



Dear colleagues

We are pleased to share with you the September edition our Monthly Bulletin with the outcomes of the Executive Committee the meeting on 8 September 2022. Prior to the meeting I met with Virginijus Sinkevičius, EU Commissioner for the Environment, to discuss the revision of the EU ambient air quality directives alongside other Brussels-based health and environmental organisations. We were also privileged to welcome MEP Dr Peter Liese to discuss with our Executive Committee. Such meetings allow us to promote European doctors' point of view to the highest levels of European policy-making.

Earlier in September we were pleased to [renew](#) our Memorandum of Federation of Veterinarians of Europe (FVE), underlining the importance of interprofessional collaboration between doctors and veterinarians in areas such as One Health.

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

Dr Christiaan Keijzer

CPME President



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EXECUTIVE COMMITTEE MEETING – 8 SEPTEMBER 2022

Finances

Draft accounts 2022

- ▶ The EC reviewed the draft accounts as of 30 June 2022.

Spending is proceeding as expected with underspends e.g. on staff costs due to the continued vacancy. Meeting costs are already subject to a cap as announced previously. Despite this, a deficit is expected at the end of the year.

Draft budget 2023

- ▶ The EC reviewed the draft 2023 budget.

As agreed at the March CPME Meetings, the draft 2023 budget has an endpoint of 1.1 million. Despite this increase there will be a deficit due to the high rate of expected inflation and consequent indexation as well as higher costs for suppliers' services. The EC agreed that the exceptional circumstances of this budget render the deficit acceptable, also because the reserves are still within the desired range.

Simulation of the budgets 2024-2026

- ▶ The EC reviewed a simulation of future budgets 2024-2026.

Even with an increase in the endpoint in 2024 as previously agreed, the estimated indexation and other cost increases would cause the budget to run at continuous deficits and deplete reserves. The EC agreed that this would not be acceptable and corrective action must be taken. The EC agreed to present a proposal at the General Assembly in October.

EXECUTIVE COMMITTEE MEETING – 8 SEPTEMBER 2022

Internal Affairs

Statutes revision

- ▶ The EC discussed the progress made regarding the send out of draft statutes and the return of proxies.

All revisions of the draft statutes have been concluded, while requests for clarification can be submitted and consulted with the lawyers.

Executive Committee meeting dates 2023

- ▶ The EC agreed on meeting dates for 2023.

Agendas of General Assembly and Board, October 2022

- ▶ The EC reviewed the agendas of the upcoming General Assembly and Board meetings which will take place in Prague on 29 October.

Jacqueline Rossant-Lumbroso appointed Rapporteur on medicine shortages

- ▶ The EC approved the nomination of Jacqueline Rossant-Lumbroso as Rapporteur on medicine shortages.

Policies

Public Consultation on EU Global Health Strategy

- ▶ The EC decided to adopt a response to the consultation on EU Global Health Strategy.

The EC introduced some minor comments to the draft response. In the section on policies with a most important impact on health goals, the EC also decided to add a point on healthy living and food systems. With regards to access to medicines and healthcare, the EC preferred to highlight access to healthcare services.

Medical Devices Regulation

- ▶ The EC decided to survey CPME members to learn more about the current situation at national level with regards to medical devices.

Based on the outcome of the survey, the EC will decide on next steps.

Substances of human origin legislative proposal

- ▶ EC decided not to engage on the legislative proposal for the time being.

CPME does not have a specific position on this topic, but might consider adopting one, provided adequate capacity exists.

EMOs' joint statements on situation of general practitioners

- ▶ The EC agreed to support the joint statements presented by UEMO for co-signature by the other EMOs.

The statements address changes to electoral rules of the representative body of doctors in Romania and the provision of GP services in Portugal.

EXECUTIVE COMMITTEE MEETING – 8 SEPTEMBER 2022

Lancet Countdown 2022

- ▶ The EC decided that the final decision will be made by the president and the rapporteur as CPME members still had a possibility to send feedback.

The 2022 brief focuses on three topics: ambient air pollution, sustainable food and diets, and greening the healthcare sector. CPME has been collaborating with the Lancet Countdown since 2018 to co-publish policy briefs on health and climate change.

