



## **Dear colleagues**

This edition follows the Board meeting held on 12 October, when we adopted a statement on medicines shortages, urging concerted EU action to secure medicine supplies for the autumn and winter season, as well as for the long-term. We must avoid a repeat of last winter, when severe shortages of essential medicines put patients at risk and the compromised the work of healthcare professionals.

We also finalised draft documents for our General Assembly, including draft policies on the health effects of cannabis and doctors' wellbeing, and draft campaign messages for the upcoming European elections next year. We look forward to discussing them with you in Tallinn from 10-11 November.

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

**Dr Christiaan Keijzer**CPME President





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#### **BOARD OF DIRECTORS MEETING - 12 OCTOBER 2023**

### **Finances**

#### Draft accounts 2023

- ▶ The Board discussed the draft accounts 2023 to date, which are progressing as expected.
- Due to more in person meetings, the travel budget for representatives is utilised fully again.

#### Draft Budget 2024

► The Board discussed the draft budget 2024 to date, which will be presented to the general assembly for decision.

The Board noted a small addition to provide for IT and office equipment.

## Options for future budgets

The Board agreed to proceed with the proposals to present options for future budgets to the CPME general assembly for decision.

#### **BOARD OF DIRECTORS MEETING - 12 OCTOBER 2023**

#### **Internal Affairs**

#### General Assembly, 10-11 November 2023, Tallinn, Estonia

► The Board discussed the draft agenda of the CPME General Assembly and Policy Sessions meetings to be held from 10–11/11/2023 in Tallinn, Estonia.

It was confirmed that an expert presentation on greening the healthcare sector and a word of welcome by the Estonian minister of health will open the meetings.

#### 2024 planning

The Board revised the dates of the Board meetings for 2024.

### Call for nominations for WG Chairs and Rapporteurs

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

### **Policies**

### Medicine shortages statement adopted

The Board decided to adopt a statement on medicines shortages considering comments shared by France and Ireland.



#### **BOARD OF DIRECTORS MEETING – 12 OCTOBER 2023**

#### Pharmaceutical legislation

The Board approved an updated amendment to the EU pharmaceutical legislation (CPME 2023/101).

The additional wording strengthens the obligation to supply medicines and is in line with CPME policy on pharmaceuticals and medicine shortages.

The Board was updated on the progress of the legislative process and highlighted that many important CPME amendments were already well reflected in the draft reports of the European Parliament e.g., on antimicrobials prescribing, obligation to file for pricing and reimbursement in all Member States, transferable exclusivity voucher and others.

CPME will use its adopted position to respond to the ongoing consultation organised by the European Commission.

### Health priorities for European elections 2024

The Board discussed and adjusted the draft campaign messages for the European elections 2024, which will be submitted to the General Assembly for adoption.

Additional feedback was provided by the Royal Dutch Medical Association, with notable additions agreed on 'Health in all policies', the One Health approach, tackling disinformation and health impact of people living in financial hardship or poverty.

### EPHA video campaign

The Board decided to participate in the European Public Health Alliance's (EPHA) video campaign on doctors and climate change.

The aim of the campaign is to empower healthcare staff to advocate locally and be part of the wider movement. Both Dr Martin Balzan and Dr Ole Johan Bakke agreed to be interviewed.



#### **BOARD OF DIRECTORS MEETING – 12 OCTOBER 2023**

#### EC call for evidence for non-EU diplomas

The Board adopted the feedback on the Commission call for evidence regarding two initiatives linked to talent mobility and qualification recognition.

The policy initiative promotes talent mobility within the European Union, which can help address labor shortages and enhance the skill set of the European workforce. The recognition of qualifications of third country nationals is essential for a dynamic European labor market.

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

The Board approved a discussion paper produced by the working group 1 of the HERA Civil Society Forum on the "Future of HERA".

The final document will be presented to the top leadership of HERA in late October.

### Policy on the health effects of cannabis

► The Board noted the progress of the policy following two open working group meetings on 28 September and 5 October

The revised version will be discussed in the public health session in Tallinn.

### Policy on doctors' wellbeing

The Board took note of the revised version of the draft policy with the input from national medical associations and EJD.

The draft policy will be discussed in the session on professional practice and health systems in Tallinn.



#### **BOARD OF DIRECTORS MEETING - 12 OCTOBER 2023**

#### **European Health Data Space**

The Board took note of the state of play of the European Health Data Space file.

