CPME MONTHLY BULLETIN

STANDING COMMITTEE OF EUROPEAN DOCTORS

DES MÉDECINS EUROPÉENS

Stay in the Loop!

March 2021

COMITÉ PERMANENT



Dear colleagues,

We are pleased to share with you the latest edition of the CPME Monthly Bulletin presenting the outcomes of the Executive Committee meeting held on 18 March 2021 and some of the latest monitoring news in EU health policy.

I would like to thank everyone for your active participation in our Board Meeting and General Assembly held on 19 and 20 March 2021. We invite you to refer to <u>this press release</u> for some of the main meeting outcomes.

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

Kind regards – stay healthy!

Prof. Dr Frank Ulrich Montgomery CPME President

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Executive Committee meeting – 18 February 2021

Internal Affairs

Revised CPME rebranding following EC 18 February 2021

The Executive Committee discussed the revised logo concept.

Different viewpoints were discussed. It was decided that the logo concepts were to be put to the CPME Board for discussion, but no decision need be taken at the Board meeting.

Virtual General Assembly

The Executive Committee took note of the CPME meetings' agendas.

Finances

Website redesign following CPME rebranding

The Executive Committee approved the offer presented for the redesign of the CPME website and recommended the General Assembly to revise the budget 2021 accordingly.

During the EC meeting held on 18 February, the CPME secretariat was tasked to get an offer from the designer Paulo José de Oliveira to redesign the CPME website, as a consequence of the CPME rebranding.

Any other Business

ECDC Advisory Forum

The Executive Committee decided to recommend Dr Ole Johan Bakke as a candidate to the Advisory Forum of the <u>European Centre for Disease Prevention and Control</u> (ECDC).

The European Commission has launched a <u>selection procedure</u> to appoint representatives of non-governmental organisations to the Forum, including one health professional representative. The deadline for submission of applications is 16 April 2021, and the new three-year-mandate starts on 11 July 2021. Previously, CPME was represented in the ECDC Advisory Forum in 2004-2016.

Monitoring

Commission proposes a digital COVID-19 certificate

On 17 March, the European Commission proposed to create a <u>Digital Green Certificate</u> to facilitate safe free movement inside the EU during the COVID-19 pandemic. This certificate would be a proof that a person has been vaccinated against COVID-19, received a negative test result or recovered from COVID-19. It would be available for free in digital or paper format, and include a QR code to ensure security and authenticity. The Commission will build a gateway to ensure that certificates can be verified and support Member States in the technical implementation. Member States would remain responsible to decide which public health restrictions can be waived for travellers but will have to apply such waivers in the same way to travellers holding a Digital Green Certificate. The proposal needs to be adopted by the European Parliament and the Council in order to be ready before the summer.

Conference on the future of Europe to launch on 9 May

On 10 March, Commission President Ursula von der Leyen, EU Parliament President David Sassoli and Portuguese Prime Minister Antonio Costa finally signed the <u>Joint Declaration on the Future</u> <u>of Europe Conference</u>. It is intended to set up a hybrid format of inter-institutional negotiations and citizen-level consultation. The EU-wide conference will begin on Europe Day, 9 May, and will give citizens the opportunity to express their expectations of European politics until spring 2022. It will address issues included in the Commission's policy priorities and the European Council's strategic agenda, including climate change, the digital transformation and social fairness. It is also open to citizens to raise additional relevant issues. In addition to a multilingual digital platform, there will be physical events in all EU countries as soon as the pandemic situation allows again. The conference is co-chaired by the three institutions. An Executive Committee will be formed shortly, representing the three institutions equally, to oversee the work of the conference and prepare its plenary sessions. National parliaments will be granted observer status. More information can be found <u>here</u>.

Stricter rules to protect workers by reducing exposure to carcinogens

On 25 March, the European Parliament's Committee on Employment and Social Affairs (EMPL) voted for stricter EU rules to better protect workers from exposure to carcinogens, mutagens and reprotoxic agents at work. Since autumn, CPME has participated in the <u>Stop Cancer at Work</u> <u>campaign</u> which has called on the European Commission to take action to protect workers, including healthcare professionals. In the healthcare sector alone, 12.7 million workers in Europe are exposed to hazardous medicinal products at work. The Carcinogens and Mutagens Directive will be now revised for the fourth time on the basis of new scientific and technical developments.