Support to the Ireland's alcohol labelling legislation

- ▶ The EC decided to give support to Ireland's alcohol labelling legislation with a submission drafted by the Irish Medical Organisation (IMO) in the context of the latest round of EU scrutiny.

CPME was invited to give support by the Alcohol Action Ireland, a member of CPME's Brussels-partner European Alcohol Policy Alliance (Eurocare).

Call for evidence on digital skills

- ▶ The EC adopted a response to a call for evidence on digital skills from the European Commission towards a Council Recommendation on improving the provision of digital skills in education and training.

The response had previously been reviewed and approved by the CPME rapporteur on digital skills, Prof. Dr. Sebastian Kuhn.

EXECUTIVE COMMITTEE MEETING – 8 SEPTEMBER 2022

EU Air Quality Directives

- ▶ The EC decided to ask CPME members to co-sign and/or send a letter to their health and environment ministers calling on the EU to fully align the ambient air quality directives with the WHO guidelines in the upcoming revision of the directives.

Moreover, the EC supported the idea to send a joint letter to the next presidencies of the Council of the EU.

Call for evidence on digital education

- ▶ The EC adopted a response to a call for evidence on digital skills from the European Commission towards a Council Recommendation on Digital education.

The response had previously been reviewed and approved by the CPME rapporteur on digital skills, Prof. Dr. Sebastian Kuhn.

Position on the European Health Data Space

- ▶ The EC discussed the draft, in particular on the points related to telemedicine and doctor's personal notes and proposed specific wording to be discussed within the WG Digital Health.

European Doctors and Veterinarians reaffirm their partnership on One Health

To enhance further cooperation on the One Health approach in Europe, the Standing Committee of European Doctors (CPME) and the Federation of Veterinarians of Europe (FVE) have renewed their [Memorandum of Understanding](#).

The signed memorandum emphasises that European doctors and veterinarians strive to continue to lead the way in preventing zoonoses, containing antimicrobial resistance and providing healthcare for humans and animals by recognising the interdependence of the two sectors and the implementation of science-based approaches. FVE and CPME agreed to work together on several actions ranging from assisting policy makers and awareness raising to improving uptake of prudent prescription practices and promoting research and development of new tools for use in both human and animals.

CPME and FVE reiterated their commitment to the One Health approach in their missions at a meeting hosted by the Veterinary Faculty of the University of Utrecht in the Netherlands on 1 September.

Both organisations have already been working extensively together. Since 2013, we have jointly highlighted best practices such as prevention to combat human diseases and antibiotic resistance, as well as, to promote One Health culture in education and healthcare practice. Going forward, CPME and FVE will aim to expand interdisciplinary collaboration in all aspects of healthcare for humans, animals and the environment.

Register for CPME Board, General Assembly and Policy Sessions' meetings 28-29 October, Prague and Hybrid

Registration for the CPME meetings in October 2022 is available [here](#).

Guests who wish to participate in the Gala dinner by 12 October 2022 should:

- Please pay the amount of €100 by transfer to the following bank account: IBAN BEO6001377838722 BIC GEBABEBB of the bank BNP Paribas Fortis SA.;
- Specify in the communication section: "CPME Gala Dinner 28 October 2022", the name of the person making the reservation and the number of people for whom the reservation is made (e. g. "Gala Dinner 28 October 2022 - Dr Reed – 2 persons).

President to speak at Parliament Debate on engaging patients to fight AMR

Our President Dr Christiaan Keijzer will speak at the Parliament Roundtable Debate entitled "Engaging with patients and closing knowledge gaps to fight antimicrobial resistance: the role in infection prevention and antimicrobial stewardship".

The event will take place in a hybrid format on Thursday 27 October from 10.00 to 11.30 CEST, kindly hosted by MEP Ondřej Knotek (Renew Europe, Czech Republic), and under the patronage of the Czech Presidency of the Council.

Registration and the agenda is available [here](#).

