



## Dear colleagues

This edition follows our fruitful Executive Committee, General Assembly, Board and Policy Sessions that took place in Prague from 27–29 October. Thank you to everyone who participated, and we sincerely thank the Czech Chamber for hosting us so warmly and generously.

Among the outcomes of our General Assembly was the adoption of updated statutes, providing our association with a sound legal basis for the years to come. We were also humbled to be joined by Iryna Mazur online in Kiev who updated us on the immensely challenging situation for health professionals in Ukraine. Our policy discussions focused on the European Health Data Space, revision of the general pharmaceutical legislation and climate. The outcomes will be published through dedicated press releases in the coming days and weeks and provide a foundation for our continued advocacy at European level.

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

**Dr Christiaan Keijzer**  
CPME President



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## Finances

### Draft accounts 2022

- ▶ The EC took note of the actual accounts which are following expected expenditure.

The most noticeable deviation is the cost for consultancy which results from lawyers' fees for the statute revision exceeding expectations.

### Draft budget 2023

- ▶ With a view to the draft budget 2023, the EC discussed the deficit.

MPH reported on the expected indexation on salaries and rent, while the endpoint was raised in accordance with the General Assembly's decision in March. It was confirmed that the economic context can be considered exceptional, and the reserves are robust enough to absorb the forecast deficit. However, the EC agreed that no option to cut costs should be left unconsidered. It was proposed to also consider the broader context of inflation across Europe. The EC agreed to present the draft budget to the membership for decision and report on the discussion.

### Automatic indexation

- ▶ The EC decided to ask the membership on the automatic indexation of the budget.

As discussed in the General Assembly in March, it is proposed to apply indexation in line with the official Belgian estimates as of 2024.

## Internal Affairs

### Meeting dates 2024

- ▶ The EC agreed to propose the dates of 22-23 March and 14-16 November 2024 to the membership.

The French Medical Council indicated a potential conflict on the November date, this is to be reviewed.

### Chair of WG on Healthy Living

- ▶ The EC was informed that Dr Patrick O’Sullivan will step down from his position as a chair of the working group after the meeting in Prague on 28 October.

The EC agreed to look for a successor from the members of the WG.

### Proposal to explore Memorandum of Understanding or strategic partnership from Healthcare Without Harm

- ▶ The EC agreed to explore the proposals for a Memorandum of Understanding or strategic partnership with Health Care Without Harm (HCWH).

The Secretariat will report to the EC with a concrete proposal, including a report on the funding of HCWH.

## EXECUTIVE COMMITTEE MEETING – 27 OCTOBER 2022

## Magazine editorial

- ▶ The EC agreed that Dr Ole Johan Bakke will be author of the editorial of the next magazine.

The editorial will have a focus on Climate and Health, including reference to our climate policy and the Lancet Countdown EU brief.

## Procedure for nomination of WG chairs/rapporteurs

- ▶ The EC agreed that nominations of rapporteurs and WG chairs should be captured in a simple template submitted by the corresponding national medical association (NMA).

This would clarify the origin of nominations to positions in CPME and also responsibilities upon the nominating NMA e.g. in relation to covering rapporteurs' or WG chairs' travel expenses for CPME general assemblies.

## Topics for Member's Conference 2023

- ▶ The EC agreed that the topic should be on the implementation of electronic health records solutions (EHR) to explore what it means in daily practice in connection with the European Health Data Space.

The EC agreed that concrete experiences should be presented.

## Status of nominations of experts to the IMMUNION network

- ▶ The Secretariat clarified that there was a proposal for a declaration of interest in line with EMA requirements however the European Commission was requested to decide who is responsible for verifying the accuracy of declarations made.

The prospective experts shall be informed following a meeting in November 2022.

## Policies

### Lancet Countdown on Health and Climate Change

- ▶ The EC took a note that the Lancet Countdown [Policy Brief for Europe 2022](#) was published on 27 October at an online event launch.

The policy brief will be shared among the CPME members but more importantly the EU policymakers. This year's policy brief focuses on sustainable food and diets, ambient air pollution, and the greening of the healthcare sector.

### Joint statement on General Pharmaceutical Legislation revision

- ▶ The EC decided to send this item for decision to the Board.

The EC was briefed that the drafting process which was a cooperative effort with other health stakeholders to comment on the upcoming revision of the legislation.

### Medical Devices Regulation

- ▶ The EC decided to draft a letter to the European Commission and approve it by written procedure.

The results of the internal survey for CPME members indicated a future problem with access to medical devices due to the lack of capacities on the side of notified bodies.

