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## Dear colleagues

This edition follows the Board meeting held on 13 April and a fruitful high-level conference on antimicrobial resistance (AMR), which was warmly hosted by the Swedish Medical Association on 27 April. Doctors, national policymakers, representatives of the European Commission and health stakeholders all contributed to an excellent discussion and we will share a full report soon.

The conference took place the day following the proposals for the [revision](#) of the EU's pharmaceutical legislation and [Council Recommendation](#) on AMR. The proposals will now go under intense negotiations and we will continue to defend European doctors' position to EU policymakers.

We were also active during European Immunization Week, which emphasised the need to catch up on missed vaccinations to prevent large outbreaks of vaccine-preventable diseases. We hope you enjoy reading about this and much more in this month's edition.

**Dr Christiaan Keijzer**

CPME President



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## BOARD OF DIRECTORS MEETING – 13 APRIL 2023

## Finances

### Actual accounts January–March 2023

- ▶ The Board discussed the actual accounts, noting that the deficit is 18 069 EUR higher than the budgeted, largely due to the unaccounted income from the IMMUNION project. This will be included in the draft actual accounts once the ongoing final financial reporting has been concluded.

## Internal Affairs

### CPME event calendar

- ▶ The Board reviewed the event calendar and noted an upcoming Doctor MEPs Roundtable on 22 September.

An additional meeting of the European Health Union Network is being discussed to take place in the European Parliament in May.

## Policies

### European Commission's public consultation on the evaluation of the legislative framework for tobacco control

- ▶ The Board adopted a response to the public consultation.

The European Commission is currently evaluating the legal framework for tobacco control due to factors such as the rapid rise in novel tobacco and nicotine products and recent technical developments. The consultation gathers knowledge and qualitative/quantitative data on the implementation of the Tobacco Products Directive and the Tobacco Advertising Directive.

**BOARD OF DIRECTORS MEETING – 13 APRIL 2023****Project proposals on mental health of the health workforce**

- ▶ The Board agreed to provide a letter of support to a project proposal lead by University College Dublin.

The Board agreed to decline an invitation to support a second proposal on the same topic due to a lack of information.

**Revision of the Pharmaceutical Legislation**

- ▶ The Board noted developments on the revision of the pharmaceutical legislation, noting that we have received no response to our joint letter to the European Commission, and that the proposal is expected to be published on 26 April.

**EU Clinical Trials Information System (CTIS)**

- ▶ The Board agreed to send a survey to NMAs regarding the functioning of the EU Clinical Trials Information System.

The German Medical Association has received concerning reports about the malfunctioning of the EU Clinical Trials Information System. The Secretariat will prepare a short survey and will share it with the Board for approval.

**European Medicines Agency**

- ▶ The Board took note that we submitted a response to the satisfaction survey launched by the European Medicines Agency.

**BOARD OF DIRECTORS MEETING – 13 APRIL 2023**

## **Invitation from the Bewell project to join the Steering Committee of the Pact for Skills**

- ▶ The Board agreed to accept the invitation from the Bewell project to join the Steering Committee of the Pact for Skills, and to co-sign the partnership manifesto.

CPME is an associated partner in the project.

## **Turkish Medical Association**

- ▶ The Board noted that the TMA will have another legal hearing on 22 June.

The Board will await further information before making a decision whether to attend, taking account of the elections in Turkey.

## **Cannabis**

- ▶ The Board noted that a first draft CPME policy on cannabis will be prepared in the coming weeks in preparation for the next General Assembly.

The Board discussed ongoing developments in Germany, Ireland and Malta.

## European doctors discuss how to tackle AMR in medical practice and EU legislation

The Standing Committee of European Doctors (CPME) and the Swedish Medical Association organised a [high-level conference](#) of doctors, national policymakers, representatives of the European Commission and health stakeholders on how to address antimicrobial resistance (AMR).

The event took place the day following the proposals for the [revision](#) of the EU's pharmaceutical legislation and [Council Recommendation](#) on AMR. In addition, the topic is also high on the agenda of the Swedish presidency of the Council of the European Union.

"AMR is one of the greatest threats to human health. Existing antibiotics are losing their effectiveness and not enough novel antibiotics are in development. The risk is growing that doctors are not able to treat patients."

SMA President Dr Sofia Rydgren Stale said "Doctors have a key role in keeping antibiotics working through prudent prescription and responsible use. We must also work according to the One Health approach, bringing together the human health, veterinary and environmental sectors."

CPME President Dr Christiaan Keijzer "We welcome the ambition expressed by the EU on antibiotics in recent years, but we call for more action. The widespread shortages of antibiotics across Europe that occurred this winter must not happen again. We urge decisive measures to be taken to prevent shortages and to ensure a stable supply of antibiotics in the future.

