CPME MONTHLY BULLETIN

Stay in the Loop!

July 2021

Dear colleagues,

We are pleased to share with you the latest edition of the CPME Monthly Bulletin with the Executive Committee outcomes of the virtual meeting held on 8 July.

The Executive Committee was informed about the ongoing work on the new website. Also, the Executive Committee adopted draft responses to the public consultations on the European health Data Space and on European Digital Principles.

Furthermore, I am happy to say that the planning for our General Assembly and Board meeting in physical format in November in Oslo is ongoing. We look forward to hopefully see all of you in person again.

We hope the bulletin is informative and we invite you to consult our latest news and the members' section of our [website](#).

I hope that you enjoy your summer break and stay healthy!

Kind regards,

Prof. Dr Frank Ulrich Montgomery
CPME President

Table of Contents

Executive Committee meeting – 08 July 2021

Internal Affairs

CPME new website project
The Executive Committee was informed of the progress regarding the new website structure.

EC members and some users of the website have been invited to a session with the IT developer to test the design. The session is scheduled for 22 July 2021.

CPME EJD CIFS digital leadership course
The Executive Committee approved the application / nomination package of the Digital Leadership Course 2021 "Health trends & Application of Futures Thinking – How to develop or adapt your current strategies to face the digital health transformation and prepare digital health leaders?". The package will be circulated to CPME members once EJD agrees.

CPME Secretariat has worked on eligibility criteria included in the application and nomination forms. These documents together with the concept note will form a package to be shared with a call to members for expression of interest. EJD is currently reviewing the package as well.

Policies

CPME response to the public consultation on the European Health Data Space
The Executive Committee adopted the draft CPME response as recommended by the eHealth WG at its meeting on 24 June 2021.

On 19 February 2020, the European Commission put forward a [European data strategy](#) to create a single market for data, where personal and non-personal data will flow freely within the EU and across sectors for the benefit of businesses, researchers and public administrations.
To complement the horizontal framework of the common data space, captured by the [Commission's Proposal on a European Data Governance (Data Governance Act)](#), a European Health Data Space (EHDS) will be established with sector-specific legislation.
This public consultation is structured in three sections:
- the use of health data for healthcare provision, research and innovation as well as policy-making and regulatory decision;
- the development and use of digital health services and products; and
- the development and use of Artificial Intelligence systems in healthcare.

CPME response to the public consultation on European Digital Principles
The Executive Committee adopted the draft CPME response as recommended by the eHealth WG at its meeting on 24 June 2021.

Reacting to the EU policy developments related to the e-Evidence Regulation on 13 July, the CPME Secretariat requested the CPME President and CPME Vice President for eHealth to add a sentence in the response to reinforce the need to respect professional secrecy and confidentiality in the online environment, which both agreed to.

Commission proposal for a Regulation on electronic evidence in criminal matters
The Executive Committee agreed that CPME cooperates and supports the upcoming advocacy actions of the [European Digital Rights (EDRi)](#) on the [e-Evidence Regulation](#) in relation to professional secrecy and confidentiality.

The Executive Committee also paved the way for further cooperation in other areas, such as the [e-Privacy Regulation](#), where professional secrecy and confidentiality could be potential issues as well.

Expert nomination of EMA Workshop on Artificial Intelligence 14-15 September 2021
The Executive Committee appointed CPME Rapporteur on AI, Prof. Dr Christian Lovis, as the expert to represent CPME at EMA meetings in September.

The EMA Good Clinical Practice Inspectors Working Group (GCP IWG) is organising a virtual meeting on 14-15 September to continue discussing with stakeholders on "Artificial intelligence in clinical trials – ensuring it is fit for purpose" and has launched a call for expression of interest with deadline until 15 July 2021.

The main goal of the meeting is to facilitate a mutual understanding of the expectations from stakeholders, including patients, healthcare professionals, academia, industry, investigators and GCP inspectors for the use of artificial intelligence (AI) in clinical trials and future EMA's guidance. The meeting will address different ethical, quality and regulatory aspects.

Directive on the protection of children from the marketing of unhealthy food
The Executive Committee decided to endorse the key demands of the new draft EU directive on marketing of unhealthy food to children.

The initiative aiming to control the marketing of nutritionally poor foods to children is led by the European Public Health Alliance (EPHA). The launch is planned for autumn 2021.

Commission delegated regulation supplementing Regulation 2019/6
The Executive Committee learned about recent developments related to the CPME letter to ENVI MEPs.

