

### **CPME MONTHLY BULLETIN**

## Stay in the Loop!



July 2020

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 09 July 2020.

The CPME Executive Committee discussed several items, including the organisation of a European memorial to doctors fallen in the fight against COVID-19 and the proposal by the Federation of European Academies of Medicine (FEAM) to become a Forum partner.

We invite you to check the section on Covid-19 on our website, in particular the national reports which are published here: <a href="https://www.cpme.eu/covid-19-section/national-updates/">https://www.cpme.eu/covid-19-section/national-updates/</a>

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 – 09 July 2020

#### Internal affairs

#### Requests to join European projects/tenders

The Executive Committee decided to keep and follow the process comparable to <u>Annex 3</u> of the CPME Rules of Procedures dealing with endorsement requests.

#### European memorial to doctors fallen in the fight against COVID-19

The Executive Committee welcomed the CPME-FNOMCeO joint initiative for a European memorial to doctors fallen in the fight against COVID-19.

The CPME President Prof. Dr Montgomery reported about his virtual meeting with the President of the Italian Federation of the Orders of Doctors and Dentists (FNOMCeO) Dr Anelli on 8 July 2020. They discussed about the idea to organise a memorial event in February 2021. The CPME President offered to prepare a commemorating plaque to be posted at the Codogno Hospital, the most hit hospital during the COVID-19 pandemic in Italy. FNOMCeO offered to be in charge of the ceremonial logistics. In the coming weeks the CPME and FNOMCeO Secretariats will draft a concept which will be presented to the Executive Committee. Prof. Montgomery and Dr Anelli agreed to meet in Rome in October to discuss and finalise the organisation.

#### **Policies**

#### Proposal by the Federation of European Academies of Medicine (FEAM)

The Executive Committee decided to apply becoming a <u>FEAM Forum Partner</u> provided the fee doesn't exceed 1000 EUR.

This partnership allows for in-depth discussions of topics also on CPME's policy agenda. The Forum will not publish its own position statements or any formal recommendations, i.e. CPME does not endorse anything while getting engaged. Given the credibility of FEAM events, active Forum participation might lift the CPME profile in policy development.

#### EU-OSHA Healthy Workplaces Campaign 2020-2022

The Executive Committee decided to renew its partnership for the next <u>Healthy Workplaces</u> <u>campaign</u> of the European Agency for Safety and Health at Work (<u>EU-OSHA</u>).

The objective of the Healthy Workplaces campaigns is to raise awareness on safety and health at work by providing free practical guides to companies and associations. In particular, the 2020-22 campaign will focus on tackling work-related musculoskeletal disorders, one of the most prevalent type of work-related health problem in Europe. It will take a comprehensive view of the causes of this persistent problem and aim to disseminate high-quality information on the subject, encourages an integrated approach to managing the problem, and offers practical tools and solutions that can help at workplace level.

CPME has been a member of the Healthy Workplaces partnership since 2011.

#### **CPME Roundtable Meeting for Doctor MEPs**

The Executive Committee took note of the roundtable meetings CPME is planning to organise for doctor MEPs.

CPME organised similar roundtable meetings for doctor MEPs in 2015. MEP Manuel Pizarro (S&D/PT) has already expressed his interest in co-chairing such meetings. These meetings would be organised by CPME in cooperation with the offices of the hosting MEPs. Currently, there are

24 MEPs with a medical degree. The topics would follow the European Parliament's agenda and CPME's own priorities. Preferably, 2-3 actual topics (e.g. COVID-19, MFF) could be discussed per meeting.

#### **Coalition for Vaccination**

The Executive Committee took note of the developments of the project proposal CPME together with the other Coalition for Vaccination co-chairs are preparing.

<u>EuroHealthNet</u> has been chosen to coordinate the project which would aim at creating a central website for healthcare professionals and students on vaccination training and information. The deadline for submission is 6 August 2020.

#### Outcome-based healthcare

The Executive Committee decided to postpone the agenda item to the next in person meeting in September also allowing for a reflection about the <u>EPF position on the same matter</u>.

#### WHO-Europe European Programme of Work 2020-2025

The Executive Committee adopted the CPME response to the consultation on the WHO-Europe European Programme of Work 2020-2025.

