



CPME MONTHLY BULLETIN

Stay in the Loop!

January 2022

Dear colleagues,

We are pleased to share with you the latest edition of the CPME Monthly Bulletin with the outcomes of the Executive Committee the meeting on 20 January 2022. The new year brought new beginnings as we welcomed our newly elected Vice Presidents Dr Marily Passakiotou and Dr Jacqueline Rossant-Lumbroso for the first time.

Our meeting kicked off with a discussion with Dr Andrzej Rys (Director for Health Systems and Products at DG Santé), who provided an overview of their agenda for 2022. Whilst the COVID-19 pandemic remains at the forefront, there is much more on the horizon including pharmaceuticals, the European Health Data Space and the revision of blood tissues and cells rules.

To complement the Commission's upcoming agenda, this issue contains details of the priorities of the French presidency of the Council of the EU, as well as the trio Presidency's programme for the next 18 months alongside Czechia and Sweden. There is a rich agenda and plenty for European Doctors to contribute to in the months ahead.

In addition, the members of the Executive Committee discussed the Revision of EU Air Quality Directives and took note of the State of Health in the EU country profiles.

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

Kind regards,

*Dr Christiaan Keijzer
CPME President*

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Executive Committee meeting – 20 January 2022

Exchange with Dr Andrzej Rys

DG Santé priorities for 2022 are fighting COVID-19, pharmaceuticals, the European Health Data Space and revision of blood tissues and cells rules

The EC held an exchange with Dr Andrzej Rys (Director for Health Systems and Products at DG Santé), who provided an overview of their agenda for 2022.

Dr Rys reaffirmed that ending the COVID-19 pandemic remains the most important item on the European Commission's Directorate General SANTE's ([DG SANTE](#)) agenda. This is closely followed by the revision of the [General Pharmaceuticals legislation](#) where the Commission plans to propose a package of regulatory changes by the end of 2022. The [European Health Data Space](#) will also be a priority of DG SANTE, where discussion on the file will continue as soon as the Commission adopts it in April 2022. DG SANTE also plans to revise the [Regulation on Blood tissues and Cells](#), as these rules are more than 20 years old and need to be updated in view of the scientific development. On healthcare professionals, Dr Rys mentioned that the Commission will continue with the joint action related to work force. The recently adopted [EU4Health programme](#) will also allocate funding for the training of healthcare professionals, and the European Commission will also push for the digital skills agenda.

Policies

Revision of EU Air Quality Directives

The Executive Committee approved that the President and Rapporteur take the final decision on the consultation process.

As part of the [European Green Deal](#), the EU is revising its Ambient Air Quality Directives (AAQ) to align them more closely with the [recommendations of the World Health Organization](#). CPME has already [responded](#) to a public consultation on the same topic based on its [2019 policy on air quality and health](#). The European Commission has now invited CPME and other stakeholders to complete a targeted survey on the same topic. The targeted survey is seeking expert opinions on the technical aspects of the revision of the AAQ directive. CPME does not have such expertise, and therefore the response will be based on the template provided by the [Health and Environment Alliance \(HEAL\)](#), CPME's long-term Brussels partner in environmental health issues.

Research project on medical cannabis across Europe

The Executive Committee decided to not disseminate the survey on medical cannabis among CPME Membership.

The [European Association for Clinical Pharmacology and Therapeutics \(EACPT\)](#) Young Clinical Pharmacologists Working Group Medical invited CPME to disseminate their survey assessing how medical cannabis and other cannabis-based products are perceived by European healthcare professionals. The Executive Committee decided to not disseminate the survey as medical cannabis is not a CPME priority and is out of CPME's scope.

State of Health in the EU

The Executive Committee took note of the country health profiles.

As part of the State of the Health in the EU Cycle, the European Commission has published the [biannual country health profiles for all Member States](#) which map the status quo on health status, trends in risk factors, and health systems performance. Overall trends include a continued and severe impact by the pandemic, including a decrease in life expectancy. An analysis of the EU countries health systems resilience concludes that health systems need to evaluate if innovations introduced during the pandemic can be continued to improve patient care. The Country health profiles are also accompanied by a [Companion Report](#) which highlights a selection of horizontal observations based on the analysis of the country profiles.

