



Dear colleagues

This edition follows our General Assembly, which took place in Dublin from 20–21 March with a rich variety of discussions and policies adopted. We thank the Irish Medical Organisation for hosting the meeting so warmly and professionally. The conference on digital determinants of poor health organised by the IMO was particularly impactful and thought-provoking .

The opening event was followed by productive discussions. The General Assembly adopted a policy on gambling and gaming alongside a policy on the optimisation of the healthcare workforce. Amendments to the EU’s Biotech Act, Medical Devices Regulation and Digital Omnibus were also adopted.

We welcome you to read all this and more in this month’s edition.

Dr Ole Johan Bakke

CPME President



TABLE OF CONTENTS

Board of Directors meeting – 19 March 2026

- ▶ Financial Affairs 3
- ▶ Internal Affairs 3
- ▶ Policies 4

CPME News

- ▶ Outcomes of CPME GA and Policy Sessions, Dublin 6
- ▶ ‘Move fast and break things’ must not endanger patient safety: Medical devices must remain under safeguards of the AI Act 7
- ▶ CPME signs joint letter from civil society calling for scope and integrity of the AI Act to be preserved 8
- ▶ Meeting with Irish Permanent Representation to the EU: Presidency will prioritise Biotech Act and Medical Devices 8
- ▶ European Doctors warn that the optimisation of the healthcare workforce must put patient safety and quality of care first 9
- ▶ European Doctors call for urgent EU action on gambling and gaming harms 10
- ▶ European doctors discuss Irish and EU action on digital health harms 11
- ▶ CPME signed Joint Open Letter on EU Deportation Regulation (“Return Regulation”) 12
- ▶ CPME presented at the i2X project annual meeting 12

Monitoring

- ▶ Monitoring 13

Financial Affairs

Draft final accounts 2025 and simplified balance sheet

- ▶ The Board closed the draft final accounts 2025.

The Treasurer presented the consolidated overview of last year's spending with the result confirmed as a surplus of 120 967 EUR. The draft final accounts were forwarded to the General Assembly for approval.

Internal Affairs

General Assembly

- ▶ The Board took note of the agenda and schedule of the CPME meetings.

The Secretary General highlighted the new meeting features such as the feedback option ahead of the General Assembly and the new format of the EMOs' input, both responding to the evaluation of past meetings.

Invited medical associations

- ▶ The President updated the Board on invitations to the presidents of the medical associations of Belgium, Italy, Portugal and Spain to attend the General Assembly.

Policies

Annual update on the EMA Union list of Critical Medicines

- ▶ The Board approved CPME's input to the 2026 Annual Revision of the Union List of Critical Medicines. It was confirmed that the input concerns changes to the existing list.

EAT-Lancet EU Policy Action Brief

- ▶ The Board decided not to join an initiative to co-create an EAT-Lancet EU Policy Action Brief. The invitation came from a diverse group of food system stakeholders including the Physicians Association for Nutrition (PAN International). The brief indicates a level of detail which goes beyond CPME's current policies.

Invitation to TEHDAS-X Project as impact partner

- ▶ The Board agreed to sign the draft letter of intent, with the objective of participating in the project, represented by the Secretariat and where necessary by the Chair and members of the WG Digital Health. CPME input should be limited to the activities where there is a clear added value for CPME members, e.g. access to funds or training.

Policy documents to be presented to the General Assembly

- ▶ The Board reviewed the draft documents to be presented to the General Assembly for decision, and the comments received.

BOARD OF DIRECTORS MEETING – 19 MARCH 2026**Invitation to join EPF project on digital medical devices**

- ▶ The Board decided to decline the invitation to join the project proposal due to the specific focus of the project and the scope of the CPME contribution foreseen. Also, resource wise, staff time required for contributing would need to be reallocated from other projects.

Invitation to join Label2Scale project

- ▶ The Board decided to decline the invitation to join the proposal as the available resources were already tied to the ongoing i2x project and policy agenda.

Invitation to co-sign Médecins du Monde / PICUM statement

- ▶ The Board agreed to co-sign the joint Médecins du Monde open letter opposing new EU rules on compromised healthcare for undocumented third-country nationals (see page 12).