In addition to the CPME meeting with EMA and the exchange of letters with FVE, Prof. Montgomery reported on the CPME cooperation with MEP Häusling who has formally objected to the delegated regulation. Prof. Montgomery participated in a press briefing and a meeting with various MEPs organized by MEP Häusling to further explain our arguments and gain broader

support from the Parliaments' political groups. The ENVI Committee voted on the objection to the delegated regulation - following CPME's arguments - on Tuesday, 13 July, results of which are accessible [here](#).

Lancet Countdown Report on Health and Climate Change
The Executive Committee took note that CPME is invited to collaborate with the 2021 EU policy brief of the Lancet Countdown report on health and climate change.

Dr Martin Balzan, CPME Rapporteur on Environmental Health & Climate Change, has expressed his availability to review the brief. CPME has collaborated with the Lancet Countdown since 2018.

Any other business

VAC-PACT Vaccination Project
The Executive Committee took note that the revised VAC-PACT toolkit materials will be available for approval before the next meeting.

The Executive Committee members will be informed by email. The VAC-PACT pilot project aiming to improve uptake and confidence in vaccines for patients with chronic diseases, families and supporting communities will end on 31 August 2021.

International Calendar
The Executive Committee considered the international calendar.

Monitoring

Your feedback is needed to evaluate the EU cross-border healthcare directive

The European Commission is carrying out an [evaluation of the directive on patients' rights in cross-border healthcare](#), ten years after the adoption of this law. The Commission invites also doctors to respond to this consultation as they may have experience of patients seeking planned healthcare in another EU country. The consultation seeks to find out whether barriers still exist for patients to access healthcare in another EU country and to enforce their rights when asking for health costs reimbursements. You can respond to the questionnaire easily in any official EU language until 27 July 2021. An EU login account is needed but can easily be created.

Submission deadline extended: Model Access Solutions

The Patient Access Partnership (PACT) launched an open call under "Model Access Solutions", its latest initiative. The project is part of the new strategy focus of PACT to identify and share solutions to equitable access across Europe. It intends to provide stakeholders and member states with an online collection of models of excellence in the field of access to healthcare, supplemented by a dedicated workshop to explore how they can be replicated by stakeholders or on local, regional or national level. For more information, please see [here](#).

Any stakeholder with an initiative aimed to improve equity of access to health and related patient care is eligible to [submit an initiative](#) until Sunday, September 26th 2021.

Code of Conduct for Responsible Food Business and Marketing Practices

On 5 July, the European Commission launched the [EU Code of Conduct for Responsible Food Business and Marketing Practices](#) which is one of the first deliverables of the Farm to Fork Strategy. It sets out the actions that food processors, food service operators and retailers can voluntarily commit to undertake to improve and communicate their sustainability performance, for example in relation to food consumption patterns for healthy and sustainable diets. The code was developed by companies and associations in the food sector in cooperation with the Commission but also other stakeholders. CPME also attended some of the meetings organised during the process, which started in December 2020. The code has already been signed by 65 food sector operators.

New ECDC report "Countering online vaccine misinformation in the EU /EEA"

On June 29, the ECDC published the report ["Countering online vaccine misinformation in the EU /EEA"](#) with a focus on misinformation related to vaccination against measles (in combination with mumps and rubella), Human papillomavirus (HPV), Influenza and COVID-19. The report explores the evidence base for how to counter online vaccine misinformation in the EU /EEA, current strategies used by public health authorities in a selection of EU countries and training needs on this topic.

Launch of the EU Knowledge Centre on Cancer

On 30 June, the European Commission launched the [Knowledge Centre on Cancer](#), a new online platform to gather evidence and coordinate actions against the number one cause of death among people under 65 years of age in Europe. The centre is the first "flagship action" delivered under the Europe's Beating Cancer Plan and it is managed by the Joint Research Centre which is the Commission's science and knowledge service.

Its aim is to map the latest evidence of cancer, provide healthcare guidelines and quality assurance schemes, as well as monitor and project trends in cancer incidence and mortality across the EU.

New EU occupational health strategy

On 28 June, the European Commission adopted the [EU strategic framework on health and safety at work 2021-2027](#). The new strategy focuses on three cross-cutting objectives, namely managing change brought by green, digital and demographic transitions as well as changes to the traditional work environment, improving prevention of accidents and illnesses and increasing preparedness for any potential future crises. The Commission will also prepare an EU-level initiative related to mental health at work that assesses emerging issues related to workers' mental health and puts forward guidance for action. Moreover, the Commission will ask the expert panel on effective ways of investing in health to deliver an opinion on supporting the mental health of healthcare workers and other essential workers by the end of 2021. In addition, the Commission calls on the EU Member States to actively address hazards in the healthcare sector by putting in place and implementing safe working procedures and providing appropriate training.