Monitoring

Innovative Health Initiative (IHI)

IHI seeks representatives for their Science and Innovation Panel

The Innovative Health Initiative (IHI) is looking for people who want to represent healthcare communities in their new [Science and Innovation Panel](#) (SIP). The panel will play a significant role in setting IHI's priorities and designing the calls for proposals.

IHI is looking for people with proven experience in providing scientific and technical advice in areas relevant to IHI. Healthcare community applicants will have to demonstrate proven competence and expertise in representing stakeholders involved in healthcare for at least one of the following groups: patients, healthcare professionals, healthcare providers, regulatory bodies, HTA (health technology assessment) bodies, or healthcare payers.

The **deadline** to submit an expression of interest is **21 February 2022**, 23:59 CET (Central European Time / Brussels time), following the instructions on the [SIP page of our website](#). If you want to apply, we advise you to read the full [call for expressions of interest](#) carefully when preparing your expression of interest. For additional questions, don't hesitate to contact us via sip@ihi.europa.eu.

Funding Programmes

Stick to Science campaign urges EU, UK & Switzerland to reach association agreements for Horizon Europe

The [Stick to Science](#) online signature campaign was launched on 8 February urging EU leaders, as well as the UK and Swiss governments, to place science collaboration before politics, and to quickly agree the UK's and Switzerland's association to [Horizon Europe](#) (the EU's funding programme for research and innovation) and an open and inclusive [European Research Area](#). At the time of writing the campaign has over 3,500 signatories,

The Trade and Cooperation Agreement between the EU and the UK (TCA) agreed the UK's association in December 2020 and universities, businesses and research institutions have been preparing research proposals on this basis. However, the association has stalled amid post-Brexit trade arrangements and in December CPME co-signed a [joint statement](#) of the European Health Stakeholder Group urging the access of UK bodies to Horizon Europe. Switzerland's potential association is delayed after it stopped negotiating an [institutional agreement](#), unrelated to scientific research.

The initiative is open for both individuals and organisations [to sign](#).

Commission adopts 2022 EU4Health work programme

On 14 January 2022, the European Commission adopted the [2022 EU4Health work programme](#). In 2022, the EU4Health will continue to invest in building stronger, more resilient health systems and pave the way for the European Health Union. With a budget of over €835 million, the new work programme will provide an unparalleled level of EU investment in health and ensure ambitious and decisive action in four focus areas:

- Crisis preparedness
- Disease Prevention
- Health System and Healthcare workforce
- Digitalisation

Cancer

Commission launches new initiatives to increase equal access for all to cancer prevention and care

On 2 February 2022, the Commission [launched](#) four new EU Cancer Plan actions to support Member States in addressing inequalities, improving screening and vaccination against HPV, and supporting persons who have experienced cancer:

- The **Cancer Inequalities Registry**: It will identify trends and disparities between Member States and regions. The [registry](#) will guide investment and interventions at EU, national and regional level.
- A **cancer screening call for evidence**: It will be used to update the 2003 Council Recommendation on screening. This is part of the Cancer Plan's target to ensure that 90% of the EU population who qualify for breast, cervical and colorectal cancer screenings are offered it by 2025.
- A **Joint Action on HPV vaccination**: It will support Member States to increase public understanding and awareness of HPV and promote vaccination uptake. The action will contribute to the elimination of cervical cancer by vaccinating at least 90% of the EU target population of girls against HPV, and significantly increase the vaccination of boys by 2030.
- The **EU Network of Youth Cancer Survivors**: It will strengthen long-term follow-up in cancer care plans at national and regional level. It will also connect young persons with a history of cancer and their families as well as informal and formal carers.

MEPs call for a more effective EU strategy to beat cancer

On 16 February, the European Parliament adopted its [final recommendations](#) for a comprehensive and coordinated EU strategy to fight cancer (BECA Committee report). MEPs call for effective prevention measures at national and EU level, based on independent scientific expertise. These include funding programmes encouraging people to stop smoking and promoting actions to reduce and prevent alcohol-related harm as part of a revised EU alcohol strategy. MEPs also demand a mandatory and harmonised EU front-of-pack nutritional label for food products as well as setting occupational exposure limit values for at least 25 additional substances. In addition, the recommendations highlight better access to cross-border health care and clinical trials for cancer patients, as well as shortages of cancer medicines.

