



# **Dear colleagues**

As we publish this Bulletin in the first weeks of June, the European elections have taken place and the next EU legislature will start to take shape. In the Board meeting on 23 May, we discussed the health aspects of the political parties' manifestos (links included on page 9) and we look forward to advancing our positions in the <u>Health Check</u> in the next political mandate.

We welcome feedback on the election discussions in your country and to know if national medical associations already have relations or knowledge of the incoming MEPs on health-related topics. We are very happy to support you in reaching out.

The Board also approved CPME's participation as a partner in the i2X project proposal, which, if funded, will trial the practical implementation of European Health Records in real life.

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 - 23 MAY 2024**

#### **Finances**

# Management of CPME reserves

The Board decided to diversify CPME reserves across several savings accounts that offer higher interest rates than the current accounts without any risks.

Future options will be evaluated as to feasibility.

#### **Policies**

### Participation in i2X project proposal

The Board decided to accept the invitation to join the i2X project and to approve the financial CPME commitment of 123 000 EUR with the equivalent of 15 person-months.

If funded, the project will trial the EEHRxF in real life, dealing with practical implementation. The final proposal was submitted with a slightly reduced budget of 115,667 euros corresponding to 11 person months. The project would be 50% funded by the European Commission, and CPME co-finances 50%, mainly in kind with staff working time. The CPME contribution would be 57,833 euros.

# EU4Health consultation response

The Board decided to submit a draft response to the targeted stakeholder consultation about EU4Health Annual Work Programme 2025.



#### **BOARD OF DIRECTORS MEETING - 23 MAY 2024**

#### Second revision of Union List of Critical Medicines

The Board decided to adopt a response to a draft Council of Europe Guidance Document on Traceability of Medicines in Hospital Settings.

#### **Critical Medicines Alliance**

The Board decided to accept an invitation to join the Working Group (WG) 1 on 'Strengthening manufacturing capacities in the EU for critical medicines to better prevent and fight their shortages'. Final representation shall be determined after the first meeting.

#### Real4Reg consortium survey

The Board decided not to disseminate the link to the online survey to CPME members to contribute to the European research project Real4Reg with a view to lack of capacity.

# Lancet Countdown on Climate Change and Health

The Board took note of the Lancet Countdown <u>policy priorities</u> for Europe data sheet CPME co-published with Lancet Countdown, the Health and Environment Alliance (HEAL), and the Association of Schools of Public Health in the European Region (ASPHER).

CPME has collaborated with Lancet Countdown since 2018. This year's publication highlights heat-related health impacts, climate-related health inequalities, and the urgency to act on climate and health.



#### **BOARD OF DIRECTORS MEETING - 23 MAY 2024**

# WHO/Europe survey on doctors' mental health

The Board noted the WHO Europe initiative on the Survey on Doctors' Mental Health...

CPME, along with other EMOs such as EJD and UEMS, also participated in a consultation call. The final version of the survey will be presented to the Board for decision. The WHO aims to establish this as an annual pan-European survey. EMOs will discuss this topic jointly at the next EMOs presidency meeting, particularly focusing on how to circulate the survey towards the end of the year once it is finalised.

# **European Parliament elections**

The Board took note of the Secretariat's first analysis of how political manifestos address European doctors' ambitions for 2024-2029. It was agreed to take this into account when contacting MEPs after the elections.



#### **CPME NEWS**

# Lancet Countdown and European doctors emphasise better climate policy equals better health

The Lancet Countdown, the Standing Committee of European Doctors (CPME), the Health and Environment Alliance (HEAL) and the Association of Schools of Public Health in the European Region (ASPHER) have <u>published</u> the policy priorities on climate change and health:

- 1) Prevent heat-related health impacts
- 2) Prioritise reducing climate-related health inequalities
- 3) Take urgent action on climate and health

We call for a coordinated approach across all sectors to reduce greenhouse gas emissions, and urge Europe to act now to align climate policies to improve mitigation and adaptation, while protecting public health.

The priorities were developed by selecting key indicators from the Lancet Countdown's 2024 Europe Report on Health and Climate Change.

According to the report, there were over 60,000 estimated heat-related premature deaths in the summer of 2022. Therefore, countries in Europe should develop comprehensive heat health action plans at national and local levels to promote health equity to protect particularly vulnerable populations.

