



CPME MONTHLY BULLETIN

Stay in the Loop!



November 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 meeting held on 25 November 2021.

The members of the Executive Committee discussed necessary and potential changes to the CPME Statutes that are required by the new Belgian law. Moreover, the Executive Committee decided to support and promote the Healthcare without Harm campaign to preserve colistin for human health. Also, the Executive Committee approved CPME's co-signature of the joint statement calling for a quick conclusion of administrative procedures granting UK bodies access to the next Horizon Europe calls for funding.

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

My term as President is now coming to an end and I would like to thank all of you for the support, guidance and commitment that you have provided to the Executive Committee 2019-2021. Over the past three years we have professionalised our work internally and increased our visibility externally and I am pleased to hand over the Presidency to my successor, Dr Christiaan Keijzer. I look forward to supporting the newly-elected Executive Committee 2022-2024 to continue advancing CPME from strength to strength.

Kind regards,

Prof. Dr Frank Ulrich Montgomery
CPME President

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Executive Committee meeting – 25 November 2021

Internal Affairs

CPME Statute Revision Process to comply with new Belgian law

The Executive Committee discussed changes to the CPME Statutes and Rules of Procedures in view of new Belgian legal requirements CPME has to comply with as of 2023.

The Secretary General informed the General Assembly on 27 November 2021 about the process and the biggest changes to expect, i.e. a merger of the membership categories associate members with observers, restructuring of the Board and empowerment of the General Assembly and abolition of weighted voting in the Board.

The Belgian lawyers currently draft texts which will further be discussed by the Executive Committee and shared with the CPME Board to be discussed in the spring 2022 meeting. The General Assembly should adopt changes in the autumn meeting 2022 as the new Belgian law is applicable as of 2023.

Policies

Healthcare Without Harm (HCWH) campaign to preserve colistin for human health

The Executive Committee decided to support and promote the HCPWP's campaign to include colistin on the list of antimicrobials reserved for human use only. EC members took note that the Commission is currently preparing a list of antimicrobials that will be banned from the use in animals.

With the entry into force of the new [EU Veterinary Medical Products Regulation](#) in January 2022, the European Commission is developing a list of antimicrobials to be banned in food production to tackle antimicrobial resistance. The list of antimicrobials reserved for human use only will be based on criteria described in a delegated act that CPME has been opposing over the last months. The criteria are very stringent, and it will be difficult to legally ban antimicrobials from the use in animals. Colistin, which its use is restricted in human health, is one of the last-resort antimicrobials used in farming. With this mind, [Health Care Without Harm](#) (HCWH) has launched a campaign to safeguard colistin and ban its use in EU food production as well as in meat imports.

Vaccination Session in the next CPME Meetings

The Executive Committee decided that the University of Antwerp can organise a vaccination communication session along one of the CPME Meetings in 2022 as part of the IMMUNION project.

The [Coalition for Vaccination](#) and the IMMUNION project (“Improving IMMunisation cooperation in the European UNION) work to deliver better vaccine education to healthcare professionals and better information to the general public. [IMMUNION](#) will strengthen collaboration between healthcare professionals and other stakeholders, and address issues of access to accurate, evidence-based information about vaccination. Both the University of Antwerp and CPME are partners in this two yearlong project (2021-2023) to strengthen the Coalition for Vaccination.

European Health Stakeholder Group (EHSG) joint statement on research cooperation post-Brexit

The Executive Committee approved CPME’s co-signature of the joint statement calling for a quick conclusion of the administrative procedures granting UK bodies access to the next Horizon Europe calls for project funding. The CPME Secretariat will liaise with the BMA on the next steps.

The informal [European Health Stakeholders Group \(EHSG\)](#) composed of industry and civil society organisation following the impact of Brexit on health has invited CPME to co-sign a letter calling for a speedy clarification of UK bodies access to the [EU Horizon Europe research programme](#). According to the EHSG, there is a delay on the confirmation of the conditions of access for UK bodies, which presents risks to current and future research projects.

