COMITÉ PERMANENT DES MÉDECINS EUROPÉENS
STANDING COMMITTEE OF EUROPEAN DOCTORS

CPME MONTHLY BULLETIN

Stay in the Loop!

June 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 17 June.

The Executive Committee discussed various issues, amongst them the events held in the beginning of June as well as the planning of future CPME events.
Further points of discussion were the CPME draft response to the consultation on the taxation of tobacco products and new products as well as the CPME feedback to the Commission's roadmap on a declaration of digital principles.

I would also like to highlight the various opportunities to actively participate. The CPME questionnaire on triage protocols and COVID-19 is still open for input. Additionally, the EU-founded IMMUNION project has launched a survey on vaccination training for healthcare professionals, which we invite you to participate in. CPME is also looking for experts to represent CPME at an online workshop, organised by EMA. Further information can be found below.

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

Kind regards,

Prof. Dr Frank Ulrich Montgomery
CPME President

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Executive Committee meeting – 17 June 2021

Internal Affairs

Copenhagen Future Institute – leadership course

The Executive Committee approved the concept note and commissioned the Secretariat to proceed with drafting eligibility criteria together with EJD.

The project implements the CPME policy on digital competencies and provides concrete support to members. It also extends the range of tools CPME has, to implement policy and assist members.

CPME events: reporting on past events

The Executive Committee was provided an update on the events CPME has hosted this past month: the MEP Doctors' Roundtable, the CPME event on telemedicine and the third online debate on interprofessional education and the One Health approach in professional practice.

I) CPME co-hosted MEP Doctors' Roundtable, supported by MEP Dr Manuel Pizarro and MEP Dr Peter Liese, which took place on 1 June. The event was attended by seven MEPs from three different political groups. The discussions showed that the initiative was well-received and future meetings will be welcomed.

II) The CPME event on telemedicine, sponsored by the Portuguese Presidency, took place on 1 June. A report is accessible here. The recording will be available shortly.

III) CPME co-organised the third online debate on interprofessional education and the One Health approach in professional practice. The webinar brought together around 90 participants including academics, policymakers, professionals and students. The recording is now available here and a short report of the meeting will be added to the CPME website shortly.

CPME events: planning for future events

The Executive Committee was updated on the planning for future events hosted by CPME

Following exchanges with the Taipei Representative Office in Brussels, CPME invited them to share Taiwan's experience of the COVID-19 pandemic with CPME members.
The Executive Committee was also informed that the health unit of OECD offered to present its work on data collection following a discussion of the CPME paper on lessons learnt from the COVID-19 pandemic at a recent meeting. Moreover, the EC welcomed the opportunity and suggested inviting OECD to present to the CPME membership at the November CPME meetings. At this regard, CPME Secretariat will liaise with OECD and the Norwegian Medical Association.

Policies

Consultation on the Taxation of Tobacco Products and New Products

The Executive Committee approved the draft CPME response to the European Commission's public consultation on the taxation of tobacco products and new products.

The current EU rules are reviewed because they date from 2010 and the minimum tax rates have lost their effect. Moreover, the current rules are not able to cope with market developments and the entry into the market of new tobacco and nicotine products. The initiative is part of the EU's beating cancer plan. The members of the CPME WG on Healthy Living had an opportunity to comment on the draft.

Joint EMOs statement on burn-out among doctors

The Executive Committee approved CPME's co-signature of the joint EMO's statement on burn-out among doctors.

This statement was presented by CEOM at a recent meeting of the EMOs' WG on Violence Against Health Professionals with an invitation for action by the EMOs. CPME Secretariat will confirm and support dissemination.

CPME Feedback to Commission's roadmap on a Declaration of digital principles

The Executive Committee took note of the feedback and was informed that the draft CPME response to the public consultation on the same topic (deadline on 2 September 2021) will be discussed at the next meeting of the eHealth WG on 24 June.

The feedback can be found here.

Draft directive on the protection of children from the marketing of unhealthy food

The EC took note that CPME is participating in an initiative of several health NGOs to launch a new directive to protect children from the marketing of unhealthy foods.