European Parliament

Parliament updates the composition of its committees and subcommittees

In MEPs updated the [number of members in the Parliament's 20 committees](#) and 3 sub-committees, and the political groups determined who will sit in each committee. The ENVI Committee has gained 7 members bringing its membership to 88 members. The full list of committees and members is available [here](#).

French Presidency of Council of EU briefs European Parliament Committees on its priorities

On 27 January, Minister for Solidarity and Health Olivier Véran [briefed ENVI Committee MEPs on the priorities of the French Presidency of the Council of the EU](#). He said that the French Presidency would focus on reaching an agreement on the regulation of serious cross-border threats to health. Currently, the ENVI Committee plans on submitting the regulation on cross-border threats to health and the revision of the ECDC mandate for a final vote in the European Parliament plenary meeting in March. The Presidency will also work on strengthening EU healthcare cooperation, the EU's role in global health, the future of the Health Union, mental health, digitalisation in healthcare, as well as rare diseases and antimicrobial resistance. MEPs questioned the minister on the European Health Union, Covid-19 and cancer treatments, digitalisation, health inequalities, women's health and abortion rights.

Antimicrobial Resistance (AMR)

ICARS published a report from the Virtual Call to Action on AMR Conference

The International Centre for Antimicrobial Resistance Solutions (originally a Danish government initiative that became independent last year, focused on supporting the development and implementation of AMR solutions in LMICs) published a [report](#) from its Virtual Call to Action on AMR Conference held in November 2021. It outlines key discussions from the conference, including details of tested interventions and lessons learned from countries around the world. The Centre also shared a set of 5 'success stories', outlining some of the pioneering initiatives working to tackle AMR around to world, also available [here](#).

State of Health in Europe

State of Health in the EU publishes country health profiles

As part of the State of Health in the EU cycle, the European Commission has published the biannual country health profiles for all Member States which map the status quo on health status, trends in risk factors, and health systems' performance assessment. There is also an analysis of health systems' resilience, which largely focusses on pandemic management, however there is also an outlook on national reforms submitted for EU funding as a Recovery and Resilience Plan.

Overall trends include a continued and severe impact by the pandemic, including a decrease in life expectancy, but also highlights the impact of other risk factors, including avoidable behavioural and environmental risks as well as health inequalities. It also concludes that health systems need to evaluate if innovations introduced during the pandemic, in particular in digital health, can be continued to improve patient care. There is also a strong emphasis on the need for further investment in the health workforce as shortages are a key constraint on building resilience.

These trends are discussed in the companion report accompanying the individual assessments. They are further complemented by the latest Health at a Glance publication by OECD which looks at data relating to the key challenges described.

- [Health at a Glance](#)
- [Companion report](#)
- [Country health profiles](#): Each Member State's country health profile is available in its own language and English.

e-Health

Healthy data

The European Commission funded 'Healthy Data' consultation is inviting views on the reuse of data and the role citizens play in the management and use of health data. The results will feed into recommendations for the Commission on how to engage citizen in the future European Health Data Space. You can share your views on the use of health data and/or complete a [quick 3 minute test](#).

Council of the EU

18-month Programme of the Council

The trio-presidency of France, Czechia and Sweden have published a [common agenda](#) determining the topics and major issues that will be addressed by the Council over the upcoming 18-months. Under the heading 'Building a Europe that protects health', the trio commits to promote a one health approach, from research to production, improved coordination at EU level and encouraging further measures to tackle AMR. The trio will conclude negotiations and support the implementation of the European Health Union package, including the HERA.

The presidencies will work to ensure the availability of COVID-19 vaccines and access to medicines through a more robust supply chain for medicinal products and support work on upgrading legislation in the field of medicinal products based on the Pharmaceutical Strategy for Europe.

