



Dear colleagues

We are pleased to share with you the May edition of the CPME Monthly Bulletin with the outcomes of the Executive Committee the meeting on 27 May 2022. This month's meeting was particularly special as we were delighted to appoint Sarada Das as Secretary General. The Executive Committee felt she was the clear and outstanding choice to take over the role given her wealth of knowledge and experience representing the medical profession at European level. We look forward to working together with Sarada to continue developing CPME as a strong and independent voice of the medical profession in the EU.

Last month, our association organised a panel at the prestigious Computers, Privacy and Data Protection conference on 25 May and with 18 other health and animal welfare organisations called on the European Commission to step up the fight against antimicrobial resistance.

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

Dr Christiaan Keijzer

CPME President

CPME.EU

1



TABLE OF CONTENTS

Executive Committee meeting – 27 May 2022

•	Finances	4	
•	Internal Affairs	4	
•	Policies	5	
CPME News			
•	Sarada Das appointed Secretary General	7	
•	Annabel Seebohm bids farewell	7	
•	European doctors urge the leaders of Iran to stop imminent execution of Dr Ahmadreza Djalali	7	
•	The European Commission must preserve vital antibiotics for human health and protect animal welfare	8	
•	Panel on the Role of Ethic Committees in the European Health Data Space	8	
•	European Health Union Network launch event	9	
•	Empowerment in Health and Care Conference	9	
٠	Trainers of doctors wanted!	9	
•	Give Kids a Break! What next for EU action to protect children from harmful food marketing?	10	
Monitoring			
•	Launch of work on a new EU Global Health Strategy	11	
•	New rules on in vitro diagnostic medical devices to become applicable	11	
•	WHO and Medicines Patent Pool announce agreement with US National Institutes of Health for COVID-19 health technologies	11	
•	European Commission secures agreement with BioNTech-Pfizer to adapt delivery schedules to Member States' needs	12	
•	European Commission publishes report on operation of Directive 2011/24/EU on the application of patient's rights in cross-border healthcare	12	
•	ECDC publishes Risk Assessment of Monkeypox multi-country outbreak	13	

3



TABLE OF CONTENTS

•	WHO working closely with countries responding to monkeypox	13
•	Update of common list of COVID-19 rapid antigen tests	14
>	New estimates on excess deaths associated with COVID–19 in 2020 and 2021	14
•	Launch of EU FAB call	14
>	Extension of the EU COVID Certificate	15
•	Turkish Medical Association Symposium on Infodemic	15
•	European Medicine Agency publishes revised guideline on evaluation of human medicines for the treatment of bacterial infections	15
	European Health Data Space Regulation	16
•	Feedback period for the European health data space	16
•	Council approves Data Governance Act (DGA)	16
•	New EU strategy to protect and empower children in the online world	17
•	2030 policy programme 'Path to the Digital Decade': the Council adopts its position	17
•	Telecommunications Council Meeting	17
•	Digital Services Act	18
•	TEHDAS activities	18
•	New estimates on excess deaths associated with COVID-19 in 2020 and 2021	19
•	WHO publishes report on impact of tobacco industry on the environment	19
•	Proceedings of the 75th World Health Assembly	20
•	World Health Statistics 2022	20
•	New WHO European Regional Obesity Report 2022	21

EXECUTIVE COMMITTEE MEETING – 27 MAY 2022

Finances

Current accounts 2022

The EC took note of the current accounts as of 30 April.

In particular, the costs of the rebranding exercise, the legal fees relating to the statutes' revision as well as the accounting for the IMMUNION project were noted.

Internal Affairs

Sarada Das appointed new Secretary General

The EC approved the appointment of Sarada Das as Secretary General as of 1 June 2022.

Alexander Jäkel confirmed as Chair of Digital Health Working Group

► The EC confirmed Alexander Jäkel (German Medical Association) as chair of the Working Group.

In-person meetings for Working Groups

► The EC considered the feasibility of convening in-person meetings of CPME WGs outside the context of General Assemblies/Board meetings.

