



## Dear colleagues

We are pleased to share with you the July edition our Monthly Bulletin with the outcomes of the Executive Committee the meeting on 7 July 2022. The most significant item on our agenda was again the revision of our association's statutes and we agreed to include a special session on this topic during our meetings in Prague on 28 October, prior to the proposed adoption on 29 October.

We also took note of a fourth project of the Ukraine Medical Help Fund. With a value of €370,000, it will deliver material to help maternity wards in Mykolaiv, general intensive care material for Cherkov, and tourniquets for Odessa.

We invite you to read about this and much more, and wish you healthy summer months.

**Dr Christiaan Keijzer**

CPME President



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## EXECUTIVE COMMITTEE MEETING – 7 JULY 2022

## Internal Affairs

### Statutes revision

- ▶ The EC reviewed draft 4 of the new statutes and decided on some of the outstanding questions.

These included the clarification that candidacy to the Board of Director is open also to all delegates not only heads of delegation, however every member can only nominate one candidate. It was also decided to add the exclusivity clause from Art. 5.4 of the current statutes. All references to data having to be from the last financial year were deleted. Further comments on the French translation will be provided by CNOM. CPME Secretariat will process all changes and send to the lawyers. The revised draft will be sent for approval by written procedure. The EC also confirmed that the Royal Dutch Medical Association, the Norwegian Medical Association, the Greek Medical Association and the Finnish Medical Association will be named in the convening notice as members proposing the amendment to the statutes.

### Ukraine Medical Help Fund continues to send aid

- ▶ The EC took note of the ongoing activities of the Ukraine Medical Help Fund in collaboration with WMA and EFMA, including the approval of a fourth project with a value of €370,000, which is being coordinated via the Saxonian State Chamber of Physicians and the NGO 'Hope for Ukraine'.

The project will deliver material to help maternity wards in Mykolaiv, general intensive care material for Cherkov, and tourniquets for Odessa.

### CPME to continue participating in Digital Leadership Course

- ▶ The EC agreed that it was beneficial to continue with the digital leadership course together with EJD. The funding needed to be discussed further.

## EXECUTIVE COMMITTEE MEETING – 7 JULY 2022

## Agendas of General Assembly and Board, October 2022

- ▶ The EC reviewed the draft agendas for the October meeting.

It was decided to schedule a special session to discuss the statutes. The EC also agreed to liaise with the Czech Medical Chamber on the members' conference.

## Policies

### Consultation on Sustainable EU Food Systems

- ▶ The EC agreed on a response to the consultation.

### Feedback on European Health Data Space

- ▶ The EC agreed to prepare a shorter version to reply to the Commission's feedback mechanism and for the WG to continue to work on the detailed CPME position on the EHDS.

The detailed will be submitted for adoption by the CPME Board in Prague. CPME Secretariat will circulate the document for comments and approval by written procedure.

### Expert Group of the AMR One Health Network

- ▶ The EC agreed to apply to become a member of the Expert Group of the AMR One Health Network

## EXECUTIVE COMMITTEE MEETING – 7 JULY 2022

## Expert Panel report on AMR

- ▶ The EC approved feedback on the European Commission's Expert Panel opinion on Managing antimicrobial resistance across the health system.

The feedback notes that only the benefits of telemedicine are present and will include our position on the topic, emphasising that telemedicine is not without risk and is not suitable in all scenarios. We also note that the opinion should pay greater attention to antimicrobial use in food-producing animals, emphasise the importance of training of healthcare professionals and doctors' access to better and faster diagnostic tools.

## E-evidence

- ▶ The EC took note of the EU developments. The EC agreed that CPME Secretariat prepares a letter to NMA's informing about pending points in on-going discussion, calling Member's to follow-up on previous meetings with their Ministries of Health and Justice.

## CPME NEWS

## CPME publishes first edition of new magazine

On 20 July, we were proud to publish the [first edition](#) of the new CPME magazine. The magazine is latest milestone in our ongoing rebranding exercise, and extends our new visual identity with a modern and dynamic design that showcases our latest news, feature articles, member articles and guest articles. We hope you enjoy reading it and don't hesitate to contact if you have an idea for a member article in the next edition.