The Secretariat has prepared a second lobbying package for CPME members which will be presented at the Tallin GA.

### Statement on Doctors' right to Strike

The Board took note of the CPME Statement on Doctors' right to strike in support of the British Medical Association's action on a national strike bill.

The statement is envisaged to be adopted in the Tallinn GA.

#### Letter and testimonials received from the Israeli Medical Association

The Board took note of a letter describing the effects of the terrorist attack on health. The Board also took note of the CPME reply to the letter.



# European Doctors urge immediate action on medicine shortages for autumn and winter season

CPME released a <u>statement</u> expressing concern on the continuously urgent problem of medicine shortages, calling for concerted action at the EU level to secure medicine supplies for the autumn and winter season and in the longer perspective.

Recently, national medical associations have reported that the problem of medicine shortages has become systemic across seasons and types of medicinal products, which is impacting patient safety and the practice of healthcare professionals. CPME provided recommendations to the European Commission and the Member States on forecasting and production, communication for healthcare professionals, an EU list of critical medicines, a solidarity mechanism and EU stockpiling, procurement and dependency on third countries.

# Doctor MEP Roundtable discusses most pressing issues facing EU health policy

Around 30 participants from across Europe joined co-chairs MEP Sara Cerdas and MEP Peter Liese on 10 October to discuss the EU's current health policy agenda, addressing topics such as the European Health data Space, the Ambient Air Quality Directives, and the Health Workforce shortages. The meeting also focused on the health agenda in the European Parliament until the end of the legislature and looked ahead to the priorities for the next legislature and the future of the Parliament's SANT committee.

MEP Cerdas said "The protection of public health is a shared competence. We can act on health determinants and on primordial prevention, such as food labelling, alcohol, tobacco and air quality." In view of next year's European elections, MEP Liese said "In addition to European health, we need to communicate the benefit of working together in Europe. The value of the Union must not be forgotten."



# Joint letter to EU Environment Ministers: health sector calls for clean air to prevent disease and save lives.

CPME, with seven other health organisations, sent a <u>letter</u> to the EU environment ministers on the EU Ambient Air Quality Directives. The Council of the EU is expected to adopt their approach to the trilogue between the EU institutions before the end of the year. The undersigned urge the ministers to step up on the European Commission's proposal, to reduce ill-death and health costs.

# Accessibility, resilience and effectiveness: European doctors' proposed amendments to EU pharmaceutical reform

CPME has <u>proposed improvements</u> to the European Commission's proposal for the reform of the EU pharmaceutical legislation. The proposed amendments are guided by three principles: accessibility, resilience, and effectiveness.

The proposal has a strong focus on addressing medicine shortages and strengthening security of supply, especially by proposing earlier notifications, clear definitions of shortages and an obligation of having in place shortage prevention plans. The proposed amendments further improve this by introducing communication about shortages and alternatives for prescribers, as well as by establishing safety stocks of medicines.

The CPME proposal moreover advocates for an obligation to file for pricing and reimbursement in all Member States where medicines are approved, a definition of "innovative medicines", for including quality of life in the definition of unmet medical need, and for a strengthened regulatory framework to ensure evidence provided and before the authorization of medicines is robust and based on randomised clinical trials.



# European healthcare professionals urge vaccination for COVID-19 and seasonal influenza

The Coalition for Vaccination <u>issued</u> a statement on the autumn-winter vaccination season 2023-24, calling for countries to make influenza and COVID-19 vaccination easily accessible particularly to high-risk population groups such as people with co-morbidities, the immunocompromised, the elderly and pregnant women.

Also, healthcare professionals who are more exposed to the risk of infection and who need to protect their patients should get vaccinated against influenza, complete their COVID-19 vaccination series and receive the potential additional dose.

# Dimitri Eerens and Clémence Albert-Lebrun joined Secretariat as Interns

Dimitri Eerens joined the Secretariat on 2 October. He holds a Bachelor's degree in European Public Health and is currently pursuing a Master's degree in Governance and Leadership in European Public Health. Prior to joining CPME, he researched medical deserts as a trainee at the European Commission in DG SANTE.

Clémence Albert-Lebrun joined the Secretariat on 9 October. She holds a Bachelor's degree in social science and public affairs, and two Master's degree in EU political affairs. Prior to joining CPME, she worked as a research assistant on the resilience of EU healthcare systems, and then for the European Commission's Joint Research Centre on economic policies.