On 13 May, CPME co-organised a <u>webinar</u> on the role and responsibility of different actors of the healthcare system in climate change mitigation and adaptation. Dr Ina Kelly, Chair of the CPME Working Group on Climate Change, emphasised to the participants that "A transformational vision is required from our politicians for a more sustainable and resilient Europe".

CPME has collaborated with Lancet Countdown since 2018 and <u>raised</u> the climate to one of our highest priorities of our organisation. Our Health Check for Europe 2024-2029 <u>highlights</u> taking climate action for better health as one of European doctors' five ambitions to continue building the European Health Union.



#### **CPME NEWS**

# CPME President contributes to Belgian presidency conference calling for coordinated action on AMR

On 6-8 May the Belgian presidency held a high-level meeting on how the EU should coordinate its response to AMR. CPME President Dr Christiaan Keijzer was member of the panel discussion on "The EU AMR Targets: How to ensure efficient implementation?" that took place on 8 May.

He underlined the pivotal role that doctors have in the prudent use of antimicrobials in stewardship teams and as being a valuable source of information not just for patients but also for other healthcare professionals.

He also highlighted the need for an effective approach to antibiotic innovation. In the context of the general pharmaceutical revision, he stressed the CPME view that the Transferable Exclusivity Voucher is not the way forward and that we are encouraged to see that other solutions are on the table, like a milestone payment reward scheme which is a producer's incentive at different steps of R&D. The goal would be to reward the innovators but decouple the revenue from the new antibiotic from the quantity sold (delinkage).

During the wrap-up, Frank Vandenbroucke, the Belgian Vice-Prime Minister and Minister of Health, who is currently holding the Presidency of the Council of the EU and must therefore remain neutral in discussions, highlighted the CPME position on the Transferable Exclusivity Voucher.

# **Meeting Report with DG SANTE on EHDS**

On 28 May 2024, CPME met with Mr Marco Marsella and Dr Aurora Joala (a medical doctor from Estonia) at DG SANTE premises. The meeting's objective was to present CPME health check, the CPME statement on EHR systems and exchange on the European Health Data Space (EHDS) implementation. Please find the report <a href="here">here</a>.



#### **CPME NEWS**

# German Medical Assembly reaffirms doctors' commitment to defending democracy

The CPME President and Secretary General attended the annual meeting of the German Medical Association which took place in Mainz in May, joining a large delegation of international guests, including WMA President Dr Lujain Alqodmani and AMA President Dr Jesse Ehrenfeld, who gave opening addresses.

In a resolution entitled 'Never again is now: Physicians in Germany stand for democracy, pluralism, and human rights', the German medical community reaffirmed its commitment to the values of the Declaration of Geneva as well as the Declaration of Berlin on Racism in Medicine adopted by the World Medical Association in 2022, and a joint declaration of the health sector co-signed at national level.

Additionally, the assembly adopted a resolution on EU affairs, addressing i.a. the need to maintain the attractivity of the medical profession, to continue the revision and implementation of the legislative processes, take effective action to protect young people from alcohol and tobacco, and to further tackle environmental pollutants to reduce the negative impacts on health.

In a pre-conference, there was a discussion on the situation of junior doctors and the needs to both update medical education, while also enabling working conditions which meet the needs and expectations of the next generation of doctors.

Please find both statements <u>here</u> (the statement on EU affairs is available in German only).



#### The Commission looks to future of European Health Union

The <u>Communication</u> on the European Health Union (EHU) highlights the progress made in EU health policy in the last mandate. The communication has a chapter entitled "Looking ahead", highlighting the following:

- Particular attention should be paid to AMR, climate change-induced health threats, and that the EHU requires cooperation at all levels in a One Health approach
- Medicine shortages will be addressed by the pharmaceutical legislation, the European Medicines
  Agency and the Critical Medicines Alliance, and that instruments such as joint procurements
  could be further explored in the area of medicines for rare diseases and orphan medicines
- Europe would benefit from strengthened medical research, and a boost in biotechnologies and biomanufacturing. In addition, the EU should continue to work on making clinical trials attractive, efficient and fast.
- Continuous need to strengthen health systems, "with a resilient, well-trained health workforce at the heart".
- Non-communicable diseases remain a top priority, with a focus on prevention across a lifetime and promotion of healthy lifestyles and policy coordination across sectors.
- All has the potential to revolutionise healthcare in the EU and that we should explore how to integrate All into healthcare and the digital upskilling of healthcare professionals.

