



Dear colleagues

This edition follows the Board meeting held on 18 January, when we met in Brussels for our first in person meeting of 2024. Following the meeting, on 22 January, I presented our ambitions to continue building the European Health Union to the President of the European Parliament, MEP Roberta Metsola, as we <u>launched</u> our <u>Health Check for Europe 2024–2029</u> for the upcoming European elections in June.

In the manifesto, adopted at our General Assembly in November, we welcome that European countries have made advances in collaboration on health in recent years, and urge the EU not to take a step backwards. The elections are a key moment in shaping the EU for the next five years and we will continue to collaborate with policy-makers and partners to provide a strong voice for European doctors in solidarity for a bright and healthy future for our continent.

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

Dr Christiaan KeijzerCPME President





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Finances

Draft 2023 accounts

The treasurer presented the draft final 2023 accounts which are still being consolidated ahead of the external audit.

Whilst the accounts are not final yet, it is estimated that the deficit will be significantly lower than budgeted.

Draft 2024 budget

► The Board discussed savings to present to the General Assembly in March, which will be modelled prior to the next Board meeting.

Preliminary 2025 budget

The Board discussed considerations for the 2025 budget based on debates at the Board and General Assembly with the objective to eliminate the continued deficits and stabilise CPME finances.

It was agreed to model changes to president, vice-president and treasurer fees, as well as the new participation fee, and calculate the requirement to balance the budget for the next Board meeting.



Internal Affairs

Rules of Procedure

The Board agreed for text proposals to be presented at the next Board meeting and to pursue the update in 2024 with the help of an external consultant.

The Board took note of proposed amendments to the Rules of Procedure. Following the adoption of the new CPME statutes in 2022, specific provisions have been amended, but the full alignment with remains to be completed. In addition, new provisions are proposed to clarify reimbursement of travel expenses, and the requirements for general assemblies, as well as transparency requirements and declarations of interest.

Planning for General Assembly in March 2024

The Board discussed the draft agenda for the next General Assembly in Ljubljana, 22-23 March 2024.

Cooperation with Taiwan Medical Association

The Board discussed future cooperation with and potential associated membership of the Taiwan Medical Association. It was agreed to maintain relations at their current level.

European elections 2024

The Board noted the finalised print version of the Health Check manifesto and the plans for dissemination.

The Board took note that the campaign will be launched by presenting the document to the President of the European Parliament and a press release had been prepared for the occasion.



Policies

Quality of Basic Medical Education

► The Board approved the CPME draft survey on the Quality of Basic Medical Education.

The Members' feedback will guide future input and identify priorities for the discussions in CPME GA in Ljubljana in spring 2024.

European Electronic Health Record Exchange Format

The Board took note of a draft statement and a draft letter.

The Board decided to delay the sending of the letter to DG SANTE and DG CNECT until after a meeting with the Commission on 25 January.

Health situation in Gaza

The Board decided to endorse a shortened version of the WMA statement.

BeWell Skills Monitor

► The Board decided to disseminate a survey to all CPME members.

Medical devices

The Board decided to prepare a response to relevant questions in cooperation of the corapporteurs on medical devices and the president based on CPME's existing policies.



Turkish Medical Association

The Board took note of the developments in the legal proceedings of the Turkish Medical Association (TMA).

The reasoned decision for the dismissal of the 11 members of the Central Council was published on 20 December 2023. The TMA Central Council filed their appeal on 4 January. The secretariat will follow up with the TMA and WMA to coordinate future actions.

European Health Data Space

The Board reviewed the draft statement highlighting key CPME positions for the final phase of the EHDS legislative negotiations.

The priorities had been identified in the WG online meeting on 10 January 2024 the statement was still being consolidated with the Rapporteur and the WG chair, pursuant to the comments received by WG participants. The Board agreed that the final details would be approved by the WG chair and the president.

National surveys

The Board agreed to send to members questionnaires from Norway on Recognition of Specialist training in EU countries and from Czechia on Benefits for overtime work.

Critical Medicines Alliance

The Board agreed that CPME should apply to join the Critical Medicines Alliance and propose Dr Christiaan Keijzer as representative.

EMOs joint letter on reduction of doctors' remunerations

The Board approved a request from the Romanian College of Physicians for a joint letter of the European Medical Organisations opposed to national reforms which lead to a reduction of doctors' remunerations.