CPME President reported about his intervention at WHO-Europe where Non-State actors shared views on WHO/Europe's forthcoming European Programme of Work. The webinar was held on 26 June 2020 and hosted by WHO-Europe Regional Director Dr Hans Kluge. CPME's invitation to speak at the event as representation of the medical profession can considered to be a positive sign of WHO-Europe's intentions to engage with stakeholders more actively and will hopefully be followed by similar opportunities in future. The Executive Committee discussed the European Programme of Work in the context of overall WHO policy, agreeing that the commitments on universal health coverage remain very relevant even in the European region

## CPME draft response to Digital Doc Thematic Network Survey on Challenges, Recommendations and Best Practices

The Executive Committee adopted the <u>draft response</u> to Digital Doc Thematic Network Survey on Challenges, Recommendations and Best Practices as recommended by the CPME Working Group on eHealth on 2 July 2020, with the additional comments provided by Prof. Dr Sebastian Kuhn on 7 July 2020.

CPME's response will feed in the work of the Digital Doc Network whose final objective is drafting a Joint Statement that builds up on the <u>Rotterdam principles</u> and proposes a new set of recommendations for action on the following:

- advance digital knowledge, skills and competences as a new core component of training for future and current doctors;
- promote innovative structures and networks to create diversity in digital skills training for medical doctors;
- embed in co-creation training for doctors in institutional digitalisation strategies and policies; and,
- increase interoperability and mobility for medical students, doctors, patients and data. The Network also intends to collect and share best practices of policy and support mechanisms that help implementing digital knowledge, skills and competences in medical education.

Further webinars are expected to discuss and develop the Joint Statement and a physical meeting in the second half of the year is being planned in conjunction with the German Presidency of the Council of the EU.

## CPME response to the EU Health Support Consortium on Stakeholders Survey Assessing Member States' Rules on Health Data in light of the GDPR EC 2020/042

The Executive Committee adopted the <u>draft response</u> to the <u>EU Health Support Consortium</u> on Stakeholders Survey Assessing Member States' Rules on Health Data in light of the GDPR, as recommended by the CPME Working Group on eHealth on 2 July 2020, with the additional comments provided by the Norwegian Medical Association on 3 July 2020.

CPME's response will feed into the work of the Consortium which has been tasked by CHAFEA (executive agency of the EU which manages the Health Programme) and DG SANTE to conduct a study examining Member States' rules governing the processing of health data, highlighting possible differences and identifying elements that might affect the cross-border exchange of health data in the EU. The final report initially foreseen for May, is now planned to be concluded by the end of July 2020.

The results of this Consortium will shape the discussions of the creation of the EU Health Data Space and also on possible governance structures at EU level on the secondary use of health data.

#### International calendar

The Executive Committee took note of the International calendar. Due to the Covid-19 outbreak, most of the upcoming meetings and conference have been cancelled or postponed.

### **Monitoring**

New Council conclusions on excise duty on manufactured tobacco and on future administrative cooperation

The Council of the EU has approved conclusions on <u>future administrative cooperation in the field of taxation in the EU</u> as well as <u>structure and rates of excise duty applied to manufactured tobacco</u>. While administrative cooperation helps national tax authorities collect and safeguard tax revenues, a close cooperation between these bodies is important to detect and reduce tax fraud. Highlighting that consumption of tobacco products remains one of the greatest avoidable and preventable health risks in the EU, the conclusions stress that the rules for indirect taxes have become less effective for certain products. As such, there is a need for harmonisation of definitions and tax treatment of novel products like liquids for e-cigarettes and heated tobacco products as well as for those substituting tobacco whether or not containing nicotine as to avoid legal uncertainty and regulatory disparities in the EU. Moreover, the conclusions note that illicit trade in raw tobacco together with tobacco products remains substantial and continues to constitute a source of concern. Thus, a system to control the movement of raw tobacco and tobacco products is necessary. Most importantly, better functioning of the internal market needs to be ensured together with the objectives of revenue, public health and public security.

#### Inception Impact Assessment: Legislative governance of common EU data spaces

On 3 July, the European Commission published an <u>Inception Impact Assessment</u> informing about its plans to propose a regulation for the governance of common European data spaces. The inception impact assessment is open for feedback until 31 July. An Impact Assessment is developed to prepare a policy initiative. It proposes measures

- to unlock more publicly held data for research serving the common good, where the use is conditional on the respect of rights of others (right to the protection of personal data, intellectual property rights, including trade secrets, and other commercially confidential data),
- to support voluntary data sharing by citizens ('data altruism') in compliance with EU data protection rules or companies voluntarily agree to use of non-personal data they hold;
- and to set up an EU-level governance structure to prioritise standardisation needs and improve data interoperability, lowering transaction costs resulting from technical barriers, but also from costs of establishing data sharing from a legal and technical perspective.

This initiative intends to further complete a single market for data. Some Member States have taken legislative action addressing the problems described above (for example France, Germany and Finland on facilitating re-use of public sector data), whereas others have not. The Commission also wishes to avoid fragmentation.