CPME NEWS



Outcomes of CPME GA and Policy Sessions, Dublin

Following our General Assembly and Policy Sessions in Dublin on 20–21 March 2026, kindly hosted by the Irish Medical Organisation (IMO), all the key outcomes and links are available on the members' [meeting page](#).

Please find below the following key documents:

- [Slides](#) containing the key outcomes for dissemination
- [Policy](#) on the optimisation of the healthcare workforce
- [Policy](#) on gambling and gaming
- [Proposed amendments](#) on the Biotech Act
- [Proposed amendments](#) on the Medical Devices Regulations Revision
- [Proposed amendments](#) to the Digital Omnibus on AI
- [Proposed amendments](#) to the Digital Omnibus on Data
- Presentations from the national reports are available on the [meeting page](#)
- Photos from the meeting are available [here](#) and [here](#).

The following pages provide more information for each of the outcomes.

‘Move fast and break things’ must not endanger patient safety: Medical devices must remain under safeguards of the AI Act

CPME has adopted proposed amendments to the [Digital Omnibus on AI](#) and the proposal for a targeted revision of EU rules on [medical devices and in vitro diagnostics](#). European doctors reaffirm that the EU co-legislators must maintain medical devices and in vitro medical devices within the scope of the AI Act, and apply the requirements for high-risk AI systems set out in Chapter III, Section 2 of the AI Act.

CPME President Dr Ole Johan Bakke said “European doctors emphasise that the technology sector’s philosophy to ‘move fast and break things’ cannot be applied to medical innovation. We acknowledge the imperative to enhance European competitiveness, however if patients’ lives and public trust are damaged in the process, then this will ultimately inhibit the uptake of AI in healthcare.

“We must be clear: the accelerated process of the Digital Omnibus goes beyond simplification and threatens to become reckless and undemocratic deregulation without proper scrutiny from stakeholders, such as ethicists and healthcare professionals. European doctors cannot accept that high-risk AI innovation in medical devices will take place without the proper safeguards in place.”

Prof. Dr Christian Lovis, CPME rapporteur on AI, said “Different AI systems realities come into play. For example, deep learning algorithms for image recognition are distinct from generative AI systems such as medical scribe applications. The use of generative AI is adaptive and the same prompt may not deliver the same result twice. This requires appropriate safeguards and tailored rules such as human oversight.”

CPME Vice President Dr Péter Álmos added “European doctors are against the dilution of clinical evidence requirements for high-risk devices, we stress that direct clinical evidence from the manufacturer is essential to ensure patient safety and maintain public trust.”

CPME signs joint letter from civil society calling for scope and integrity of the AI Act to be preserved

CPME signed the [letter](#) together with a broad coalition consumers, hospitals and healthcare services, conformity assessment bodies, and academia to raise concerns about the weakening of the EU's AI Act.

The joint letter to the European Commission, Cypriot Presidency of the Council of the EU and Members of the European Parliament reaffirms our concerns that high-risk medical devices and in vitro medical devices would be removed from the scope of the AI Act, among similar concerns from other sectors. Read more in the monitoring (page 17).

Meeting with Irish Permanent Representation to the EU: Presidency will prioritise Biotech Act and Medical Devices

On 1 April, the CPME secretariat held a meeting with the Permanent Representation of Ireland to the EU to discuss the health priorities of the Irish Presidency of the Council of the EU from July to December 2026. The health attaché indicated that a key focus will be the follow up of the health package presented by the European Commission in December 2025.

The Biotech Act and the revision of the Medical Devices Regulation will be the highest priorities. The Council has less scrutiny over the Safe Hearts Plan, and the attaché indicated that the proposal for the revision Tobacco Products Directive will likely be published too late for them to work on, despite noting that it is a priority of the Irish government. The attaché discussed with interest the recently published policies on the optimisation of the healthcare workforce, and gambling and gaming.

European Doctors warn that the optimisation of the healthcare workforce must put patient safety and quality of care first

CPME urges policy-makers to invest in staffing, training, and medical expertise in response to growing workforce and efficiency pressures, in a newly adopted [policy](#) on the optimisation of the healthcare workforce.

