



## CPME MONTHLY BULLETIN

*Stay in the Loop!*

May 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 27 May 2021.

The Executive committee discussed several items, including the up-dated Terms of Reference of the new WG on Medical Ethics and COVID-19 and the invitation to join the MHE's Mental Health Advocacy Platform.

Over the past weeks, CPME hosted three successful events: 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 veterinarians, dentists and pharmacists. Each event was well-received, strengthened CPME's visibility as an opinion leader and reinforced ties to the EU institutions.

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

## Table of Contents

<b>Executive Committee meeting – 27 May 2021 .....</b>	<b>3</b>
<i>Internal Affairs .....</i>	3
<i>Policies .....</i>	3
<i>International calendar .....</i>	4
<b>Monitoring .....</b>	<b>5</b>
<i>Agreement on the Digital COVID Certificate .....</i>	5
<i>EU digital COVID Certificate goes live with 7 countries .....</i>	5
<i>SAVE THE DATE - EFMA Virtual Meeting.....</i>	5
<i>New Report on the Application of the Tobacco Products Directive .....</i>	6
<i>Zero pollution action plan .....</i>	6
<i>Commission consults on Digital Principles .....</i>	6
<i>PGEU Position Paper on the Lesson learned from the COVID-19 pandemic .....</i>	6
<i>Commission Published Draft Regulations on AI .....</i>	7
<i>Consultation on European Health Data Space launched .....</i>	8
<i>EMA consultation on naming of COVID-19 vaccine variants .....</i>	8
<i>European Data Protection Board on Data Governance Act.....</i>	8
<b>CPME News .....</b>	<b>9</b>
<i>CPME social media.....</i>	9
<i>NMA survey on triage protocols in context of COVID-19.....</i>	9
<i>Survey on vaccination training for healthcare professionals .....</i>	9
<i>Recent publications on the CPME Website .....</i>	10

## Executive Committee meeting – 27 May 2021

### Internal Affairs

#### **Belgium's new Association and Company Code (CAC)**

*The Executive Committee was informed that the necessary statutory changes following Belgium's new Association and Company Code (CAC) must be finalised by end 2023.*

The lawyer is suggesting conducting the process in 2022. The legal fees will amount to a maximum of 13.000 EUR provided no additional legal services are needed. The quote does not include notarial fees.

#### **Bosnia and Herzegovina (BiH) and CPME observership**

*The Executive Committee was informed that Bosnia and Herzegovina (BiH) can be admitted into observership without a statute change in the November GA provided under BiH law the BiH agreement is a de facto association agreement.*

Should the agreement not meet the standard of a de facto association, the statutes will need to be changed allowing for other solutions. However, for legal reasons, this change cannot be done separately from the CAC process, i. e. the observership can be accomplished in 2022.

### Policies

#### **Medical Ethics and COVID-19**

*The Executive Committee approved the updated [terms of reference](#).*

The EC reviewed the changes the new WG on Medical Ethics and COVID-19 made to the terms of reference during its first web-meeting. It was explained that the changes intend to focus activities of the WG and avoid duplication with the work of other CPME WGs and the WMA. The ethical dimension of the questions discussed by the WG will complement the existing discussions.

#### **European Health Union**

*The Executive Committee was informed that CPME has been promoting the [CPME position papers](#) on the three EHU proposals in the European Parliament (EP) over the past months and held a series of meetings with members of the European Parliament (MEPs) and assistants.*

From the draft reports and proposed amendments, many key points from the CPME position papers have been taken up by MEPs, including:

- Strengthening EMA's and ECDC's competences,
- prevention as a key objective in the new framework,
- giving more weight to the Health Security Committee,

- improving data protection for patient data,
- collecting public health data,
- cooperating with third countries,
- improving stakeholder involvement including in consultative bodies at the EMA such as Medicines Steering Group
- strengthening ECDC's mandate regarding animal health
- improving the definition of medicine shortages and making information public
- introducing sanctions for manufacturers of medicines who breach reporting obligations on shortages.

There is support to collect standardised public health data, however the EP did not explicitly pick up the idea of using this data to create benchmarks for health systems' capacities. The [European Economic and Social Committee](#) however has reflected CPME's call for a ratio of minimum capacity per population unit.