Final results are expected in August 2020. Further workshops will be organised on data platforms and consultations with stakeholders organised through the <u>Big Data Value Association</u> (industry-driven international not–for-profit organisation which is the private counterpart to the European Commission to implement the '<u>Big Data Value Public-Private Partnership Programme'</u>). Targeted dialogues with SMEs will be organised 2020, as well as sectoral events, allowing for interaction in specific areas, in particular health, industrial manufacturing, agriculture and law enforcement. Economic, social, environmental, fundamental rights, simplification and/or administrative burden impacts are expected. CPME is monitoring the evolution of the legislative framework and will continue to contribute to the overall debate.

#### EMA is looking for experts on the use of AI in clinical trials

The European Medicines Agency (<u>EMA</u>) is seeking to identify experts among patients and healthcare professional to share their experience with the use of AI in the medical field, particularly to discuss practical use cases and challenges validating AI tools. For that purpose, the Agency is organising a meeting "Artificial intelligence in clinical trials – ensuring it is fit for purpose" taking place on 22 September between 14.30-19.15 (CET).

It will include a discussion on the status of current and immediate future use of AI in clinical trials, use cases for the use of AI in clinical trials and the validation of AI in clinical research and other related fields, among others. Should anyone with the required expertise would like to join the meeting, please send the CPME Secretariat a short (no more than 150 words) CV indicating your expertise on the topics discussed. The final decision on participation will be made by the Agency's Inspections Office together with members of the GCP-IWG. The deadline for application is Thursday, 23 July 2020.

#### Adding COVID-19 to Directive on the protection of workers

The European Parliament's Employment and Social Affairs Committee (EMPL) agreed with the European Commission to classify SARS-CoV-2 as a risk group 3 biological agent, adding more safeguards to protect workers. EU member states must implement the Directive by 24 November 2020 and ensure that employers provide written instructions and display notices for all workers exposed to COVID-19. Risk group 3 biological agent means one that can cause severe human disease and present a serious hazard to workers. It may present a risk of spreading to the community, but there is usually effective prophylaxis or treatment available. Please find the new Directive here.

### Modelling the diffusion of COVID-19

On 30 June, the eHealth Network published a <u>report</u> on a common approach on the use of anonymised and aggregated mobility data for modelling the diffusion of COVID-19, and optimising the effectiveness of response measures, including confinement (and deconfinement), "stay at home recommendations", other social distancing measures or travel related recommendations. The report encourages the collection, harmonisation and sharing of epidemiological data from national websites at subnational level in order to effectively model the expected epidemic trend at European level. A minimum set of COVID-19 related data is suggested, including i) number of cases (see <u>case definition of ECDC</u>), ii) fatalities, iii) recovered cases, iv) hospitalised cases (both current number and new admission of COVID-19 confirmed cases), v) COVID-19 confirmed cases in ICU (both current number and new admission of COVID-19 confirmed cases), and vi) COVID-19 test performed per week.

The Network has also published a <u>progress report</u> on Member States development and implementation of the Commission Recommendation for a <u>'Common EU Toolbox on Mobile applications to support contact tracing in the EU's fight against COVID-19'</u>, published earlier this year.

# EMA is creating a pool of people who have had personal and confirmed experience with COVID-19

EMA is planning to create a pool of people with personal and confirmed experience with COVID-19, to be involved as patient/carer experts in the EMA information activities. Anyone with the above-mentioned experience willing to apply to participate in the pool, please contact the CPME Secretariat.

## Court rules that pharma companies are not allowed to supply free samples of prescription-only medicines to pharmacists

According to the European Court of Justice, Article 96(1) of the Community Code (Directive 2001/83/EC) must be interpreted as meaning that only persons entitled to prescribe medicinal products subject to medical prescription, "namely doctors", may receive free samples of such products. Pharmacists are, therefore, excluded from that right. Nevertheless, the court continuous, EU law does not prohibit the distribution to pharmacists of free samples of medicinal products for which a prescription is not required. The ECJ considered that in restricting the group of potential beneficiaries of free samples of prescription-only medicines, the Community Code had sought to deal with a potential danger inherent in such medicines. According to the ECJ, over-the-counter medicines do not present such a danger, and this would explain the possibility for pharmacists to receive samples of such medicines. The judgment was made in a response to the request submitted by the German Federal Court of Justice related to a case in which Novartis asks the German courts to prohibit the generic manufacturer ratiopharm from distributing free samples of the medicinal product to pharmacists claiming that such distribution is contrary to German law on medicinal products.