Across Europe, ageing populations, more complex care needs, and workforce shortages are putting growing pressure on health systems to deliver care with limited capacity and resources. Efforts to optimise healthcare are important, but are increasingly driven by factors which put economic considerations above clinical and ethical objectives.

CPME President Dr Ole Johan Bakke said "European doctors welcome efforts to improve the efficiency healthcare services however, it cannot come at the expense of safety, quality, or professional autonomy. Real reform starts with investing in sufficient numbers of well-trained doctors and protecting the standards patients deserve."

"We need innovation in technology such as improved digital tools and artificial intelligence, but it must add value to our work, as user-unfriendly and poorly implemented tools further diminish the time available for patient care."

CPME Vice President Dr Andreas Botzlar added "These changes demand clear accountability, appropriate supervision, and real consultation with doctors so that reforms strengthen professional standards and protect the quality of healthcare. While task shifting can play a role when properly designed, it often adds to doctors' responsibilities for supervision, training, and managing complications, and these realities need to be recognised and supported."

"European doctors are concerned that without appropriate safeguards, short-term efficiency measures could undermine health outcomes and medical standards, and erode patient trust."

European Doctors call for urgent EU action on gambling and gaming harms

The Standing Committee of European Doctors (CPME) urges policymakers to take immediate and coordinated action to address the growing public health crisis posed by gambling and gaming. In a newly adopted [policy](#), the medical community warns that the rapid expansion of online platforms, combined with aggressive marketing and addictive design features, is driving harmful behaviours across Europe, particularly among young people.

Gambling, now widely accessible both online and offline, is increasingly recognised as a major public health issue. It is associated with serious consequences including financial hardship, mental illness, family breakdown, and increased risk of suicide. While often perceived as an individual issue, doctors stress that its impacts extend to families, communities, and future generations.

CPME President Dr Ole Johan Bakke said “Gambling and gaming are no longer isolated entertainment activities. They are powerful commercial forces shaping bad health outcomes. Without decisive policy intervention, harm will continue to grow, especially among vulnerable populations.”

CPME Treasurer Prof. Dr Ray Walley added “Advertising, marketing, promotion and sponsorship of gambling and gaming must be ended. We also need a harmonised and mandatory EU-wide age verification solution. This would protect especially youth and the most vulnerable who are routinely exposed to gambling product advertising, industry messaging and sponsorship, particularly online.

“It is time to position gambling and gaming as commercial determinants of health where profit-driven strategies contribute to significant health harms.”

The new CPME policy also emphasises the need for evidence-based prevention and treatment strategies, alongside better training for healthcare professionals to identify and address gambling and gaming related harm. Moreover, it highlights how the gambling industry is expanding through online platforms, legalisation, and media and sports partnerships.

European doctors discuss Irish and EU action on digital health harms

A core topic of the members conference at the General Assembly, hosted by the Irish Medical Organisation (IMO), was the digital determinants of poor health, such as social media, AI, pornography and gambling.

The IMO is advocating for greater action to protect children from on-line harm. Professor Matthew Sadlier said “A ban on social media for under-16s is imperative given the overwhelming negative impact social media is having on our children’s health, including features such as infinite scroll, recommender algorithms, and exposure to predatory behaviour. In the face of overwhelming evidence we cannot abdicate our responsibilities for our children’s health to social media companies and we must legislate.

“In addition, the scale and pace of change in pornographic material compared to just a few short years ago has been overwhelming and disturbing. Now, pornography increasingly features extreme acts including gender-based violence and is widely accessible. Appropriate age verification systems must be put in place.”

CPME President Dr Ole Johan Bakke added “CPME is grateful to learn from the national debate on digital health in Ireland, and the leading advocacy of the IMO. The media environment is changing due to the growing importance of digital technology, online platforms, and the rising importance of new media players, such as influencers. We must protect citizens, particularly minors, from harmful media content and digital tools, as well as addictive designs, in the evolving digital landscape.

“For example, we urge the EU to take action to minimise the exposure of children to the marketing of unhealthy foods and drinks in the expected revision of its Audiovisual Media Services Directive. Action on the commercial determinants of health, including the aggressive marketing of tobacco, alcohol, ultra-processed foods and sugary drinks, must remain in the EU’s new cardiovascular health plan. European doctors call on the incoming Irish Presidency of the Council of the EU to take account of the digital determinants of poor health in its programme from July to December 2026.”