# **Professional Practice and Health Systems**

# OECD data on health systems per country

OECD has published its <u>2023 update</u> of data on health system characteristics. The data covers healthcare financing and coverage arrangements, healthcare delivery systems including employment status and remuneration of healthcare professionals and data on health workforce training, scope of practice and resilience, as well as data on governance and resource allocation. The database can be consulted per country.



# **Digital Health**

### Council identifies main digital priorities for the next legislative cycle

The Council underlines that its <u>main priority</u> for the next mandate is the "effective, coherent, and efficient implementation" of recently adopted laws with the minimum administrative burden for public and private players. A "common European approach to innovative digital technologies" is of key importance for EU's competitiveness. The reinforcement of the EU's competitiveness in the digital transformation requires attracting and retaining digitally skilled workforce.

Member states have acknowledged the importance to ensure a safer, responsible, and trustworthy online environment. Member states also underline that this digital transformation should go in hand with the green transition, and sustainability objectives.

In addition, the Council conclusions emphasise the importance of the international dimensions of EU digital policy. It addresses digital sovereignty, digital rules and governance, the societal effects of digitalisation, digital infrastructure, the data strategy, and digital governance

### Council approves conclusions on cybersecurity

The Council has approved <u>conclusions</u> on the future of cybersecurity aiming to provide guidance and setting the principles towards building a more cybersecure and more resilient Union. The Council conclusions emphasise the need to prioritize implementation, enhance coordination, and prevent fragmentation of cybersecurity regulations within sector-specific legislation.

A multistakeholder approach that involves collaboration with the private sector and academia is encouraged by the Council to address the skills gap. Additionally, the external dimension is underscored, emphasising the importance of an active international policy to strengthen cooperation with third countries. Given the evolving threat landscape, the Council invites the European Commission and the High Representative to present a revised cybersecurity strategy.



# Guidelines on the responsible use of generative Artificial Intelligence in research

The Commission and the European Research Area countries and stakeholders have jointly put forward a set of <u>guidelines</u> to support the European research community in their responsible use of generative Al. The recommendations address key opportunities and challenges, building on principles of research integrity, offering guidance to researchers, organisations and funders for a joint approach in Europe. The guidelines will constantly be updated.

# Council gives final green light to AI Act

The Council of the EU <u>adopted</u> the AI Act, which will address the risks and promote "responsible innovation," and aims to harmonised rules on AI. After being signed by the presidents of the European Parliament and of the Council, the legislative act will be published in the EU's Official Journal in the coming days and enter into force twenty days after this publication. The AI act will apply two years after its entry into force, with some exceptions for specific provisions.

#### The Commission established AI Office

The Al Office within the Commission was implemented to strengthen EU leadership in safe and trustworthy Artificial Intelligence. It will play an important role in shaping the development, deployment, and use of AI in the EU. It is composed of 5 Units: Regulation and Compliance, AI Safety, Excellence in AI and Robotics, AI for Societal Good, and AI Innovation and Policy Coordination.



#### Pharmaceuticals and Healthcare

#### ECDC survey marks increase in HAIs and antibiotic consumption

ECDC has published the <u>results</u> of its third point prevalence survey (PPS) of healthcare-associated infections (HAIs) and antimicrobial use in acute care hospitals, with data for 2022-2023. Compared to the previous survey in 2016-2017, there is an increase of 2.6 percentage points in antimicrobial use, with 35.5% of patients receiving at least one antimicrobial agent. There was a significant impact of SARS-CoV-2 as the fourth most common microorganism in HAIs. Overall, respiratory tract infections, including pneumonia and healthcare-associated COVID-19, remain the most frequent and account for almost a third of all reported HAIs. The report suggests that universal masking in healthcare settings during flu season should be considered. Urinary tract infections, surgical site infections, bloodstream infections, and gastrointestinal infections are also highly prevalent. The report emphasises the opportunity to prevent up to 20% of infections, e.g. with measures such as hand hygiene..

