



Vice President Ole Johan Bakke speaks on air quality in Brussels (see page 6)

Dear colleagues

This edition follows the Board meeting held on 25 May, when the Board discussed a draft policy on the health effects of cannabis, approved a short questionnaire on the functioning of the Clinical Trials Information System and decided to endorse the European Institute of Women's Health's EU Manifesto for Women's Health.

As we approach the summer, the European institutions are working on some important health files and we continue to defend European doctors' positions. The European Commission is expected to publish its "Comprehensive Approach to Mental Health" and the European Parliament and the Council of the EU will decide their opinions on the proposal for a directive on ambient air quality and cleaner air for Europe in the coming weeks. Intense discussions are continuing on the European Health Data Space and the revision of the EU's General Pharmaceutical Legislation.

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 – 25 MAY 2023

Internal Affairs

Non-members included in internal communication

- ▶ The Board agreed to consolidate internal communications to address only members.

Insofar as this requires a revision of the Rules of Procedure, the Secretariat will prepare a draft for the next meeting of the Board of Directors on 15 June.

Policies

European Parliament action on health workforce

- ▶ The Board decided to collaborate and support MEP Tilly Metz on addressing staff shortages of health and care workers in the EU but decided not to formally co-sign a letter with them.

EMA representation

- ▶ The Board decided to switch the CPME representatives for the roles at the Healthcare Professionals' Working Party (HCPWP) at the European Medicines Agency.

Marcin Rodzinka-Verhelle (EU Policy Adviser) will become a full member of HCPWP, and Dr Keijzer becomes the alternate member.

BOARD OF DIRECTORS MEETING – 25 MAY 2023

Draft policy on health effects of cannabis

- ▶ The Board took note of the first draft of the CPME policy on the health effects of cannabis, advising on its revision.

The CPME Working Group on Healthy Living will discuss the draft and the scope of the policy in an online meeting on 8 June.

CPME endorses EU Manifesto for Women's Health

- ▶ The Board decided to endorse the European Institute of Women's Health (EIWH)'s EU Manifesto for Women's Health.

The manifesto outlines key priorities for improving the health and wellbeing of women across the life-course, such as the pay and pension gap, the Work-Life Balance Directive, HPV vaccination, and an EU mental health strategy.

Update on European Health Data Space

- ▶ The Board took note of the Secretariat's analysis of tabled amendments by the European Parliament on the European Health Data Space.

The Board commented that almost all CPME amendments have been taken up by MEPs, underlining the high impact that CPME has achieved. Please see our members' only analysis [here](#).

Questionnaire on Clinical Trials Information System (CTIS)

- ▶ The Board approved a short questionnaire on the functioning of the CTIS to be sent to CPME members.

BOARD OF DIRECTORS MEETING – 25 MAY 2023

Update on revision of the EU general pharmaceuticals legislation

- ▶ The Board took note of the latest developments regarding the publication of the revision of the EU general pharmaceutical legislation, including the contents of the proposals for the Directive and the Regulation, the rapporteurs from the European Parliament and the expected timeline.

Turkish Medical Association

- ▶ The Board took note of that the TMA will have another legal hearing on 22 June, and that the situation will become clearer following the elections in Turkey.

Revision of the EU Ambient Air Quality Directives

- ▶ The Board noted that the Health and Environment Alliance (HEAL) has offered to support any national medical association to be active nationally on the revision of the EU Ambient Air Quality Directives as the European Parliament and the Council of the EU are currently considering the Commission's proposal on a revision.

Any national medical association wishing support is invited to contact the CPME secretariat.

Dr Ole Johan Bakke contributes to panel at Clean Air Europe for All Conference

Dr Ole Johan Bakke, Vice President of CPME, attended the Clean Air Europe for All conference as a panel speaker, where he shared valuable insights on the topic of air pollution. Organised by The European Respiratory Society, The International Society for Environmental Epidemiology, and the Health Effects Institute, this conference aimed to address the pressing issue of air quality.

During his panel session, Dr Bakke emphasised the importance of training current and future doctors to raise awareness and inform the public about the health impacts of air pollution. He also highlighted the need for aligning the EU air quality standards with the guidelines provided by the World Health Organization (WHO) and the scientific evidence regarding the health effects of air pollution. You can find the event recording [here](#).