### AMEE survey on CPD

- ▶ The EC decided not to support the request for dissemination for an AMEE survey on CPD.

## EXECUTIVE COMMITTEE MEETING – 27 OCTOBER 2022

## AI liability directive

- ▶ The EC took note of the new Directive proposal and requested monitoring on the definition of 'users'. The WG Digital Health will analyse further the proposal and recommend next steps.

## Revision of the Product Liability Directive

- ▶ The EC took note of the new Directive proposal and suggested that the WG Digital Health would analyse further the proposal and recommend next steps.

## e-Evidence Regulation

- ▶ The EC took note of the state of play of the Regulation and of the next lobby actions of the informal coalition led by EDRI.

The EC agreed that the draft joint letter should be circulated by email to be approved by written procedure.

## Arrest of TMA President Prof. Dr. Şebnem Korur Fincancı

- ▶ The EC adopted a statement condemning the arrest of the President of the Turkish Medical Association.

Prof. Korur Fincancı was arrested following an interview which included a discussion on the use of chemical weapons. The CPME statement will be disseminated to members and all relevant contacts at EU level.

# Outcomes of CPME GA, Board and Policy Sessions, 28-29 October 2022, Prague

## Revised Statutes and Rules of Procedure

The General Assembly approved the revised Statutes and Rules of Procedure. The main change concerns the simplification of CPME's structure in which the current Board is dissolved, and its competences are integrated into those of the General Assembly. The current Executive Committee becomes a Board of Directors. There is also a simplification of the membership categories to two: full members and associate members. The latter will include both National Medical Associations including current observers and organisations with association status. The role of the Secretary General has also been elaborated. Furthermore, there are now provisions for digital meetings. The Statutes will enter into force following validation by a Belgian notary.

## Policy discussions

The policy outcomes of the meetings were:

- A Position on European Health Data Space was discussed and adopted
- A Position on the revision of the EU general pharmaceutical legislation was discussed and adopted
- It was decided to sign a Joint Statement on the Revision of the Pharmaceutical Legislation
- A Policy on Climate Change and Health was adopted with the agreement that a summary would be developed based on the main points of the policy.
- Delegates supported the proposed scope of a new CPME policy on antimicrobial resistance.

## Dates for next General Assemblies

24-25 March 2023, Dubrovnik, Croatia

10-11 November 2023, Estonia

22-23 March 2024, Location TBC

Date TBC 2024, Netherlands



## **European Doctors condemn the arrest of Şebnem Korur Fincancı and call for her immediate release**

CPME [condemns](#) the detention and judicial harassment of Şebnem Korur Fincancı, the President of the Turkish Medical Association, and joins the World Medical Association in calling for her immediate release.

The arrest follows a media interview calling for an investigation of the possible use of chemical weapons in Kurdish regions. We support the call for independent investigation into the reported use of such weapons and, as in previous cases, we appeal to the Turkish authorities to respect their obligations under international law.

We ask you to please take action to raise awareness among your national governments and especially the ministry of health regarding the detention of Turkish Medical Association President Prof. Dr Şebnem Korur Fincancı. We invite you to use the [CPME statement](#) calling for her immediate in your communication.

## **Lancet Countdown policy brief 2022**

On 27 October, the annual [Lancet Countdown policy brief](#) on health and climate change was published and launched by CPME, the Lancet Countdown and the Association of Schools of Public Health in the European Region (ASPHER). This year's brief focuses on data and policy recommendations in three key areas: sustainable food and diets, ambient air pollution, and greening of the healthcare sector.

## CPME signs joint letter to EMA calling for clinical trials transparency

CPME has joined a group of 10 health organisations [concerned](#) about a worrying approach of the European Medicines Agency regarding clinical trials transparency.

Earlier this year, EMA released a consultation guidance document on how to approach the protection of personal data and commercially confidential information in clinical trials documents submitted to the Clinical Trials Information System (CTIS). The draft version of this guidance document offers a possibility of deferring publication of underlying clinical trial protocols for up to 5 years after trial end.

If approved by EMA, this would mean that protocols of Phase II and Phase III\* of clinical trials of medicines will not be available to medical researchers, systematic reviewers and public health bodies for 5 years after a trial is concluded. Protocols contain information on trial design, including measures taken to minimise bias, statistical methods, and dosage regimes. This information is essential for the medical community to be able to interpret trial outcomes.

CTIS serves to implement EU pharmaceutical law in the Clinical Trials Regulation, which requires pharmaceutical companies to include detailed information in protocols. Crucially, the Regulation contains no provision which could be used as basis for delaying the publication of protocols. To the contrary, it clearly states that the “information in the EU database should be public, unless specific reasons require that a piece of information should not be published.” According to EMA, a functionality allowing for deferral has been introduced to reduce the burden of redaction of commercially confidential information.