MEPs support strengthening the EU air quality standards

On 25 March, the European Parliament voted for updating the EU air quality standards and aligning them with WHO guidelines and the latest scientific evidence, as also CPME has advised to do in its 2019 policy on air quality and health. The MEPs voted on the Javi López (ES / S&D) report on the implementation of the Ambient Air Quality Directives (AAQD) which sends a strong signal to the European Commission how seriously the Parliament takes the issue of air quality. CPME and other health and environmental NGOs sent a joint letter to MEPs ahead of the plenary.

Call for Abstracts for the EHMA 2021 Annual Conference

EHMA launches the <u>EHMA 2021 Call for Abstracts</u> and invites all interested stakeholders to submit their cutting-edge research on health management.

"We welcome abstracts addressing the conference theme 'Health Management: managing the present and shaping the future' and one or more of the following sub-themes:

- Governance and leadership
- Person-centeredness and care integration
- Managing the digital transformation
- Improving healthcare access and outcomes
- Environmental sustainability of health services
- Health workforce

Participate in the EHMA 2021 Annual Conference by sharing your research with the full health management ecosystem. Highlight best practices and share innovative ideas and knowledge on health management with leading experts in the field. Your research will be fundamental to identify, discuss and address current and future needs of health management in Europe and worldwide.

Abstracts may be submitted for either:

- Oral presentation
- Poster
- Karolinska MMC/EHMA Research Award (PhD Award)

All abstracts must be submitted by Monday, 3 May 2021 at 9 AM CEST. Please <u>read carefully the submission guidelines</u>. If you have any questions, please contact <u>chiara.gonzi@ehma.org</u>

Do not miss the opportunity to take part in the preeminent European conference on health management and share this exciting news with your colleagues and network! We look forward to seeing you at EHMA 2021! "

Please submit your abstract <u>here</u>.

EDPS comments on the European Health Union Package

On 18 March, the EDPS published its <u>formal comments</u> to the 3 draft proposals for regulation for a European Health Union. Several recommendations from the EDPS are already reflected in CPME position papers (please see <u>here</u>). In brief, the EDPS welcomes the unified approach to tackle cross-border health threats while respecting the role and competences of EU member states national health system.

Comments on the a regulation for serious **cross-border threats to health**:

- a data protection impact assessment (DPIA) should be made prior to deploying the use of surveillance systems and AI, via the digital platform (Article 14), and for the Early Warning and Response System (EWRS) (Article 18);
- an additional implementing or delegated act specifying the roles of the actors involved in the processing of personal data is required;
- transfers of personal data to 3rd countries and international organisations (WHO) need to comply with Chapter V of the Regulation 2018/1725 and the ECJ case law (e.g. Schrems II).

Comments on the amending regulation establishing the ECDC:

- the categories of individuals who will have their personal data processed, the categories of personal data and the safeguards applied to protect the rights and freedoms of the individuals (e.g. prevent abuse or unlawful access or transfer and storage periods), should be clearly indicated in the regulation;
- the tasks that will entail processing of personal data under the ECDC's new remit (from epidemiological to coordination and cooperation tasks) should be clearly indicated;
- the use of anonymous data should be the norm, and when not possible, use pseudonymous data;
- again recommends clear identification of the main actors involved in the processing of personal data, defining the controller, the processor and joint processor. The ECDC should not be seen as a processor;
- the principle of purpose limitation is not being complied with in relation to the processing of health data. Article 6(3)and Article 11(2)(d) should be further specific;
- again refers that a DPIA needs to be conducted prior to the deployment of the epidemiological surveillance platform, as it represent a high risks for the rights and freedoms of individuals.

Comments on the regulation extending EMA's mandate:

- the EDPS recommends that specific provisions on the application of data protection law are included in the proposal;
- the role of entities when processing electronic health data outside of clinical studies must be covered in the proposal;
- o a clear definition of data generated outside the scope of clinical trials should be included.