European petition on clean air

The Health and Environment Alliance (HEAL), CPME's Brussels partner on environmental health topics, plans to hand over a petition on clean air to the European Parliament on 26 June. Just like CPME, the petition calls on the EU to urgently and fully align its air quality standards with the WHO guidelines and the latest available science. You can sign the petition, which currently has over 125,000 signatures, [here](#).

HEAL have offered their expertise to assist national medical associations wishing to be active nationally through articles or op-eds prior to upcoming votes in the European Parliament. If you would be interested in such assistance, please contact the CPME secretariat.

Civil society calls on the Commission to release mandatory alcohol labelling proposal immediately

CPME, together with a major alliance of European civil society organisations, has sent an [open letter](#) to the European Commission calling for the proposal for mandatory labelling of the list of ingredients and the nutrition declaration of all alcoholic beverages promised in the Europe's Beating Cancer Plan.

It underlines that “labelling of alcoholic beverages is an important measure to implement as part of a broader strategy to fight alcohol related harm, alongside other effective policy tools proposed in the European Beating Cancer Plan, the WHO SAFER recommendations and the WHO European Framework for Action on Alcohol 2022–2025 which was unanimously adopted by all WHO European Members States at the WHO 72nd Regional Committee Meeting in Tel Aviv in 2022.”

CPME at international conference on data protection

On 24 May, Senior Policy Adviser Sara Roda, spoke at the well-known international conference on Computers, Privacy & Data Protection (CPDP 2023). The [panel](#) discussed the “The European Health Data Space and secondary use of data: is it possible to balance individual interests with the ultimate need for data sharing to facilitate research?” and was composed by speakers from academia, regulator, healthcare professionals and industry.

Ms Roda presented the CPME position on the secondary use of data, focusing in particular on the attack to medical confidentiality and professional secrecy, as well as on how to make patients’ rights compatible with further processing (Article 33 paragraph 5 of the EHDS proposal). The discussion was lively, addressing medical confidentiality, Health Data Access Bodies expertise and resources, data quality requirements, interplay with clinical trials regulations, among others.

CPME attends German Medical Assembly

The CPME President and Secretary General attended the four-day German Medical Assembly which brought together medical representatives from all over Germany to discuss health policy and professional practice. International guests were invited to join several side events, including a seminar on the German health system and a session on the creation of self-regulatory structures with an outlook for the medical profession in Ukraine. Delegates of the Ukrainian Medical Associations, a member of parliament and representatives of various civil society organisations were present alongside other NMAs.

During the event, the GMA discussed [digitisation](#), [climate](#), [health education in schools](#), [medical studies](#), [free practice of medicine](#), [reforms in the healthcare system](#), and issued a [call](#) for a national drug reserve. The German Medical Assembly also [re-elected](#) Dr Klaus Reinhardt as president.

MONITORING

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 Parliament's Public Health subcommittee (SANT) discusses AMR, NCDs and holds exchange of views with EMA and HERA

The SANT Committee [meeting](#) on 5 May included an exchange of views on EU Action to combat antimicrobial resistance (AMR). Rapporteur Timo Woelken welcomed the Council Recommendations on AMR. He highlighted the need for ambitious national targets for tackling AMR through the One Health approach. He stressed the need for new incentives for new antimicrobials, alternative treatments such as bacteriophages and diagnostic tests.

The rapporteur of the own-initiative report on NCDs, Erik Poulsen, highlighted the role of NCDs in premature mortality and the quality of life. He noted the need for prevention and early diagnosis, as this can substantially impact the quality of life. He called for action on limiting harmful substances across the EU. He plans to present the draft report in mid-July; amendments are due by the end of July.

During its meeting on 24 April, the SANT subcommittee held an [exchange](#) of views with Ms Emer Cooke, Executive Director of the European Medicines Agency (EMA), and Mr Pierre Delsaux, Director General of the Health Emergency Preparedness and Response Authority (HERA). The European Parliamentary Research Service also presented a study titled '[Increasing European added value in an age of global challenges: Mapping the cost of non-Europe \(2022-2032\)](#)'.