The EC reviewed the Rules of Procedure. With a view to the legislative agenda of the coming months, it was agreed that in-person meetings may be a helpful tool in exceptional cases. To launch planning, it was proposed to ask the Digital Health WG which members would be interested in attending an in-person meeting in June and whether their NMAs would be willing to cover the cost. The planning will build on this feedback.

EXECUTIVE COMMITTEE MEETING – 27 MAY 2022

Policies

Amendments to IMCO-LIBE draft report on AI Act

The EC adopted the amendments as proposed. The dissemination will be coordinated by CPME Secretariat.

ACN Webinar: Adult Vaccination challenges and EU cooperation

The EC decided to decline the invitation to speak at the Active Citizenship Network (ACN) online roundtable on adult vaccination challenges and EU cooperation, sponsored by GSK, MSD, Pfizer, and Sanofi.

The EC also had a discussion on CPME participation in relationships with industry stakeholders.

Preliminary analysis of draft European Health Data Space regulation

► The EC took note of the preliminary analysis of the draft Regulation.

It was reported that the deadline for commenting on the legislative proposal is currently in the last week of July. CPME Secretariat will arrange for an in-person meeting of the WG Digital Health in June (if financially feasible) and coordinate the drafting of a position paper.

Antimicrobial resistance

The EC took note of our response to the European Commission's public consultation on the list of antimicrobial medicines reserved for treating humans.

A follow-up meeting has been planned with the European Commission and EMA on 8 June. The EC will discuss the Commission's feedback on 16 June before considering future actions, for example at national level.



EXECUTIVE COMMITTEE MEETING – 27 MAY 2022

Update on EU4Health project call

The EC was informed that the EU4Health call had been submitted by the project coordinators Aristotle University Thessaloniki on 24 May.

The current proposal foresees a CPME budget of around 404 000 EUR which includes 20% cofunding by CPME. The volume of work would require an additional staff member to be employed for the duration of the project. To facilitate accounting, it is proposed to consider separating the project budgets from the overall CPME budget.

Participation in the Lancet Countdown 2022 EU policy brief

The EC took note that CPME will collaborate with the 2022 Lancet Countdown EU Policy Brief as it has done annually since 2018. The launch of the global report and the regional policy briefs will take place in mid-October 2022.

UEMS statement on private practice

The EC was informed that UEMS recently presented the outcomes of a survey on doctors in private practice and proposes for future joint action by the EMOs on the topic.

The EC will be informed as soon as a proposal is received.

NACE explanatory notes on categories after review

The EC was informed that the European Commission is in the process of revising the explanatory notes for the updated Statistical classification of economic activities in the European Community (NACE).

CPME is invited to comment on the activities relating to doctors. It was agreed to circulate the draft for further review.



Sarada Das appointed Secretary General

We are delighted to <u>announce</u> that Sarada Das has been appointed Secretary General. The appointment took immediate effect from 1 June.

Sarada joined CPME in 2009 and has served as Deputy Secretary General since 2016. Ms Das holds a B.A. in European Studies and an LL.M. in European Law from the University of Maastricht.

Sarada said "I am honoured and privileged to have been appointed CPME Secretary General and thank the Executive Committee and our members for their trust in me. I thank Annabel very much for her dedication and wish her all the very best.

"Recent years have proven the indispensable role that doctors play in European society and how vital collaboration is across borders and at EU level. I look forward to continuing to support our members and to collaborate with our partners across Europe to make the voice of European doctors heard."

Annabel Seebohm bids farewell

Annabel Seebohm <u>left</u> her position as CPME Secretary General following six years in the role. On 1 June she took up the position of Secretary General of COCIR, a European trade association representing the medical imaging, radiotherapy, health ICT and electromedical industries.

Annabel said "It has been an honour to serve European doctors for the past six years. I dearly thank the CPME members and colleagues for your trust, support, encouragement, excellent cooperation and also for the enjoyment working for and with you."

European doctors urge the leaders of Iran to stop imminent execution of Dr Ahmadreza Djalali

European doctors join the World Medical Association in urging the leaders of the Islamic Republic of Iran to stop the imminent execution of Dr Ahmadreza Djalali. We appeal for all necessary action to ensure Dr Djalali's human rights are respected in line with the commitments Iran has made under international law. See WMA's letter here.

