Dear colleagues

This edition follows our Board meeting held online on 11 December, when the Board discussed the planning for a joint policy briefing with WMA on the Declaration of Helsinki in Brussels, and the proposed EU Biotech Act. The event took place on 14 January to discuss solutions that maintain high ethical safeguards in clinical trials and when using biotechnologies. In this Bulletin, we also include a comprehensive update on EU legislation, as significant developments related to CPME priorities took place in December.

In December, I was honoured to attend the 100th anniversary of the Panhellenic Medical Association (pictured above) which was an inspiring moment to celebrate the past and future.

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 – 11 December 2025

CPME News

Feature: EU policy update

Monitoring

Internal Affairs

General Assembly minutes

- The Board approved the extract of General Assembly minutes held on 25 October 2025.

Invitation to speak at the PAIME Congress

- The Board decided to decline the invitation to speak at the International Session on Physicians' Mental Health which will take place within the framework of the PAIME Congress, organised by the Spanish General Medical Council (OMC).

Joint policy briefing with WMA on Declaration of Helsinki

- The Board took note of the progress made in the preparation of the joint policy briefing with WMA on Safeguarding Bioethics in clinical trials in a competitiveness-driven EU.

Joint Action HEROES webinar

- The Board approved the draft concept note for a Community of Practice webinar meeting hosted by CPME under the Joint Action HEROES.

The Secretariat will proceed with contacting the proposed speakers.

Policies

European Parliament workforce report

- The Board approved of the voting recommendations with minor revisions.

Following discussion, the Board agreed to include an additional recommendation to oppose amendment 616 on vaccination of healthcare professionals.

Response to Joint Action TEHDAS 2 public consultation

- The Board took note of the CPME responses and the work involved from the Working Group Digital Health and the Secretariat.

The TEHDAS2 joint action prepares the ground for the harmonised implementation of the secondary use of health data in the European Health Data Space, and the responses covered numerous topics. A summary of the responses is available here.

It was added that a statement compiling these main statements could be drafted to be used during the discussions of the implementing legislation on the European Health Data Space Regulation.

Response to Joint Action Xt-HER

- The Board took note of the response. It was reported that CPME highlighted some aspects of the CPME Policy on the European Health Data Space, including that data from wellness apps should not increase documentation burden or cause alert fatigue, and the risk of EHR file to be less suitable as a clinical tool.

FEMS statement on arduous work

- The Board decided to request the Working Group on Professional Practice to consider the link to national level legislation and possible interactions. The endorsement of the statement is therefore currently on hold, pending further review.

Invitation to co-sign Call to Action on Life-Course Immunization

- The Board decided to decline the invitation from the World Federation of Public Health Association (WFPHA) to co-sign a Call to Action on Life-Course Immunization. The initiative is part of a broader project supported by a charitable donation from Pfizer and mainly endorsed by international/global organisations.

CPME proposed amendments to the Critical Medicines Act

- The Board was updated on a minor revision of the proposed amendments to the Critical Medicines Act based on input from the Slovenian Medical Chamber (SMC) and the Danish Medical Association (DMA). The Working Group on Pharmaceuticals agreed both in its meeting on 30 September 2025 and confirmed such decision at the policy session in Athens on 24 October 2025 to accept these comments.

Spanish General Medical Council (OMC) initiative on Digital Credentials

- The Board took note of the project and recognised the importance of the initiative as it would allow identification and authentication of European doctors online and offline, using a professional digital wallet.

100th anniversary of the Panhellenic Medical Association

In December, Dr Ole Johan Bakke attended the 100th anniversary of the Panhellenic Medical Association (PhMA) and presented congratulations and gratitude to our long-standing member on behalf of CPME. PhMA has been a member since 1981, making an invaluable contribution, notably through people such as Dr Emmanuel Kalokerinos served as CPME President from 1995-1997, as well as those who served as Vice Presidents, most recently Dr Anastasios Vasiadis and Dr Marily Passakiotou.

CPME President interviewed at the General Assembly of the Spanish General Medical Council

Dr Bakke also presented CPME's activities at the General Assembly of the Spanish General Medical Council in Madrid. He also attended a meeting at the ministry and gave an interview with the NMA's journal, highlighting CPME's work on topics such as the health workforce and digitisation.

