



CPME MONTHLY BULLETIN

Stay in the Loop!

April 2021



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 08 April 2021 and some of the latest monitoring news in EU health policy.

The Executive Committee discussed, amongst other items, the next steps of the CPME rebranding and the Terms of Reference of the new CPME Working Group on Ethics and COVID-19 treatments.

It is my pleasure to announce that CPME has been accepted as a stakeholder in the TEHDAS Joint Action on the European Health Data Space. We invite all members who are part of the CPME WG eHealth and are interested in the specific topics to contact the CPME secretariat or sara.roda@cpme.eu. Additionally, I would like to highlight our invitation to members interested in blood, tissues and cells to inform us if you would like to represent CPME at meetings organized by DG SANTE as well as by the consultancy company ICF.

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

Kind regards – stay healthy!

Prof. Dr Frank Ulrich Montgomery
CPME President

Table of Contents

Executive Committee meeting – 8 April 2021	3
<i>Internal Affairs</i>	3
<i>Policies</i>	3
<i>Any other Business</i>	4
Monitoring	5
<i>EDPB – EDPS joint opinion on Digital Green Certificate</i>	5
<i>Council agrees its negotiating mandate on the Digital Green Certificate</i>	5
<i>ISO Standards</i>	6
<i>Call for expression of interest on blood, tissues and cells</i>	6
<i>European Commission launches public Consultation for HERA</i>	6
CPME News	7
<i>CPME social media</i>	7
<i>Joint Action on the European Health Data Space (call for interested members)</i>	7
<i>CPME Statement on Shaping healthcare Interoperability Policy</i>	8

Executive Committee meeting – 8 April 2021

Internal Affairs

WG on Ethics and COVID-19 treatments

The Executive Committee approved the WG Terms of Reference.

The EC reviewed the draft Terms of Reference prepared in follow-up to the request from the CPME Board to set up a working group to discuss medical ethics in the context of treatments and other issues during the COVID-19 pandemic. Moreover, it was proposed to extend the scope of activities to also address risk assessment. The EC members took note of Dr René Héman's offer to chair the WG and appointed him.

CPME Branding Strategy

The Executive Committee discussed the position of the Board about the new logo proposal and asked the designer to redesign the logo accordingly to be presented to the EC and later to the Board. In parallel he will start with the website rebranding.

Policies

Alcohol & tobacco bought abroad – review of EU tax rules

The Executive Committee adopted the draft [CPME response](#) to [the public consultation on alcohol and tobacco bought abroad](#), related to the revision of the Directive 2008/118/EC on cross-border acquisitions of excise goods by private individuals.

The CPME response highlights that lowering the current guide levels for the maximum amount of tobacco products and alcoholic beverages that travelers can carry into the country would be the most efficient solution to the current public health issues with cross-border acquisition of alcohol and tobacco.

Under current rules, excise duty on alcohol and tobacco bought by a private individual for their own use and transported to another EU country is only paid in the country where the goods were bought. This is the case even if they bring these goods into another Member State. For both alcohol and tobacco products, the misuse of cross-border shopping rules for private individuals is a source of concerns for several EU countries due to lost revenues and the negative impact on the effectiveness of national public health policies.

This public consultation aims to ensure that all relevant stakeholders have an opportunity to express their views on the current rules and its future. This consultation includes questions on the effects of the current system, along with possible changes.

Green Paper on Ageing

The Executive Committee adopted the draft CPME response to the public consultation on [Green Paper on Ageing](#).

The European Commission's Green Paper frames the debate on ageing by setting out the speed and scale of the demographic changes, as well as the impact this has across policies, covering everything from promoting healthy lifestyles and lifelong learning to strengthening health and care systems to cater for an older population.

Based on the results of the public consultation, which is open until 23 April 2021, the Commission will consider possible policy responses to reinforce efforts in Member States and regions to address the issues around ageing.

Shaping the Healthcare Sector Interoperability

The Executive Committee adopted the [draft CPME statement Shaping the Healthcare Sector Interoperability Policy](#).

