



## Dear colleagues

We are pleased to share with you the June edition of the CPME Monthly Bulletin with the outcomes of the Executive Committee the meeting on 16 June 2022. The most significant item on our agenda was the revision of our association's statutes following the special session for members on 6 May. We will discuss again during our meeting in July as we prepare for the foreseen adoption during our General Assembly in Prague in October.

We also adopted a response to the European Commission consultation on the revision of the EU School Fruit, Vegetables and Milk Scheme, feedback to the Evaluation of the Legislative Framework for Tobacco Control and a survey response on 2017 EU One Health Action Plan against AMR.

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

**Dr Christiaan Keijzer**

CPME President



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## EXECUTIVE COMMITTEE MEETING – 16 JUNE 2022

## Internal Affairs

### Statutes revision

- ▶ The EC addressed the open questions resulting from the membership consultation and online session relating to the statutes' review.

The EC discussion included the description of the CPME membership and their legal personality, the possibility to waive membership fees, and reporting obligations. As to the definition of 'major decisions' in relation to the future Board of Directors' scope of activities, it was agreed to keep the text in the statutes succinct and consult the lawyers on the possibility to include a more detailed description in an external document. The EC also highlighted the need to clarify the rules for the nomination of candidates to the Board of Directors to ensure coherence with current processes. The lawyers will be asked to process all input into a new draft which will be presented at the EC meeting on 7 July.

## Policies

### Response to consultation on EU school fruit, vegetables and milk scheme adopted

- ▶ The EC adopted the CPME response to the European Commission consultation on the revision of the EU School Fruit, Vegetables and Milk Scheme

The scheme is part of the Commission's Farm to Fork Strategy with the goal of creating a favourable food environment that makes it easier to choose a healthy and sustainable diet. The review will contribute to Europe's Beating Cancer Plan to improve health promotion through access to healthy diets.

## Policies

### CPME feedback to the Evaluation of the Legislative Framework for Tobacco Control adopted

- ▶ The EC adopted the CPME feedback to the Evaluation of the Legislative Framework for Tobacco Control.

The European Commission will evaluate related directives and policies due to factors such as the rapid rise in emerging products and recent technical developments. The feedback will be submitted with a more detailed response provided by the Smoke Free Partnership (SFP). CPME is a member of the SFP Coalition.

### Report of meeting with European Commission and European Medicines Agency on AMR

- ▶ The EC took note of recent meeting between the European Commission, the European Medicines Agency, the German Medical Association and the Secretariat on the list of antimicrobial medicines reserved for treating humans.

The proposed list does not contain a single antimicrobial currently authorised for veterinary use. During the meeting Prof. Dr. Winfried Kern (Faculty of Medicine, Albert-Ludwigs-Universität Freiburg) provided a summary of his expert opinion, criticising the omission of polymyxins (including colistin), third and fourth generation cephalosporins and fluoroquinolones.

### Survey response on 2017 EU One Health Action Plan against AMR adopted

- ▶ The EC adopted a survey response on the 2017 EU One Health Action Plan against AMR.

The EC added that emphasis should be placed on providing training on guidelines for general practitioners. The responses are likely to feed into a renewed plan.

## **CPME co-organises launch of European Health Union Network at European Parliament**

On 30 June, the launch event of the European Health Union Network took place at the European Parliament, to discuss questions about EU integration within the field of health and health policy. The initiative is coordinated by the office of MEP Istvan Ujhelyi and CPME with the support of AIM, EPF and HOPE.

## **CPME co-signs the ‘Oslo Declaration’ to reduce harmful use of alcohol**

European civil society organisations representing doctors, researchers, alcohol policy experts, cancer patients, and public health advocates issued a united call for policy action to curb alcohol harm – [the Oslo Declaration](#) – named after the 9th European Alcohol Policy Conference which took place earlier in June. CPME was represented by President Dr Christiaan Keijzer.

## **Event report: "Challenges of Health Data in Europe - Are we preparing?"**

On 6 April, the Conseil National de l'Ordre des Médecins (CNOM) and the Standing Committee of European Doctors (CPME) organised within the context of the French Presidency of the Council of the European Union, a conference to discuss and address benefits and challenges of the digital transformation in healthcare in Europe, with the objective of building trust while enabling science. Read the full event report [here](#).