CPME signed Joint Open Letter on EU Deportation Regulation (“Return Regulation”)

CPME’s co-signed a [joint open letter](#) from healthcare professionals opposing the Commission’s proposed [Return Regulation \(2025\)](#), which introduces a streamlined EU system for returning undocumented third-country nationals, replacing the 2008 Return Directive.

The proposal raises concerns regarding “detection” measures that could involve reporting obligations for healthcare professionals, as well as the expansion of detention grounds, including for children, and provisions limiting healthcare in detention to emergency care and essential treatment, potentially restricting access and creating inconsistencies across Member States.

On 25 March, the European Parliament’s plenary voted on its report, a proposal aimed at streamlining the detection, detention, and deportation of undocumented migrants across Member States. The vote passed through an alliance between centre-right and far right MEPs. The draft will now be further negotiated in trilogues between the EU institutions.

CPME presented at the i2X project annual meeting

Sara Roda (CPME Senior Adviser) and Iztok Štrotl (Medical Chamber of Slovenia) presented at the annual meeting of the i2X project on the implementation of the European Electronic Health Record Exchange Format (EEHRxF), including ways to reduce administrative burden.

At the centre of this session is a survey coordinated by the University of Thessaly (Greece) in collaboration with CPME. The annual meeting discussed preliminary data on the experience of healthcare professionals using electronic health record systems. Find out more and participate in the survey [here](#).

Political Outlook

Council of Europe Strategic plan on human rights in biomedicine and health for 2026–2030

On 4 March, the Council of Europe launched a [Strategic Plan for Human Rights in Biomedicine and Health](#), which will span from 2026 to 2030 and aims to safeguard human rights, democracy, equity and dignity and the centre of biomedicine and health. The plan outlines nine objectives grouped under four themes: safeguard, adapt, anticipate and engage. These themes seek to enhance the implementation of the Convention on Human Rights and Biomedicine, update legal instruments to remain fit for purpose, explore emerging ethical and human rights, and foster improved stakeholder engagement.

European Commission launches Gender Equality Strategy

On 3 March, the Commission [presented](#) its Gender Equality Strategy for the period of 2026 to 2030, identifying healthcare as a key priority area. In the health domain, the strategy aims to minimise the health gap by promoting gender-sensitive medical research, diagnostics, and treatment, in cooperation with the World Health Organisation (WHO) and European Medicines Agency (EMA). The collaboration with WHO will focus on improving the monitoring and analysis of gender inequalities to enhance quality and accessibility of care. The initiative with EMA aims to assess the feasibility of introducing a “gender-sensitive check” across the pharmaceutical chain, from formulation to final distribution, to ensure medicines are safe and effective across genders. Finally, the strategy supports revisions of the Clinical Trials Regulation, under the Biotech Act to ensure women are sufficiently represented in clinical trials and improve treatment for vulnerable groups, including pregnant and breastfeeding women.

MONITORING

Professional Practice

Parliamentary question: Establishing a warning system for disqualified medical professionals

On 27 March, European Commission Executive Vice-President Roxana Mînzatu [responded](#) on behalf of the European Commission to a question posed by several MEPs regarding migration of medical professionals who have lost their licenses to other Member States. The MEPs asked for the necessity of a joint warning system, the introduction of a dedicated initiative for this alert mechanism, and whether the Commission will assess the balance between free movement and the protection of patients.

In Mînzatu's response, she references the existing Alert Mechanism under Directive 2005/36, stating that additional IT developments will be taking place in March and April. Mînzatu notes that due to the national competency of health, the extent to which the Commission can intervene past monitoring may be limited; nevertheless, improvements can be considered and that concerns may be addressed under the Implementation Report, recently adopted in February and through the upcoming Skills Portability initiative. CPME has been monitoring and commenting on the debate.

Encouraging progress in inclusive health policies for refugees and migrants

On 26 March, the WHO released its [report](#) on promoting the health of refugees and migrants. The WHO highlights that about one billion people globally are a migrant or a refugee, and they still face many obstacles to healthcare. Some successes, like increased use of evidence and data in migrant and refugee health and increased insurance coverage in some countries are highlighted in the report. However, the report underlines many gaps remain, like how merely 37% of countries collect data on migrant and refugee health (33% in the WHO Europe Region) and only 42% of countries include them in emergency preparedness, with 40% of countries doing so in the WHO Europe region.