## MONITORING

## Conference on the Future of Europe

### Final health outcomes of the Conference on the Future of Europe

The four health outcomes from the [report](#) on the final outcomes on the Conference on the Future of Europe are as follows:

- Ensure that all Europeans have access to education on healthy food and access to healthy and affordable building blocks of a healthy lifestyle in particular by setting minimum standards for food quality, educating people about healthy habits from early age, encouraging dialogue with the food chain actors from production to sale, supporting at EU level the provision of healthy, varied and affordable food, and investing in research on the impact of antibiotics and the effect of hormonal substances in human health.
- Reinforce the resilience and quality of our healthcare system, through the creation of a European Health Data space, adequate working conditions, ensuring strategic autonomy at EU level to avoid dependency on third countries for medicines and medical devices, further coordinating and funding existing health research and innovation programmes without undermining other health-related programmes, investing in the health system, and issuing strong recommendations to the Member States to invest in effective, affordable, high-quality and resilient health systems.
- Adopt a holistic approach to health, addressing, beyond diseases and cures, health literacy and prevention, and fostering a shared understanding of the challenges faced by those who are ill or disabled, in line with the “one health approach”, which should be emphasised as a horizontal and fundamental principle encompassing all EU policies.
- Establish a ‘right to health’ by guaranteeing all Europeans have equal and universal access to affordable, preventive, curative and quality health care.



## MONITORING

## Pharmaceuticals & Healthcare

### HERA announced 3 key health threats to prepare against in the future

As foreseen in the Work Plan for 2022, HERA [identified](#) 3 health threats that require coordination of measures at EU level in the context of medical countermeasures. The list consists of pathogens with high pandemic potential, chemical, biological, radiological, and nuclear threats and AMR. Throughout 2022, HERA has consulted Member States, Union and national agencies, Chief Medical Officers, international actors and experts on the threat prioritisation exercise. Preliminary results were presented to the HERA Advisory Forum, which CPME is a part of.

### Identifying and addressing medicine shortages during public health emergencies

EMA's Medicines Shortages Steering Group [adopted](#) the list of the main therapeutic groups of medicines used in emergency care, surgery, and intensive care. The list forms the basis from which EMA will draw up concrete lists of critical medicines needed to deal with a specific 'public health emergency' or a 'major event'. The medicines on this list are monitored closely because of a possible increased risk in shortages.

### Commission publishes blood, tissues and cells proposal

On 14 July, the European Commission published its [proposal](#) for a regulation on rules for blood, tissues and cells. The proposal details how the Commission aims to improve the safety and quality standards for people treated with substances of human origin (SoHO), donors, and children conceived through medically assisted reproduction. The proposal combines two directives – one for blood and the other for tissues and cells – into a single regulation.

## MONITORING

## Could a public infrastructure overcome market failure in biomedical R&D?

The Science and Technology Options Assessment (STOA) Panel of the European Parliament has investigated the feasibility of creating a large-scale European public infrastructure aimed at addressing vulnerabilities linked to the research, development, production, and distribution of medicines. This work builds on the Pharmaceutical Strategy for Europe. The STOA Panel will host a [workshop](#) for public health experts and stakeholders in September 2022 to discuss the state of play of the Pharmaceutical Strategy and the feasibility of creating an advanced EU pharmaceutical infrastructure for the research and development of novel medicines and treatments. Participants can join remotely, as well as in person.

## EMA issued guidance on the prevention of shortages of medicines for human use

EMA published a [guidance](#) for patients and healthcare professionals with good practices and examples of actions to prevent and manage shortages of medicines. The key recommendations have been prepared based on consultations with members of patients and healthcare professionals working parties existing at EMA and they draw on practices and initiatives from individual EU Member States. A full list of recommendations is available [here](#).