### Medical devices: new guidance for industry and notified bodies

The EMA revised the <u>guidance</u> available to applicants, marketing authorisation holder and notified bodies of medical devices. It is a question-and-answer document which provides considerations on the implementation of the regulations on medical devices and on in vitro diagnostic devices. The revision is based on the experience gained since the implementation of the new regulations and actual cases encountered.

# The Commission developed clear rules for joint clinical assessments

On 23 May, the Commission adopted new <u>rules</u> for the joint clinical assessments of medicines at Union level. This contributes to faster access to medicines for EU patients. The new rules define the timelines and the steps for conducting EU joint clinical assessments. These rules are the first of six acts to be adopted in 2024 under the HTA Regulation. The joint clinical assessments will start in January 2025 for medicinal products with new active substances for the treatment of cancer and for advanced therapy medicinal products.



# The Council adopts new measures to help prevent shortages of medical devices

The Council has adopted new rules updating the law on medical devices in order to help prevent shortages and ease the transition to greater transparency and access to information. The <u>regulation</u> amends the legislation on medical devices by extending the transition period for certain in-vitro diagnostic medical devices (IVDs), enabling a gradual roll-out of the European database on medical devices (<u>EUDAMED</u>), requiring manufacturers to give prior notice about any interruption of supply of critical medical devices and IVDs. These changes will enter into force after being published in the EU's Official Journal.

## The Council adopts new rules on substances of human origin

On 27 May, the Council adopted a <u>regulation</u> on substances of human origin (SoHo). Its main aim was to ensure better protection for donors. The regulation in addition aims to improve the safety and quality of blood, tissues and cells used in healthcare, facilitate cross-border circulation of these substances in the EU, facilitate access to SoHo through different measures, and finally also ensure better protection for recipients and children born following medically assisted reproduction. The regulation will now be signed by the Council and the EP, and will enter into force 20 days after being published in the EU's Official Journal.



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

#### The Council adopts the revised 'breakfast directives'

On 29 April, the Council formally adopted <u>updated rules</u> on the composition, labelling and naming of honey, fruit juices, fruit jams, and dehydrated milk. The main improvements include the labelling of the country of origins of honey blends, categorisation of fruit juice, increase in fruit content in jams, and the authorisation to use treatments that produce lactose-free dehydrated milk products.

#### Report on trends in adolescent substance use

The WHO report presents that alcohol is the most frequently consumed substance among adolescents and e-cigarettes are more popular in adolescents than conventional cigarettes. Cannabis use shows a slight decrease in adolescents and the gender gap is rapidly closing. The report in addition highlights the need for comprehensive measures to be implemented such as an increase in excise taxes, limiting the availability of nicotine and tobacco products and alcohol, banning all flavouring agents and enforcing a comprehensive ban on advertising, promotion and sponsorship opportunities.

#### EU task-force to coordinate One Health action

The EU agencies ECDC, EMA, the European Environment Agency (EEA), the European Chemicals Agency (ECHA), and the European Food and Safety Authority (EFSA) will cooperate on a <u>One Health cross-agency task force</u> to implement a <u>joint framework for action</u> over the next three years (2024-2026), focusing on strategic coordination, research coordination, capacity building, stakeholder engagement and joint inter-agency activities.



#### New EEA report on water-related health impacts on climate change

On 15 May, the European Environment Agency (EEA) published a report 'Responding to climate change impacts on human health in Europe: focus on floods, droughts and water quality'. The report underscores the critical need to urgently implement existing EU legislation notably various European climate, water, and health policies and integrate them further, and roll out the already existing solutions across all sectors and government levels to protect lives, prevent adverse health outcomes and increase wellbeing. Climate change impacts the water cycle, causing flooding, water scarcity and drought. In addition, climate-related changes in water quality threaten human health.

The EEA also published a report on <u>'Urban adaptation in Europe'</u> report, highlights the urgent need to adapt European cities to climate change and policies that have been developed on an EU and national level.

# ECDC Framework for prevention of communicable diseases and related special health issues

The ECDC has developed a new <u>framework</u> for the prevention of infectious diseases, which reframes and broadens the traditional approach to infectious disease prevention. It prioritises vaccine-preventable diseases and AMR as its main focus areas. It also focuses on socio-economic risk factors, health promotion, and health literacy. The framework has three objectives: to develop a plan for strengthening prevention, to facilitate exchange of knowledge, skills and experience, and to foster collaboration with external partners and stakeholders.