MONITORING

Public Health

Commission publishes evaluation of key EU tobacco control files

On 2 April, the European Commission published their [evaluation](#) of the Tobacco Products Directive, the Tobacco Advertising Directive, and other related tobacco control policies across the EU. It concludes that the EU needs stronger tobacco rules to protect public health from the rise of new nicotine products like vapes, nicotine pouches and heated devices. The report activates the start of the legislative process to revise both directives, which the Commission has promised to deliver by the end of the year. Public health experts and NGOs have criticised the Commission for continued delays to the reform. The Commission will carry out an impact assessment ahead of the proposal.

New ECDC guide helps Europe turn lessons learned from public health emergencies into strengthened preparedness and response

On 25 March, ECDC published a [guide](#) for reviewing responses and preparedness for public health emergencies. The guide will help prepare the review process, conduct it and follow up on it. According to ECDC it is essential to learn from every public health emergency to continuously improve the preparedness and response.

New WHO Guidance Helps Countries to Institutionalise Simulation Exercises to Strengthen Health Emergency Readiness

On 24 March, the World Health Organization issued a [press release](#) regarding guidance for national institutionalised health emergency exercises. The WHO notes that with crises becoming more common, ad hoc exercises are not strong or reliable enough to sufficiently prepare nations for emergencies. Planned institutionalised approaches are needed instead, like National Health Simulation Exercise Programmes (NHSEP), which have been successfully implemented in Ukraine.

MONITORING

Report on Council of European Dentists event on sugar

On 25 March, the Council of European Dentists (CED) arranged an event together with Italian MEP Dario Tamburrano (The Left) regarding sugar in terms of disease prevention. Sugar was identified as a major driver behind various non-communicable diseases and for tooth decay, even among minors. Strategies of preventions of such diseases were discussed, including awareness raising activities, such as informing consumers and educating minors. Further, regulatory options were explored, for example making healthy alternatives more economically accessible, raising sugar taxes and advertising bans, especially regarding ads targeting minors. It was highlighted that such prevention would be economically efficient by reducing working hours lost and health system burden. The different powerful sugar industry lobbies were criticised, and the need for an EU-based approach to combat them was expressed. CED provided a list of demands regarding sugar regulation.

An [event report](#) is available on our members area.

Pharmaceuticals & Healthcare

EDPB and EDPS support harmonisation of clinical trials under EU Biotech Act, but call for specific safeguards for sensitive health data

On 12 March, the European Data Protection Supervisor (EDPS) issued a joint [statement](#) with the European Data Protection Board (EDPB) on the harmonisation of the Clinical Trials Regulation in the Biotech Act. While the bodies were supportive of many key elements of the act, they underlined the importance of data protection of sensitive health data and provided recommendations for improvement. Among the recommendations were asks for clarification of the roles of data holders regarding trial funders and conductors, specification that the 25-year data retention would not apply to personal data, coherence with the AI Act and requirement of pseudonymisation of data where possible.

MONITORING

Digital Health

Council and European Parliament are ready to enter into trilogues on Digital Omnibus on Artificial Intelligence

The Council [published](#) its mandate for the negotiation with the Parliament on the Digital Omnibus on AI. Contrary to the European Parliament, the Council maintains Annex I with Sections A and B without changing the Medical Devices Regulation, reinforcing the unified assessment procedure while the conformity assessment body would be those of the sectoral legislation, an approach which is closer to the CPME call to maintain the current legal structure.

The Council also confirms as a prohibited practice will be added that placing AI systems on the market capable of generating non-consensual intimate images and child sexual abuse material; maintains obligations on providers and deployers to ensure a sufficient level of AI literacy for their staff and persons operating with AI; and while registration of low and medium risk AI (Article 6(3)) is to be streamlined but is still required; restricts to exceptional cases the processing of special categories of data for bias detection and correction and to the extent of being 'strictly necessary'; and introduces a new article on testing high-risk AI systems in real-world conditions outside regulatory sandboxes. The Council also supported a delayed application of AI Act rules, pushing the date to December 2027, or August, 2028, depending on the product.