There are also many proposed amendments in the EP to extend the mandate of the European Centre for Disease Prevention and Control ([ECDC](#)) further: many MEPs support including non-communicable diseases in the mandate, for example. There are also calls for the ECDC to e.g. carry out on-site audits of preparedness capacity, and to collect information on treatment of future pandemics.

CPME Secretariat is currently analysing the amendments and will publish voting recommendations ahead of the EP's committee votes, which are scheduled for the end of June. CPME Secretariat is also liaising with health attachés to understand the Member States' positions. This will be pursued over the coming weeks.

#### **CED-CPME-PGEU Consensus Framework on Digital Transformation of Healthcare**

*The Executive Committee proposed minor amendments to clauses 1.4, 3.3 and 4.5 of the draft consensus framework ([CPME 2021/042 REV2](#)) and was supportive of suggestions by the European Patients' Forum ([EPF](#)) on patient empowerment and digital equity.*

The Consensus Framework addresses 4 areas: digital health, health data sharing, online provision of medicines and telemedicine. The EC agreed to delegate the final approval to the CPME President Prof. Montgomery and Vice-President Dr Walley, unless it involved substantial changes. If the latter, the document would need to be resubmitted for EC approval.

#### **MHE's Mental Health Advocacy Platform**

*The Executive Committee decided that CPME can join the new Mental Health Advocacy Platform established by [Mental Health Europe](#) to advocate for a European mental health strategy or an action plan.*

Currently, the EU does not have a plan for an integrated approach to address mental health. The Platform aims to gather various stakeholders.

#### **International calendar**

*The Executive Committee considered the International calendar.*

## Monitoring

### Agreement on the Digital COVID Certificate

On 10 May, the European Parliament and the Council reached an agreement on the Commission's proposal for a regulation governing the EU Digital COVID Certificate (previously called the Digital Green Certificate). This means that the certificate should be ready by the end of June, as planned. The regulation should enter into force on 1 July, with a phasing-in period of six weeks for the issuing of certificates for those Member States that need additional time. Please find more [here](#).

### EU digital COVID Certificate goes live with 7 countries

On 1 June, seven EU Member States – Bulgaria, the Czech Republic, Denmark, Germany, Greece, Croatia and Poland – have connected to the technical gateway and started issuing first EU certificates. Certain countries have decided to launch the EU Digital COVID Certificate only when all functions are deployed nationwide. The Regulation will apply from 1 July. An updated overview with a map is available on a dedicated Commission [webpage](#).

SAVE THE DATE - EFMA Virtual Meeting  
Should the Covid-19 Vaccination be Mandatory?  
24th June 2021, 10h00 – 12h00 CEST

## SHOULD THE COVID-19 VACCINATION BE MANDATORY?

**24<sup>TH</sup> JUNE 2021**

**Time: 10:00 am - 12:00 noon CEST**

- Welcome and Opening
- General overview of the current situation in Europe
- Question - Should the Covid-19 Vaccination be Mandatory?
- Poll of all participants
- Arguments in favour of Mandatory Vaccination
- Arguments against Mandatory Vaccination
- Open Discussion
- Wrap-up for and against
- Poll of all participants
- Conclusions

Updated agenda and technical details will follow soon.

## New Report on the Application of the Tobacco Products Directive

On 20 May, the European Commission published a [report](#) on the application of Tobacco Products Directive (TPD). The report reveals that the Commission found deficiencies in the transposition of the Directive particularly with provisions related to certain definitions, ingredients and emissions, and e-cigarettes. The report concludes that the TPD has provided added value and contributed to the improvement of public health.

## Zero pollution action plan

On 12 May 2021, the European Commission adopted the EU Action Plan "[Towards a Zero Pollution for Air, Water and Soil](#)" which is a key deliverable of the European Green Deal. It sets out an integrated vision for 2050 when pollution should be reduced to levels that are no longer harmful to human health and natural ecosystems. The plan considers relevant EU policies to tackle and prevent pollution. As part of the plan, the EU will review relevant legislation to identify remaining gaps. As CPME has called, in 2022 the Commission will propose the EU's air quality standards to be aligned more closely with the WHO recommendations which will be updated later in 2021.