MONITORING

WHO Moscow office to be relocated to Copenhagen

European countries have succeeded in [moving](#) the World Health Organization (WHO) away from Moscow after a year-long campaign. During a special session of the WHO's Regional Committee for Europe on Monday, EU countries (except Hungary), Iceland, Norway, the UK, and Ukraine called for the WHO to close its office in Moscow for non-communicable diseases. By January 1, 2024, the office will be relocated to Copenhagen.

Professional Practice and Health Systems

Romania seeks EU-wide solution to address shortage of doctors

Romania has seen an increase in the number of doctors, but the current ratio (346 doctors per 100,000 inhabitants) is still not enough, and stakeholders say EU-wide solutions should be found with the proper implementation of the post-pandemic Recovery Fund.

Health minister Rafila [stated](#) that doctors in rural areas must be provided with solutions for their offices and for their families to practice without worries. Doctor Gindrovel Dumitra, a member of the Romanian College of Physicians, states that the shortage of ATI and surgery specialists is growing. According to him, the possibility of a malpractice lawsuit is one of the reasons young people avoid these specialties. Romanian MEP Tudor Ciuhodaru, vice-chair of the Subcommittee on Public Health and member of the ENVI committee suggests modular multifunctional medical centre with EU funds to readdress the lack of infrastructure and specialists. He indicated that several activities for women and children, cardiovascular pathology, strokes, etc... may be sponsored by EU funding". He concluded that the EU's support in member states' health systems could resemble the European civil protection mechanism, but it would be permanent rather than only activated when a crisis arises.

MONITORING

Pharmaceuticals and Healthcare

EMA published guidance for industry on medicine shortages prevention

European Medicines Agency published a new guidance document on addressing medicine shortages by the industry. The document titled "[Good practices for industry for the prevention of human medicinal products shortages](#)" recommends good practices to marketing authorisation holders, wholesalers, distributors and manufacturers on shortage prevention for human medicines.

Fluoroquinolone antibiotics: reminder of measures to reduce the risk of long-lasting, disabling and potentially irreversible side effects

As a result of the [risk](#) of disabling, long-lasting and potentially irreversible side effects, EMA's safety committee, PRAC, reminds healthcare professionals not to use fluoroquinolone antibiotics. As a result of an EU-wide review of these rare, but serious side effects, these restrictions were introduced in 2019. According to an EMA-funded study, fluoroquinolone antibiotics are still prescribed outside their recommended uses, despite the reduction in their use.

EU health ministers discussed medicine shortages

EU health ministers assembled in Sweden to [debate](#) medicine accessibility at a time when shortages of medicines are still viewed as a threat that could materialise. Antibiotic, paracetamol, and ibuprofen medicine shortages were reported throughout the bloc this winter, and possible shortages are already estimated for the next winter. Ministers emphasise that there is no need to wait for the European Commission's recent proposal for pharmaceutical legislation, while it addresses the issues.

MONITORING

EU countries have proposed to create a "Critical Medicines Act"

A proposal to establish a ["Critical Medicines Act"](#) that would mirror European initiatives towards self-reliance in microchips has received support from the majority of the countries in the EU. The act would promote the production of essential medicines, pharmaceutical ingredients, and other basic chemical inputs, reducing dependence on big producers like China and India. The concept is further developed in a position document dated 2 May 2023 that was created by the Belgian government and endorsed by 18 other nations, including France and Germany.

Review of transparency rules for the EU Clinical Trials Information System (CTIS)

The EU Clinical Trials Information System (CTIS) is used to submit information about clinical trials, and the European Medicines Agency (EMA) has started a [public consultation](#) to assess the transparency requirements for publishing these data. Stakeholders are invited to submit their opinions with an online form on June 28, 2023.

The public consultation follows a [joint letter](#) by 10 health organisations, including CPME, expressing concern about the European Medicines Agency's approach regarding clinical trials transparency. CPME has prepared a survey for members.