## MONITORING

## COVID-19

### Global regulators agree on key principles on adapting vaccines to tackle virus variants

On 30 June, regulators from around the world [discussed](#) emerging evidence to support adaptation of COVID-19 vaccines as the SARS-COV-2 virus continues to evolve during a workshop co-chaired by the EMA and FDA under the umbrella of the International Coalition of Medicines Regulatory Authorities. The meeting focused on identifying key principles to support the adaptation of COVID-19 vaccines to better match Omicron variants of concern, and on ensuring global regulatory alignment.

### Launch of the COVID-19 impact on nutrition Analytical framework

The COVID-19 pandemic shocked the world affecting organizations and institutions that supported the delivery of nutrition programs at all levels. To respond to the needs of the nutrition community, the Agile Core Team for Nutrition developed an analytical framework for exploring pathways for the impact of COVID-19 pandemic on key nutrition outcomes. More on this framework can be found [here](#).

### ECDC and EMA update covid vaccine recommendation

The ECDC and EMA are [recommending](#) that 2nd booster doses of mRNA COVID-19 vaccines be considered for people between 60 and 79 years old and people with medical conditions putting them at high risk of severe disease.

## MONITORING

## Non-communicable diseases (NCDs)

### Member States may be liable for health damage caused by excessive air pollution

Advocate General Juliane Kokott [takes](#) the view that an infringement of the limit values for the protection of air quality under EU law may give rise to entitlement to compensation from the state under 3 conditions; (1) the limit values for pollutants in ambient air and the obligations to improve air quality laid down by EU directives were intended to confer rights on individuals, (2) serious breach of the rules on the protection of air quality concerns all periods during which the respective applicable limit values were exceeded without there having been an air quality improvement plan that did not contain any manifest defects, and (3) there has to be a causal link between the serious breach and specific damage to health.

## Ukraine

### The Burden of war on Ukrainian doctors

Healthcare staff in Kyiv have [reported](#) increasing numbers of patients, with many struggling to access health services and medicines in the country that has been under attack from Russia since the end of February. Around 600 medical facilities have been destroyed or damaged and 200 medical emergency vehicles have been shot or taken by Russian forces. The number of patients with decompressed advanced cirrhosis, toxic hepatitis, and autoimmune diseases have increased.

## MONITORING

## Digital Health

### Political agreement on the Digital Decade policy programme

On 14 July, the European Parliament and the Council of the EU reached a [provisional agreement](#) on the 2030 Policy Programme: Path to the Digital Decade (final text not yet available). The programme sets up a monitoring and cooperation mechanism to achieve the common objectives and targets for Europe's digital transformation set out in the [2030 Digital Compass](#). It concerns for example the objective that 100% of Union citizens shall have access to electronic health records (EHR) and that 100% of Union citizens have the possibility to use an electronic identification (eID). Next Steps: the Digital Decade policy programme will enter into force after being formally approved by the two co-legislators. As a first step, the Commission and Member States will develop KPIs to measure progress towards the 2030 digital targets. Member States shall have 9 months to present their first national strategic roadmaps, which will launch the cooperation cycle. CPME recommends its members to participate in drawing up these national strategic roadmaps. CPME commented on the [2030 Path to the Digital decade](#).

### Protecting mental health in the digital workspace

On 5 July, MEPs [adopted](#) a resolution demanding preventive measures against “technostress” – the stress linked to work-related technology use – and over-connection, to tackle mental health issues and boost the benefits of working from home. Parliament asks the EU institutions and member states to further regulate digital work to protect mental health, in cooperation with employers and workers’ representatives. The Commission, the European Agency for Safety and Health at Work and member states should include mental health in their health crisis and pandemic emergency response and preparedness plans. MEPs call for a directive on minimum standards and conditions to ensure all workers the effective right to disconnect, and to regulate the use of existing and new digital tools for work purposes.