## **Marcin Rodzinka-Verhelle joins the Secretariat**

We are delighted to welcome Marcin Rodzinka-Verhelle to the Secretariat as Policy Advisor. Marcin has a Master's degree in Public Health (Health Economics and Governance of Health Systems) from the Jagiellonian University Medical College in Cracow (Poland). He was the Vice-Chair of Sustainable and Healthy Lifestyles Committee of the 5th European Health Parliament. Prior to joining CPME, Marcin worked on health policy and global equitable access to health technologies with European Public Health Alliance, Global Health Advocates and Mental Health Europe. He also worked with the National Institute of Public Health in Poland.

## **CPME accepted to Civil Society Forum of HERA Advisory Forum**

CPME has been accepted to the Civil Society Forum as a sub-group of the HERA Advisory Forum at the European Commission's new Health and Emergency Preparedness Response Authority. The CPME President will be the representative. EFN will also be represented on the forum. CPME attended the [first meeting](#) on 29 June and reported on lessons learnt from the pandemic.

## **Give Kids a Break! What next for EU action to protect children from harmful food marketing?**

On 28 June, CPME and other organisations supporting the [healthy food marketing campaign](#) co-organised an event in the European Parliament and online to discuss what the EU can do to protect children from harmful food marketing.

## MONITORING

## Cross-border threats to health

### Agreement on new Regulation on serious cross-border threats to health

The EU co-legislators have reached political agreement on the new Regulation on serious cross-border threats to health. While the text awaits publication, the negotiator on behalf of the European Parliament MEP Dr Véronique Trillet-Lenoir has [indicated](#) that it includes explicit commitments to prevention, One Health and Health in All Policies, all of which CPME supported.

It also foresees stress tests for national health systems, including better data on intensive care capacities, which was part of CPME's request for minimum capacity benchmarks. The outcomes of these stress tests will be published alongside Commission recommendations. In relations to medicines, she reports a strengthening of access to essential medicines and better information on stocks and production capacities.

The Commission will also have the possibility to introduce exclusivity clauses in joint procurement contracts, however it seems that Member States retain some scrutiny on this. The text is also supposed to include stronger consultation mechanisms for stakeholders and foresee a greater involvement of the European Parliament, not least by introducing a parliamentary review of HERA's functioning by 2024, to assess whether it should become a standalone agency. In terms of competences, the Commission will be able to call a public health emergency at EU level, which for example would trigger the monitoring of medicine shortages.

Also the Health Security Committee composed of national authorities will be able to adopt guidance on prevention and control measures. In next steps both the Council and the European Parliament have to formally adopt the text for it to enter into force. CPME Secretariat will continue to monitor the implementation.



## MONITORING

## Antimicrobial resistance (AMR)

### Objection to reserve list of antimicrobials for human use defeated

On 23 June, by a margin of only 11 votes, the European Parliament rejected a resolution objecting to the list of antimicrobial medicines reserved for treating humans. CPME co-signed a letter with 16 other organisations which was sent to all MEPs prior to the vote. The European Commission was expected to receive feedback from the WTO on June 20, and it is likely to move forward with the proposed list in the coming days.

### Draft opinion on Managing antimicrobial resistance across the health system

The Expert Panel on effective ways of investing in health presented its [draft opinion](#) on Managing antimicrobial resistance across the health system at a virtual hearing on 20 June 2022. Additional comments are by 13 July 2022 and the Panel will finalise its work in the next months. The opinion is likely to feed into an upcoming Council recommendation on AMR and the successor of the EU's One Health Action Plan against AMR, which finishes at the end of 2022.

## Monkeypox

### HERA secures vaccines for EU Member States in response to the Monkeypox outbreak

HERA has [signed](#) a contract with Bavarian Nordic to purchase 109,090 doses of their 3rd generation vaccines in response to the current monkeypox outbreaks. This agreement will make vaccines available in all EU countries, Norway and Iceland.

## MONITORING

## COVID-19

### EMA adopts first list of critical medicines for COVID-19

On 7 June 2022, EMA's Medicines Shortages Steering Group (MSSG) [adopted](#) the list of critical medicines for the COVID-19 public health emergency. The medicines included in the list are authorised for COVID-19 and their supply and demand will be closely monitored to identify and manage potential or actual shortages. The published list contains all approved vaccines and therapeutics in the EU to prevent and treat COVID-19.

### EMA recommends Valneva's COVID-19 vaccine for authorisation in the EU and Nuvaxovid for adolescents aged 12 to 17

EMA has [recommended](#) granting a marketing authorisation for COVID-19 vaccine Valneva for use in the primary vaccination of people from 18–50 years of age. It is the 6th vaccine in the EU for protecting against COVID-19, and together with the vaccines already authorised, will support vaccination campaigns in EU Member States during the pandemic. It also [recommended](#) granting an extension of indication for the COVID-19 vaccine Nuvaxovid to include use in adolescents aged 12–17 years. This vaccine has already been authorised for adults aged 18 and above.