The European Commission launched a public consultation on "[Shaping the future public sector interoperability policy](#)" to gather stakeholders' views on possible objectives and policy actions for enhancing interoperability in the public sector in the EU. The results will feed into the impact assessment on a future interoperability policy.

Any other Business

The revision of the BTC (blood, tissues and cells) legislation

The Executive Committee decided to ask members to nominate an expert to participate in a series of [workshops](#) on behalf of CPME, see call below. The German Medical Association having a department dealing with this legislation will be directly contacted.

The EC members learnt that the European Commission is [revising the Blood, tissues and cells legislation](#) and that CPME has been invited to participate in three workshops. More information on this topic can be found in the Monitoring section below.

Dr MEPs roundtable

The Executive Committee was informed that the Secretariat is currently relaunching a new cycle of Dr MEP roundtable.

MEP Pizarro (PT, S&D), MEP Liese (DE, PPE), MEP Zacharopoulou (FR, RE) agreed to co-chair. The next roundtable will be held online on 25 May 2021, 11h00-12h30. CPME members are invited to join. An invitation will follow in the coming weeks.

In 2015, CPME together with MEP Elena Gentile (IT, S&D) organised informal roundtable meetings on health topics for doctor MEPs. The objective was to develop activities throughout the parliamentary term 2014-2019 to defend and guarantee the right to health for a healthier society by sharing knowledge and expertise between doctor MEPs and CPME. CPME is now reproposing a new cycle of roundtables. The topics would follow the European Parliament's agenda and CPME's own priorities.

Monitoring

EDPB – EDPS joint opinion on Digital Green Certificate

On 6 April, the EDPB and the EDPS issued a [joint opinion](#) on the two proposals for a Regulation on the so called “Digital Green Certificate” (DGC). The DGC establishes a common framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, testing and recovery certificated. This with the aim of facilitation the exercise of the right to free movement within the EU during the CPVID-19 pandemic. The data protection authorities highlight the need to mitigate the risks to fundamental rights of EU citizens and residents that may result from issuing the DGC, including its possible unintended secondary uses. The EDPB and EDPS underline that the use of the DGC may not, in any way, result in direct or indirect discrimination of individuals and must be fully in line with the fundamental principles of necessity, proportionality and effectiveness and have a proper legal base., The proposal must not lead to the creation of a central database of personal data at EU level. In addition, it must be ensured that personal data is not processed any longer that what is strictly necessary and that access to and use of this data is not permitted once the pandemic has ended. The authorities also alert for the risks of falsifying the certificates in order to be able to travel more freely and of member states deciding to re-use the data certificates for domestic purposes not foreseen in the regulations. The opinion welcomes the fact that the Regulations envisage that a mew certificate should be issued if data on an existing certificate are inaccurate or outdated, thus clarifying how the right to rectification applies.

Council agrees its negotiating mandate on the Digital Green Certificate

On 14 April, the EU ambassadors [agreed](#) for a mandate for negotiations with the European Parliament on the European Commission’s [proposal](#) for a Digital Green Certificate. However, the Council highlighted that the certificate is not a precondition to exercise free movement rights and it is not a travel document. Moreover, it strengthened data protection provisions throughout the text, in particular on the. Basis of the joint opinion of the European data protection supervisor and the EDPB.

ISO Standards

ISO TS 82304-2 'Health software – Quality and reliability of health and wellness apps' is published for comments. This initiative was presented at the eHealth Stakeholders Group on 29 January 2021 (see slide 28 of [CPME Info 042-2021](#)). Technical and editorial comments are welcomed until 14 May on the method to assess whether health and wellness apps are reliable and safe. The results of the method will be used to calculate a score for a label. The label assists the individual to compare apps and to select the one that suits the individual needs. Comments can be channelled through the national standards institutes (the National Member Bodies of CEN / CENELEC) or through the EC liaison representatives on CEN / TC 251 Health informatics. CPME received the draft standard via the eHealth Stakeholders Group and is analysing on whether it should provide comments to the document. For more information please see [here](#).