The work is led by the European Public Health Alliance (EPHA). CPME will be invited to endorse the key demands of the draft directive.

Any other business

The Veterinary Medicines Regulation

The EC decided to refer the decision on the CPME's response to the draft delegated act to written procedure.

The Secretariat should prepare a letter calling on MEPs to veto the draft delegated act and send it to EC members along with background information, so that an informed decision can be made.

Executive Committee members also learnt about the Germanwatch request to support its campaign and the German Medical Association activities in this context.

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 this directive on patients' rights in cross-border healthcare, ten years after the adoption of this law. The Commission also invites doctors to respond to this consultation, as they may have experience with 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 the reimbursement of healthcare relates costs. **You can respond to the questionnaire easily in any official EU language until 27 July 2021** ***(an EU login account is needed, which can easily be created).***

European Semester spring package comments on healthcare budgets

The European Commission has published its Spring Package for the European Semester cycle. The reports assess opportunities for reform of public spending to accelerate post-pandemic recovery, which complements the reforms and EU financial support approved under the Resilience and Recovery Facility. The package includes recommendations for economic coordination as well as surveillance reports, which identify priorities for action at national level. This included measures relating to the healthcare system. Such as the continuation of "clawback" programmes in Greece, and professionals, e.g. a reference to the lack of reforms in the area of professional regulation in Germany.

Council COVID-19 Travel Measures Recommendations

The Council of the EU is recommending a common approach to COVID-19 travel measures in the EU- The recommendations include a common criterion for mapping COVID-19 risk levels, testing and quarantine exemptions for vaccinated and recovered persons, and an Emergency Brake mechanism where Member State can introduce their own measures when the epidemiological situation in a region deteriorates rapidly, or where variants of concern are detected.

European Child Guarantee

On 14 June, the Council of the EU adopted a recommendation establishing a European Child guarantee, which aims to prevent and combat social exclusion of children. Recommendations include guaranteeing effective and free access to early childhood education and healthcare as well as guaranteeing at least one healthy meal each school day and effective access to healthy nutrition.

International Roundtable on Vaccination

The International Roundtable on Vaccination webinar, co-organised by the World Medical Association, The Pontifical Academy for Life and the German Medical Association, is scheduled to take place on July 1st at 11:00 am UTC.
In light of the COVID-19 pandemic, the event aims to highlight the importance of vaccine equity, the dangers of vaccine hesitancy as well as the tension between freedom of choice and common good internationally. For more information, please see here. To register for the event, click here.

14th World Conference on Bioethics, Medical Ethics and Medical Law

Registrations to the event are open until July 31, 2021.
The deadline for abstract submission for the 14th World Conference on Bioethics, Medical Ethics and Medical Law (scheduled to take place from 7-10 March 2022 in Proto, Portugal), has been extended until the 15th of July 2021.
For more information, click here.

UK adequate status in data protection laws

On 17 June, Member State unanimously approved the European Commission's draft adequacy decisions for the UK. The effects of this approval will be that personal data can continue to flow from the EU to the UK without any further safeguard being necessary. Through this legal framework, both parties acknowledge that they will provide an equivalent level of data protection, in full respect of privacy laws and fundamental rights. Only the draft decisions have been published. For further information, please see here.

State of implementation of the OECD AI Principles – Insights from national AI policies

On 18 June, OECD published a first report on the state of implementation of the OECD AI principles among governments. This report represents a conceptual framework, provides findings, identifies good practices and examines emerging trends in AI policy. The report builds on the expert input provided at meetings of the OECD.

Commission welcomes political agreement on HTA regulation

The Commission welcomes the political agreement on the Health Technology Assessment (HTA) Regulation reached by the European Parliament and the Council. The regulation will replace the current system of EU-funded project-based cooperation between Member States on HTA with a permanent framework for joint work. The new framework will also work on joint clinical assessments, cover joint scientific consultations, identify emerging health technologies and work on voluntary cooperation. The regulation does not impact on Member States' current responsibility for the management of their health services, including pricing and reimbursement.