MONITORING

World Health Organization

CPME follows WHO Europe discussions on digital health, workforce, medicines, alcohol

CPME attended the WHO–Europe Regional Committee meeting in Tel Aviv which took place from 12–14 September. The meeting saw the adoption of several reports and strategies:

- The report on [‘Health and care workforce in Europe: time to act’](#) includes country profiles for all WHO–Europe Member States mapping workforce numbers, density and trends, as well as data according to age, gender, and number of foreign–trained professionals. The main recommendations cover the need for sufficient education opportunities, health workforce planning policies, attention to working conditions and professionals’ wellbeing, and the development of recruitment and retention strategies with a focus on rural areas. Under the heading of ‘innovative workforce policies’ the report also recommends enhanced task–shifting while acknowledging that this must be in coherence with national systems.
- With the new [digital health action plan](#) for the WHO European Region 2023–2030, WHO–Europe sets out strategic priorities around setting norms, building governance capacity, creating networks and supporting horizon scanning to assist Member States in the digital transformation of health systems. The latter includes the engagement with patient and professional associations. The action plan also identifies guiding principles, including the recognition of patients’ and doctors’ needs and expectations. Reference is made to the policy context, including the need to align with EU activities such as the European Health Data Space.
- 53 countries signed a [statement](#) committing to identify solutions to improve access to medicines in the European Region. The signatories agreed to launch a multistakeholder platform that will build on the work done by the Oslo Medicines Initiative. The platform will be hosted and facilitated by WHO/Europe.

MONITORING

- The Health System in Action ([HSiA](#)) Insights are a set of short summaries that capture what is happening in non-EU Member States. They highlight progress and challenges country by country; and provide context for the WHO/Europe's European Programme of Work and its Roadmaps for Health and Wellbeing.
- The WHO European [Framework for Action on Alcohol](#) (2022–2025) lays out priority areas for action to achieve the target of a 10% relative reduction in alcohol per capita consumption by 2025. The six priority areas at the national and subnational levels are pricing, marketing, availability, health information (with a focus on labelling), health services' response, and community action.

New policy briefs support country strategies to control and eliminate monkeypox in the WHO European Region

WHO Europe has [launched](#) a series of new policy briefs on monkeypox for the WHO European regions, which cover 53 countries across Europe and central Asia. The briefs will support Member States that are already responding directly to the outbreak and help to prepare those that have not yet reported cases.

European Region averts further backsliding in routine immunisation but falls short of full recovery

The [percentage](#) of children around the world who received 3 doses of the vaccine against diphtheria, tetanus and pertussis (DTP3) fell 5% points between 2019 and 2021 to 81%, according to official data published today by WHO and the United Nations Children's Fund (UNICEF).

MONITORING

EU Political Outlook

Ministers discuss Ukraine, vaccination, cancer care

On 7 September, the [Ministers of Health held the usual informal Council meeting](#) under the Czech presidency. The agenda included a discussion with the Ukrainian Minister of Health, Viktor Liashko, not only with regard to continued support during the war, but also the future of the Ukrainian health system, covering i.a. the need for quality of care and the mobility of professionals. The ministers also discussed vaccinations. With the plan to adopt Council Conclusions on vaccination in December, the debate addressed the need for action to increase vaccine coverage and mitigate the polarisation of opinions. In the context of a joint meeting with the HERA committee, ministers concluded that in relation to COVID-19, only the new vaccines will be distributed after 19 September, and orders for the previous vaccines will be postponed depending on need, to avoid obsolescence. Lastly, ministers also discussed cancer care, in particular its availability and early screening programmes. This discussion will be feed into the Council Recommendation on Cancer Screening, which are to be adopted at the December Council.

Initiative on mental health announced in State of the Union address

European Commission President Ursula von der Leyen announced a new initiative on mental health in her State of the European Union [address](#) on 14 September. The details of the initiative will be presented in 2023, with a comprehensive approach to mental health [promised](#) to the European Parliament. The announcement of the initiative was the only direct reference to health in the speech, which focused broadly on the EU's solidarity with Ukraine and introduced plans to mitigate energy prices.

MONITORING

EU sets out to measure progress on Green Deal environment and climate goals

The Commission [presented](#) a list of headline indicators for monitoring progress towards the EU's environment and climate goals to 2030, as well as the 2050 long-term vision to 'live well, within planetary boundaries. The new Monitoring Framework under the 8th Environment Action Programme aims to foster transparency and inform Europeans about the impact of EU climate and environmental policy.