## Call for rapporteurs

CPME is looking for new rapporteurs and chairs of the working groups:

- Chair for the Working Group on Climate Change
- Co-rapporteur on the independence of the medical profession
- Rapporteur on Refugee Health
- · Chair of the Working Group on Healthy Living

CPME members are welcome to propose experts, including those beyond their delegations to CPME if they can assist them in fulfilling their role (see Rules of Procedure) by sending an expression of interest to **secretariat@cpme.eu**.

#### Chair for the Working Group on Climate Change

This WG recently completed a policy on climate change and health. CPME keeps promoting this policy as it tackles various aspects of climate chance, including the emissions of healthcare sector. CPME is also very active in the revision process of the EU air quality directives. The EU institutions are currently forming their position in order to start the trilogue negotiations. Finally, the annual Lancet Countdown process on climate change and health is expected to start soon. Since 2018, CPME has been co-publishing briefings and recommendations for EU policymakers.

### Co-rapporteur on the independence of the medical profession

Following discussions at the CPME meetings in March, a survey will be carried out to map challenges to the independence of the medical profession in Europe. The co-rapporteur will cooperate with the responsible VP and secretariat to design and evaluate the survey for presentation at a forthcoming meeting. Members' requests for support in this matter will also be consulted with the rapporteurs.



#### Rapporteur on Refugee Health

CPME is seeking for a new rapporteur on refugee health, noting the increased interest in the topic in light of the rising numbers of refugees resulting i.a. from the war in Ukraine.

In the CPME statement on the medical treatment of refugees, CPME emphasises doctors' ethical responsibility for equitable care to all patients, irrespective of status. CPME also implements its policy on refugee doctors. By joining CPME as a rapporteur, you will work alongside CPME secretariat to contribute to the development and implementation of effective policies in the field of refugee health.

#### Chair for the Working Group on Healthy Living

This WG is dealing mainly with alcohol, nutrition, and tobacco policies but it has also discussed other topics such as physical activity. Currently, it is drafting a policy on the health effects of cannabis. In the near future, it aims to contribute to the following EU's legislative processes: the introduction of European alcohol and front-of-pack nutrition labelling rules, the revision of the directives on tobacco products, taxation, and advertising. Moreover, CPME and a number of other organisations are developing a campaign on unhealthy food marketing.

# CPME has published an open letter supporting the call for the release of the hostages held by Hamas

The <u>letter</u> echoes the urgent call for the immediate release of the hostages held by Hamas and for their return to safety without further harm.



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.

## **European Political Outlook**

#### The European Commission adopts its 2024 Work Programme

Largely based on President Von Der Leyen's 2023 State of the Union speech, the <u>Work Programme</u> outlines key successes from the past four years, including the construction of the European Health Union with the creation of HERA, Europe's Beating Cancer Plan, the European Health Data Space, the reform of the pharmaceutical legislation, and the EU Global Health Strategy. The <u>Communication</u> also presents new initiatives for the end of this Commission's mandate, with a strong focus on the EU's competitiveness.

### Several health-related items at European Parliament plenary session

MEPs adopted the <u>proposal</u> for a Regulation on Establishing the Ukraine Facility in first reading. This facility should respond to the healthcare needs of Ukraine, improve and strengthen the social care systems, and rebuild and improve healthcare facilities, focusing on trauma care. The Parliament also adopted amendments to the Union Civil Protection Mechanism and discussed a resolution on mental health at work.

## 73<sup>rd</sup> session of the WHO Regional Committee for Europe

The <u>three-day event</u> (24-26 October) in Astana, Kazakhstan brought together health ministers and high-level delegates from the 53 Member States of the WHO European region, as well as representatives of partner organisations and civil society. Marking the 75th anniversary of the WHO, the conference agenda included discussion on a <u>Resolution to protect and support health and care workers across Europe and Central Asia</u>, a <u>Roadmap on antimicrobial resistance</u>, and updates on the development of the <u>Preparedness 2.0 Strategy and Action Plan</u>.



# The European Commission presented its Demography Toolbox to the Council of the European Union

The Commission's <u>Communication</u> presents a set of policy tools available to Member States for managing demographic change and its impact. The Communication notably highlights the consequences of Europe's ageing population, the necessity for health promotion and disease prevention targeted towards youth, the challenges faced by healthcare professionals in Europe, and the central role that they can play to address these issues, pending that they be properly equipped with and trained to use digital resources.