Safeguarding Ethical Standards in Europe's Evolving Clinical Trials Landscape

As the EU advances competitiveness in life sciences, CPME and the World Medical Organisation held a policy briefing on 14 January to underline the need to preserve strong bioethical safeguards. The event will highlight the risks of deregulation and reaffirms the Declaration of Helsinki.

A press release is available here and a report will be included in the next edition of the Bulletin.

i2x Project: Short survey on needs assessment remains open

The i2x needs assessment survey will capture doctors' real experiences with the use of electronic health records. The survey is targeted to individual doctors, consists of 20 questions and is anonymous. The deadline is 2 February 2026, **For more information and to participate in the survey, please visit:**
https://ec.europa.eu/eusurvey/runner/2e07e9f3-7b0c-dc7c-c26d-50354ab780b8

Your insights will help build a European Health Data Space that is technically robust, clinically relevant, and grounded in practical usability. The survey will be disseminated among health professionals associated with the i2x project, including CPME members, EMOs and other health professions, such as PGEU (Pharmacists) and EFN (nurses).

Background

CPME is a partner of the i2X project - Intelligent Implementations of the European Electronic Health Record Exchange Format. The results will the basis of a deliverable, coordinated by the University of Thessaly (Greece) in collaboration with the CPME, which gathers evidence on the current experience of healthcare professionals using EHR systems. The survey is one of the main contributions from CPME in the project and has the potential to influence the implementation of the future standard for the EHR exchange format.

For questions, please contact: Haralampos Karanikas (University of Thessaly) h.karanikas@gmail.com and Sara Roda (sara.roda@cpme.eu).

For more information and to participate in the survey visit: https://shorturl.at/SDIIZ

Or scan to complete the survey:

European doctors' highlights of 2025

In 2025, CPME continued to advance the combined voice of the medical profession in European policy. We brought the voices of doctors from over 30 countries to the European Parliament, called for immediate action on the health workforce, and advocated on a wide variety of topics in public health, pharmaceutical and digital policy.

Read a short summary of some of the key moments and publications of 2025 in the report published on our website.

Health call for decisive, domestic EU climate mitigation to prevent disease and reduce cost

Ahead of the upcoming interinstitutional negotiations on the EU's climate ambition beyond 2030, CPME alongside other health sector organisations, representing healthcare and medical professionals, patients, and public health experts from across Europe, urged the EU institutions to place people's health at the centre by agreeing on a decisive EU 2040 climate ambition.

EU policy update

We provide an update on a busy period of policy news, with numerous major developments related to CPME priorities.

EU general pharmaceutical legislation agreed

On 11 December, the EU institutions reached an agreement on the revision of the EU's general pharmaceutical legislation.

The agreement included:

- Regulatory protection: companies placing a new medicine on the market benefit from an eight-year data protection period (and a one year of market protection)
- Availability of medicines: Member States will have the power to require companies to supply medicines benefiting from regulatory protection in sufficient quantities to meet patient needs.
- The "Bolar Exemption": An extended intellectual property exemption is adopted, ensuring that generic versions of a medicine can be made available on day one after the intellectual property rights have expired.
- AMR: a new transferrable exclusivity voucher incentivising pharmaceutical companies to help combat antimicrobial resistance by developing priority antibiotics.

European Commission's Health Package

On 16 December 2025, the European Commission put forward a health package which comprises proposals for the Biotech Act, the Medical Devices Regulations revision and the Safe Hearts Plan.

Biotech Act

The proposal includes measures such as:

- Strategic Health Biotechnology Projects: Regulatory support, and priority access to EU and national funding for high-impact biotech initiatives.
- Clinical Trials Efficiency: Amendments to the Clinical Trials Regulation to reduce administrative delays, improve coordination, and increase predictability.
- Advanced Therapies & Biosimilars: Flexible regulatory tools for Advanced Therapy Medicinal Products and streamlined support for biosimilar development while maintaining safety standards.
- AI and Biosecurity: EMA guidance to ensure safe, compliant use of AI across biotech product lifecycles, alongside measures to prevent biotechnology misuse.
- Supplementary Protection Certificates (SPC): Targeted 12-month SPC extension for biotechnology-derived products and ATMPs meeting specific criteria

CPME and the WMA will discuss the ethical dimension of the proposal in a policy briefing on 14 January (see page 7). Please find the CPME input to the preparatory phase here.