Professional Practice

More transparent and predictable working conditions for workers in EU

On 1 August 2022, the deadline was set for EU Member States to transpose the Directive on transparent and predictable working conditions into national law. The Directive provides more extensive and updated labour rights and protection to the 183 million workers in the EU. With the new rules, workers will have the right to more predictability in their working conditions, regarding assignments and working time. More information on this Directive can be found [here](#).

MONITORING

Pharmaceuticals & Healthcare

Pharmaceutical legislation revision faces delay

According to [media reports](#), the publication of pharmaceutical legislation proposals will be postponed to next year (instead of December 2022). The reason behind it is that the Regulatory Scrutiny Board assessed the proposals to have negative impact on the European pharmaceutical industry, hampering the exclusivity rules. This development is not official yet, as neither the European Commission nor the RSB published any documents.

EMA confirms biosimilars can be interchanged

The European Medicines Agency, together with the Heads of Medicines Agencies, issued a [joint statement](#) on scientific rationale supporting interchangeability of biosimilar medicines in the EU. Until now, biosimilars approved via EMA could be used interchangeably if the national regulatory agency allowed it. From a scientific viewpoint, interchangeability of approved biosimilars has always been considered acceptable and did not raise any concern. However, EMA has to date not issued any recommendation on interchangeability. Member States will continue to decide which biological medicines are available for prescribing in each territory and whether automatic substitution is allowed at pharmacy level.

New co-chairs of Working Parties at EMA

Two Working Parties at the European Medicines Agency – Health Care Professionals and Patents and Consumers – elected their new co-chairs for a mandate of 2022–2024. The European Society of Medical Oncology's Rosa Giuliani will be co-chair of the Health Care Professionals' Working Party, while the European Heart Network's Marilena Vrana will co-chair the Patients' and Consumers' Working Party. EMA is expected to publish a press release soon.

MONITORING

Auditors say that EU must learn lessons from COVID-19 vaccine procurement

The European Court of Auditors published a [special report](#) analysing EU performance in COVID-19 vaccine procurement. The auditors concluded that the EU succeeded in securing initial portfolio of vaccines after some challenges, but the performance of the process has not been sufficiently assessed. The report suggests 3 recommendations for the EU: produce pandemic procurement guidelines and/or lessons learnt for future negotiating teams; carry out a risk assessment of the EU's procurement approach and propose appropriate measures; run exercises to test all parts of its updated pandemic procurement framework, including information and intelligence gathering, to identify any weaknesses and areas for improvement and publish the results.

Member States suggest actions to tackle AMR

The AMR One Health Network is an informal collaborative group coordinated by the European Commission (and led by France) that brings together human health, veterinary and environmental health experts from EU countries, with the objective to improve the EU efforts to fight against AMR. The subgroup established under this informal network came up with [almost 300 proposals](#), that may provide the European Commission with a useful "toolbox" with numerous and detailed proposals for concrete actions that could be taken or coordinated at EU level to fight the growing public health threat that is AMR. The top 10% of recommendations relate to the veterinary sector.

BioMed Alliance survey on medical devices

The BioMed Alliance together with the European Society of Cardiology launched a [survey](#) to find out more about the potential issues in availability of medical devices. Disruptions are likely to occur due to a low capacity of notified bodies under the new Medical Devices Regulation.

MONITORING

Accelerating Clinical Trials in the EU: publication of 2022–2026 workplan

The European Commission (EC), the Heads of Medicines Agencies (HMA) and the European Medicines Agency (EMA) have published the [2022–2026 workplan](#) of the initiative Accelerating Clinical Trials in the EU (ACT EU). ACT EU, launched in January 2022, seeks to transform how clinical trials are initiated, designed and run. The aim is to further develop the EU as a focal point for clinical research, promote the development of high-quality, safe and effective medicines, and to better integrate clinical research in the European health system. The multi-annual ACT EU workplan builds on the Clinical Trials Regulation (CTR), which became applicable in January 2022.

Pandemic instrument should be legally binding

The intergovernmental Negotiating Body (INB) members [agreed](#) that they will work to conclude a new, legally binding international pandemic agreement. The INB's work aims to ensure better preparedness and equitable response for future pandemics, and to advance the principles of equity, solidarity, and health for all. They are working to conclude this agreement in May 2024.