DG SANTE discusses potential of EU4Health programme

On 24 March, the European Commission held an online workshop to discuss the EU4Health programme to collect stakeholder feedback on the four strands of the programme, disease prevention, the European Health Data Space (EHDS), crisis preparedness and health systems. CPME contribute to the discussion on digital health. Presentations and web streaming will be available <u>here.</u>

Council finally agrees its negotiating position on joint HTA

Member states agreed on a mandate to start trilogue on joint health technology assessment. The proposal has been stuck in the Council for years and most recently, a stumbling block in discussions concerned the approval process for joint clinical assessments. Finally, on 24 March, EU countries agreed that whenever possible, the coordination group will act by consensus but when it falls short, majority voting will apply, with each member country having one vote. When a vote takes place, members can ask for "divergent opinions to be recorded." Member countries that perform their own national assessments of health technologies will have to "give due consideration" to joint clinical assessments, at least including them in the documentation of their own national-level assessments. The Council also proposes that countries ultimately "remain responsible for drawing conclusions at national level on the clinical added value of a health technology," and these will depend on the "specific health care context." The Council position also stresses that companies developing medical technologies will have to submit data at the European level only once, without having to make repeat submissions throughout the bloc. If member countries decide they need more information, however, they may perform additional assessments and ask companies to submit more details about their products. The negotiations with the Commission and European Parliament will start in the coming weeks.

EP committee on AI to continue until March 2022

The European Parliament has extended the lifetime of the temporary committee on AI by 6 months till March 2022. The committee was <u>mandated</u> to ensure coherence of policies and explore impact i.a. on economic growth, health, education, environment, and transport.

Together for a Healthier and Greener future

Healthcare Without Harm Europe has launched a new network "Doctors for Greener Healthcare". This new network aims to bring doctors from across Europe to collaborate and share best practice with a view to reducing the impact of healthcare on the environment. Members will receive regular updates and sustainable healthcare news and join an international network of like-minded professionals. Find out more <u>here</u>.

Data Governance Act (DGA)

On 10 Marc, the European Data Protection Supervisor and the European Data Protection Board adopted a joint opinion on the Data Governance Act. The EDPB and the EDPS acknowledge the legitimate objective of the DGA to improve the conditions for data sharing in the internal market, and invite the co-legislators to ensure that the future DGA is fully in line with the EU personal data protection legislation. In particular, the DGA should ensure consistency with the GDPR with regard to the competence of the supervisory authorities, the roles of the different actors involved, the legal basis for the processing of personal data, the necessary safeguards and the exercise of the rights of the data subjects. The proposal should also clarify that the reuse of personal data held by public sector bodies may only be allowed if based in EU or Member State law. Such laws should include a list of clear compatible purposes for which further processing may be lawfully authorised or constitutes a necessary and proportionate measure in a democratic society to safeguard the objectives referred to in Article 23 of the GDPR (e.g. public health, public security, etc.). On data sharing service providers, the opinion highlights the need to ensure prior information and controls for individuals, taking into account the principles of data protection by design and by default, transparency and purpose limitation. Moreover, the modalities upon which such service providers would effectively assist individuals in exercising their rights as data subjects should be clarified. On data altruism, the DGA should better define the purposes of such general interest and it should be organised in a way that it allows individuals to easily give, but also, withdraw their consent. The opinion also recommends the adherence to a code of conduct or certification mechanism by data sharing service providers or data altruism organisations. Background info: The DGA aims to foster the availability of data by increasing trust in data intermediaries (providers of data sharing services) and by strengthening data-sharing mechanisms across the EU. The DGA intends to promote the availability of public sector data for reuse, sharing of data among businesses and allowing personal data to be used with the help of a 'personal data-sharing intermediary'. The DGA also seeks to enable the use of data for altruistic purposes.

Council adopts conclusions on the EU's cybersecurity strategy

On 22 March, the Council adopted conclusions on the EU's cybersecurity strategy for the digital decade. The conclusions note that cybersecurity is essential for building a resilient, green and digital Europe, highlighting a number of areas for action in the coming years. Among other:

- plans to create a network of security operation centres across the EU to monitor and anticipate signals of attacks on networks;
- the need for a joint effort to accelerate the uptake of **key internet security standards**, as they are instrumental to increase the overall level of security and openness of the global internet;
- the need to support the **development of strong encryption** as a means of protecting fundamental rights and digital security, while at the same time ensuring the ability of law enforcement and judicial authorities to exercise their powers both online and offline;
- the proposal on the possible establishment of a cyber intelligence working group to strengthen EU INTCEN's dedicated capacity in this domain.