## **Professional Practice and Health Systems**

Frank Vandenbroucke, the Belgian Health Minister and Deputy Prime Minister raised the idea of a review of the European Union's directive on professional qualifications

Belgium will emphasize the importance of addressing the healthcare workforce issue during its upcoming presidency of the European Council.

He suggested that the European Commission initiate a discussion on the implications of marketdriven legislation on professional qualifications. Vandenbroucke stressed the importance of investment in the healthcare workforce and the need for reforms to address the crisis. He called for greater flexibility in allowing individuals with different competencies to work together more effectively.

We will follow up with the Commission on this matter and address the subject during our upcoming CPME webinar focused on enhancing the quality of basic medical education in December.



#### Pharmaceuticals and Healthcare

## Commission publishes its Communication on Addressing Medicine Shortages in the EU

The <u>Communication</u> complements the proposed <u>reform of the pharmaceutical legislation</u>, putting forward some <u>key measures</u> to tackle foreseen shortages this winter and in future years. Key measures include a <u>Voluntary Solidarity Mechanism</u> which allows Member States to support each other and reallocate supplies, and the creation of a Critical Medicines Alliance starting in early 2024, bringing together national authorities, industry, civil society representatives, the Commission and EU agencies. CPME published a <u>statement</u> on medicines shortages prior to the communication.

#### Council and Parliament strike deal on EMA fee system

The presidency of the Council and European Parliament negotiators <u>reached</u> a provisional agreement on a regulation to modernise and simplify the structure of fees payable to the European Medicines Agency (EMA). The Commission <u>welcomed</u> the political agreement. EMA charges a fee for processing applications from companies to launch a medicine on the market, as well as tasks such as pharmacovigilance. For 2023, fees and charges accounted for around 89% of the agency's budget.

#### European Parliament draft reports on the pharma package published

Draft reports from rapporteurs <u>Pernille Weiss</u> and <u>Tiemo Wölken</u> have been published. The secretariat has analysed the reports and will report during the upcoming General Assembly. Many important CPME amendments were already well reflected in the draft reports of the European Parliament e.g., on antimicrobials prescribing, obligation to file for pricing and reimbursement in all Member States, transferable exclusivity voucher and others.



# Pharmaceutical groups fined 13.4 million euros by the European Commission for breaching anti-trust rules

The companies fined include Alkaloids of Australia, Alkaloids Corporation, Boehringer, Linnea and Transo-Pharm, for agreeing to set the minimum sales prices and allocate quotas for distributors.

#### EMA alert over falsified Ozempic pens

The European Medicines Agency has been notified by national authorities that pre-filled pens falsely labelled as the diabetes medicine Ozempic have been identified at wholesalers in the EU and the UK. These <u>reports</u> come in the wake of an increase in demand for Ozempic, which led to a shortage situation. Since EMA sent out the alert, several patients have been hospitalised in Austria because of suspected fake pens. The Austrian Office of Safety in Health Care suggested that the shortage is being exploited by criminal organisations.

# Council agrees on its negotiating mandate on the proposed regulation on blood, tissues, and cells

The <u>regulation</u> ensures better protection of donors, recipients and children born following medically assisted reproduction, with a strengthened legal framework and additional flexibility to keep up with scientific and technical developments. It strongly emphasises that donations should always be unpaid and voluntary and widens the definition of "substances of human origin". This agreement will allow the Council to begin trialogues with the Commission and Parliament.

### High-level Conference "One Health for All, All for One Health" upcoming

The event aims to discuss how to mainstream the One Health approach, based on the lessons learnt from the Covid-19 pandemic. It will take place on 13 November in Luxembourg and will be livestreamed on <a href="mailto:this.page">this.page</a>.



#### **Public Health and Disease Prevention**

# European Parliament adopts new rules to protect EU workers from asbestos

The plenary <u>adopted</u> a directive that will decrease the occupational exposure limit of asbestos and calls for the use of more modern and accurate technology to detect the presence of thin asbestos fibres. The Council <u>voted favourably</u> on this Directive on 23 October, meaning the directive will enter into force 20 days after its publication in the Official Journal of the EU, after which Member States will have two years to implement these rules in their national legislation.

# The European Commission, the ECDC and WHO Europe call for vaccination against Covid-19, influenza and RSV

The <u>Communication</u> published earlier this October emphasises the role of healthcare professionals in the efficient roll-out of vaccination campaigns.