HERA signs Joint Procurement contract for Pandemic Influenza Vaccine

The European Commission [signed](#) a framework contract for the joint procurement of Adjupanrix, a pandemic influenza vaccine, with the pharmaceutical company GSK. 12 member states and other joint procurement countries are participating in the agreement, under which they can purchase up to 85 million vaccine doses if necessary, in the event of an influenza pandemic.

MONITORING

Public Health and Disease Prevention

Sir Michael Marmot warns of increased illness and death due to energy cost increases

In an [article](#) in The Guardian, former BMA and WMA president Sir Michael Marmot discusses the impact the high energy costs can be expected to have on the health of the population. He cites that reduced capacity to pay for heating and concomitant reduced incomes will aggravate the negative health impacts of insufficient housing, not only through cold, but also mould and dampness leading to both physical and mental ill health. He provides estimates of long-term sickness and deaths attributable to cold homes and calls for political action to correct failures in the energy market and investment in adequate housing.

A new EU approach on cancer detection – screening more and screening better

The European Commission [presented](#) a new approach on cancer detection under Europe's Beating Cancer Plan in order to help Member States to improve the cancer screening rates, targeting more risk groups and more cancer types. The proposed recommendation sets a new course for the EU Cancer Screening Scheme to ensure cancer screenings for 90% of those who qualify by 2025.

MONITORING

Commission's Joint Research Centre (JRC) published four reports on labelling

On 9 September, the European Commission's Joint Research Centre (JRC) has [published](#) four reports on labelling which synthesise the current scientific evidence regarding front-of-pack nutrition (FOP) labelling, origin labelling and digital means to convey food information, as well as analyse the market in terms of labelling of alcoholic beverages. The Commission is expected to publish its proposal for harmonised mandatory front-of-pack nutrition (FOP) labelling and alcohol labelling by the end of this year.

Commission registers a new European Citizens' Initiative on Tobacco

On 24 August, the Commission [registered](#) a European Citizens' Initiative (ECI) called 'Call to achieve a tobacco-free environment and the first European tobacco-free generation by 2030'. The initiators request that the Commission propose legislation to ban the sale of tobacco and nicotine products to people born after 2010. Additionally, the initiative calls for concrete actions to achieve tobacco-free and cigarette-butt-free environments. The organisers have six months to begin accepting signatures. The ECI will need action from the Commission if it collects one million affirmative responses in a year from at least seven different Member States.

MONITORING

COVID-19

ECDC–EMA statement on booster vaccination with Omicron adapted bivalent COVID–19 vaccines

The European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA) issued a [joint statement](#) providing updated public health considerations on the use of the newly authorised adapted COVID–19 vaccines to support the planning of the autumn and winter vaccination campaigns.

EU response to COVID–19: preparing for autumn and winter 2022–2023

In its recent Communication, the European Commission outlined a list of actions and recommendations for autumn and winter 2022–2023 with regards to the COVID–19 pandemic. The Commission urges Member States to quickly take the necessary measures to avoid a surge of cases in autumn and winter, causing unnecessary human suffering and putting further strain on healthcare systems, economies, and society in general. The summary of the Communication can be found [here](#).

Special Committee on COVID–19 in the European Parliament met with the pharmaceutical companies

Special Committee on the COVID–19 pandemic [welcomed](#) the representatives of four pharmaceutical companies on 5 September 2022. The representatives of Gilead Sciences, Sanofi, AstraZeneca, and Moderna shared their views on past and present manufacturing, distribution and equitable access of the COVID–19 vaccines and therapeutics. The debate focused on the activities undertaken to develop vaccines for new variants, the authorisation process, and transparency of contracts.

MONITORING

Exchange of views between European Commission and Health Ministers on COVID-19

The European Parliament's Special Committee on the COVID-19 pandemic [held](#) an exchange of views with Sandra Gallina, Director-General for Health and Food Safety, and Health Ministers from Finland, Belgium, and Romania on 30 August. In particular, the meeting discussed how Advanced Purchase Agreements were drawn up, the lessons learned and how the EU and Member States will handle them in the future.