Patient and public interest cannot be overridden by a claimed administrative burden of medicine developers. As sponsors and investigators do not routinely make protocols public on a voluntary basis, regulatory intervention is the only means by which consistent and timely protocol disclosure can be assured.

## European healthcare professionals underline the importance of routine vaccination

The Coalition for Vaccination, co-chaired by CPME, published a [statement](#) underlining the importance of routine vaccination.

In July, WHO and UNICEF warned that the global vaccination coverage continued to decline in 2021, with 25 million children missing out on lifesaving vaccines. Inadequate coverage levels have already resulted in avoidable outbreaks of measles and polio, also in Europe. For example, in August, there were signs of the polio virus spreading in London. Moreover, the war in Ukraine has led to millions of refugee children who must be protected and whose vaccination schedule should be updated.

Healthcare professionals should ensure that children are up-to-date on their routine and COVID-19 vaccines particularly now when the schools have started again. This is crucial to be protected against serious, sometimes deadly diseases, despite the challenges and disruptions caused by the COVID-19 pandemic.

It is important that healthcare professionals engage in continuous professional education and are updated with the latest scientific evidence, in order to recommend vaccinations and strengthen the positive influence of healthcare providers on vaccine confidence.

The Coalition for Vaccination reaffirms that vaccination is a safe and efficient way of protecting individuals and populations from vaccine-preventable communicable diseases. Healthcare professionals are trusted sources of information for parents, and they can help families make informed decisions that contribute to public health.

## CPME NEWS

## Call for Chair of CPME working group on healthy living

CPME is currently looking for a chair for the working group on healthy living which works on policy areas on alcohol, tobacco, nutrition, and physical activity. Current activities include for example legislative dossiers on alcohol and nutrition labelling as well as on tobacco taxation. Please contact the secretariat in case you are interested in this interesting position: [markus.kujawa@cpme.eu](mailto:markus.kujawa@cpme.eu)

## Proposal for the revision of the EU air quality directives

On 26 October, the European Commission published their proposal for the new EU air quality directives. The [proposed revision](#) will set interim 2030 air quality standards, aligned more closely with WHO guidelines, while putting the EU on a trajectory to achieve zero pollution for air at the latest by 2050, in synergy with climate-neutrality efforts. Together with a number of health and environmental organisations CPME has been calling on the EU to align the directives with the latest WHO guidelines by 2030 at the latest. The Commission proposal fails to address the urgency to act as it will take effect progressively, with different targets for 2030, 2040, and 2050 – giving industry and authorities time to adapt and invest where necessary. Our reaction was [quoted](#) in the Guardian.

Next, the proposal will be considered by the European Parliament and the Council in the ordinary legislative procedure.

## European Antibiotic Awareness Day (EAAD) 2022

CPME is once again collaborating with ECDC for the 15th European Antibiotic Awareness Day, which takes place on 18 November with the theme “preventing antimicrobial resistance together”. EAAD is organised in partnership with the World Antimicrobial Awareness Week, organised annually by the World Health Organization from 18 to 24 November.

All the latest information on the campaign is available [here](#).

## Coalition for Vaccination conference

On 17 January, CPME and the other Coalition for Vaccination co-chairs will organise a conference in Brussels to present the results of the EU co-funded IMMUNION project which is coming to an end in March 2023. The event also aims to discuss the future of the Coalition with the European institutions.

Registration is available [here](#).

## Reports

During September and October, our EU Policy Intern, Silvia Gonzalez Vidal, attended the following external events, meetings and webinars regarding the different policy areas. A report on each is available on the website.

[Report on eCAN Joint Action Kick-off event](#)

[Report on SFP Online Coalition Meeting](#)

[Report on the Webinar of the EP Interest Group on Innovation in Health and Social Care: "Strengthening the resilience and skills of the future health workforce in Europe"](#)

[Report on the Webinar "COVID-19 and mental health: taking forward the lessons learned"](#)

[Report on DG SANTE Meeting on new legislation on SoHO](#)

[Report on "World Mental Health Day: Migrants, Refugees and Mental Health" EP event](#)

[Report on 2022 Thematic Networks: Pitch webinar](#)

[Report on BeWell Strategy-building Workshop](#)

## World Medical Association General Assembly

From 5 to 8 October, delegates from 57 national medical associations around the world attended the [annual General Assembly](#) of the WMA. On this occasion, the delegates discussed the situation in Ukraine and Iran, the ethical use of social media, and the use of telehealth. An [updated](#) version of the International Code of Medical Ethics was agreed and published.