The Commission presents a communication on early lessons learnt from COVID-19

The European Commission is presenting a communication on the early lessons learnt from the COVID-19 pandemic over the past 18 months and building on them to improve action at EU and national level. The communication outlines 10 lessons learnt on what has to be improved and what can be done in the future. Among these:

- The EU should lead efforts to design a new robust global surveillance system based on comparable data
- For clearer and more coordinated scientific advice to facilitate policy decisions and public communication, the EU should appoint a European Chief Epidemiologist and a corresponding governance structure by the end of 2021
- The European Health Union should be adopted swiftly, before the end of the year and coordination and working methods should be strengthened between institutions
- HERA should be operation by 2022 and a Health Important Project of Common European Interest should be set up as soon as possible to enable breakthrough innovation on pharmaceuticals
- EU FAB facility should ensure that the EU has enough "ever-warm" capacity to produce 500-700 million vaccine doses per year, with half of these doses to be ready in the first 6 months of a pandemic

The full communication document is available here.

The ENVI Committee votes on changes to the EMA mandate

The ENVI committee adopted its negotiating position on the extension of the EMA mandate with 68 votes in favor, 3 against and 8 abstentions. The position is scheduled to be voted on during the plenary in July. MEPs propose the creation of an interoperable digital EU database to monitor and report on shortages of medicinal products. Each EU country would develop a platform for the real-time monitoring of medicinal supply, aiming to detect, predict and prevent shortages. MEPs also want to implement coordinated, well-designed and large-scale clinical trials to obtain reliable evidence. The full press release is available here.

Artificial intelligence at the top of the agenda

On 2 June, IMCO and AIDA Committees held a discussion with European Commission Executive Vice President Margrethe Vestager on the AI Regulation. MEPs highlighted that the EU rulebook on artificial intelligence has to guarantee transparency, safety and human oversight. The Regulation aims to strengthen AI uptake, investment and innovation across he EU as well as to guarantee the safety and fundamental rights of people and support businesses. The Greens noted that they wish to avoid fragmentation, achieve a functioning Digital Single Market without unnecessary cross-border barriers to free movement of goods and services, while protecting EU citizens. Improving healthcare is a key cornerstone, along optimizing the use of scarce resources and fight against climate change. For MEP Dragos Tudorache (Renew, RO), Chair of the AIDA Committee, there is a need to strengthen the protection of EU citizens' rights and privacy; to remove any unnecessary regulatory burdens and provide regulatory clarity for companies (start-ups and SMEs in particular) supporting innovation. He noted the need to educate citizens on AI, train specialists on AI and ensure that Member States are aligned on the implementation of the AI Act MEP Tudorache noted the need to work with the US and other democracies to ensure AI is developed according to democratic values worldwide. He said that AI is a geopolitical subject, and the EU is a geopolitical actor. IMCO Committee will take the lead in the EU Parliament and ENVI will issue an opinion.

WHO on personal data

On 8 June, WHO/Europe released easy-to-implement steps to allow any organisation in public health to increase its level of data protection compliance. The document entitled "The protection of personal data in health information systems – principles and processes for public health", is part of WHO/Europe's work to support Member States in strengthening their health information systems (HIS). For further information, please see here.

European Data Protection Board on Data Governance Act

On 28 May, the EDPB adopted a statement on the data governance act (DGA). It highlights that the data re-use, sharing and also availability of data may generate benefits, but also various types of risk of damages to the persons concerned and society as a whole, impacting individuals from an economic, political and social perspective. The EDPB urges co-legislators to address the issue explained in the EDPB-EDPS Joint Opinion on the DGA of March 2021, to avoid that the DGA creates a parallel set of rules, not consistent with the GDPR, as well as with other Union law, which would result in insufficient safeguards for individuals and difficulties in the practical application.