The European Commission must preserve vital antibiotics for human health and protect animal welfare

European doctors and 18 other health and animal welfare organisations released a joint statement calling on the European Commission to step up the fight against antimicrobial resistance. The statement raises concerns about the absence of vital antimicrobials on the <u>draft list of</u> antimicrobials to be reserved for human health.

Panel on the Role of Ethic Committees in the European Health Data Space (EHDS)

On 25 May, we hosted a panel during the 15th International Conference on Computers, Privacy and Data Protection (CPDP 2022). The speakers included Mr Guillaume Byk, from the European Commission (DG SANTE) who explained the Commission's proposal and how ethics where considered in the text; Dr Mélodie Bernaux of the French Ministry of Health, presenting the European Ethical Principles for Digital Health; Dr Otmar Kloiber, Secretary General of the World Medical Association, clarifying it matters to consider the WMA's Declarations of Taipei and Helsinki; and Ms Annika Eberstein, Interim Secretary General at COCIR, bringing the perspective of the medical imaging, radiotherapy, health ICT and electromedical industries. The panel was moderated by Dr. Sjaak Nouwt of the Royal Dutch Medical Association. A flyer provides full background.



European Health Union Network launch event

MEP Istvan Ujhelyi and CPME are delighted to invite you to the launch of the European Health Union Network to discuss questions about EU integration within the field of health and health policy. The launch event will take place on **30 June from 12:30 to 14:00** at the Spinelli A3G3 room in the European Parliament, Brussels (Belgium). Please confirm your registration via this link. An agenda for the event will shortly follow. This initiative is coordinated by the office of MEP Ujhelyi and CPME with the support of AIM, EPF and HOPE.

Empowerment in Health and Care Conference

On 13-14 June, the Centre for Empowering Patients and Communities (CEmPaC) organises a conference exploring the core themes of empowerment in health and social care and some cutting edge practices. CPME is represented in the CEmPaC Advisory Board by Dr Katrín Fjeldsted. Please find more information and link to register here.

Trainers of doctors wanted!

CPME as a co-chair of the <u>Coalition for Vaccination</u> is a partner in the EU-funded IMMUNION project which will organise an online train-the-trainer session on vaccine confidence and communication on 21 June at 13-16 (CEST). The target audience is trainers of (future) healthcare professionals from all EU member states who are involved in vaccination training and education. The registration is free of charge, and a link with more information can be found <u>here</u>.



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

On 28 June, organisations such as CPME supporting the healthy food marketing <u>campaign</u> will coorganise a <u>debate</u> on the next steps for EU action to protect children from harmful food marketing. You can join the event at the European Parliament or online. Please register <u>here</u>.



European Commission

Launch of work on a new EU Global Health Strategy

EU Commissioner for Health Stella Kyriakides and EU Commissioner for International Partnerships Jutta Urpilainen <u>made</u> a statement at the G7 Development and Health Ministerial Meeting launching the beginning of the work on the new EU Global Health Strategy. The strategy will form part of the new EU initiative the Global Gateway and will help improve health systems to effectively prevent and respond to global health threats with a view of address inequalities and advancing universal health coverage.

New rules on in vitro diagnostic medical devices to become applicable

As of 26 May 2022, new rules on in vitro diagnostic medical devices will become applicable.

WHO and Medicines Patent Pool announce agreement with US National Institutes of Health for COVID-19 health technologies

WHO's COVID-19 Technology Access Pool (C-TAP) and the Medicines Patent Pool (MPP) finalised a licensing agreement with the United States National Institutes of Health (NIH) for the development of several innovative therapeutics, early-stage vaccines and diagnostic tools for COVID-19. The licenses, which are transparent, global and non-exclusive, will allow manufacturers from around the world to work with MPP and C-TAP to make these technologies accessible to people living in low-and middle-income countries. Licensing the NIH technologies to MPP under the auspices of C-TAP will allow greater access to these technologies and hopefully lead to the development of commercial products that can address current and future public health needs. For the full list of technologies, please consult the following link.