## MONITORING

## Joint opinion on EHDS

On 14 July, the European Data Protection Board (EDPB) and the European Data Protection Supervisor (EDPS) have adopted their [Joint Opinion on the European Commission's Proposal for the European Health Data Space \(EHDS\)](#). The EDPB and the EDPS welcome the idea of strengthening the control of individuals over their personal health data. However, they draw the co-legislators' attention to a number of overarching concerns and urge them to take decisive action. In particular, they acknowledge that the description of the natural persons' rights in the Proposal is not consistent with the GDPR and there is a substantial risk of legal uncertainty for individuals who may not be able to distinguish between the two types of rights. Health data from wellness apps and other digital health applications should be excluded from being made available for secondary use (data not of the same quality and can be highly invasive and reveal particularly sensitive information, such as religious orientation). The question of consent in secondary use was raised and an obligation to store personal electronic health data in the EU should be introduced. Data protection authorities should be the only competent authorities responsible for data protection issues and remain the only point of contact for individuals. Overlap of competences should be avoided and fields of and requirements for cooperation should be specified.

## European Parliament adopts the Digital Services Package

The Commission [welcomes](#) the adoption by the European Parliament of the Digital Services Act and Digital Markets Act, proposed by the Commission in December 2020. The Digital Services Package sets out a first comprehensive rulebook for the online platforms that we all depend on in our daily lives. It will create a safer and more open digital space, grounded in respect for fundamental rights.

## MONITORING

## AI Act

The Czech Presidency circulated a discussion paper on “four high-level outstanding issues which require more thorough discussion,” namely the definition of AI, the categorisation of high-risk systems, the governance structure and the national security exemption. In the document, the Czechs set out different scenarios on each topic, which range from maintaining the status quo via moderate changes to more significant redesigns of the provisions. Member States have been asked to express their preferred options and provide a justification. The paper indicates that the upcoming Presidency will act in continuity with the French one, but will show flexibility on the more contentious points. The paper was discussed at the Telecom Working Party on 5 July, and a new compromise text will circulate by 20 July. Member States will then have until 2 September to provide written comments. [Read more](#).

In the European Parliament, a [joint discussion between the IMCO and LIBE committees](#) was held on 30 June to consider the more than 3000 amendments tabled by the MEPs on the proposal. The leading rapporteurs mentioned that a vote on the text in October was “very optimistic”, but they are still aiming to reach a Parliament deal by the end of the year.

## e-Evidence Regulation

A trilogue between the French Presidency and the EP was held on 14 June (please see Presidency note [here](#)) to find a preliminary political agreement on technical points and to continue with a more political debate on the remaining differences. In hope of finding an agreement, another trilogue took place on 28 June where the co-legislators [reached a political agreement in certain areas](#). The informal coalition that CPME participates in this file is considering preparing a joint political statement in view of the Czech Presidency. CPME intends to launch another advocacy action among its Members, preparing a template letter to be sent to both Health and Justice Ministers in order to continue to show interest in monitoring and follow-up on the discussions.

## MONITORING

## NIS2 final steps

The Network and Information Security (NIS) Directive is the first piece of EU-wide legislation on cybersecurity, and its specific aim was to achieve a high common level of cybersecurity across the Member States. While it increased the Member States' cybersecurity capabilities, its implementation proved difficult, resulting in fragmentation at different levels across the internal market. To respond to the growing threats posed with digitalisation and the surge in cyber-attacks, the Commission submitted a proposal to replace the NIS Directive and thereby strengthen the security requirements, address the security of supply chains, streamline reporting obligations, and introduce more stringent supervisory measures and stricter enforcement requirements, including harmonised sanctions across the EU. The proposed expansion of the scope covered by NIS2, by effectively obliging more entities and sectors to take measures, would assist in increasing the level of cybersecurity in Europe in the longer term, including health. The co-legislators reached a provisional agreement on the text on 13 May 2022. The text now needs to be adopted formally by both institutions, with the Parliament due to vote on in plenary in October. Please see [here](#) further information.

## Data Act competency split

The Conference of Committee Chairs in the European Parliament shared its recommendation for the allocation of competencies across the different committees involved. The opinion states that JURI and IMCO should have shared competencies on the entire file. The legal affairs committee would get exclusive competencies on the protection of Intellectual Property rights and the provisions regarding private contracts, whereas the internal market committee would lead on the part related to interoperability and cloud switching. The division of tasks with LIBE was maintained, but the big loser is ITRE which sees its role significantly downsized. The [final decision will be taken soon](#).



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