"The revised pharmaceutical legislation and the Council recommendation offer an opportunity to enact past political commitments of the EU and all Member States. The proposals foresee many good provisions to tackle the threat of AMR, such as prudent use and infection prevention and control measures to environmental impact. However, we need more discussion around the right way to incentivise innovation. Health and healthcare must come first."

## World Medical Association Council Meeting

Around 200 delegates from nearly 40 national medical associations attended the 223rd [WMA Council Meeting](#) in Nairobi, Kenya, from 20–22 April, including CPME's President Dr Christiaan Keijzer and Secretary General Sarada Das.

The meeting resulted in the agreement of several policies to be presented to the WMA's General Assembly in Kigali, Rwanda, in October for approval. The WMA policy on electronic cigarettes will be strengthened to highlight the harmful effects of e-cigarettes and electronic nicotine delivery systems, especially for children, adolescents, and young adults. A statement on primary care was agreed upon, recommending ways to improve primary health care to ensure adequate financial resources, equipment, and a well-trained primary care physician supply. Moreover, the Council agreed to revise its policy on ethical issues during times of armed conflict and the Council adopted a resolution on the human rights violations against the Uyghurs.

Professor Jungyul Park, Vice President of the Korean Medical Association, was elected Chair of the WMA Council. Dr Rudolf Henke (Germany), member of the Executive Board of the German Medical Association, was elected Treasurer.

## CPME endorses joint statement on Mental Health

CPME has endorsed [a joint statement](#) on Mental Health in All Policies which was presented in the annual EU Health Policy Platform meeting of the European Commission on 19 April.

The statement recommends the EU and its member states to implement a comprehensive, multi-sectoral approach to mental health, strengthening systems and mobilising different stakeholders to implement integrated mental health promotion, prevention and support at local, regional, national and European levels.

## European Immunization Week 2023

The World Health Organization, UNICEF, and the European Commission, along with other partners, aim to [protect](#) vulnerable populations from COVID-19 through vaccination while also ensuring that routine vaccinations for other diseases are not missed. The pandemic has disrupted routine vaccinations, with over one million children in Europe and Central Asia missing some or all vaccinations since 2020. The equity gap in vaccination coverage among countries and their populations is widening, with middle-income countries reporting coverage below 90% for one or more vaccines in 2021. The European Immunization Week 2023 emphasises the need to catch up on missed vaccinations to prevent large outbreaks of vaccine-preventable diseases. Collaboration and solidarity are essential to building resilient health systems and protecting global health security.

CPME was active on social media throughout the week. On CPME's Twitter, Dr Jacques de Haller [highlighted](#) that vaccination of girls and boys against the Human Papilloma Virus could prevent infections and related diseases. CPME's President, Dr Christiaan Keijzer, [stressed](#) the safety and efficiency of vaccinations to protect individuals and populations from vaccine-preventable communicable diseases.

Further, the recently published ["Poliomyelitis situation update" report](#) by the ECDC reveals that during the period of 2012 to 2021, an estimated 2.4 million children in the EU/EEA may not have received three doses of polio-containing vaccines on schedule. Furthermore, the ECDC's recently released ["Measles Annual Epidemiological Report 2022"](#) emphasises the dangers of having pockets of under-vaccinated populations or groups that have not received any immunisations at all.



## Stop Cancer at Work welcomes new EU guidelines and list of hazardous medicinal products, but more needs to be done

[The Stop Cancer at Work](#) coalition [welcomes](#) the new European guidelines for the safe management of hazardous medicinal products (HMPs) at work, which have been published by the European Agency for Safety and Health at Work (EU-OSHA). For years we have been campaigning for better protection for workers exposed to these potentially life-threatening drugs. Every year more than [12.7 million](#) healthcare workers in the EU are potentially exposed to HMPs which can mutate our DNA, cause cancer or are toxic to fertility and babies.

Employers, workers and Member States now all need to work together to raise awareness of the risks of HMPs, increase best practice and ensure that the guidelines are properly implemented and applied. Although the guidelines will help prevent future occupational exposure of millions of Europeans to these drugs, further changes are needed in the European legislation to provide legal security for workers and employers.

We call on the European Commission to formally adopt and implement the agreed legal definition of HMPs in the 2022 [Carcinogens, Mutagens and Reprotoxic Substances Directive \(CMRD\)](#), and include it in Annex I during the legislation's next revision. Similarly, the Commission should also adopt and use the European Trade Union Institute (ETUI) [list](#) to indicate which HMPs fall under the legislative scope of the EU.

Overall, the guidelines set out that workers need to be protected throughout the whole life cycle of HMPs, from manufacture, transport, preparation, administration, laundry to waste disposal and that information needs to flow between these different stages. The guidelines aim to reduce disparities between Member States and sectors by ensuring comprehensive guidance is available to all stakeholders and provide a useful reference point and support for training activities. They also set out a baseline for good practice by healthcare and veterinary workers handling HMPs across the EU. The guidelines will need to be revised regularly in the future, responding and adjusting to improvements in best practice and technology.