### Start of rolling review for adapted Comirnaty and Spikevax COVID-19 vaccines

Versions of [Comirnaty](#) and [Spikevax](#) that has been modified to offer stronger defence against a particular strains or variations of SARS-CoV-2, have begun a rolling review processes at EMA. The first section of the review will concentrate on CMC (chemistry, manufacturing, and controls). EMA will get further information as the businesses develop the modified vaccines, including information on the immunological response and information on its effectiveness against Omicron subvariants.

## MONITORING

## Non-communicable diseases (NCDs)

### EU NCDs initiative guidance document published

On 22 June, the European Commission published the Healthier together and EU NCDs initiative [guidance document](#) and launched an initiative to support EU Member States to reduce the burden of NCDs by addressing the leading causes of avoidable premature death in Europe and improving citizens' health and well-being. The initiative identifies actions and the available legal and financial supporting tools across five main areas: cardiovascular diseases, diabetes, chronic respiratory diseases, mental health and neurological disorders, as well as their main contributing factors. It will have a budget of €156 million under the 2022 work programme of the EU4Health programme.

### Commission proposes to prohibit flavoured heated tobacco products

On 29 June, the European Commission [proposed](#) to prohibit the sale of flavoured heated tobacco products in the EU. This proposal is a response to the recent Commission [report](#) showing a 10% increase in the sales volumes of heated tobacco products in more than five EU member states. Next, it will undergo a period of scrutiny by the Council and the European Parliament.

### New EEA Report: Exposure to pollution causes 10% of cancer cases

On 28 June, the European Environment Agency (EEA) published a new [report](#) which concludes that exposure to air pollution, second-hand smoke, radon, ultraviolet radiation, asbestos, certain chemicals and other pollutants causes over 10% of all cancer cases in Europe. It however reminds that environmental and occupational cancer risk factors are largely preventable. The report calls for better data on exposure to environmental and occupational cancer risks, with more evidence needed on the risk of low levels of exposure to multiple carcinogens. Moreover, the EEA report provides a brief overview of the evidence on the environmental and occupational determinants of cancer in Europe and of EU policy responses.

## European Council

### European Council grants EU candidate status for Ukraine, Moldova

On 23 June, the European Council [granted](#) candidate status to Ukraine and Moldova. The Council is ready to grant the status of candidate country to Georgia once the priorities specified in the Commission's opinion on Georgia's membership application have been addressed. The progress of each country towards the European Union will depend on its own merit in meeting the Copenhagen criteria, taking into consideration the EU's capacity to absorb new members.

### Country Specific Recommendations

The Council [approved](#) its Country Specific Recommendations on the National Reform Programmes of the Member States for 2022 as well as the Council's views on the revised Stability or Convergence Programmes. CPME Secretariat is working on a revised CPME members' briefing on the European Semester to also include the Recovery and Resilience Facility's activities.

### Council adopts negotiating mandate on strengthening the role of the EU Drugs Agency

On 9 June 2022, the Council [adopted](#) a negotiating mandate for the EU Drugs Agency proposal, which aims to transform the existing European Monitoring Centre for Drugs and Drug Addiction into a full-fledged agency with a stronger function. The new legislation will provide the agency with the tools needed to respond more efficiently to emerging health and security threats posed by illicit substances, better support member nations, and contribute to a better international situation.

## MONITORING

## Digital Health

### Guideline on electronic exchange of health data under cross border 2011/24/EU

The eHealth Network published their 3rd edition of the Guideline on electronic exchange of health data under the cross-border Directive 2011/24/EU. This guideline is not-binding, but this guideline is addressed to EU Member States and concerns the implementation of cross-border electronic health data exchange. The guideline can be found [here](#). An additional version was released focusing on the ePrescription and eDispensation of authorised medicinal products under the cross-border Directive. This guideline can be found [here](#).

### Internal Market Committee adopts the Digital Services Act

On 16 June 2022, the IMCO Committee [approved](#) the provisionally achieved agreement with EU governments on the Digital Services Act (DSA), with 36 votes in favour, 5 against, and 1 abstention. Together with the Digital Markets Act (DMA), the DSA creates ground-breaking guidelines for a user-friendly, open, and competitive digital environment for years to come. Penalties for non-compliance might total up to 6% of a platform's total global revenue.

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