## Commission consults on Digital Principles

On 12 May, as a follow-up to the [Digital Decade](#) Communication of 9 March, the Commission published a roadmap and launched a [public consultation on a set of European Digital Principles](#) to promote and uphold EU values in the digital space. The Commission wants to produce a joint interinstitutional solemn declaration of the Commission, European Parliament and the Council by the end of 2021. The objective of these principles is to define the 'European way' in the digital society, guiding the EU and Member States when designing digital rules and regulations. The public consultation is open until 2 September. The CPME Secretariat is analysing the documents and will propose a draft response for discussion in the eHealth WG. It can be a good opportunity to promote the right for a "clean data slate" at the age of 18 which CPME advocated in the [CPME Policy on the European health Data Space](#) and also to defend the need for IT professionals to abide to ethically-based codes of conducts and be subject to regulatory oversight and sanctions ([CPME response to the EU Data Strategy](#)).

## PGEU Position Paper on the Lesson learned from the COVID-19 pandemic

The Pharmaceutical Group of the European Union (PGEU) has published an [overview of community pharmacists' experience during the pandemic](#), highlighting i.a. how pharmacists' scope of practice was extended and adapted to for example administering vaccines, adapting the packet size of medicines dispensed to reduce repeat visits and offering testing services.

## Commission Published Draft Regulations on AI

On April 21, 2021, the EU Commission presented the much expected [proposal for a Regulation on Artificial Intelligence](#) (Artificial Intelligence Act; AIA), which will be complemented by a new [Coordinated Plan 2021](#). The latter outlines the policy changes and investment at Member States level to strengthen Europe's position in the development of human-centric, sustainable, secure, inclusive and trustworthy AI. Moreover, the Commission presented a [Proposal for a Regulation on machinery products](#), a [Communication on fostering a European Approach for AI](#), [an impact assessment](#) and a [study supporting the impact assessment](#). In the AIA proposal, the EU Commission follows a risk-based approach, with four levels:

- 1) **Unacceptable risk** - AI systems considered a clear threat to the safety, livelihoods and rights of people will be banned. This includes AI systems or applications that manipulate human behaviour to circumvent users' free will (e.g. particularly young people) and systems that allow 'social scoring' by governments.
- 2) **High risk AI systems** - critical infrastructures (e.g. transport) that could put the life and health of citizens at risk; educational or vocational training, that may determine the access to education and professional course of someone's life (e.g. scoring of exams); safety components of products (e.g. AI application in robot-assisted surgery); employment, workers management and access to self-employment (e.g. CV-sorting software for recruitment procedures); essential private and public services (e.g. credit scoring denying citizens opportunity to obtain a loan); law enforcement that may interfere with people's fundamental rights; migration, asylum and border control management (e.g. verification of authenticity of travel documents); administration of justice and democratic processes (e.g. applying the law to a concrete set of facts).

High-risk AI systems will be subject to strict obligations before they can be put on the market, e.g. risk assessment and mitigation systems, high quality datasets feeding the system, logging of activity to ensure traceability of results, detailed documentation providing all information necessary on the system and its purpose for authorities to assess its compliance, clear and adequate information to the user, human oversight measures; high level of robustness, security and accuracy. All remote biometric identification systems are considered high risk and subject to strict requirements. Their live use in publicly accessible spaces for law enforcement purposes is strictly defined and subjected to authorisation by a judicial or other independent body and to appropriate limits in time, geographic reach and the data bases searched.

- 3) **Limited risk**, where specific transparency obligations will be required (e.g. chatbots - users should be aware that they are interacting with a machine).
- 4) **Minimal risk**: the vast majority of AI systems fall into this category and there is no intervention in this regard. These AI systems only represent minimal or no risk for citizens' rights or safety.

In terms of governance, the Commission proposes that national competent market surveillance authorities supervise the new rules, while the creation of a European Artificial Intelligence Board will facilitate their implementation, as well as drive the development of standards for AI. Additionally, voluntary codes of conduct are proposed for non-high-risk AI, as well as regulatory

sandboxes to facilitate responsible innovation. CPME Secretariat is analysing the legislative proposal and it will be discussed at the next eHealth WG meeting. Special attention will be given to the definition of AI, the high-risk AI classification rules and the obligations for users (where Doctors fit into this category). The CPME Secretariat has also contacted the CPME rapporteur on AI, Prof. Dr. Christian Lovis for further insights.