## 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.

### Pharmaceuticals and Healthcare

#### Reform of the EU pharmaceutical legislation

A new directive and a new regulation were proposed by the Commission on 26 April 2023, revising and replacing the existing general pharmaceutical legislation (Regulation 726/2004 and Directive 2001/83/EC) and the legislation regarding medicines for children and rare diseases (Regulation 1901/2006 and Regulation 141/2000/EC, respectively).

The reform includes the proposal for the [pharmaceutical regulation](#), the proposal for the [pharmaceutical directive](#), a [communication](#) on the pharmaceutical reform and antimicrobial resistance, and the proposal for a [Council Recommendation](#) on stepping up EU actions to combat antimicrobial resistance in a One Health approach (AMR).

The revision aims to achieve the following main objectives:

1. Ensuring that safe, effective, and affordable medicines are available to all patients across the EU on a timely and equitable basis;
2. Assuring that medicines are accessible to patients in all EU countries will enhance the security of supply;
3. Providing an attractive environment for research, development, and production of medicines in Europe;
4. Making medicines more environmentally sustainable;
5. Incorporating a One Health approach to address antimicrobial resistance (AMR) and pharmaceutical residues in the environment. CPME's initial reaction was included in Reuters' [report](#).

## MONITORING

## WHO/ECDC report: AMR threatens patient safety in European Region

The second "Surveillance of Antimicrobial Resistance in Europe" [report](#), released by WHO/Europe and the European Centre for Disease Prevention and Control (ECDC) on 14 April, reveals high percentages of resistance to last-line antibiotics, like carbapenems, in a number of the WHO European Region's member states. Data from 2021 are included in the study. Southern and eastern regions of the Region were observed to have higher levels of AMR.

## EU to test disputed incentive scheme to develop novel antibiotics

The European Commission will investigate incentives and a new pricing mechanism for antibiotics in its pharmaceutical regulations. In its overhaul of EU pharmaceutical laws, the Commission [suggested](#) a 15-year trial of a 'transferable data exclusivity voucher programme' for new antibiotics to incentivise their development. In practise, the voucher will offer the developer of the new antibiotics an extra year of regulatory data protection, which can be utilised for one of its own medicines or sold to another marketing authorisation holder.

## EU Political Outlook

### First meeting of European Parliament Subcommittee on Public Health (SANT)

The [first ever meeting](#) of the European Parliament's Subcommittee on Public Health (SANT) decided to request authorisation for own initiative reports on joint procurement for joint purchasing of medicines and its storage, on mental health, and on non-communicable diseases. It was determined that SANT will hold hearings on the revision of the pharma legislation (with a focus on orphan drugs), on non-communicable diseases, on cross-border health care, and on mental health amongst youth.

## Professional Practice and Health Systems

### WHO released the largest global collection of health inequality data

[The Health Inequality Data Repository](#), launched by the WHO, is a comprehensive global collection of publicly accessible disaggregated data and information on population health and its determinants. It comprises of 59 datasets from more than 15 sources and has around 11 million data points. The repository provides for tracking health inequities among population groups and over time by categorising data according to group characteristics, ranging from education level to ethnicity. The data include measurements of over 2000 variables broken down by 22 aspects of disparities.

### April Infringements package: Working conditions

The Commission [calls on Italy](#) to prevent abusive use of fixed-term contracts and avoid discriminatory employment conditions in the public sector. On 19 April, the Commission decided to send a reasoned opinion to Italy (INFR(2014)4231), since it failed to adequately transpose into national law Council Directive 1999/70/EC, which prohibits discrimination against fixed-term workers and requires Member States to implement measures to prevent and penalise the abusive use of fixed-term contracts or relationships. For several categories of public sector workers in Italy, Italian law does not sufficiently prevent and punish the abusive use of consecutive fixed-term contracts. This includes healthcare workers.

## MONITORING

## Public Health and Disease Prevention

### Germany wants EU cannabis law changes and German Medical Association response

After the European Commission rejected the initial legislative draft, the German government opted to focus its work on small-scale personal use cultivation. Health Minister Lauterbach [stated](#): "Individuals should be able to receive up to 50 grammes of cannabis per month via "cannabis clubs," which are defined as limited distribution by non-profit organisations for personal usage. While minors will continue to be prohibited from consuming cannabis, there will be a monthly restriction of 30 grammes for everyone under the age of 21.

The German Medical Association [criticised](#) the plans, arguing that legalisation leads to increased consumption, particularly among vulnerable groups like young people, and reduces awareness of the risks of drug use.