- Dr. Osahon Enabulele, former President of the Nigerian Medical Association, was installed as the 73rd President of the WMA for 2022–23.
- Dr. Lujain Alqodmani, a leading public health doctor from Kuwait, was elected unopposed as President elect of the WMA. She is the first Arab to be elected President and will take up her post at the WMA's General Assembly in Kigali, Rwanda in October 2023.
- Dr. Tohru Kakuta (Japan) was elected unopposed as Vice-Chair of Council.
- Dr. Jacques de Haller, President of the Swiss Association of General Practitioners and a former CPME President, was elected Chair of the Associate Members.

## Protecting Health Care From Violence - A Global Dialogue For Peer Exchange Of Good Practice

On 1 December, the WMA, together with the International Council of Nurses, the International Committee of the Red Cross and the International Hospital Federation, will join a conversation with the international health care workforce. The collaboration aims to raise awareness of the global trend of violent incidents against health care settings and personnel and identify strategies and actions to address and mitigate violence. Participants can submit questions before the session and join a direct conversation with the panelists. Registration is available [here](#).

## EU Political Outlook

### Commission work programme 2023

On 18 October, the European Commission [adopted](#) its 2023 Commission work programme setting out the next steps in its bold and transformative agenda in the face of Russia's aggression against Ukraine, rising energy prices and the knock-on effects on the economy, while defending Europe's democratic values and pursuing our long-term goals and interests. Following this work programme, in the field of health the Commission will:

- Continue with the implementation of the Beating Cancer Plan by putting forward a Recommendation on vaccine-preventable cancers and an update of the smoke-free environments Recommendation.
- Move forward on the implementation of the European Health Data Space.
- Adopt a comprehensive approach to mental health.
- Keep on building on the HealthyLifestyle4All initiative and its Youth Ideas Labs.

### Council adopts law on the emergency framework regarding medical countermeasures

EU ministers adopted a [new EU law](#) which facilitates the timely purchase of and access to medicines, vaccines and raw materials, activates emergency funding and enables the monitoring of production facilities when another health crisis hits.

## MONITORING

## Council adds new building blocks to European Health Union

New regulations have been [adopted](#) by the Council to improve the EU's capacities to respond to future pandemics and other cross-border health crisis:

- Measures to better anticipate and respond to serious cross-border health threats. The new rules include improved prevention, preparedness and response planning at EU and national levels. The Commission will be able to formally recognise a public health emergency at EU level, which would trigger stronger intra-EU cooperation and allow for the timely development and stockpiling of medical countermeasures. The legislation also clarifies the procedures for jointly procuring medicines and medical devices.
- Extended mandate of the European Centre for Disease Prevention and Control (ECDC): The ECDC has also been strengthened in the areas of surveillance, early warning, preparedness and response. The ECDC will cooperate with the EU institutions and national authorities to coordinate data collection and monitor the capacity of national health systems.
- Emergency Framework Regulation. The Emergency Framework Regulation will provide extra powers to the European Health Emergency Preparedness and Response Authority (HERA) and allow the establishment within HERA of a Health Crisis Board. The Regulation also enables the activation of the EU fab facilities, emergency research and innovation plans and access to emergency funding.

In light of this, DG SANTE in collaboration with the Ministry of Health of Luxembourg is organising a hybrid high-level Conference on COVID-19 lessons learned and looking ahead to ensure a stronger EU Health Security Framework on 22 -23 November 2022, European Convention Centre Luxembourg. Registration is available [here](#).



## MONITORING

## EU-US: strengthened cooperation in health

Commissioner for Health and Food Safety, Stella Kyriakides, and Secretary of the Department of Health and Human Services, Xavier Becerra met in Washington DC to [reaffirm](#) their shared commitment for the EU and the US to work closely in the area of health and strengthen cooperation. The discussions during the meeting focused on health preparedness and response, cancer, and global cooperation.

## European Commission selects the 2022 Thematic Networks

The European Commission has [designated](#) the following four proposals for the 2022 Thematic Networks:

- “DisQo anti-discrimination & health equity” led by the European Public Health Alliance
- “HIV, Tuberculosis, viral hepatitis and sexually transmitted infections” led by EU Civil Society Forum
- “Managing Health Inequalities in the EU through Artificial Intelligence” led by Brunel Centre for Artificial Intelligence: Social & Digital Innovations and Health Action International
- “Mental health in all policies” led by Mental Health Europe.