# Irish government approval raises the age of sale of tobacco to 21

The Minister for Health and the Minister for Public Health, Wellbeing and the National Drugs strategy of Ireland have <u>announced</u> that the Cabinet has approved a proposal for legislation that will increase the age of sale of tobacco to 21. Ireland will be the first country in the EU to introduce this measure. The proposal is designed to accelerate the goal of reducing Ireland's adult smoking rate to less than 5% of the population.



# WHO/Europe report warns of lethal levels of salt consumption and uncontrolled high blood pressure

A new WHO/Europe report "Action on salt and hypertension" calls for an integrated approach to reduce salt intake and improve detection and control of hypertension. Cardiovascular diseases (CVDs) are the predominant cause of disability and premature death in the European Region, causing over 42.5% of all deaths annually. Men in the region are almost 2.5 times more likely to die from CVDs than women. Excessive salt consumption is the main driver of hypertension and, subsequently, deaths from heart attacks, strokes, and other CVDs. The report presents stronger actions which can be taken by decision makers, such as: introducing mandatory policies to reduce salt intake, resist industry opposition, treat hypertension effectively, improve guidelines, enhance patient knowledge, adopt a patient-centred approach, implement gender-responsive policy, and strengthen supply chain resilience.

# Increasing number of measles cases in Europe

A joint press release from the WHO and UNICEF alerts about the continuous surge of measle cases across Europe, putting millions of children at risk. In 2023, there were over 300 000 cases of measles worldwide and the numbers reported so far for 2024 show that we might exceed this number. It is important to keep in mind that a majority of these cases occur in Asia however, the disease has been spreading to Europe. The press release warns countries which do not have measle cases or outbreaks to be proactive in planning and preparing to prevent the virus from spreading. We must also continue to vaccinate all susceptible individuals, intensify case finding and contact tracing, and use epidemiological data to identify coverage gaps.

# Activists press for EU-wide abortion right

Activists have launched a European Citizens' Initiative called "My voice, My Choice". It aims to establish an EU fund to cover abortion costs for women who can't access the procedure in their home countries and choose to travel to another EU country with more liberal abortion laws. The petition gained 100.000 signatures in its first week.



#### 77th World Health Assembly

The annual World Health Assembly took place in Geneva from 27 May – 1 June 2024.

### Resolution on climate change and health adopted

A <u>resolution on climate and health</u> calls upon countries to commit to strengthen the implementation of WHO's global strategy on health, environment and climate change, adopting a health-in-all policies approach, without diverting resources meant for primary health care. It also mentions environmentally sustainable health systems and supply chains. Moreover, the resolution requests to support countries in the development of national strategies for sustainable and climate-resilient health systems by, among other actions, capacity-building of health professionals and providing training to health professionals.

# International Health Regulations amended, and pandemic agreement negotiations extended for up to one more year

The WHO's International Health Regulations were successfully <u>amended</u>, including a definition of a pandemic emergency and a commitment to solidarity and equity on strengthening access to medical products and financing. while the WHA passed a resolution agreeing to prolong work on a global pandemic agreement for up to another year.

The European Commission <u>welcomed</u> the revised International Health Regulations, saying it delivers on one of the key goals in the EU's Global Health Strategy and strengthens the external dimension of the European Health Union. The statement says it is a signal that international solidarity and collaboration on important health issues remains strong.

The World Medical Association made several statements to the WHA.



# Horizon Europe pre-commercial procurement call for greener healthcare

The Topic Pre-commercial procurement (PCP) for environmentally sustainable, climate neutral and circular health and care systems (HORIZON-HLTH-2024-CARE-14-01) is open for applications until 26 November 2024 17:00 (Brussels time). This pre-commercial procurement call targets consortia of health procurers who want to procure together the development of innovative solutions for environmentally sustainable, climate neutral and circular health and care systems. Indicative budget is € 15 million.

More information on PCPs guidelines can be found in the <u>Innovation Procurement guidelines</u> and in the <u>general Annex H of the Horizon Europe WP2O23-2O25</u>. An overview of other funded activities by the Commission in Innovation Procurement for healthcare can be found <u>here</u>.



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