### The future of drug monitoring in Europe until 2030: A report summarising the findings and lessons learnt from the EMCDDA's 'futures study'

Drug use patterns and drug market developments in Europe are becoming more complex and dynamic, which has major implications for drug monitoring and research. EMCDDA conducted a [futures exercise](#) in 2030 based on this observation to inform its strategic reflections on improving its activities in light of the ongoing rapid changes in the information environment and the likely emergence of new information needs in the coming decade. Furthermore, the report discusses the possible increased commercialisation of cannabis products and evolving cannabis policies.

## MONITORING

## Report: Hexahydrocannabinol (HHC) and related substances

The European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) published a [report](#) on hexahydrocannabinol (HHC) and semi-synthetic cannabinoids (SSC), which are rapidly evolving markets, have relatively limited information currently available. Section 1 presents an overview of the European situation but it is necessarily incomplete, stressing the importance of monitoring closely. Several developments have already taken place in some countries during 2023, such as law enforcement seizures and changes in legal status, and where possible, updates have been made.

## Ombudsman finds lack of transparency in Commission meetings with tobacco lobbyists

On 18 April, the EU Ombudsman launched an own-initiative inquiry to examine the transparency of meetings between the European Commission and representatives of the tobacco industry. The Ombudsman's [preliminary view](#) is that the failure of the Commission to proactively publish details of its meetings with tobacco lobbyists is maladministration as is its failure to keep minutes of all such meetings. [Smoke Free Partnership \(SFP\)](#) strongly endorses the preliminary conclusions of the EU Ombudsman and urges the Commission to put the recommendations into practise in order to increase transparency, record-keeping, and the evaluation of "necessity" when interacting with representatives of the tobacco industry.

## First climate case heard at the European Court of Human Rights

For the first time, an international human rights court in Europe heard two hearings on claims that aimed to hold governments accountable for their participation in the climate crisis and for neglecting to protect citizens from growing impacts of climate change like heat waves and flooding. In this [first case](#), Verein KlimaSeniorinnen Schweiz and Others v. Switzerland, it is alleged that Switzerland's failure to do its "fair share" to reduce emissions in accordance with limiting the increase in temperatures to no more than 1.5°C threatens the lives and health of elderly women who are more vulnerable to extreme heat spells. The applicants in this case are a group of approximately 2,000-member Swiss senior women's society and four individual elderly women.

## MONITORING

## WHO launched new initiative to improve pandemic preparedness

WHO released an [initiative](#) designed to help countries better prepare for future pandemics. The initiative provides guidelines on integrated planning for responding to any respiratory pathogens, such as influenza or coronaviruses. The new PRET Initiative, or Preparedness and Resilience for Emerging Threats, includes the most recent tools and methodologies for shared learning and collective action developed during the COVID-19 pandemic and other recent public health emergencies. PRET represents an evolution in WHO's approach to pandemic preparation by focusing on modes of transmission rather than specific diseases.

## Free e-cigarettes to be handed out in anti-smoking drive in England

One million smokers will be given a free vaping starter kit and pregnant women will be offered financial incentives to encourage them to give up tobacco product with England's [new "swap to stop" national scheme](#). Almost 1 in 5 of all smokers in England will be provided with a vape starter kit alongside behavioural support to help them quit the habit as part of a series of new measures to help the government meet its ambition of reducing smoking rates below 5% by 2030. In an effort to stop vapes from being supplied to minors without proper authorisation, the government announced that a new trading standards enforcement unit will be established.

## MONITORING

## Digital Health

### Accelerating the digitalisation of key public services

A [report](#) on accelerating digital public services that support the functioning of the single market was adopted by the Parliament on 18 April. The MEPs highlight the many advantages of the digitalisation of public administration to increase transparency, resilience, and reduce administrative barriers for citizens, businesses, and SMEs. It also calls for ensuring interoperability between different data spaces (health, justice, public procurement).

### A call to action on very powerful AI from the European Parliament

A group of MEPs working on the EU's Artificial Intelligence Act have written an [open letter](#) calling for the law to ensure that the new wave of very powerful AI develops in a "human-centric, safe, and trustworthy" direction. Co-rapporteurs Brando Benifei and Dragoş Tudorache, along with 10 MEPs from various parties, called on European Commission President Ursula von der Leyen and U.S. President Joe Biden to convene a high-level global Summit on Artificial Intelligence, with the view to agree on a preliminary set of governing principles for the development, control, and deployment of very powerful artificial intelligence.



## MONITORING

## Looking ahead

3–4 May	Informal meeting of employment and social affairs ministers
4–5 May	Informal meeting of health ministers
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
29–30 June	European Council

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**CONTACT**

For feedback, further information, questions or to express an interest to contribute to future editions, please contact:

**Calum MacKichan**  
calum.mackichan@cpme.eu

Rue Guimard 15 1040  
Brussels, Belgium

T: +32 2732 72 02  
E: secretariat@cpme.eu  
www.cpme.eu

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