Measures for disease prevention and the promotion of healthy environments and lifestyles will include the implementation of Europe's Beating Cancer Plan. The trio will work with the WHO, and other relevant UN agencies, to strengthen its capacity to deal with global health.

Additionally, the three Presidencies will work on the Commission's proposal on the establishment of a European Health Data Space.

European Medicines Agency

Clinical Trials Information System (CTIS) goes live

On Monday, the Clinical Trials Information System (CTIS) went live. Patients, healthcare professionals and the general public can access the public Clinical Trials website at euclinicaltrials.eu. When clinical trial applications have been submitted through CTIS and authorised by Member States, they will be openly accessible via the "Search clinical trials page". The public searchable database will gradually contain more information as sponsors and Member States use it to initiate and oversee clinical trials. Sponsors can visit the public Clinical Trials website at <https://euclinicaltrials.eu/home>. They are encouraged to review the [CTIS online modular training programme](#) for information on how to use CTIS. Sponsors can also consult the [CTIS Sponsor Handbook](#). They can make use of a [transition period](#) for submitting clinical trials to CTIS. The Clinical Trials Regulation and CTIS will strengthen clinical trials in the EU, ensuring better outcomes for patients and supporting the attractiveness of the European Union as a location for clinical research.

EMA organises a multistakeholder workshop on its extended mandate

The extended EMA mandate that will see the Agency assume a broader role in preparing for health crises came into effect on 1 February. On this occasion, EMA will hold a virtual “Multistakeholder Workshop on EMA’s extended mandate”, which has been tentatively scheduled for 1 April 2022 from 09:00 to 16:15 CET.

The objectives of the workshop are to:

- Inform stakeholders about the mandate extension
- Explain plans for implementation of new EMA processes and timelines
- Listen to stakeholders’ views and any concerns
- Discuss processes and opportunities for further engagement

The workshop will be broadcast live and a recording will be made available after the meeting. Registration will open soon.

Regulation reinforcing the EMA published in Official Journal of EU

The regulation [reinforcing EMA’s role in crisis preparedness and management for medicinal products and medical devices](#) has been published today in the Official Journal of the EU. This officially concludes the legislative process for an important pillar of the European Health Union. The new regulation enters into force on the day following this publication and becomes applicable as of 1 March 2022, except for the provisions on shortages of critical medical devices which will apply as of 2 February 2023.

CPME News

Social media

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Join the new CPME WG on climate change

CPME recently decided to establish a new working group on climate change. The first meeting will take place under the CPME session on public health and disease prevention on Friday, 25 March. Should you be interested in joining the WG (mailing list), please contact Markus Kujawa at markus.kujawa@cpme.eu.

EMA brings the warnings and advice on new COVID-19 treatment, Paxlovid to doctors' attention

The EMA [recommended](#) the use of oral antiviral medicine Paxlovid for treating COVID-19 in adults who do not require supplemental oxygen and who are at increased risk of the disease becoming severe. Along with the recommendation, EMA asked CPME to support the Agency in reminding healthcare professionals of the warnings and advice included in the product information, in particular:

- the medicines (and also the herbal product St. John's wort (*Hypericum perforatum*), that are contraindicated to be used concomitantly with Paxlovid,
- the need to review concomitant medicines before and during treatment with Paxlovid and
- the need to monitor patients for the adverse reactions associated with any concomitant medicine.

In [this letter](#) you may find the relevant sections of the summary of product characteristics for which EMA would like to draw your particular attention.

In addition, you can also find a search tool for the drug-drug interactions by scanning a QR code or copying URL from the package leaflet or the product's outer carton.

'Get Well, Stay Well' Webinar Series

This spring, the Centre for Empowering Patients and Communities (CEmPaC) is organising a series of webinars based on their 'Get Well, Stay Well' course. These webinars focus on topics such as food, sleep, self-care, and confidence building. CPME is represented in the CEmPaC Advisory Board by Dr Katrín Fjeldsted. Please find the full webinar programme [here](#).

Recent publications on the CPME Website

CPME news section:

[Civil Liability for AI – Product Liability Directive needs to be amended](#)

[Welcome to the 36th edition of the CPME Newsletter!](#)