Monitoring

Cancer

Roadmap for Europe's Beating Cancer Plan

On 17 November, the European Commission published an [implementation roadmap](#) and progress indicators for Europe's Beating Cancer Plan to monitor developments on the ten flagship initiatives as well as its other actions. In June, the Commission already launched the Knowledge Centre on Cancer followed by the launch of the HealthyLifestyle4All initiative in September. Work is also progressing in a number of areas including the revision of the Council Recommendation on cancer screening and a new Cancer Inequalities Register. The roadmap provides clear timelines also to legislative processes CPME is following, such as the rules on cross border purchases of alcohol and tobacco, alcohol labelling, FOP nutrition labelling and the EU's air quality standards.

BECA Committee voted on the report on cancer

On 9 December, the Special Committee on Beating Cancer (BECA) of the European Parliament adopted its [final proposals](#) on how to strengthen the EU's role in the fight against cancer (report by MEP Dr Véronique Trillet-Lenoir). The key recommendations include facilitating access to cross-border health care and clinical trials for cancer patients, extending the use of joint procurement procedures, managing shortages of cancer medicines, guaranteeing the "Right to be Forgotten" as well as ensuring equal access to innovative cancer drugs and treatments. The first proposal is however to take stronger EU action to address key risk factors and social determinants of cancer. CPME's lobbying activities were successful as prevention is on the top of the proposal. Moreover, CPME and other health NGOs successfully opposed a number of proposed amendments to promote "harm reduction" approaches and reference the use of novel tobacco and nicotine products. As concrete actions the BECA report proposes to increase excise duties for all tobacco products, ban characterising flavours in tobacco products, evaluate health risks related to novel tobacco and nicotine products, improve labelling of alcohol beverages, prohibit alcohol sponsorship of sport, and introduce mandatory and harmonised EU front-of-pack nutritional label. Moreover, the report highlights reinforcing the role of health professionals in cancer care. The mandate of the BECA committee ends on 23 December 2021. Parliament's plenary is expected to adopt the report in early 2022.

Nutrition labelling

EFSA opinion on FOP nutrition labelling

On 15 November, the European Food Safety Authority (EFSA) published a draft opinion on setting an EU-wide scheme for a front-of-pack (FOP) nutrition label. However, it does not evaluate or propose a particular nutrient profiling model for FOP nutrition labelling. It only provides advice to policy-makers about which nutrients and non-nutrient components of food to consider for inclusion in nutrient profiling models where excessive or inadequate intakes are associated with risks of long-term disease. Please find more [here](#).

OECD

Registration opens for webinar on State of Health in the EU – OECD Country Health Profiles 2021 and Companion report

On the 13th of December, the European Observatory on Health Systems and Policies will host a webinar on the new 2021 Country Health Profiles from 10:30 – 11:30 CET. High-level representatives from the European Commission, the OECD and the European Observatory on Health Systems and Policies will present key findings from the new series of Country Health Profiles (EU27 + Iceland and Norway) and the Companion Report that highlights a selection of cross-cutting issues drawn from the Country Health Profiles and showcases the responses to the COVID-19 pandemic. The link to register for the webinar can be found [here](#).

The 2021 Country Health Profiles and Companion report will be available on 13 December on the websites of the [Observatory](#), the [OECD](#) and the [European Commission](#).

OECD 2021 Health at a Glance country profiles published

OECD has published the latest [Health at a Glance](#) including country notes for i. a. Austria, France, Germany, Italy, Spain, Switzerland, the United Kingdom. The analysis focusses on the effect of the pandemic on health systems, as well as long-term trends. It provides data on mental health showing rates of depression and anxiety doubling in some countries compared to pre-pandemic baselines, as well as the impact on non-communicable disease such as cancer. It also portrays the increase in health spending, but notes that there is a persistent shortage of health professionals. The report also reports on factors linked to 'unhealthy lifestyles' in particular the continued need to reduce smoking and heavy drinking, as well as the situation on obesity.

World Health Organization

WHO cautions against mandatory vaccination

On 7 December, Dr Hans Kluge, WHO Regional Director for Europe, stated that mandates around vaccination are an absolute last resort and only applicable when all other feasible options to improve vaccination uptake have been exhausted. He however said that in some environments they have proven effective to increase vaccine uptake, but the effectiveness of mandates is very context specific. Please find the full statement [here](#).

New WHO Report on green spaces and mental health

WHO/Europe has published a new report [Green and Blue Spaces and Mental Health](#) providing new evidence and perspectives for action. Its key findings show that most green space types yield positive effects on both short-term and long-term mental health outcomes. Moreover, benefits of blue spaces and the coast were found across all studies. Therefore, the report recommends taking a holistic approach that encompasses the role of nature to provide ecosystem services, including a wide range of health and well-being benefits, but also assessing green and blue space benefits and trade-offs in planning and managing city transformations because of their important role in addressing urban health.