Commission proposes transformation of EU economy and society to meet climate ambitions

On 14 July, the European Commission adopted the "Fit for 55 in 2030" legislative package as part of the European green deal. The proposal adopted aim to make European climate, energy, land use, transport and taxation policies fit for reducing net greenhouse gas emissions by at least 55% by 2030. The Commission emphasised the importance of taking immediate action on climate change, citing benefits such as cleaner air, healthier citizens, and a healthier planet to hand over to future generations.

Civil Liability on AI

On 30 June, the Commission published an inception impact assessment on "Adapting liability rules to the digital age and circular economy". It reflects on the future legal framework which must adapt to new emerging technologies (e.g., robotics, internet of things and AI) and the circular economy which aims at extending the life of materials (e.g., upgrades, repairs). The framework needs to strike a balance between promoting innovation and the following objectives: (i) legal certainty to industry about the risk they take in the course of their business, (ii) prevent damage and (iii) compensation to injured parties. The shortcomings that the framework would need to solve among other, are:

* Intangibility of digital products (if damage caused by software can lead to compensation and its classification as a product)
* Connectivity and cybersecurity (if the notion of defect covers cyber vulnerabilities)
* Complexity (difficulty in identifying the person responsible)

The policy options proposed by the Commission range from adapting the strict liability rules to cover intangible products and address defects resulting from updates, hacking, etc., to reducing obstacles to receive compensation by alleviating the burden of proof, reverse the burden of proof or reduce time limits and minimum threshold for damage to property. Feedback is open until 28 July 2021. CPME Secretariat would recommend waiting for the public consultation to provide a reply, which is to be expected in a few months.

Tobacco traceability system

On 9 July, the EDPB made public an opinion on the tobacco traceability system. The opinion addresses three questions related to the different roles of actors involved in the tobacco traceability system established under the "Tobacco Products Directive".

Standardisation strategy

On 28 July, the Commission published a [roadmap for a European "Standardisation strategy"](#). The Commission is preparing a communication that aims to address the challenges that the European standardization system is facing. Feedback is sought particularly on 1) whether the current European standardisation system is fit for purpose to support European strategic interests; 2) how the EU can leverage and promote global leadership in standards-setting; 3) whether changes in governance and working methods are required to improve the performance of the European standardization system. This initiative will take stock of the evidence gathered in the impact assessments of the Medical Devices Regulation, the evaluation and impact assessment of the Machinery Safety Directive, the impact assessment of the Artificial Intelligence Regulation, the impact assessment of the Batteries Regulation as well as ongoing reviews, such as the evaluation of the Construction Products Regulation and stakeholder feedback on the General Product Safety Directive. The deadline to provide feedback is on 9 August 2021. CPME Secretariat is monitoring the development.

COVID Certificate implemented

On 28 June, the Commission published the [implementing decision](#) laying down technical specifications and rules for the EU Digital COVID Certificate. On 30 June, the eHeallth network issued [Guidelines on Validation of EU Digital COVID Certificates](#). Following the entry into force of the [EU Digital COVID-19 Certificate Regulation](#), the eHealth Network Subgroup on Technical Interoperability, in cooperation with airline experts propose possible scenarios and technical solutions to swiftly implement the verification of COVID Certificates in the context of air travel. The Regulation allows passenger transport services operators to process data to verify and confirm the holder's vaccination, test result or recovery. The data processed for this purpose shall not be retained. The verification should preferably take place before arrival at the airport and only once in the passenger journey.

WHO guidance on Ethics & Governance of Artificial Intelligence for Health

On 28 June, the [WHO issued guidance on ethics and governance on AI for health](#). According to the report, ethics and human rights must be at the heart of the design, deployment and use of new technologies using AI. The report summarises laws, policies and principles that could apply to the use of AI. It identifies six core principles [(i) protect autonomy; (ii) promote human well-being, human safety, and the public interest; (iii) ensure transparency, explainability, and intelligibility; (iv) foster responsibility and accountability; (v) ensure inclusiveness and equity; (vi) promote AI that is responsive and sustainable], and ethical challenges. The report also discusses liability regimes, elements for a governance framework on AI in health (including on data, control and benefit-sharing, private and public sector, among others), and concludes with recommendations for AI technology developers, ministries of health and healthcare providers.