CPME NEWS

European doctors launch ambitions to continue building European Health Union to President Metsola

CPME <u>launched</u> five ambitions to keep building the European Health Union in a meeting with the President of the European Parliament, MEP Roberta Metsola.

The <u>Health Check for Europe 2024–2029</u> sets out a vision for the EU's health priorities ahead of the upcoming European Parliament election in June.

We urge European policy-makers to:

- Tackle the health workforce crisis
- Ensure a safe digital transformation of healthcare
- Enable healthier living
- Guarantee accessibility and effectiveness of medicines
- Take climate action for better health

CPME President Dr Christiaan Keijzer said "Whilst European countries have made huge advances in collaboration on health in recent years, we cannot take a step backwards.

"The COVID-19 pandemic has shown that health is the foundation of our economy and society, and exposed that problems that have not been solved. Our health systems still suffer from deep structural flaws and our health workforce is exhausted and undervalued.

"The European Health Union is not complete: the EU needs a coherent long-term vision for health in Europe and beyond for equitable access to healthcare for patients.

"European doctors remain strongly committed partners in making these ambitions a reality."

The PDF and social media resources are available here.



CPME NEWS

CPME endorses WMA statement on medical neutrality

CPME has <u>endorsed</u> the statement made by the World Medical Association on 15 October 2023. The statement expresses the WMA's commitment to the principles of medical neutrality and support to healthcare professionals.

Council of Europe Conference on health literacy and human rights in Rome

On 12 December, Dr Katrín Fjeldsted, CPME Past President, <u>attended</u> the Council of Europe Conference on health literacy and human rights in Rome. The event launched the <u>Guide to health</u> <u>literacy</u> comprised of five actionable components for health systems and users of health systems, namely: access to valid health information; access to appropriate care; communication between individuals, health professionals and health authorities; shared decision-making regarding treatments and care; access to digital spaces to understand and use health services.

Coalition for Vaccination welcomes Council recommendation on vaccine-preventable vaccines

On 31 January, the European Commission put forward a Council recommendation to support EU Member States in their efforts to prevent cancer through vaccination against Human papillomaviruses (HPV) and Hepatitis B virus (HBV), as well as improving the monitoring of coverage rates. The Recommendation includes a series of measures such as providing vaccination free of charge and/or fully reimbursed, ensuring that vaccination is easily accessible, and integrating vaccine-preventable cancer immunisation into national cancer plans. CPME advised the Commission to set the Europe's Beating Cancer Plan's goal to vaccinate at least 90% of the EU target population of girls by 2030 also for boys. Please find the Coalition for Vaccination, co-chaired by CPME, reaction here.



CPME NEWS

European Medicines Agency requests healthcare professional 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 so they can be passed on to EMA.

Antibiotic	Situation
Amoxicillin/clavulanic acid	<e.g. <x="" availability="" formulations="" hcps="" limited="" member="" no="" of="" paediatric="" requiring="" states="" switch="" to="" x,="" y,="" z:=""> as alternative antibiotic treatment ></e.g.>
Azithromycin	
Clarithromycin	
Cefotaxime	
Ceftriaxone	
Piperacillin/tazobactam	
Paracetamol and ibuprofen in formulations such as syrup and suppositories	
Cough syrups for children	



The Secretariat monitors the news and uploads <u>weekly monitoring reports</u> the members' section of the website. In the following pages we include a selection of the most relevant news items.

EU Political Outlook

The Council of the European Union adopted conclusions on the 2024 European Semester

The European Semester is the framework which ensures effective coordination of economic and social policies in the EU. The Economic and Financial Affairs Council recently approved <u>conclusions</u> on the strategic priorities and orientations for economic and social policies in 2024. In the section on macroeconomic stability, the text notably states that disparities in access to healthcare negatively contribute to productivity gaps between European regions. Furthermore, it emphasises that equal opportunities for education and training need to be ensured to counter shortages in key sectors, including healthcare and STEM.

The European Commission responded to the European Ombudsman's questions on the EU WhoisWho directory

After the European Commission's decision to remove all names of staff under the level of Head of Unit from the EU WhoisWho directory, a civil society organisation lodged a complaint with the European Ombudsman condemning this decision. The organisation argued that removing these names hindered civil society from openly engaging with the Commission. CPME sent a letter supporting this claim. In its <u>response</u>, the Commission explains that this measure aims to protect its staff from undue influence and pressure. According to the letter, several incidents were reported, including instances where Commission staff were targeted by Members of the European Parliament.