Commercial determinants of health

On 5 November, the WHO launched their [page on commercial determinants of health](#), meaning the private sector activities that affect people's health positively or negatively. These determinants impact a wide range of health outcomes including obesity, diabetes, cardiovascular health, cancer, road traffic injuries, mental health and malaria. There are however effective public health actions to respond to these determinants, which are key to building back better after COVID-19. Examples of actions governments around the world are taking to address commercial determinants to improve public health include bans on tobacco or junk food advertising, or taxes on sugary drinks.

ECDC

New ECDC micro training on vaccine acceptance and uptake

The European Centre for Disease Prevention and Control (ECDC) has developed a new 30-minute e-learning course for healthcare professionals aiming at increasing understanding of the drivers of vaccine acceptance and design targeted strategies to increase vaccine uptake. The course teaches for example how to describe the 5C model and advocate for its use in diagnosing barriers to vaccine acceptance and uptake. Please find the e-learning course [here](#).

Council and EP reach a provisional agreement on ECDC

On 29 November, the co-legislators reached a [provisional agreement on extending the mandate of ECDC](#). To generate timely and comparable data, the ECDC will coordinate the standardisation of data collection procedures, data validation, analysis and dissemination of data at EU level. It will develop risk assessments and maintain databases for epidemiological surveillance and work towards harmonised approaches to data collection and modelling to produce comparable EU-wide data. The ECDC will also:

- establish an EU Health Task Force of experts to assist with preparedness and response planning as well as with local response to outbreaks, in coordination with the European Union Civil Protection Mechanism and other international mechanisms;
- monitor the capacity of national health systems to detect, prevent, respond to and recover from communicable disease outbreaks, identify gaps and provide science-based recommendations;
- organise visits to member states to provide additional support to the national preparedness and response planning activities;
- ensure that experts and stakeholders, including civil society organisations, contribute to its advisory work;
- provide technical and scientific assistance to national authorities to develop their capacity to detect and sequence the genomes of infectious agents
- monitor the uptake of vaccination against major communicable diseases across the EU, taking into account the specificities of national and regional vaccination schedules;
- facilitate fighting against misinformation on vaccination and the causes of vaccine hesitancy.

Parliament and Council now need to endorse the agreement, before it can enter into force. We are waiting for the publication of the texts to compare the final version with [CPME's position on ECDC](#).

e-Health

Council and EP reach provisional agreement on Data Governance Act

On 30 November, the co-legislators reached a [provisional agreement](#) on a new law to promote the availability of data and build a trustworthy environment to facilitate its use for research and the creation of innovative new services and products – trilogue negotiations have now concluded. The Data Governance Act (DGA) will create a mechanism to enable (safe) reuse of certain categories of public-sector data that are subject to the rights of others. The Commission will set up a European single access point with a searchable electronic register of public-sector data. This register will be available via national single information points. The DGA also makes it easier for individuals and companies to make data voluntarily available for the common good, such as medical research projects. The DGA is setting the scene for the future European Health Data Space. The Act is now subject to final approval by the European Parliament and the Council.

European Parliament adopts report on draft Cybersecurity Directive

On October 28, 2021, the European Parliament’s Committee on Industry, Research and Energy (ITRE) [adopted the draft report on measures for a high common level of cybersecurity across the Union, repealing Directive \(EU\) 2016/1148](#) (“NIS2 Directive”). The [NIS2 Directive](#) will broaden the scope of the existing NIS Directive to apply to “important sectors,” such as waste management, postal services, chemicals, food, **medical device manufacturers, digital providers** and producers of electronics, **in addition to “essential sectors.”** The NIS2 Directive imposes specific cybersecurity requirements relating to incident response, supply chain security, encryption and vulnerability disclosure obligations. The NIS2 Directive also aims to establish better cooperation and information sharing between EU Member States, and create a common European vulnerability database. The draft report will be voted in Plenary on 10 November, following which negotiations with the European Council will begin.

