveness discussed measures to support SMEs

The discussion followed the Commission's "SME relief package" published in September. Ministers exchanged views on how to support and relieve SMEs from burdensome procedures. Some suggestions include the simplification of taxes, using digital technologies to reduce burden and improve resilience, and facilitating access to skilled staff.

### Council and Parliament strike a deal on the Cyber Resilience Act

The co-legislators reached an agreement on the Cyber Resilience Act, which aims to improve the level of cybersecurity of digital products. The cybersecurity requirements for all hardware and software will be proportionate to their perceived level of risk.

## MONITORING

## Institutions came to an agreement on the AI Act

The Commission, Parliament and Council successfully ended negotiations on the AI Act, after more than 3 days of discussion. The text introduces dedicated rules for general purpose AI models, aiming to ensure transparency. AI systems will be categorized by level of risk, and subject to safety requirements accordingly. The final agreement notably clarifies and adjusts the requirements to make them less burdensome for stakeholders and more technically feasible, for instance with provisions specific to SMEs.

## Parliament calls for new EU rules to address digital addiction

MEPs adopted a report calling for the development of ethical digital products that do not rely on addictive designs. The text urges the Commission to address existing legal gaps and to introduce new legislation against addictive design for more consumer protection. MEPs highlight the risk of digital addiction for concentration, cognitive ability, and mental health, and call for further research.

## Council agreed on its position on the Cyber Solidarity Act

The proposed regulation aims to protect critical entities and services, such as hospitals and public utilities, against cyber-attacks. It includes the creation of a 'European cyber shield', a pan-European infrastructure composed of national and cross-border security operations centres. The text also foresees the creation of a cyber emergency mechanism to increase preparedness and enhance incident response capabilities in the EU.

## The European Medicines Agency published the 2024–2028 AI Workplan

Published by the EMA and the Heads of Medicines Agencies (HMAs), the workplan aims to ensure that the European Medicines regulatory network remains at the forefront in benefitting from AI in medicines regulation.



## MONITORING

## Ukraine

### **The European Commission allocated €4 million to improve healthcare for Ukrainian refugees and displaced persons under temporary protection**

The project aims to strengthen the capacity of national health systems to cope with the influx of persons fleeing the war in Ukraine and improve access of refugees to healthcare. Initiatives funded include integrating displaced health workers from Ukraine into the health workforce of host countries and strengthening networks of healthcare workers to provide specific healthcare assistance needed by refugees.

### **The WHO and the Ministry of Health of Ukraine signed a Biennial Collaborative Agreement to enhance partnership and strengthen health system resilience**

The agreement sets out the health priorities with which the WHO will support Ukraine. This includes effective and timely emergency response services, an integrated package of health services for all, preventing future disease outbreaks, tackling non-communicable diseases, and strengthening health institutions to contribute to Ukraine's EU accession process.

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