## Commission launches European Skills Agenda for sustainable competitiveness, social fairness and resilience

On 1 July, the Commission presented the new European Skills Agenda. It calls for collective action, defines a strategy to ensure that skills lead to jobs, identifies financial means to foster investment in skills, intends to support people to build their skills throughout life and sets quantitative objectives for upskilling (improving existing skills) and reskilling (training in new skills). This to be achieved within the next 5 years. The Agenda proposes 12 actions (see Q&A): 1) launch a Pact for Skills in November 2020, bringing together public and private stakeholders to draft and sign a Charter that will define key principles to up- and re-skill the workforce – health area has been identified as a priority due to COVID-19 pandemic where health workers were required to acquire skills and undergo training in infection-containment, quarantine protocols, protective gear use and clinical management responsibilities. In addition, to successfully deploy new digital technologies such as artificial intelligence (AI), basic and advanced digital skills will be required; 2) Strengthening skills intelligence, by embedding the idea of 'skills for jobs' and using AI and big data to define new jobs profiles based on specific skills sets; 3) EU support for national upskilling action strategies, in particular to encourage breaking of gender and other discriminatory stereotypes and to focus on digital and green transitions. Through the forthcoming Pact on Migration and Asylum, the Commission intends to relaunch the Blue Card Directive to attract highly skilled workers. It also intends to provide legal migration places and explore legal migration instruments with third countries; 4) Proposal for a Council Recommendation on Vocational Education and Training for sustainable competitiveness, social fairness and resilience, with the aim for organisations providing education and training deliver relevant skills throughout the entire lifelong learning continuum, in particular programmes tailored to green and digital transitions; 5) Rolling out the European universities initiative and upskilling scientists, by developing a European Competence Framework for researchers, defining a taxonomy of skills for researchers and developing open science; 6) Skills to support the green and digital transitions. In relation to the latter, the Commission will update the Digital Education Action Plan to improve digital literacy, skills and capacity, and implement the Digital Europe programme, strengthening investments in supercomputing, artificial intelligence, cybersecurity and the development of advanced digital skills, among other; 7) Increasing Science, Technology, Engineering and Mathematics (STEM) graduates, fostering entrepreneurial and transversal skills, such as working together, critical thinking, problem solving, empathy and adaptation to change in complex environments (due to increasing influence of robots and algorithms in the labour market), providing a strategic framework for their recognition in Europe; 8) Skills for Life, working on new priorities for the European Agenda for Adult Learning to motivate and enable adults to learn and support crisis resilience; 9) Initiative on Individual Learning Accounts, supporting tools that offer incentives for people to train (ex. funds, training or educational leaves, etc.). Broad consultations with Member States, social partners and stakeholders are expected; 10) A European approach to micro-credentials, developing EU standards which address minimum requirements for quality and transparency. This initiative builds on the results of the evaluation of the 2012 Council Recommendation on Validation of non-formal and informal learning published in parallel with the Skills Agenda; 11) New Europass Platform; and 12) Improving the enabling framework to unlock Member States' and private investments in skills. CPME will be attentive to whether these initiatives could have an impact in doctors' qualifications and medical practice.

### **CPME** news

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### Recent publications on the CPME website

#### Members' section:

CPME response to Thematic Network on Digital Skills for future-proof Doctors (Digital Doc)

Survey on Challenges, Recommendations and Best Practices, 9 July 2020

CPME consultation response to WHO-Europe Programme of Work 2020-2025

CPME Response EUHealthSupport Stakeholder Survey, 9 July 2020

<u>Draft minutes of the virtual members' session on COVID-19, 3 April 2020</u>

Draft minutes of the virtual members' session on COVID-19, 12 June 2020

Report of the Ad-hoc meeting of the Advisory Group on the Food Chain and Animal and Plant

Health on the EU's Farm-to-Fork Strategy – 17 June 2020

Letter EUHealthSupport Consortium, 23 June 2020

<u>Digital Doc Thematic Network Survey Challenges Recommendations Best Practices, 10 July 2020</u>

Digital Doc Thematic Network Webinar slides Andrea Woltman, 18 June 2020

<u>Digital Doc Thematic Network Concept Learning Outcomes</u>

Draft CPME response EUHealthSupportConsortium stakeholder survey, 10 July 2020

Agenda CPME Working Group eHealth online meeting, 2 July 2020

DRAFT Minutes CPME Working Group eHealth online meeting – 27 April 2020

Report on web-meeting with OECD Head of Health division Ms Francesca Colombo, 10 June 2020

#### CPME news section:

Welcome to the 32nd edition of the CPME newsletter

<u>European organisations come forward with recommendations on how the EU could help bring</u> fair pharmaceuticals prices

Response to the roadmap to the European Commission's Pharmaceutical Strategy

CPME consultation response to WHO-Europe Programme of Work 2020-2025