## Address by President Charles Michel at the World Health Summit

On the occasion of the World Health Summit, [President](#) of the European Council, Charles Michel paid tribute to all Ukrainian health professionals for their brave work and stated European Union is determined to play a prominent role in an inclusive process to strengthen the WHO and committed to health matters across the globe, currently updating EU's Global Health Strategy.

## MONITORING

## Tracking the EU Commissioners' commitments: Stella Kyriakides, Commissioner for Health and Food Safety

The European Commission presented a [briefing](#) that tracks the EU Commissioners' commitments and provides an overview of the state of play. Without assessing the impact or added value of the initiatives launched, please see below an overview of actions launched by Stella Kyriakides, Commissioner for Health and Food Safety, in relation to her mandate:

On supply of affordable medicines: Kyriakides remarked the legal obligation on the pharmaceutical industry to ensure that patients have access to and supply of medicines, as well as the need to develop a holistic pharmaceutical strategy. The Commission published its "Pharmaceutical Strategy for Europe" in 2020. Then, in 2021, the Commission presented its Roadmap on the revision of the general pharmaceutical legislation and a proposal for revision of pharmaceutical legislation was announced for end 2022.

On medical devices: The Commissioner committed to implementing a modernised and more robust legislative framework for medical devices. The new Medical Devices Regulation was adopted in 2022 and the In-Vitro Medical Devices Regulation entered into force in 2022.

On Health Data Space and e-health: Kyriakides declared her will to maximise the potential of digital technologies and AI by creating a European Health Data Space. The Commission published A European strategy for data in 2020, which proposes the creation of this common European Health data space.

On Anti-microbial resistance (AMR): Commissioner advocated for an international agreement on the use and access to anti-microbials and for a European one-health action plan against AMR. The Commission's Pharmaceutical Strategy for Europe of 2020 includes as a main objective addressing unmet medical needs in the area of AMR.

On HTA: The Commissioner expressed that she would try to build a consensus in order to get the Commission's proposal approved. The new Regulation on HTA of 2021 will apply from 12.01.2025.

## MONITORING

On vaccination: Kyriakides's original commitment was meant to address vaccine hesitancy related to long-known diseases. However, due to the pandemic, most of the actions in the field of vaccines have focused on Covid. That is the case of the European strategy for COVID-19 vaccines presented by the Commission in 2020 to accelerate the development, manufacturing and deployment of vaccines.

On Beating Cancer Plan: Making a difference in the life of cancer patients was stated as a guiding principle for the Commissioner. The Commission delivered the Europe's Beating Cancer Plan in 2021 and the fight against cancer is also addressed in the Commission's 2020 Farm to Fork Strategy and Pharmaceutical Strategy.

On organ donation: Kyriakides was expecting the evaluation on a strategy for Europe on organ donation at the end of 2019 to define the future roadmap. On July 2020, the Commission published a "Statement on Organ Donation and Transplantation and the COVID-19 pandemic". On July 2022, the Commission also proposed a revision of the Blood Directive 2002/98/EC and the Tissues and Cells Directive 2022/98/EC.

On mental health: Kyriakides stated that mental health usually does not receive the attention that it deserves, and she would work to reverse that trend. On this topic, the Working Group on Health of the Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases (SGPP) continued its work on mental health. But also in the current context post-pandemic, particular attention is given to the mental health aspects of the COVID-19 crisis and the war in Ukraine

On research and innovation, Commissioner was committed to investing in research for European health. Since then, health research has been supported by the EU4Health programme, adopted in 2020 to tackle cross-border health threats and create resilient European health system with a budget of EUR 5.1 billion, and also by the Horizon Europe Programme with its Health Cluster.

## MONITORING

## Council adopts EU law on adequate minimum wages

The Council of the EU finally adopted a [directive](#) which establishes procedures for the adequacy of statutory minimum wages, promotes collective bargaining on wage setting and enhances the effective access to minimum wage protection for those workers who are entitled to a minimum wage under national law.

## Council and EP agree on adapting EU standardisation rules

The Council and the European Parliament have [reached](#) a provisional political agreement on the proposal to amend the European Standardisation Regulation proposed by [the Commission](#). The proposed amendment introduces new requirements for European standardisation organisations to ensure the involvement of national standardisation bodies and the promotion of European values.

## MONITORING

## Pharmaceuticals & Healthcare

### EPP and Renew MEPs write to the European Commission to defend industry's interest

32 MEPs and 3 MPs wrote a [letter](#) to the European Commissioners responsible for health, R&D and industry arguing for more flexibility from the regulators to create a "highly competitive" pharmaceutical research environment, as well as for more access to health data for the private companies. The letter argues in favor of further strengthening incentives for the development of new medicines. The signatories ask the European Commission not to link incentives with an obligation to launch medicines in all EU Member States, as this option appeared to be considered by the Commission for the upcoming revision of the EU general pharmaceutical legislation.