Use of antibiotics in animals is decreasing

On 30 June, EFSA, ECDC and EMA published a report on "[Antimicrobial consumption and resistance in bacteria from humans and animals](#)". The report observes that the use of antibiotics has decreased and is now lower in food-producing animals than in humans suggesting that the measures taken to reduce use are proving to be effective. There are links between antimicrobial consumption in animals and AMR in bacteria from food-producing animals, which in turn is associated with AMR in bacteria from humans (e.g., Campylobacter spp. Bacteria). The use of a class of antibiotics called polymyxins, which includes colistin, nearly halved between 2016 and 2018 in food-producing animals. However, polymyxins and tetracyclines are still used more in food-producing animals than in humans. Aminopenicillins, 3rd and 4th generation cephalosporins and quinolones (fluoroquinolones and other quinolones) are used more in humans than in food-producing animals. The report's conclusions are positive and do not contradict the arguments used by CPME in our opposition to be the draft Commission delegated regulation on reserving certain antimicrobials for humans.

Commission lessons learnt - legislation, data, European chief epidemiologist

On the 15 June, the European Commission [presented](#) a communication on the early lessons learnt from the COVID-19 pandemic over the past 18 months. The communication outlines 10 lessons learned on what needs to be improved and what can be done in the future. Among the lessons learned, the Commission recommends that the EU should lead efforts to design a new global surveillance system based on comparable data, the appointment of a European Chief Epidemiologist, and the swift adoption of the European Health union legislative package.

CPME News

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CPME meets Slovenian presidency

CPME Secretariat met with the health attachés of the Permanent Representation of Slovenia for an exchange on the presidency's policy planning. The attachés confirmed that the priorities are the conclusion of negotiations on the European Health Union proposal, as well as cancer policy with a link to action on tobacco control policy, health systems resilience, pharmaceuticals in particular medicine shortages and global health. The latter topics will be addressed in four Council conclusions. The presidency will also continue the debate on the European Health Data Space in the context of its overall focus on digitalisation. Stakeholders are invited to join the high-level conference on the implementation of innovative solutions for resilient health systems on 15 and 16 July, as well as a conference on cancer policy taking place on 13 and 14 December.

CPME members' session on Taiwan's experience of the COVID-19 pandemic

On 8 July, H.E. Ambassador Dr Ming-Yen Tsai of the Taipei Representative Office in the EU and Belgium, as well as Dr Song-En Huang, Medica officer at the Taiwan Centres for Disease Control, presented Taiwan's experience of preparing for and managing the COVID-19 pandemic. IN her presentation, Dr Huang described the action taken at different phases of the pandemic, emphasising the importance of learning the lessons of preparedness from an earlier SARS pandemic, as well as managing pandemic fatigue. The presentation is available at CPME Info 101-2021.

CPME call for action to protect professional secrecy and confidentiality

On 5 July, CPME met with European Digital Rights (EDRi), a network organisation that defends and promotes human rights in the digital environment, in relation to the Commission's proposal for a regulation on European Production and Preservation Orders for electronic evidence in criminal matters (e-Evidence Regulation). This proposal was presented by the Commission in 2018 to allow national judicial or administrative authorities to issue **cross-border data access orders for criminal investigations**. These orders compel an internet provider to produce or preserve electronic evidence, which could be personal data from social media content, email, messages and "cloud" data, located in another Member State. The new Council's position **downgrades certain safeguards and oversight measures that could have a serious impact on medical confidentiality and professional secrecy**. For example, patient information is exchanged with the doctor in his / her professional function and such information is disclosed by the internet provider without patient consent or doctor's knowledge. The CPME Executive Committee discussed this issue on 8 July and supported coordinating advocacy actions with EDRi in this area. Parallel to this initiative, CPME is also assessing bilateral lobby actions with CCBE (an organisation representing lawyers) and preparing a lobby letter for CPME Members calling them for action. Please stay tuned in the next days!

Is the Future Bright for Telemedicine – European Doctor's talk Digital

On 30 June, the video recordings of the CPME panel discussion on the future of telemedicine was published, along with the event recap report – please see here. The event was hosted by the Portuguese Presidency during the eHealth Summit (the main event on innovation and the digital transformation in health).

Recent publications on the CPME Website

Members' section:
[Presentation on COVID-19 in Taiwan by Dr Song-En Huang, 8 July 2021](#)
[Draft CPME Feedback on the Revision of rules on information provided to consumers for alcoholic beverages](#)
[Is the Future Bright for Telemedicine – European Doctor's Talk Digital](#)
[CPME Monthly Bulletin – June 2021](#)

CPME news section:
[CPME response to the public consultation on a set of European digital principles](#)
[CPME response to the public consultation on the European health data space](#)
[ENVI Committee objects to prioritising animal welfare over human health](#)
[ENVI Committee for a stronger legal framework against future pandemics](#)
[CPME Feedback on the Revision of rules on information provided to consumers for alcoholic beverages](#)
[Consensus Framework on the Digital Transformation of Healthcare](#)
[Is the Future Bright for Telemedicine – European Doctor's Talk Digital](#)