Commission signs Joint Procurement contract with HIPRA for COVID-19 vaccines

HERA has [signed](#) a joint procurement framework contract with the company HIPRA HUMAN HEALTH for the supply of their protein COVID-19 vaccine. 14 Member States and countries are participating in this joint procurement, under which they can purchase up to 250 million doses. The vaccine will be rapidly available to the participating countries, as soon as it receives a positive assessment by the EMA.

Committee of Ministers responds on public health measures

The Committee of Ministers has [responded](#) to the Parliamentary Assembly Recommendation 2210 (2021) "Beating COVID-19 with public health measures" by welcoming the Assembly's attention to the COVID-19 pandemic from the perspective of effective and sustainable management. It emphasises the relevance of the European Social Charter and the importance of promoting co-operation and guaranteeing the right to the protection of health.

MONITORING

Digital Health

EDPS/EDPB on combating child sexual abuse online

On 29 July, the EU data protection regulators issued a Joint Opinion on the Commission's Proposal to combat child sexual abuse online. The Proposal aims to impose obligations related to detecting, reporting, removing and blocking known and new online child sexual abuse material (CSAM), as well as the solicitation of children, on providers of hosting services, interpersonal communication services, software application stores, internet access services and other relevant services. The authorities believe that the Proposal, in its current form, may present more risks to individuals, and, by extension, to society at large, than to the criminals pursued for CSAM. The lack of detail, clarity and precision of the conditions for issuing a detection order for CSAM and child solicitation does not ensure that only a targeted approach to CSAM detection will effectively take place. There is a risk that the Proposal could become the basis for a generalised and indiscriminate scanning of content of all types of electronic communications. Further information: [press release](#), [opinion](#).

Digital identity and data sovereignty

In July, the European Economic and Social Committee (EESC) adopted an [opinion](#) on the Digital identity, data sovereignty and the path towards a just digital transition for citizens living in the information society ([TEN/773](#)). The Committee requests that all sectors using personal data and biodata to be regulated in a clear manner and in full compliance with fundamental human rights, and calls for the GDPR to be updated accordingly. The EESC believes that digital identity, digital means of payment and incorporation into virtual and augmented reality platforms should remain tools that only complement the physical existence that we knew before the adoption of these technologies and should not abusively replace other existential patterns. The EESC calls for clear anti-discrimination provisions in all future legislative proposals on digital identity and is against the introduction of a system that keeps close tabs on European citizens, tracks them and/or monitors their activities and behaviour. On AI, the Committee requests the development of common ethical rules that ensure free access to the source codes of algorithms. The Committee considers that informed consent on data use must be implemented for both personal and non-personal data.

MONITORING

Ukraine

Ukraine's health system prepares for a challenging winter ahead

At the six-month mark of the war in Ukraine, the country's badly affected but still resilient health system is [taking stock](#) of lessons learned in providing life-saving care with the support of WHO and partners as it prepares for a challenging winter ahead. Dr Jarno Habicht stated that "WHO is stepping up its efforts with the Ministry of Health to ensure that the health workforce is prepared with the necessary skills to respond to mounting needs as winter approaches".

EU4Health association agreement with Ukraine

The European Commission [signed](#) an agreement associating Ukraine with the EU4Health programme. This agreement will open access for Ukraine to EU funding in the area of health. It will enable the Ukrainian health system to respond to immediate needs and contribute to long-term recovery. The agreement will be retroactive to 1 January 2022, allowing Ukraine to participate in the calls launched from September 2022.

New EU medevac hub in Poland

The EU has opened a new hub for medical evacuations of Ukrainian patients near the Polish city of Rzeszów. Its nearby airport manages two medevac flights a week, financially supported by Norway. The hub is financed by the EU Civil Protection Mechanism and provides 24/7 nursing and medical care including screening, vaccination and mental health support services before patients are transferred to hospitals outside of Poland at which treatment is continued.

100,000 doses of the Janssen vaccine delivered to Ukraine

A total of 100,000 doses of the Janssen COVID-19 vaccine were [delivered](#) to Ukraine under the COVAX initiative and distributed to 22 regions in the country by the Ministry of Health.

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