On 27 March, the European Parliament adopted its Report on the Digital Omnibus on AI. Crucially, it foresees to exclude medical devices from the scope of the AI Act, not applying the requirements for high-risk AI systems set out in Chapter III, Section 2 of the AI Act. It also foresees other facilitations for regulatory requirements, however similarly to the Council it provides for a ban of nudification apps. The trilogues have started, with the aim to conclude negotiations by the end of April.

CPME will provide a lobbying package to members to support efforts to call for the rejection of the plans to remove medical devices from the scope of the legislation, and will continue efforts to inform the trilogues accordingly.

MONITORING

Member States pursue social media bans, outpacing Brussels

On 31 March, the Parliament Magazine published its [review](#) of the new social media age restriction laws currently being adopted across EU Member States, thus putting pressure on the Commission to act to create more harmonised regulations according to the article. As of now, 10 EU countries are in different stages of instituting some kind of social media age restriction, following growing scepticism of the effect of social media on the younger generation, and its potential links to mental illnesses. Australia's ban of social media for people under 16, with fines for platforms allowing such access has also served as an inspiration and is being monitored closely. New EU legislation would, according to the article, either come from a revision of the Digital Service Act, a new legislative package or both.

On 27 March, Politico [reported](#) on Austria's recent ban of social media for under 14-year-olds, and its governments intent to pursue an EU wide age restriction policy through the Digital Service Act.

Media reports in March suggested that the European Commission informed tech stakeholders that there are early drafts of an EU law to restrict children's access to social media, which would introduce age limits and determine which social media platforms this would apply to. This is to be enforced by an EU age verification wallet which is currently being tested in 6 Member States. Further information is expected following the conclusion of an expert panel on protecting minors from online harm which was convened by the Commission .

MONITORING

AI Research: 1 of 3 use AI for healthcare advice, the need for AI-regulation to realise its potential and prediction model guidance

On 25 March, a [poll](#) conducted in the United States found that almost a third (32%) of respondents used artificial intelligence for health information or advice during the past year. Of those using AI for health, 41% report sharing personal medical information such as test results and health records. Such data sharing is concerning for privacy reasons according to the majority of respondents in the survey. Responses highlight key underlying factors regarding the use of AI for health matters including concerns over accessibility, affordability, privacy, speed of results, and health seeking behaviors.

On 12 March, the European Research Council published a [report](#) regarding EU financed AI research, demonstrating the potential of AI models, provided wisely designed governance structures are in place. AI products were found in areas of disease detection, personalised risk predictions, diagnosis, prognosis, treatment, clinical trials and drug development. The ERC is however highlighting the importance of EU regulation such as the AI Act for the products to realise the full potential of AI. Needs identified included provision of governance structure to secure validation of products, risk management, high-quality data, transparency, human oversight and data protection.

In the February issue of the Lancet Digital Health, Clifton et. al. published a [comment](#) regarding when to and not to use machine learning in risk prediction models. The authors argue that machine learning is useful for models with a large number of predictor variables, and that classical statistical models on the other hand are more helpful and reliable when handling fewer predictor variables and with large data sets. The authors also warned about the AI models risk of not understanding the confounding of variables and explored the potential of explainable AI models as a way of overcoming the absence of explicit interpretability.

EDITORIAL BOARD

Sarada Das

Secretary General

Sara Roda

Senior EU Policy Adviser

Markus Kujawa

Senior EU Policy Adviser

Diogo Teixeira Pereira

EU Policy Adviser

Dimitri Eerens

Junior EU Policy Adviser

EDITORS

Calum MacKichan, Ph.D.

Communication Officer

CONTACT

For feedback, further information, questions or to express an interest to contribute to future editions, please contact:

Calum MacKichan

calum.mackichan@cpme.eu

Rue Guimard 15 1040

Brussels, Belgium

T: +32 2732 72 02

E: secretariat@cpme.eu

www.cpme.eu

FOLLOW US

[X](#) [LINKEDIN](#) [BLUESKY](#) [INSTAGRAM](#) [YOUTUBE](#)