Call for expression of interest on blood, tissues and cells

The European Commission is conducting an Impact Assessment for the [revision of the EU legislation on blood, tissues and cells](#). In this context, DG SANTE is organising [workshops](#) on 4-5 May 2021 and asking also doctors to join a panel to discuss the proposals that will have been presented by tissue and cell associations. In addition, consultancy company ICF is organising workshops on the same topic on 27 April, 12 May, and 9 June. Please let the CPME Secretariat know if you are interested in representing CPME in these meetings: secretariat@cpme.eu.

European Commission launches public Consultation for HERA

On 31 March, the Commission launched an online public consultation on the Health Emergency Preparedness and Response Authority (HERA). The consultation will be open until 12 May 2021. More information about the initiative can be found [here](#). The public consultation is accessible [here](#).

CPME News

CPME social media

Follow us on:

[Twitter](#)

[Facebook](#)

[LinkedIn](#)

Joint Action on the European Health Data Space (call for interested members)

On 9 April, CPME received the confirmation of its acceptance as a stakeholder in TEHDAS Joint Action on the European Health Data Space.

The work packages and forums are:

Stakeholder forum

WP4 Policy forum (participation refers to staying informed about the developments and outputs of the forum)

WP5 Work package permanent advisory group

WP8 Work package permanent advisory group

We were only not selected for WP7 Work package permanent advisory group, although we will be included in the WP7 mailing list, where we can always provide input, views, opinions and suggestions. TEHDAS team mentioned that there had been great interest in the open call with 189 applications from 27 countries. All applications were evaluated based on the selection criteria, and decisions were made jointly by the work package leaders and the coordination team of TEHDAS. As next steps, CPME will be contacted by the work package leader of the group/forum to start the co-operation. The work schedule may vary depending on the work packages. The first Stakeholder forum event takes place in October 2021. Any CPME WG eHealth member with interest and expertise on the specific terms of reference of each work package that CPME was selected to, is warmly invited to send an email to the CPME secretariat or to sara.roda@cpme.eu. We would like to create a small group of experts in CPME that could be available to take part in the work package meetings and help commenting on the deliverables when required. We look forward to hearing from you. Background information: [CPME Info 2021-065](#); [CPME 2021/035 FINAL](#) and [CPME Info 036-2021](#).

CPME Statement on Shaping healthcare Interoperability Policy

On 8 April, the CPME Executive Committee adopted the CPME statement on Shaping the Healthcare Sector Interoperability Policy (please see [here](#)). This statement will be the CPME's response to the [public consultation launched by the European Commission on "Shaping the future public sector interoperability policy"](#). As the public consultation was very broad and the question did not allow contextualising interoperability in the healthcare sector CPME preferred to address the major challenges and particularities, offering few recommendations with a statement. The response was prepared with strong contribution from Prof Dr Georgios Raptis and the CPME eHealth Working Group.

Background: The European Commission's [Communication on Shaping Europe's digital future](#) set out as one of the key actions the development by 2021 of "a reinforced EU governments interoperability strategy", to ensure coordination and the adoption of common standards for public sector data flows and services. The results of the public consultation will feed into the impact assessment on a future EU interoperability policy.

Recent publications on the CPME Website

Members' section:

[Report on Hearing of Data Governance Act – 25 March 2021](#)

[Report on ENVI Committee meeting on Amending the Regulation establishing the ECDC – March 23 2021](#)

[CPME Semester Report – November 2020 - March 2021](#)

[Workshop on blood, tissues and cells](#)

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

[CPME Statement Shaping Healthcare Sector Interoperability Policy, 8 April 2021](#)

[CPME Monthly Bulletin – March 2021](#)

[CPME Brand Strategy & Identity Phase III – Identity Concepting – March 2021](#)

[CPME Position Paper on the Pharmaceutical Strategy for Europe](#)

CPME news section:

[The European Health Data Space – what to expect?](#)

[CPME Statement on Shaping Healthcare Interoperability Policy](#)

[CPME Response to the Public Consultation on Shopping for alcohol and tobacco products in another EU country](#)

[European doctors call for restoring balance in the pharmaceutical sector](#)

[A new CPME Policy on telemedicine](#)