Council document hints at progress on the e-Evidence Regulation file

EU co-legislators appear to be approaching common ground on several key points of the e-Evidence proposal including notification obligations, order suspensions, and grounds for refusal, according to a Council [internal document](#) of 30 September. The views of co-legislators continue to diverge in relation to the data categories that need to be notified to the authority of the executing country. Contrarily to the Council, the Parliament wants to treat content data at the same level as traffic data, which is descriptive information about online communications such as IP address, time, and location. While the internal document suggests MEPs might be willing to concede on the scope of the notification obligations, a point where they seem less open to concessions is the so-called residence criterion. According to EU countries, if an individual residing in their territory stores data in another Member State, they should be able to access it without notifying the other country. Lawmakers reject this argument, stressing that individuals might have chosen to use services abroad precisely to be better safeguarded, especially if they reside in a country where the rule of law is not ensured – further information [here](#).

FDA Issues Guiding Principles for Good Machine Learning Practice for Medical Device Development

On 27 October, the U.S. Food and Drug Administration (FDA), Health Canada and the United Kingdom’s Medicines and Healthcare products Regulatory Agency (MHRA) issued a set of ten guiding principles meant to aid the development of Good Machine Learning Practice (GMLP). For further information, please see [here](#).

CPME social media

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The launch of the 2021 Lancet Countdown on Health and Climate Change

On 2 December, CPME together with the Lancet Countdown and the European Public Health Alliance (EPHA) organised an online launch of the annual [Policy Brief for Europe](#) which was co-published by the same organisations. This year's policy brief focuses on data and policy recommendations on heat and health, urban green space, and energy systems, air pollution and health. Dr Martin Balzan participated in the panel discussion where he highlighted that the EU air quality standards should be made more stringent, fully aligned with the latest WHO recommendations. CPME has collaborated with the Lancet Countdown since 2018.

CPME and WMA joint letter on trial against Dr Şeyhmus Gökalg

On 10 November 2021, CPME and WMA sent a [joint open letter](#) to the President of Turkey H.E Mr Recep Tayyip Erdoğan, the Turkish Minister of Justice Mr Abdulhamit Gül, and the Turkish Minister of Health Dr Fahrettin Koca on the trial against Dr Şeyhmus Gökalg. CPME and the WMA call upon the Turkish judicial authorities to ensure that the proceedings are conducted in full respect of the right to a fair trial the Republic of Turkey has committed to under international law. CPME also informed the EU delegation in Turkey who will monitor the situation. WMA published a press release available [here](#).

European Parliament recognises heroic work of European Doctors

Every year, the European Parliament awards the European Citizen's prize to selected projects, individuals or groups for strengthening citizenship in the Member States. A special honour was bestowed to European doctors and European nurses. CPME and EFN were each awarded a special prize for their outstanding commitment in the corona crisis. The certificate states: "The European Parliament is keen to honour the heroic work of medical and paramedical staff amid the COVID-19 pandemic (...). This special recognition celebrates exceptional commitment to the high values of humanity, solidarity, altruism and compassion and is awarded to the Standing Committee of European Doctors representing all European doctors." An article by the CPME President and some pictures will soon be shared with CPME Members which they can publish in their medical journals.

Own initiative report on AI in the digital age

On 9 November, European Parliament Special Committee on AI (AI) considered the [draft report of MEP Axel Voss](#). MEP Voss wants to ensure Europe's AI rules becomes a global standard. The report places an emphasis on boosting the AI sector, including in health, as opposed to the stronger focus on AI risks from the political left. The MEP's criticizes that the AI Act's scope is too broad, and that the legislation should concentrate on high-risk applications. In the health sector, besides recognising the benefits on AI in several domains, it stresses that additional legal steps, time and purpose limitations introduced by the GDPR, and differing interpretation across Member States have led to legal uncertainty and lack of cooperation. He considers that specific consent obligations hinder the processing of used medical data for further analysis and studies, and that this leads to lengthy delays to scientific discoveries and a significant burden in health research. **CPME commented on the draft report proposing specific amendments to the rapporteur, shadows- rapporteurs and AIDA Committee Members.** Please see [specific amendments](#) and [letter](#). **Background:** MEP Voss had launched a public consultation in the summer on the AI Act and CPME contributed in June 2021, expressing its position on AI in healthcare and its preliminary feedback on the AI Act. CPME has requested to meet with the MEP at different occasions, which was not yet attended due to his busy agenda. Considering that he will be a key figure in the discussion on the AI Act, CPME will increase its efforts to meet with the MEP or his assistant to explain CPME's position on consent, the role of ethics committees, the use of AI in medical research and the need for a system of redress in the AI Act.