First vaccine to protect older adults from respiratory syncytial virus (RSV) infection

European Medicines Agency (EMA) has suggested a marketing authorisation in the EU for Arexvy (recombinant, adjuvanted), the first vaccine for active immunisation to protect adults aged 60 years and older against lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV). The opinion is going to be sent to the European Commission to be evaluated before a decision is made for EU-wide marketing authorisation. After authorisation approved, decisions about pricing and reimbursement will be decided at the level of each Member State, considering the possible role and usage of this medication within the framework of that nation's national health system

MONITORING

Patients, Principles and Ethics

Social Rights Tracker: Monitoring and Strengthening Economic and Social Rights in Europe

The "Action for Social Rights" Committee, a committee within the INGO Conference of the Council of Europe, has launched the [Social Rights Tracker](#) initiative. This monitoring tool aims to track the implementation of social rights and the reception of the European Social Charter in Council of Europe member states. It collects testimonies on social and economic rights, highlights non-compliance and good practices and serves as an interface between INGOs and relevant institutions. NGOs can submit alerts in different categories including health through a secure online platform, contributing to existing monitoring mechanisms and advocating for rights.

CINGO's Recommendations for Inclusive Healthcare Policies and Rights of Refugees and Migrants

In a hybrid format, the Conference of INGOs (CINGO) held its annual spring [session](#) on 24–26 April 2023. The CINGO also adopted a [Recommendation for a Global Approach of the Rights of Refugees and Migrants and the Role of Civil Society](#). As part of its recommendations on Health Care, the CINGO recommends, for example, that national policies that provide health care services, such as vaccinations, which are not just individual rights but also basic public health concerns, and mental health care, should cover all citizens on a state's territory, regardless of their administrative status.

Public Health and Disease Prevention

European institutions react to end of COVID-19 global health emergency

After a recommendation from a committee of global health experts that found the situation no longer meets the criteria to be classified as a public health emergency of international concern, WHO Director General Tedros Adhanom Ghebreyesus on Friday [announced](#) end of COVID-19 Global Health Emergency.

Emer Cooke, Executive Director of European Medicines Agency (EMA) shared a [statement](#) on the declaration: COVID-19 remains a global health threat, and with the risk of emergence of new variants, we cannot let our guard down. EMA remains fully committed to supporting the EU response to the COVID-19 threat and ensuring that new or adapted vaccines and therapeutics can be made available as needed.

WHO launched new database on physical activity in the EU

A [comprehensive database](#) on physical activity in the European Union (EU) and policies that have been implemented to support healthy active lives was unveiled by WHO/Europe on Move for Health Day (10 May). One third of EU citizens are not active enough, according to the most recent data. If everyone in the EU met the WHO recommendation of 150 minutes of moderate physical activity per week, it would significantly lower the region's rates of diabetes, cardiovascular disease, and cancer. It would also lower health care costs and save the EU's member states an estimated €8 billion annually.

Data shows that all EU countries implemented policies to increase physical activity among children and youth, 22 of them supported promotion among older adults, 20 of them supported promotion in the workplace and 23 of them produced national recommendations for health on physical activity.

MONITORING

Lessons from the COVID-19 pandemic

A [technical report by ECDC](#) presents the lessons learned from responding to the COVID-19 pandemic by public health stakeholders. Countries are encouraged to revise their pandemic and emergency plans based on this document. The continuous preparedness cycle of anticipating, responding, and recovering from an incident should include a structured review of the response to a public health threat. As a result of the COVID-19 pandemic, public health lessons should be quickly identified and used to update pandemic preparedness plans.

Ireland signs law requiring cancer warnings on all alcoholic beverages

On 22 May, Ireland [signed](#) into law the Public Health Regulations and the remaining provisions of the Public Health Act, introducing comprehensive health labelling of alcohol products. The law provides that the labels of alcohol products will state the calorie content and grams of alcohol in the product. Also, they will warn about the risk of consuming alcohol when pregnant and of the risk of liver disease and fatal cancers from alcohol consumption. Please find more [here](#). The EU is expected to introduce mandatory alcohol labelling as part of the Europe's Beating Cancer Plan but the legislative proposal from the European Commission is delayed.