Public consultation on the Data Act

On 3 June, the Commission launched a public consultation on the Data Act (deadline 3 September). This future proposal for a Regulation, expected for the Q3-Q4 of 2021 intends to complement the proposal for a regulation on European Data Governance (November 2020). Its objective is to propose measures to ensure fair access to and use of data in relation to business to business and business to government situations. Under this initiative, a review of directives 96/9/EC on the legal protection of databases is also planned. The public consultation addresses different measures in preparation of the Data Act.
It is divided in eight sections:

i) business-to-government data sharing for the public interest;
ii) business-to-business data sharing;
iii) tools for data sharing: smart contracts;
iv) clarifying rights on non-personal Internet-of-Things data stemming from professional use;
v) improving portability for business users of cloud services;
vi) complementing the portability right under Article 20 GDPR;
vii) intellectual property rights – Protection of Databases;
viii) safeguards for non-personal data in international contexts.

Civil society can also provide feedback to the inception impact assessment until 25 June. CPME will discuss at the next meeting of the eHealth WG on whether to respond to the public consultation. The Commission also published an inception impact assessment on the subject where the deadline for feedback ended on 25 June.

CPME News

CPME social media

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Kind reminder: CPME questionnaire on triage protocols and COVID-19

We invite you to please complete the CPME questionnaire on triage protocols in the context of COVID-19. Please respond to the online survey here.
The questionnaire was developed by the new CPME WG on Medical Ethics and COVID-19 which was set up upon the CPME Board's request. The objective of the survey is to map national approaches to triage protocols which address the COVID-19 situation with a view to supporting other CPME members, in particular in countries which do not have any protocols in place. We thank you for your help!

Survey on vaccination training for healthcare professionals

The EU-funded IMMUNION project is conducting a survey on vaccination training in order to develop an online platform for healthcare professionals gathering useful information and educational materials on vaccination.

The project aims to strengthen the Coalition for Vaccination, co-chaired by CPME, which brings together European associations of healthcare professionals and relevant student associations in the field. The training platform will be available on the upcoming Coalition website.

The survey is available until 4 July 2021 here: https://bit.ly/2S53Ixi

CPME successfully hosts panel on digital skills, One Health webinar, MEP Doctors' Roundtable

CPME hosted three successful events this week: the MEP Doctors' Roundtable supported by MEP Dr Manuel Pizarro and MEP Dr Peter Liese; a panel entitled " is the future bright for Telemedicine – European Doctors' Talk Digital" in the framework of the eHealth Summit organised by the Portuguese Presidency of the Council of the EU; and the third debate on interprofessional education and training on "Promoting One Health in professional practice" organised together by veterinarians, dentists and pharmacists as well as student organisations. Each event was well-received and strengthened CPME's visibility as an opinion leader, as well as reinforcing ties to the EU institutions.[LINKS]

EMA consultation: Guideline on computerised systems and electronic data in clinical trials

The European Medicines Agency launched a public consultation on a "Guideline on computerised systems and electronic data in clinical trials". Computerised systems are being increasingly used in clinical research. The complexity of such systems has evolved rapidly during the last years. There is a need to provide guidance to sponsors, CROs, investigators and other parties involved in the design, conduct and reporting of clinical trials reflective of these changes in data types and trial types on the use of computerised systems and on the collection of electronic data. This is important to ensure the quality and reliability of trial data, as well as the safety and wellbeing of the trial participants. This will contribute to a robust decision-making process based on such clinical data. The EMA "Reflection Paper on expectations for electronic source data and data transcribed to electronic data collection tools in clinical trials" started to address these when it was published in 2010. However, the development of and experience with such systems has progressed. A more up to date guideline is needed. **If you have any comments to the guidelines, please use this template and send them to CPME Secretariat (Secretariat@cpme.eu) by 30 September 2021. We will compile the responses and submit them to EMA.**

EMA call for expression of interest: Experts to represent CPME at workshop on AI

EMA's Good Clinical Practice Inspectors Working Group (GCP IWG) is organising an online workshop on 14-15 September 2021 to continue to discuss with stakeholders about *"Artificia**l** intelligence in clinical trials – ensuring it is fit for purpose"*. The aim of the meeting is to facilitate a mutual understanding of stakeholders' expectations including patients, healthcare professionals, academia, industry, investigators and GCP inspectors for the use of artificial intelligence (AI) in clinical trials. This workshop will address ethical, quality and regulatory considerations. **If you are interested in representing CPME, please send your candidacy to CPME Secretariat (Secretariat@cpme.eu) by 1 July with a short introduction (no more than 150 words) indicating your expertise on the topics discussed.** The CPME Executive Committee will decide on the CPME nominees on 8 July (more than one can be appointed and it will be up to EMA to choose the participants). EMA is also looking for **speakers** in relation to the topics to be discussed during the meeting.