### The burden of AMR in the WHO European region

A [study](#) published in Lancet Public Health provides a comprehensive set of regional and country-level estimates of the European AMR burden. The authors estimate that 541,000 deaths were associated with bacterial AMR and 133,000 deaths were attributable to AMR in the whole WHO European region in 2019.

### Chair of the European Network of Pediatric Research at EMA (Enpr-EMA) re-elected

Pirkko Lepola of the Finnish Investigators Network for Pediatric Medicines (FinPedMed) has [been re-elected](#) as Chair of Enpr-EMA's coordinating group for the next three years..

## MONITORING

## New vaccine to protect people in the EU and worldwide against dengue

EMA's human medicines committee (CHMP) has [adopted](#) a positive opinion for Dengue Tetravalent Vaccine Takeda. This is the first time the CHMP simultaneously reviews a medicinal product meant for the EU market, under the centralised procedure, and non-EU countries, under the 'EU-Medicines for all' programme – or EU-M4all. The aim of this EMA's initiative is to make innovative or generic medicines and vaccines that address unmet medical needs or are of major public health interest available in Europe and globally faster, while avoiding duplication of efforts from regulators.

## Monkeypox: Commission purchases treatment courses to meet immediate needs

The Commission has [purchased](#) over 10,000 treatment courses of tecovirimat to combat Monkeypox. This treatment is produced by the pharmaceutical company Meridian/SIGA and its acquisition has been funded by the Health Emergency Response and Preparedness Authority (HERA) and channelled through rescEU to treat patients in Member States with immediate needs.

## HERA and CEPI agree on stronger cooperation in the development of medical countermeasures

The Commission's Health Emergency and Preparedness Response Authority (HERA) and the Coalition for Epidemic Preparedness Innovations (CEPI) reached an [agree](#) to strengthen cooperation and information exchange on end-to-end vaccine research and development, manufacturing capacity and capacity building both within the EU and globally. This collaboration under the HERA Horizon 2020 will help ensuring that there are no unnecessary overlaps and that resources are used more efficiently. Both sides will exchange information on research, development, manufacturing, and other priorities relevant for medical countermeasures.

## MONITORING

## Public Health and Disease Prevention

### Commission acts to better protect people from asbestos and ensure an asbestos-free future

The Commission has [presented](#) a new approach to better protect people and the environment from asbestos and ensure an asbestos-free future. This comprehensive approach includes a proposal to amend the Asbestos at Work Directive to improve workers' protection and a communication on working towards an asbestos-free future, from improving diagnoses and treatment of diseases caused by asbestos, to identification and safe removal and waste treatment of asbestos.

### WHO releases a public health taxonomy for social listening on monkeypox conversations

The World Health Organization (WHO) has [developed](#) a public health taxonomy to support infodemic monitoring and knowledge generation from monkeypox conversations. The technical paper presents an overview of how social listening can be applied to monkeypox conversations, which can be used to generate infodemic knowledge for public health response. This approach was first used during COVID-19 and now taxonomies are employed to better organise and frame analytics, especially when integrating data sources of varying types and quality.

### Avian influenza: unprecedented number of summer cases in Europe

The European Food Safety Authority (EFSA), together with the European Centre for Disease Prevention and Control (ECDC), has [reported](#) an unprecedented number of highly pathogenic avian influenza (HPAI) virus detections in wild and domestic birds from June to September in Europe, despite no cases or only a few cases were detected during the summer period in previous years.

## MONITORING

## European Green Deal: Commission proposes rules for cleaner air and water

The Commission [has proposed](#) stronger rules on ambient air, surface and groundwater pollutants, and treatment of urban wastewater as clean air and water are essential for the health of people and ecosystems. The proposed new rules will reduce deaths resulting from levels of the main pollutant PM2.5 above World Health Organization guidelines by more than 75% in ten years. The Commission's proposal provides a clear return on investment thanks to benefits in health, energy savings, food production, industry, and biodiversity and aims to both tighten allowed levels of pollutants and to improve implementation to ensure pollution reduction goals are more often reached in practice. Our reaction was [quoted](#) in the Guardian.