Recent publications on the CPME Website

Members' section:

[Draft Minutes Session Online eHealth, 26 November 2021](#)

[Letter MEP Axel Voss Report on AI in digital age, 7 December 2021](#)

[Draft CPME Amendments Draft Report AI in Digital Age, 7 December 2021](#)

[Draft Agenda WG eHealth Meeting, 10 December 2021, online](#)

[Commission EHDS presentation, 26 November 2021, online](#)

[Report on Evaluation of European Commission on Patients' Rights in Cross-Border Healthcare
CPME Policy on Health Workforce](#)

[European Union of General Practitioners/ Family Physicians \(UEMO\) – Activity Report to CPME
General Assembly, 27 November 2021](#)

[Fédération Belge des Chambres Syndicales des Médecins/ Belgische Vereniging van
Artsensyndikaten \(BvAS-ABSyM\) – National Report, 27 November 2021](#)

[National report from the Panhellenic Medical Association, November 2021](#)

[CPME CPDP Panel, Role of Ethics Committees in EHDS – concept note](#)

[European Union of Medicine in Assurance and Social Security \(EUMASS\) – Activity Report to
CPME General Assembly, 27 November 2021](#)

[Report on EU Clean Air Forum, 18-19 November 2021](#)

[President's Report March-November 2021](#)

[CPME WG on Refugee Health – final report](#)

[Joint letter of the European Medical Organisations on the mutual recognition of EU/UK
doctors' qualifications post-transition](#)

[CPME WG on Medical Ethics and COVID-19 – DRAFT Minutes of the web-meeting, 6 July 2021](#)

[CPME WG on Medical Ethics and COVID-19 – DRAFT Minutes of the web-meeting, 18 May
2021](#)

[Briefing note on changing business model of the pharmaceutical industry](#)

[Concept note on the CPME policy on changing business model of the pharmaceutical industry](#)

[CPME Members Briefing on HERA](#)

[CPME Statement on HERA](#)

[DRAFT CPME response to the public consultation on the revision of the basic pharmaceutical
legislation](#)

[Briefing note on the Oslo Medicines Initiative](#)

[DRAFT Minutes of the Session on Pharmaceuticals, 19 March 2021, online](#)

[DRAFT Agenda of the Session on Pharmaceuticals, 26 November, Oslo](#)

[CPME Semester Report – March – November 2021](#)

[European Commission Webinar: Air Quality and Health – Revision of EU Rules, 16 November
2021](#)

[TEHDAS WPAG8 presentation e-consultation meeting, 10 November 2021](#)

[TEHDAS WPAG8 Meeting citizen e-consultation minutes, 10 November 2021](#)

[Agenda Commission eHSG, 30 November 2021](#)

[Draft minutes Commission eHSG third plenary meeting, 5 May 2021](#)

[Commission Public Consultation Form on Liability For Digital & Circular Economy](#)

[European Parliament, Comparative study in civil liability on AI 2021](#)
[Draft concept note CPME panel at CPDP – Role of Ethics Committees in European Health Data Space](#)
[TEHDAS, Deliverable M8.1 – Literature review](#)
[TEHDAS, Deliverable M8.4 – presentation of first set of data altruism definitions, use cases and findings](#)
[TEHDAS, Annex to deliverables M5.1 & M5.2 – Case studies on different governance and health data systems in Europe](#)
[TEHDAS, Deliverables M5.1 & M5.2. – Summary of results case studies barriers to sharing health data](#)
[TEHDAS, Deliverable M5.7 – Why health data is a special case for data governance](#)
[eHealth Stakeholders Group, subgroup WG5, Recommendations, 9 September 2021](#)
[eHealth Stakeholders Group, subgroup WG4, final](#)
[eHealth Stakeholders group, subgroup WG2, Vision v3](#)
[eHealth Stakeholders Group, subgroup WG2 – Actions v6](#)
[Draft Agenda Session Online eHealth, 26 November 2021](#)
[Draft Minutes WG eHealth online meeting, 24 June 2021](#)
[CPME Monthly Bulletin – October 2021](#)

CPME news section:

[Christiaan Keijzer elected new President of CPME](#)