If you like to consider this role, please see the topic workshop sessions below and let us know:

Day 1 - Session I

Can the unknown be trusted, is there an ethical expectation of transparency of decisions? Should AI be explainable? What does I mean to build ground truths and how to challenge pre-conceptions (e.g. data set selection and cleaning) in a proportionate way to avoid unintended systems behaviour (e.g. meaningful bias)? What meaningful bias can lead to a systematic disadvantage of individuals or call into question the generalizability of the results.

Day 1 - Session II

Overarching approach of "Good Design" and the establishment of "Good Machine Learning Practice" (GMLP). This is a topic that has already been hotly debated and taken up by the FDA in the field of medical devices and it is time to debate for non-medical devices as well. This topic follows on well from the first set of topics. Efforts of the industry, in which the self-defined requirements become clear. For example, the standards already set by Consort on how AI use is to be communicated in data transfers, thereby implicitly setting requirements like other standards.

Day 2 - Session III

Expectations from the regulatory side, how can the statements from the previous parts, if relevant, be verified in a regulatory assessment. Which documents, which test documentation and which tests are conceivable to prove statements about the functionality of an AI solution. Inspections take place on the concrete object and not on the concept level. The importance of the verifiability of statements about the functioning and conformity of an AI application has been particularly emphasized in the discussion. What requirements can be derived?

Where are uncertainties in the current regulatory landscape that stand in the way of developing AI systems with value? Need for guidance?

European Commission publishes "The Scientific, Technological and Societal Conditions of the End of the COVID-19 Crisis", CPME contributed.

CPME was contacted in August 2020 to contribute to the foresight study commissioned by the European Commission to support reflects on the impact of the COVID-19 pandemic. CPME specifically contributed to the Delphi survey, which was the basis of a report which developed five scenarios about 2023 Europe, with the aim for decision makers to test policy proposals against each of them and develop a roadmap for the future. The final study report including the data was now published, and can be accessed here.

Recent publications on the CPME Website

Members' section:

Concept note Copenhagen Future Institute – leadership course
Letter to MEPs on Drug resistance – criteria for identifying antimicrobial medicines reserved for treating humans
Agenda eHealth WG Meeting, online, 24 June 2021
CPME Members Briefing on AI Regulation
Draft CPME Response Public Consultation on European Digital Principles
Draft CPME Response European Health Data Space Public Consultation
Draft Minutes eHealth Session, online, 19 March 2021
CPME Event Report "Is the Future bright for Telemedicine? – European Doctors Talk Digital", online, 1 June 2021
Draft Minutes of the CPME General Assembly – 20 March 2021
Draft Minutes of the CPME Board Meeting – 20 March 2021
CPME Monthly Bulletin – May 2021
TEHDAS slides WP5, kick-off meeting, 10-11 May 2021
TEHDAS slides WP8, kick-off meeting, 26 May 2021
PPP Commission presentation on AI Regulation, 18 May 2021
Draft Deliverable TEHDAS M5.7 Elements of Governance (confidential)
Master PPT eHealth Stakeholders Group, 5 May 2021
PPP Commission EHDS stakeholder involvement eHealth Stakeholder Group, 5 May 2021
CED-CPME-EPF-PGEU Consensus Framework Digital Transformation Healthcare
CPME Feedback Roadmap on Declaration on Digital Principles

CPME news section:

European Medical Organisations on violence against healthcare professionals
CPME Response to the Public consultation on the Taxation of Tobacco Products and New Products
CPME Feedback on Declaration of Digital Principles