WHO/Europe report on valuing urban green and blue spaces for health and well-being

A [new WHO/Europe report](#) examines the health impacts of urban green and blue spaces, highlighting both positive and negative effects that are not evenly distributed. It offers methodologies for assessing their value, aiding policymakers and practitioners in designing and allocating resources to protect and enhance these spaces. In the report it highlights that green and blue spaces, including parks, gardens, street trees, and water bodies, serve as nature-based solutions for climate change adaptation, providing benefits such as urban cooling and flood risk reduction.

MONITORING

Digital Health

Swedish Presidency progress report on European Health Data Space

The [progress report](#) recognises the need for further finetuning and topical discussions on issues such as roles and responsibilities in cross-border infrastructure, the application of Chapter II to existing EHR systems, the need for European central services such as an EU HDAB, and the interplay with other legislation such as the NIS Directive and the Clinical Trials Regulation.

AI Act joint report adopted in European Parliament

On 11 May, the Internal Market Committee and the Civil Liberties Committee adopted the joint report on the AI Act, with a vast majority, paving the way for a plenary vote in mid-June. Overall, the result was positive with the exception of two areas which could result in additional administrative burdens for healthcare:

- obligation for deployers (health professionals fit into the definition) to conduct a fundamental rights impact assessment (new Article 29a). However, according to the policy makers in the European Parliament, the impact of this provision would be reduced due to the limited scope of application – only for high-risk AI systems under article 6(2) that pose significant risk and are in Annex III. AI systems that classify as medical devices would fit under Annex II; and,
- when the deployer holds exclusively data and the provider cannot have access to the data to comply with the obligations of Article 10 paragraph 6a new, then the deployer is made responsible for any infringement of article 10 (data and data governance). It is not clear which data would be involved (metadata, content data, identification data, and ultimately personal data?), and when medical confidentiality would be the reason for not sharing data. There will be penalties for not complying with this Article foreseen in Article 71(3a).

We will be analysing the impact of these provisions with the rapporteur on Artificial Intelligence and the WG Digital Health. Further information [here](#) and [here](#).

MONITORING

Clarification on the Right to Obtain a Copy of personal Data

The Advocate General of the European Court of Justice Emiliou [interpreted](#) Article 15 (3) GDPR's right to a complete and free copy of one's data on April 20. To pursue a claim for improper dental treatment, a patient requested copies of all dental treatment documents. The dentist provided copies for a cost. The patient asserted that their initial copy should be free of charge, depending on Articles 12 and 15 (3) GDPR. The Court ruled that Article 12(5) and 15(3) of the GDPR require a data controller (the dentist) to give a data subject (the patient) a copy of his medical records, even for non-data protection purposes. Doctors can request expense compensation under Article 23(1) of the GDPR, however national courts must verify the actual costs. In a doctor-patient relationship, the wording "copy of the personal data undergoing processing" in Article 15(3) of the GDPR does not give the patient a general right to a full copy of all medical file papers.

Consumers uneasy with sharing their health data, survey shows

It has been found in a [survey](#) across eight European countries that consumers are less willing to share their health data than is proposed in current EU legislation. These findings demonstrate that EU legislators must better reflect people's preferences in the European Health Data Space Regulation, which is already being discussed by EU institutions. To improve healthcare provision and make public health data available, people must feel confident sharing their health data.

Pilot project to test European digital identity wallet for e-prescriptions

The European Commission is allocating €46 million from the Digital Europe Programme for 4 pilot projects on [the European digital identity \(EUDI\) wallet](#). One of the pilot projects, [POTENTIAL](#) – Pilots for European Digital Identity Wallet Consortium, will apply the EUDI wallet to 6 use-cases including e-prescriptions. It has the objective of enabling paperless and convenient medical prescriptions, empowering citizens by giving them secure data control, allowing access to health information and providing the ability to determine when and with whom to share their health data across Europe.

MONITORING

Looking ahead

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|------------|--|
| 12–13 June | Employment, Social Policy, Health and Consumer Affairs Council |
| 12–15 June | European Parliament plenary |
| 19–20 June | Swedish Presidency Meeting on global health |
| 27 June | ENVI Committee expected to vote on EU Ambient Air Quality Directives |
| 29–30 June | European Council |
| 10–13 July | European Parliament plenary |

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