European Commission

European Commission secures agreement with BioNTech-Pfizer to adapt delivery schedules to Member States' needs

The European Commission and BioNTech and Pfizer, have <u>reached</u> an agreement to better handle Member States' COVID-19 vaccination needs in the coming months. This will guarantee that Member States have access to vaccinations when they need them, including future variant-adapted vaccines if authorized, so they can respond to any epidemiological development later this year and continue to help partner countries throughout the world. The original contractual delivery timetable will be adjusted due to this agreement. Member States will not receive the doses for the summer in September and throughout the autumn and winter when Member States are more likely to need additional vaccine stocks for national campaigns and to meet international solidarity commitments.

European Commission publishes report on operation of Directive 2011/24/EU on the application of patient's rights in cross-border healthcare

Directive 2011/24/EU on patient's rights in cross-border healthcare was evaluated in 2021. The <u>report</u> includes a summary of its findings. Prior authorization is required in all Member States, except for seven and one EEA state. The findings suggest that extensive prior authorisation is a significant barrier to cross-border healthcare, limiting the Directive's efficacy for the benefit of patients. Patient mobility decreased between 2016–2022 and patient mobility is primarily taking place between neighboring countries. The reason could also be that patients frequently have difficulty locating information and comprehending the rules that apply.



Monkeypox

ECDC publishes Risk Assessment of Monkeypox multi-country outbreak

On 23 May 2022, the ECDC published its risk assessment of the multi-country outbreak of monkeypox. In the current outbreak, the predominance of diagnosed human monkeypox cases are among men having sex with men (MSM). Although most cases in current outbreaks have presented with mild disease symptoms, the monkeypox virus may cause severe disease in certain population groups such as young children, pregnant women and immunosuppressed persons. The likelihood of cases with severe morbidity cannot be accurately estimated yet.

WHO working closely with countries responding to monkeypox

WHO and partners are <u>working</u> to better understand the extent and cause of an outbreak of monkeypox. The recent outbreaks reported across 11 countries so far are atypical, as they are occurring in non-endemic countries. WHO is working with the affected countries and others to expand disease surveillance to find and support people who may be affected, and to provide guidance on how to manage the disease.



COVID-19

Update of common list of COVID-19 rapid antigen tests

On 6 May 2022, the European Commission <u>uploaded</u> the 14th updated common list of COVID-19 rapid antigen tests.

New estimates on excess deaths associated with COVID-19 in 2020 and 2021

New estimates from WHO show that the full death toll associated directly or indirectly with the COVID-19 pandemic (described as "excess mortality") between 1 January 2020 and 31 December 2021 was approximately 14.9 million (range 13.3 million to 16.6 million). Most of the excess deaths (84%) are concentrated in South-East Asia, Europe, and the Americas. Excess mortality is calculated as the difference between the number of deaths that have occurred and the number that would be expected in the absence of the pandemic based on data from earlier years. Excess mortality includes deaths associated with COVID-19 directly (due to the disease) or indirectly (due to the pandemic's impact on health systems and society)

Launch of EU FAB call

The Commission, in collaboration with the European Health and Digital Executive Agency (HaDEA), is launching EU FAB, which is funded by HERA's annual work plan for 2022. It aims to ensure that sufficient and agile manufacturing capacities for various vaccine types are kept operational and can be activated quickly in the event of a public health emergency. The call covers manufacturing capacities for MRNA based, vector-based, and protein-based vaccines. On the 27 April the call opened and the request to participate closes by 3 June. Those who can participate are pharmaceutical companies and contract manufacturing organisations (CMOs) who are based in the EU/EEA. The factsheet can be found here.



COVID-19

Extension of the EU COVID Certificate

The LIBE Committee <u>approved</u> two reports to extend the EU Digital COVID Certificate scheme, which was set to expire on 30 June, for another 12 months. The aim is to ensure that EU citizens can benefit from their right to free movement despite of the COVID-19 pandemic's progress. The revisions not only prolong the EU Covid certificate scheme's validity until June 30, 2023, but they also let Member States issue test certificates based on new types of antigen assay testing.