## WHO and WMO launch a new knowledge platform for climate and health

The Joint Office of the World Health Organization (WHO) and World Meteorological Organization (WMO), with support from the Wellcome Trust, [launched](#) the first global knowledge platform dedicated to climate and health – [climahealth.info](https://climahealth.info) –. This new knowledge platform has been developed in response to growing calls for actionable information to protect people from the health risks of climate change and other environmental hazards, since more people than ever before are exposed to increased climate-related health risks, from poor water and air quality to infectious diseases and heat stress.

## ECDC warns of hepatitis A outbreak

The ECDC has [warned](#) that over 300 cases of hepatitis A have been found in a recent outbreak in Europe. As of 29 September 2022, 303 cases with identical or closely related strains have been identified in Austria (7), Germany (8), Hungary (161), the Netherlands (8), Slovenia (35), Sweden (8), and the UK (76). Currently available epidemiological and microbiological data suggest that human-to-human transmission has occurred, and possibly also transmission through contaminated food.



## MONITORING

## European Region-wide case studies on communicating risks and engaging communities in health emergencies

A [compendium](#) of 18 case studies looking at how risk communication and community engagement (RCCE) has been used in the WHO European Region during the COVID-19 pandemic has been published. Based on interviews with nearly 80 frontline practitioners, it provides a wealth of insights and practical experience on 4 core capacities for effective RCCE:

- Transparency and early announcement
- Coordinating public communication
- Listening through 2-way communication
- Selecting effective channels and trusted key influencers.

## Ukraine

### WHO trains health workers to provide quality care for gender-based violence survivors in Ukraine

WHO in Ukraine [trained](#) more than 60 doctors, nurses and health facility managers to provide survivor-centred care in terms of sexual and gender-based violence (GBV). With funding from the Government of Canada and support from the Ministry of Health and civil society organizations, WHO is building the capacity of Ukrainian health care workers and strengthening their response to GBV.

## MONITORING

## COVID-19

### EP debate with the pharmaceutical industry

The European Parliament's special committee on COVID-19 (COVI) [held](#) a second debate with five pharmaceutical industry representatives (Pfizer, CureVac, Novavax, Glaxo Smith Kline, and HIPRA). The debate focused on the work to develop vaccines for new variants, the authorisation process, transparency of contracts, as well as measures to ensure access to COVID-19 vaccines and treatments for low- and middle-income countries.

### Joint Statement on COVID-19 and seasonal influenza vaccinations

A potential co-circulation of COVID-19 and seasonal influenza can be expected during winter, warns a [joint statement](#) by the European Commissioner Stella Kyriakides, WHO Regional Director for Europe Dr Hans Henri P. Kluge and Director of the ECDC Dr Andrea Ammon. They reconfirmed the need to protect people's health, using all the available tools, including preparedness and public health measures in order to avoid the burden of this co-circulation on European healthcare systems. They also urged countries in the European region to prioritise protecting the most vulnerable groups by co-administering influenza and COVID-19 vaccines whenever feasible.

### EMA recommends approval of adapted Spikevax COVID 19 vaccine, as well as of Comirnaty and Spikevax vaccines for children from 6 months of age

EMA's human medicines committee (CHMP) has [recommended](#) authorising an adapted Spikevax COVID-19 vaccine targeting the Omicron subvariants BA.4 and BA.5 in addition to the original strain of SARS-CoV-2. Also, EMA's CHMP has [recommended](#) extending the use of Comirnaty and Spikevax targeting the original strain of SARS-CoV-2 to children aged 6 months to 4 years for Comirnaty and to children aged 6 months to 5 years for Spikevax.

## MONITORING

## Digital Health

### New AI Liability Package

On 28 September, the European Commission presented two legislative proposals on AI which complements the [AI Act](#):

- a directive on adapting non contractual civil liability rules to artificial intelligence ([AI liability Directive](#))
- a revision to the Product Liability Directive ([PLD](#)).

The AI Liability Directive seeks to facilitate access to information (evidence) and alleviate the burden of proof in compensation claims pursued under national fault-based liability regimes in cases where certain AI systems are involved in causing damage. The PLD concerns extra-contractual liability of producers for injuries/damage caused by lack of safety. The proposal provides compensation for material losses resulting in death, personal injury, damage to property and loss or corruption of data, caused by a defective product. In relation to AI, when AI systems are defective and cause physical harm, property damage or data loss, it will be possible for the victim to seek compensation from the AI system provider or from any manufacturer that integrates an AI system into another product. The revised PLD confirms that AI systems and AI-enabled goods are “products” and therefore fall within its scope. Compensation is then available when defective-AI causes damage without the injured person having to prove the manufacturer’s fault.