Professional Practice and Health Systems

England's junior doctors held a record-breaking strike

On 3 January, junior doctors in England started a six-day walkout, the longest strike in the 75-year history of the NHS. The British Medical Association abandoned talks with the government after being offered a pay rise of 8% to 10% in December. It is demanding a 35% improvement to cover the impact of inflation over several years.

The European Commission opened a consultation on the Professional Qualifications Directive

The Professional Qualifications Directive sets out EU-level minimum training requirements for several regulated professions, allowing some professionals to have their qualifications automatically recognised and practice their profession in another EU country. The consultation will gather feedback on updating the minimum requirements for nurses responsible for general care, dental practitioners, and pharmacists.

WHO offices for Europe and for the Eastern Mediterranean Region collaborate on fighting violence against women

The regional offices 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 officials, civil society representatives, and non-profit organisations responsible for training healthcare staff.



Pharmaceuticals and Healthcare

European Commission opened a call for expression of interest to join the Critical Medicines Alliance

The Critical Medicines Alliance was announced in last October's <u>Communication on addressing medicine shortages</u> and aims to bring together all relevant stakeholders to identify challenges, priorities, and policy solutions to tackle medicine shortages. The call is open to Member States, local and regional authorities, agencies, companies, civil society, health professionals, patients, consumers, and all other stakeholder groups. CPME will submit an application to become a member.

Institutions continue to consider a Critical Medicines Act

Last Spring, EU Member States expressed their support for a Critical Medicines Act which would support EU strategic autonomy for medicines. The European Economic and Social Committee is now proposing similar measures to strengthen the EU's domestic pharmaceutical production capacity. While the Commission has not published a legislative proposal, this is a potential health-related topic to be tackled after the elections.

WHO Europe's Novel Medicine Platform launches working group on transparency

WHO Europe's Novel Medicine Platform convened its second working group focusing on the theme of transparency. The working group aims to build trust, promote collaboration, enable horizon scanning, and develop indicators to facilitate accountability and corrective actions. At the meeting, delegates committed to improving the transparency, availability, visibility, and use of information relating to access to medicines. Dr Wolf-Dieter Ludwig spoke at the meeting, representing CPME.



Commission proposes extension of transition periods for in vitro diagnostic medical devices and mandatory reporting of impending shortages

The <u>extension</u> aims to prevent bottlenecks due to the transition to the EU Medical Device Regulation of 2017. A similar extension was put in place for medical devices at the beginning of 2023. The risk of bottlenecks is particularly high for class D in vitro diagnostic medical devices, used for instance against HIV or hepatitis. The Commission is proposing an extension from 2025 to 2027 for these high-risk devices, to 2028 for medium-risk devices, and to 2029 for low-risk diagnostics such as pregnancy tests. In return for the deadline extension, manufacturers are obliged to report any emerging shortages of medical devices and IVD medical devices to national authorities and distributors, healthcare facilities, and healthcare professionals.

DG SANTE study now includes new dashboard monitoring the availability of medical devices on the EU market

DG SANTE commissioned an ongoing study to support the monitoring of availability of medical devices on the EU market. In this context, a <u>dashboard</u> has been developed which presents an overview of existing data on the availability of medical devices and in vitro diagnostic medical devices in the EU.



European Medicines Agency published 2023 Human Medicines Highlights

In 2023, EMA recommended 77 medicines for market authorisation. Of these, 39 had a new active substance which had never been authorised in the EU. This overview includes figures on the authorisation of medicines and treatments that represent significant profess in their areas.

European Medicines Agency's safety committee recommends precautionary measures on treatment with valproate medicines

This recommendation stems from the observation of potential risk of neurodevelopmental disorders in children born to men treated with valproate medicines in the three months prior to conception. EMA now recommends that this treatment is started and supervised by a specialist, and a direct communication will be sent to healthcare professionals prescribing, dispensing, or administrating the medicine.