The Council encourages the Commission and the High Representative to establish a detailed implementation plan, and it will monitor its progress regularly with an action plan (further information please see <u>here</u>).

EPDS opinion on Cybersecurity strategy and NIS 2.0 Directive

On 12 March, the European Data Protection Supervisor adopted an <u>Opinion on the</u> <u>Cybersecurity Strategy and the NIS 2.0 Directive</u>. The EDPS welcomes the <u>Proposal for the NIS</u> <u>2.0 Directive</u>, which aims to harmonise and strengthen cybersecurity practices across the EU. The Proposal is part of the <u>EU's Cybersecurity Strategy</u> to ensure a global and open internet with strong safeguards to mitigate the risks for individuals' fundamental rights, including the right to data protection. The EDPS strongly supports the initiative to achieve technological sovereignty and stresses that the use of encryption, in particular end-to-end encryption, is crucial. Any weakening or circumvention of encryption (e.g. using mandatory backdoors, mandatory key escrow, and hidden communication channels) would devoid the mechanism of any effective protection capability and result in a loss of trust. The proposed Directive should clarify that nothing in the proposal should be construed as an endorsement of weakening endto-end encryption through "backdoors" or similar solutions.

The Council of Europe collects mental health care examples

The Committee on Bioethics (DH-BIO) of the Council of Europe has prolonged their mapping exercise to collect examples of practices to promote voluntary measures in mental health care. You can participate until 31 May 2021 by submitting examples from your country <u>here</u>.

CPME News

CPME social media

Follow us on: <u>Twitter</u> <u>Facebook</u> <u>LinkedIn</u>

SEPEN outcomes published

Following the conclusion of the SEPEN joint action in December, the <u>Mapping of national health</u> <u>workforce planning and policies</u> has finally been published. The mapping and all other outcomes including reports on workshops and webinars are available at <u>www.healthworkforce.eu</u>.

CPME Board Meeting and General Assembly

The main conclusions from our Board Meeting and General Assembly can be found in the press release, accessible <u>here</u>.

The working groups met on 19 March 2021, in preparation for this meeting.

Prof. Heidi Larson, Founding Director of the Vaccine Confidence Project presented the key findings of the <u>2020 State of Vaccine Confidence in the EU+UK report</u> in the CPME Public Health and Disease Prevention Session. The report was published by the European Commission and the Vaccine Confidence Project of the London School of Hygiene & Tropical Medicine in December 2020.

Ms Caroline Hager from the European Commission presented the forthcoming evaluation of Patients' Rights in Cross-Border Healthcare in the CPME Professional Practice and Patients' right Session. The presentation is accessible <u>here</u>.

Mr Markus Kalliola, Project Director from Sitra, presented TEHDAS in the CPME eHealth Session, the presentation of which is available <u>here</u>. On 20 March 2021, CPME submitted the application for the Joint Action on TEHDAS.

CPME Working Group on medical ethics and COVID-19

CPME invites all interested members to join a new WG on medical ethics and COVID-19, looking at e.g. triage protocols. Please email <u>sarada.das@cpme.eu</u> by 02.04.2021 if you are interested in joining.

DG SANTE discusses potential of EU4Health programme

On 24 March, the European Commission held an online workshop to discuss the EU4Health programme to collect stakeholder feedback on the four strands of the programme, disease prevention, the European Health Data Space (EHDS), crisis preparedness and health systems. CPME contributed to the discussion on digital health. Presentations and web streaming are available <u>here.</u>

Recent publications on the CPME Website

Members' section:

Markus Kalliola Presentation TEHDAS eHealth Session, online, 19 March 2021 CPME Form call for stakeholders Joint Action TEHDAS, 20 March 2021 Presentation on the evaluation of Patients' Rights in Cross-Border Healthcare, 19 March 2021 Joint Letter to MEPs on Air Quality CPME Policy on European Health Data Space – Focus on Health Research and Policy Making CPME Position on the Commission's Proposal for a Regulation amending Regulation (EC) No 851/2004 establishing a European Centre for disease prevention and control CPME Position Paper on the proposal for extending the EMA mandate Letter of nomination for new Board member and Head of delegation representing Medical Chamber of Slovenia, March 2021 National report from the Panhellenic Medical Association, March 2021 National report from the Dutch Medical Association, March 2021 CPME WG Refugee Health – Summary of WG activities Draft agenda of the special session on National Reports – March 2021 European Association of Senior Hospital Physicians (AEMH) – Activity Report March 2021 National Report from the British Medical Association, March 2021 National Report from the Israeli Medical Association, March 2021 Minutes of the annual Coalition for Vaccination meeting – 11 March 2021 CPME brand strategy Report on ENVI Committee Meeting on presentation of new cross-border threats to health regulation and strengthening the mandate of the ECDC **Background note on HERA** Concept note on the One Health webinar CPME Members' Briefing on the EU competences in public health DRAFT Minutes of the CPME WG Pharma, online, 16 February 2021 DRAFT Minutes of the CPME Session on Pharmaceuticals and Healthcare Products, online, 20 November 2020 DRAFT CPME Position Paper on the Pharma Strategy REV3 DRAFT Agenda of the CPME Session on Pharmaceuticals and Healthcare Products, online, 19 March 2021 CPME Position Paper on the Regulation extending the EMA mandate Report of CPME President 01 November 2020 - 10 March 2021 Draft CPME position on a Proposal for Regulation on ECDC mandate Draft CPME Position on Proposal for Regulation serious cross border threats to health President's Report November 2020 – March 2021 Draft CPME Policy on Telemedicine European Union of medicine in Assurance and Social Security (EUMASS) - Activity Report to CPME General Assembly, 20 March 2021 AIDA Working Paper, Hearing on AI and Health, online, 2 December 2020 Reply from Commissioner for Home Affairs Ylva Johansson to CPME Open letter on resettlement of refugees from moria, September /December 2020

Report on web-meeting with DG SANTE unit on "Performance of national health systems" with Ms Maya Matthews, 19 January 2021 Report on web-meeting with DG SANTE unit on "Cross border healthcare and tobacco control" with Ms Caroline Hager, 29 January 2021 Minutes first plenary meeting eHealth Stakeholders Group, online, 13 July 2020 Draft Work Programme, eHealth Stakeholders Group 2021 CPME presentation on EHDS, eHSG webinar, 1 February 2021 Webinar Agenda on EHDS, eHealth Stakeholders Group, online, 1 February 2021 Slides eHealth Stakeholders Group Plenary Meeting online, 4 December 2020 Poll results webinar mHealth, eHealth Stakeholders Group meeting, online, 29 January 2021 Minutes meeting DG SANTE – Digital Health Study, online, 25 January 2021 Webinar on mHealth – eHealth Stakeholders Group presentations, online, 29 January 2021 WG eHealth Priorities – 2021 Draft minutes eHealth WG meeting, online, 5 March 2021 Draft CPME Statement on Shaping the Healthcare Sector Interoperability Policy Form for Joint Action TEHDAS Open call for Stakeholders Joint Action TEHDAS open call for stakeholders – forums and groups Commission's presentation on serious cross-border threats to health regulation proposal Policy Evaluation Network report: The Healthy Food Environment Policy Index (Food-EPI) Report on the Launch of the European Climate and Health Observatory March 4th 2021 Letters from internal and external auditor, February / March 2021 Draft CPME Policy on Telemedicine Draft CPME Policy on Telemedicine Report on the Pact for skills roundtable 16 February 2021 CPME Monthly Bulletin February 2021

CPME news section:

New CPME positions on Commission's Proposals

<u>New CPME Policy on the European Health Data Space – Focus on Health Research and Policy</u> Making

New CPME Policy on Telemedicine

Outcomes of the CPME General Assembly and Board virtual meetings, 20 march 2021

CPME Position on the Commission's Proposal for a regulation amending Regulation (EC) No

851/2004 establishing a European Centre for disease prevention and control

Welcome to the 34th edition of the CPME Newsletter!

<u>CPME endorses Joint Statement to maintain the exchange of critical health data with UK</u> <u>European doctors commemorate health professionals who have lost their live to COVID-19</u>