Turkish Medical Association Symposium on Infodemic

The Turkish Medical Association (TMA) held a Symposium on "Traps in the Socialization of Information: Infodemic with the 21st Century Dynamics" on May 13 and 14, 2022. A <u>symposium statement</u> summarises the outcomes of the meeting.

Antimicrobial resistance (AMR)

European Medicine Agency publishes revised guideline on evaluation of human medicines for the treatment of bacterial infections

The EMA has published the <u>final revised guideline</u> on the evaluation of human medicines for the treatment of bacterial infections. European regulators in concert with US and Japanese regulators have agreed to align as much as possible their respective data requirements so that medicine developers can design clinical trials that meet the evidence needs of multiple regulatory agencies. The revised document includes clarifications on recommended clinical development programmes for antimicrobials intended to address an unmet need, guidance on clinical trials for certain uncomplicated infections, as well as updated guidance on displaying microbiological and clinical efficacy data in the summary of product characteristics.



Digital Health

European Health Data Space Regulation

On 3 May the Commission <u>published</u> the long-awaited legislative proposal on the European Health Data Space. The Regulation provides the rules, common standards and practices, infrastructures and a governance framework for the primary and secondary use of health data. Individuals (patients) are expected to have better control of their electronic health data: health data must be made digitally available so that the individual can easily access it and transmit it to a healthcare provider or another entity. The text also lays down rules for placing on the market electronic health records systems, particularly if they wish to be connected to the MyHealth@EU platform. This platform will become mandatory to implement by Member States by 2025 for primary use of electronic health data, and will connect national contact points for digital health and the so-called 'central platform for digital health'.

Feedback period for the European health data space

The Commission would like to <u>receive</u> feedback on the European health data space, until 5 July 2022.

Council approves Data Governance Act (DGA)

On 16 May, the Council of the EU <u>approved</u> the European Parliament's position on the Data Governance Act, meaning that the legislative act was adopted. It will be published in the Official Journal of the European Union and enter into force 20 days after publication. It will apply 15 months after entering into force.



Digital Health

New EU strategy to protect and empower children in the online world

On 11 May, the Commission adopted a new European <u>strategy</u> for a Better Internet for Kids (BIK+), to improve age-appropriate digital services and to ensure that every child is protected, empowered and respected online.

2030 policy programme 'Path to the Digital Decade': the Council adopts its position

On 11 May, the Council <u>agreed</u> on a negotiating mandate for the 2030 policy programme 'Path to the Digital Decade'. The text sets out the concrete digital targets, which the Union as a whole must achieve by the end of the decade, including for industry, and a novel form of governance between Member States and the Commission – a mechanism of cooperation. CPME commented on this file and its position will continue to be advocated to the co-legislators. In the Parliament some amendments have been introduce proposing a definition on digital skills, mental health awareness related to digital use, digital inequalities addressed –which are in line with CPME position.

Telecommunications Council Meeting

On 3 June, the <u>EU telecommunications ministers</u> discussed progress reports on the state of play of three key legislative files for the EU's digital transition – the AI Act, the elDAS regulation (electronic identification) which will provide a European digital identity framework, and the Data Act. Background information see <u>here</u>.



Digital Health

Digital Services Act

On April 23, the European Parliament and the Council <u>reached consensus</u> on the Digital Services Act (DSA), which establishes accountability standards for online platforms regarding illegal and harmful content. The DSA imposes obligations on covered entities based on their size, role and impact within the online ecosystem.

TEHDAS activities

On 18 May, Joint Action towards a European Health Data Space (TEHDAS) published a <u>report</u> with recommendations for ensuring data quality in the European health data space (EHDS) for secondary use. The purpose of this data quality framework is to ensure that health data collected across Europe and reused for policy-making, regulation and research is reliable enough and fit for purpose.