European Medicines Agency has published a major update of the SME user guide

The <u>revised user guide</u> offers comprehensive information on the EU legislative framework for medicines, outlining requirements for the development and authorisation of medicines for human and veterinary use. Sections with major changes include the Clinical Trials Regulation, which provides an overview of clinical trial regulation and the Clinical Trials Information System.



Public Health and Disease Prevention

Covid-19 vaccines saved at least 1.4 million lives in Europe

A new WHO Europe <u>study</u> revealed that since their introduction in December 2020, Covid-19 vaccines have reduced deaths due to the pandemic by at least 57%. Without the vaccines, the death toll might currently be as high as 4 million. Countries that implemented early vaccination programmes covering large parts of the population, such as Belgium, Denmark, Malta, the Netherlands, and the UK, overall saw the greatest benefits on lives saved through vaccination.

WHO reports a decline in tobacco use, and EU considers further bans of nicotine products

According to the WHO, trends in 2022 show a continued decline in tobacco use rates globally. About 1 in 5 adults consume tobacco worldwide, compared to 1 in 3 in 2000.

In the EU, the novel nicotine product "snus" was recently banned using the EU Tobacco Products Directive. New analysis now shows that the market for nicotine pouches, another novel nicotine product, has doubled between 2020 and 2021 in 5 European countries. 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.

The European Commission opened a call for evidence on the Regulation of Serious Cross-Border Threats to Health

The call for evidence will support the assessment of the operation Early Warning and Response System, and the epidemiological surveillance network. It will also cover the coordination of responses to a health crisis within the Health Security Committee, and the Commission's work in better preparedness and response activities provided for in the regulation.



WHO Europe published a new toolkit on addressing dangerous health narratives in emergencies

The WHO has developed the concept of infodemic management, a systematic way to prepare for, address and mitigate the dangers of false information, information overload and voids in health emergencies. Managing infodemics is about making sure that everyone can find and use accurate, timely and reliable information to protect their health and others'. The toolkit outlines five key steps to manage dangerous health narratives in emergencies: signal detection, signal verification, risk assessment, response design, and outreach.



Digital Health

The eHealth Network published guidelines on electronic exchange of health data

The guidelines cover <u>hospital discharge reports</u> and <u>medical imaging studies and reports</u>. They aim to establish an agreed format for interoperability and sharing of key information in healthcare settings for all EU Member States. They provide guidance to support the implementation of exchanges, and examples and references to illustrate best practice of dataset exchanges.

Decision by the Court of Justice of the EU (CJEU) on the application of the GDPR regulation

An employee of the Medical Service of the Health Insurance of Northern Rhineland claims he suffered prejudice because of illicit processing of his health data by his employer. The German Court asked the CJEU several questions pertaining to the application of the GDPR regulation in the situation where the employer acts both as employer and holder of health data. The CJEU provided clarification on the capacity of a medical service to process its employee's health data and under which conditions, as well as on data protection requirements specific to this situation, and the possibility of granting non-material damages to the employee.

The European Data Act entered into force

The European Data Act has entered into force, establishing new rules defining the rights to access and use data generated in the EU across all economic sectors. This new text should make it easier to share data. It will become applicable in September 2025.



MEPs condemn last minute changes to the AI Act

The negotiations on the AI Act ended last December, however last-minute tweaks to the text are sparking controversy in the Parliament. These changes would allow law enforcement to use facial recognition technology on recorded video footage without a judge's approval. MEP Svenja Hahn denounced an "attack on civil rights" which could enable "irresponsible and disproportionate use of biometric identification technology".

The WHO released an AI ethics and governance guidance for large multi-modal models

Large multi-modal models (LMMs) are fast growing generative artificial intelligence technology with applications across healthcare. The WHO <u>guidance</u> outlines over 40 recommendations on five broad applications of LMMs in health, namely diagnosis and clinical care, patient-guided use, administrative tasks, medical and nursing education, and scientific research. The guidance also details broader risks to health systems, such as accessibility and affordability of the best-performing LMMs.

The European Parliament suggests the creation of a European Charter for Digital Rights

MEPs have adopted a <u>report</u> suggesting measures to strengthen the rights of European citizens. Provisions cover the right to vote for mobile citizens, gender-balanced democratic representation, and easier access to participatory mechanisms. The report also suggests a binding European Charter for Digital Rights, which would ensure universal internet access, the management of one own's digital identity, and the digital inheritance of a deceased person's data.





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