The [feedback](#) period for the AI Liability Directive is open until 28 November, and the [feedback](#) period for the revised PLD is open until 30 November (extending everyday until the later proposal is available in all EU languages). CPME Secretariat is analysing the legislation and will be discussing with the CPME rapporteur on AI and the WG Digital Health on whether to prepare a response to the feedback period mechanism.

## MONITORING

## Cyber Resilience Act

On 15 September, the Commission published a proposal for a [new Cyber Resilience Act](#) to protect consumers and businesses from products with inadequate security features. It introduces mandatory cybersecurity requirements for products with digital elements, throughout their whole lifecycle, such as wireless and wired products and software. It increases the responsibility of manufacturers by obliging them to provide security support and software updates to address identified vulnerabilities and it enables consumers to have sufficient information about the cybersecurity of the products they buy and use. Further information: fact sheet, [proposal](#) and [annexes](#). CPME Secretariat consulted with the CPME Rapporteur on interoperability who noted that the proposal will affect software in healthcare as well as medical devices. It had a technical focus, not specific to healthcare, and went in the right direction. The rapporteur further noted that it did not find anything critical, and that in his opinion it is not necessary for CPME to comment. CPME does not plan to comment on the proposal.

## Use of artificial intelligence on the rise, but its impact on health still limited, new study finds

A [new study](#) by WHO and the Universitat Politècnica de València in the International Journal of Medical Informatics found out that artificial intelligence (AI) is fuelling a new revolution in medicine and in the health care sector, primarily for image analysis and disease modelling, but its impact on people's health is still limited. The review concludes that AI application most often remains limited to laboratories and testing and that its use is still scarce in clinical practice..

## MONITORING

## Interplay between data protection and competition authorities – opinion of Advocate General

The German Federal Competition Authority prohibited Meta Platforms (owner of Facebook) from processing data in accordance with Facebook's terms of service and from implementing those terms. The authority found that the data processing in question did not comply with the General Data Protection Regulation (GDPR) – cookies usage and advertising purposes – constituted an abuse of Meta Platforms' dominant position on the social network market for private users in Germany. The Court of Justice was asked whether national competition authorities were entitled to assess the compliance of data processing with the GDPR.

The [Opinion](#) delivered by Advocate General Athanasios Rantos on 20 September 2022 (Case C-252/21), takes the view that, while a competition authority does not have jurisdiction to rule on an infringement of the GDPR, it may take account of the compatibility of a commercial practice with the GDPR. A competition authority may also assess compliance with the GDPR as an incidental question, without prejudice to the powers of the competent supervisory authority under the GDPR. The AG notes that the conduct of visiting websites and apps, entering data into those websites and apps and clicking on buttons integrated into them, it is not a conduct that “manifestly makes public” sensitive personal data by the user. The user must be fully aware that, by an explicit act, he is making personal data public. Further information: [Press release](#).

## Telemedicine has clear benefits for patients in European countries, new study shows

A [new study](#) by WHO/Europe and the Faculty of Health Sciences at the Universitat Oberta de Catalunya shows that telemedicine technologies have been beneficial in the screening, diagnosis, management, treatment and long-term follow-up of a series of chronic diseases in the WHO European Region. During the COVID-19 pandemic, telemedicine use was already seen as an accessible and cost-effective approach to delivering high-quality care and reducing overall morbidity and mortality.

## MONITORING

## High-quality data to empower data-driven medicines regulation in the European Union

The joint Big Data Steering Group [set up](#) by EMA and the Heads of Medicines Agencies in the EU Member States has endorsed two documents for public consultation, one addressing the quality of all data types used in regulatory decision-making, the other one focusing on the discoverability of real-world data.

## CJEU on confidentiality of communications – general and indiscriminate retention of traffic and location data

On 20 September, the CJEU ruled another [judgment](#) on the general and indiscriminate retention of traffic and location of electronic telecommunications data, including IP addresses, under the e-Privacy Directive, in relation to the German legal framework. It considered that the German system is not compatible with the e-Privacy Directive. The Court established that the German regime did not ensure targeted data retention. It further established that the data is liable to allow “precise conclusions” concerning the private life of the person concerned.

The Court noted that the rules on access to the data cannot be a safeguard for the indiscriminate retention of the data – it added that if the retention is illegal, then access to the retained data also cannot be considered legitimate. Fourth, the Court repeated that serious crime may not be treated in the same way as national security, i.e. the margin of appreciation of the Member States is smaller. Finally, as concerns ‘targeted retention, expedited retention or retention of IP addresses’, the Court noted that, for the purposes of fighting serious crime and terrorism, Member States may exceptionally provide for more general and indiscriminate data retention, provided that adequate safeguards exist.



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