World Health Organization

New estimates on excess deaths associated with COVID-19 in 2020 and 2021

New estimates from the World Health Organization (WHO) show that the full death toll associated directly or indirectly with the COVID-19 pandemic (described as "excess mortality") between 1 January 2020 and 31 December 2021 was approximately 14.9 million (range 13.3 million to 16.6 million). Most of the excess deaths (84%) are concentrated in South-East Asia, Europe, and the Americas. Excess mortality is calculated as the difference between the number of deaths that have occurred and the number that would be expected in the absence of the pandemic based on data from earlier years. Excess mortality includes deaths associated with COVID-19 directly (due to the disease) or indirectly (due to the pandemic's impact on health systems and society)

WHO publishes report on impact of tobacco industry on the environment

The WHO report "Tobacco: Poisoning our planet" highlights that the industry's carbon footprint from production, processing and transporting tobacco is equivalent to one-fifth of the CO2 produced by the commercial airline industry each year, further contributing to global warming. Every year the tobacco industry costs the world more than 8 million human lives, 600 million trees, 200 000 hectares of land, 22 billion tonnes of water and 84 million tonnes of CO2. The majority of tobacco is grown in low-and-middle-income countries, where water and farmland are often desperately needed to produce food for the region. Instead, they are being used to grow deadly tobacco plants, while more and more land is being cleared of forests. WHO urges countries and cities to follow the Polluter Pays Principle, as well as give support to tobacco farmers to switch to sustainable crops, implement strong tobacco taxes (that could also include an environmental tax) and offer support services to help people quit tobacco.



World Health Organization

Proceedings of the 75th World Health Assembly

The 75th World Health Assembly was held in Geneva from 22 to 28 May 2022. The focus of the Assembly is on "Health for Peace, Peace for Health" for recovery and renewal. The World Health Assembly re-elected Dr Tedros Adhanhom Ghebreysus as Director General to serve a second fiveyear term. With regards to policies and decisions, delegates agreed to a landmark decision on sustainable financing for the WHO. The recommendations aim to make WHO's funding more predictable and flexible and less dependent on voluntary contributions. For instance, an increase assessed contributions is foreseen to rise from 16% of the approved Programme budget to 50% of WHO's core budget by 2030. The delegates also agreed upon new recommendations for the prevention and management of obesity over the life course as well as a set of targets to halt the rise of obesity in children under 5, adolescents and adults by 2025. Alcohol and alcohol related harm was also addressed at the assembly, with delegates agreeing on an action plan (2022 - 2030) to effectively implement their global strategy to reduce the harmful use of alcohol as a public health priority. The Working for Health Action Plan (2022-2030) setting out policy priorities to progress health workforce capacity was adopted by the Assembly. The dimensions covered by the action plan include planning and finance, education and employment, and protection and performance. Moreover, Delegates also passed a resolution for improving clinical trial capabilities, with calls for greater efficiency, funding, timely data and results sharing.

World Health Statistics 2022

WHO <u>published</u> its latest comprehensive set of World Health Statistics for 2020. 2020 data shows that service disruptions contributed to an increase in deaths from tuberculosis and malaria between 2019 and 2020. While service coverage has improved in the last 20 years, catastrophic health expenditure has worsened.



World Health Organization

New WHO European Regional Obesity Report 2022

On 3 May, the WHO European Office for Prevention and Control of Noncommunicable Diseases published a 2022 report on obesity in the WHO European Region. It highlights that almost two thirds of adults and 1 in 3 children in the WHO European Region are living with overweight or obesity, and warns of the serious health risks associated with rising levels of obesity. The report recommends a number of policy options to tackle the problem, such as restricting the marketing of unhealthy foods to children, taxation of sugar-sweetened beverages, and improving health system response for obesity management. Please find the report here.

Cancer

Glyphosate not carcinogenic

The current classification for glyphosate as a toxin that causes substantial eye damage and is harmful to aquatic life with long-term impacts should be maintained, according to the ECHA's Committee for Risk Assessment (RAC). The committee determined that the current scientific data did not fulfil the requirements for classifying glyphosate as a carcinogenic, mutagenic, or reprotoxic chemical. The full report can be found here.



EDITORIAL BOARD

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Policy Intern

CONTACT

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

Calum MacKichan

calum.mackichan@cpme.eu

Rue Guimard 15 1040 Brussels, Belgium

T: +32 2732 72 02

E: secretariat@cpme.eu

www.cpme.eu