### Institutions celebrated World Mental Health Day on 9 October

EU Health Commissioner Stella Kyriakides took advantage of this day to promote the Commission's New Comprehensive Approach to Mental Health during the <a href="high-level conference">high-level conference</a> she hosted in Brussels. The Council approved <a href="conclusions">conclusions</a> on the interconnection between mental health and precarious employment. The WHO also marked the occasion and published a <a href="report">report</a> on the mental health of refugees and migrants and new <a href="guidance">guidance</a> to improve laws addressing human rights abuse in mental health care, as well as a <a href="Mental Health Gap Action Programme">Mental Health Gap Action Programme</a> with Poland.



#### WHO published a report on healthy ageing

<u>The WHO report</u> covers the consequences of the ageing European population, suggests lifestyle improvements for older adults to improve their health and recommends policies to increase health life expectancy.

# DG SANTE has opened a call for independent experts to join the Advisory Committee on Public Health Emergencies (PHE)

The PHE provides advice to the Commission and member states in the event of serious cross-border threats to public health. <u>Deadline to apply is 15 November</u>.

## The European Agency for Safety and Health at Work (EU-OSHA)

launched its 2023-2025 Healthy Workplaces Campaign "Safe and

Healthy Work in the Digital Age"

These two-year campaigns are the flagship awareness-raising activity of EU-OSHA. The 2023-2025 campaign <u>launched this week</u> will focus on the impact of new digital technologies on work and workplaces and the associated occupational safety and health challenges and opportunities, <u>looking consecutively at 5 priorities</u> related to work in the digital age.

CPME is a long-standing partner of the Healthy Workplaces campaigns, participating since 2011.



## **Digital Health**

## Member States agree on a common position on the Interoperable Europe Act

The proposal aims to deliver more efficient digital public services across the EU. The Council <u>position</u> stands in favour of a one-stop-shop approach for interoperability solutions and community cooperation and defends an alignment of the text with the Artificial Intelligence Act and GDPR regulations.

# European Commission recommends risk assessments on four critical technology areas, including AI and biotechnologies

On 3 October, the Commission adopted a <u>recommendation</u> on critical technology areas for the EU's economic security. It identified artificial intelligence technologies and biotechnologies as presenting high immediate risks, and recommended the Member States perform risks assessments in coordination with the private sector and protecting data confidentiality.

# Committee of the Regions published annual Report on the State of Regions and Cities

The <u>report</u> highlights increasing cybersecurity risks in areas relying on technology, including health, and suggests that lack of cyber-resilience could lead to decreasing citizen trust, notably for vaccination campaigns.



# WHO outlines considerations for regulation of artificial intelligence for health

WHO released a new <u>publication</u> listing key regulatory considerations on AI for health, which include transparency and documentation, risk management, and data quality. WHO Europe is planning to establish a European Artificial Intelligence Office, with a focus on AI and precision medicine.

# The Internal Market and Consumer Protection committee (IMCO) of the European Parliament will vote to adopt a draft report on addictive design of online services

Online services may be designed in an addictive way aiming to keep the user on the app longer than intended. The rapporteur is alarmed that platforms and tech companies exploit psychological vulnerabilities and <u>calls</u> for EU legislation to protect users from addictive design.

# The European Data Protection Supervisor (EDPS) published an opinion with its final recommendations on the Al Act

The proposal is in the final stages of negotiations and allocates certain tasks to the EDPS during its implementation. The EDPS is a notified body and market surveillance authority and will assess the conformity of high-risk AI systems developed or deployed by EU institutions, bodies, offices and agencies. To adequately fulfil its role, the <u>EDPS requests</u> a clarification of its powers and tasks under the AI Act, a capacity to receive complaints from individuals, and voting rights in the AI Office's Management Board.



### **Ukraine**

# WHO installs new modular facilities in Ukraine to provide primary health care services

To ensure continued access to primary healthcare services in areas where facilities have been destroyed or are irreparable, WHO is installing modular primary care facilities in partnership with the Ministry of Health of Ukraine. The clinics can be assembled and installed within 10–14 days and can serve as replacements for up to 10 years.

# WHO assessment reveals resilience of Ukraine's primary healthcare system amid the war

The <u>report</u> takes stock of the changes in volume of services, service modalities, and working conditions for health workers. It also outlined the need for mental health services to be available for staff.



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