The Commission is requesting feedback by 22 July 2021.

### Consultation on European Health Data Space launched

The European Commission has also launched the public consultation on the European Health Data Space (deadline 26 July 2021). It focusses on 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 will prepare a response to the public consultation which will be discussed in the eHealth WG

### EMA consultation on naming of COVID-19 vaccine variants

EMA published a consultation on the naming proposals for COVID-19 variant vaccine qualifiers in order to identify potential issues at the level of prescribing, dispensing and general understanding that would prevent the safe and optimal use of these products. Please see more details [here](#). The feedback should be provided by midday on Friday, 11 June 2021. Please send the completed [form](#) directly to [HCPsecretariat@ema.europa.eu](mailto:HCPsecretariat@ema.europa.eu) or to [secretariat@cpme.eu](mailto:secretariat@cpme.eu) and we will forward it to EMA.

### 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 availability of data may generate benefits. It may also bring 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 issues explained in the EDPB-EDPS Joint Opinion on the DGA of March 2021. It should be avoided that the DGA creates a parallel set of rules, not consistent with the GDPR, as well as with other Union law resulting in insufficient safeguards for individuals and difficulties in the practical application.

## CPME News

### CPME social media

Follow us on:

[Twitter](#)

[Facebook](#)

[LinkedIn](#)

### NMA survey on triage protocols in context of COVID-19

The CPME WG on Medical Ethics and COVID-19 invites CPME members to participate in the survey on national approaches to triage protocols in the context of the COVID-19 pandemic. Please find the questionnaire [here](#). We would be grateful if you could send your reply by 23 June. In case of questions, please do not hesitate to contact [sarada.das@cpme.eu](mailto:sarada.das@cpme.eu). We thank you in advance for your participation.

### 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/2S53lxi>

## Recent publications on the CPME Website

### Members' section:

[Terms of Reference – CPME WG on Medical Ethics and COVID-19 REVISED](#)

[DG SANTE / DG RTD / HaDEA Webinar: improving vaccination uptake among disadvantaged and difficult-to-reach population groups](#)

[WHO Regional Consultation on Climate and Health](#)

[Report on Conference on Mental Health and the COVID-19 Pandemic: “Living, caring, acting!”](#)

[Report on Smoke Free Partnership Coalition call on tobacco taxation](#)

[DRAFT Overview of national triage protocols on COVID-19](#)

[EMA advises against use of ivermectin for the prevention or treatment of COVID-19 outside randomised clinical trials](#)

[ECDC data on COVID-19 vaccine doses distributed by the manufacturers to EU /EEA countries by vaccine product](#)

[Report on exchange of views between ECDC Director Andrea Ammon and ENVI Committee – 16 March 2021](#)

[Report on ITRE Meeting on Data Governance Act – 13 April 2021](#)

[Report on ENVI Committee Hearing on Regulation on Serious Cross Border Threats to Health – 22 April 2021](#)

[CPME comments to ISO-IEC-CEN-CENELEC standard health-wellness apps, April 2021](#)

[CPME Monthly Bulletin – April 2021](#)

[ISO-TC215 N3535 DTS 82304-2 Health and wellness apps – Quality and reliability, March 2021](#)

[eHealth Network Draft Guideline on the electronic exchange of health data under Cross-Border Directive 2011/24/EU, March 2021](#)

[CPME response InteropEHRate Project approach, online questionnaire, 19 April 2021](#)

[CPME contribution to the public consultation on Shaping EU Interoperability Policy, 15 April 2021](#)

### CPME news section:

[“Is the future bright for Telemedicine – European Doctors’ Talk Digital”](#)

[CPME Statement on the Digital Green Certificate](#)

[IMMUNION: Promoting vaccination uptake across the EU](#)

[CPME Response to the Public Consultation on the Green Paper on Ageing](#)

[CPME contribution to the public consultation on “Shaping Future Public Sector Interoperability Policy”](#)