Revision of the Medical Devices Regulations

The proposed simplification of rules for medical devices include:

- Streamlined Regulation: Reduced administrative burden, simpler rules, and more efficient reporting for all stakeholders.
- Proportionate Conformity Assessment: More predictable and balanced requirements, especially for low/medium-risk devices and products for small patient populations.
- Innovation Support: Targeted measures like early expert advice and regulatory sandboxes to foster breakthrough technologies.
- Legal Certainty & Digitalisation: Clearer definitions, proportional classification, use of real-world evidence, and expanded digital tools for labelling and procedures.
- EU & International Coordination: Enhanced EU-level oversight, stronger involvement of expert panels and EMA, and reinforced participation in high-standard international cooperation.

CPME is working on the evaluation and preparation of the positions with the working groups and rapporteurs.

Safe Hearts Plan

The Commission presented the Safe Hearts Plan as the comprehensive EU approach to tackle cardiovascular disease. It presents targeted measures to improve prevention, detection and treatment. CPME contributed to shaping the plan in September. Unlike the CPME recommendations, the Commission is not proposing many binding regulations.

- Tobacco Control & Prevention: The plan's flagship initiative is to modernise tobacco legislation (proposal expected in 2026) and promote vaccination against respiratory infections.
- Food & Lifestyle Measures: The Commission is studying ultra-processed foods to inform potential public health actions and plans to update recommendations on health-enhancing physical activity.
- Cardiovascular Health Checks & Care: Future proposals include Council recommendations on health checks and integrated, personalised care pathways for cardiovascular disease.
- Research & Innovation: A flagship initiative aims to address gaps in cardiovascular disease R&D.

European Commission's Omnibus proposals

The EU's 'Omnibus' is a legislative process to amend, update, or simplify multiple existing EU laws at the same time. Each Omnibus act is topic-specific (e.g., on digital or environmental policy). The current high volume of omnibus proposals reflects a shift in the EU's priorities from aiming to lead global regulation to simplifying legislation in order to boost competitiveness.

Digital Omnibus

The Digital Omnibus Packages are part of the EU legislative priorities for 2026, and on 19 November, the European Commission released two proposals:

- A proposal on AI, suggesting targeted simplification measures to certain provisions in the AI Act;

- A proposal amending a large corpus of digital legislation [the General Data Protection Regulation (GDPR), the ePrivacy Directive, the Data Act, the EU Institutions Data Protection Regulation (EUDPR), Cybersecurity Directive (NIS2), the Digital Operational Resilience Act (DORA)], and repealing several others, the Free Flow of Non-Personal Data Regulation, the Data Governance Act, the open data and the re-use of public sector information Directive, the Regulation on promoting fairness and transparency for business users of online intermediation services, among other.

For the European Commission, these are technical amendments, selected to bring immediate relief to businesses, public administrations, and citizens alike, to stimulate competitiveness.

The main voiced objectives in the text are the following:

1. Simplify and streamline the EU digital legislative framework, notably merging the provisions of the Data Governance Act, the Open Data Directive and the Free Flow of Non-Personal Data Regulation, into a single, restructured Data Act;
2. Reduce administrative burdens and compliance costs;
3. Support competitiveness and innovation in the EU digital economy;

4. Facilitate safe, trustworthy development and use of Artificial Intelligence;
5. Establish a single-entry point for all cybersecurity incidents and data breaches reports;
6. Strengthen data protection while providing clarity and consistency;
7. Repeal of the 'P2B Regulation' (platform-to-business regulation), the provisions of which were partially made redundant by the Digital Services Act.

On the same day, the European Commission released a Communication Data Union Strategy – Unlocking Data for AI planning actions in three priority areas: i) scaling up access to data for AI; ii)streamlining data rules; iii) strengthening the EU's global position on international data flows. It also launched the digital fitness check public consultation to analyse the cumulative impact of digital rules on businesses, seeking to test how they support the EU's competitiveness and where further adjustments will need to be proposed in the second half of the legislative mandate – the 'stress-test' of the digital acquis.

While the Digital Omnibus Package has been welcomed by the industry, there have been several criticisms from civil society, namely those defending digital rights and privacy in Europe (please see here and here). From a general point of view, the amendments weaken privacy and, considering the current geopolitical situation, they are seen as serving the pressures from the US digital industry to diminish fundamental rights and values in Europe.

CPME will analyse the Digital Omnibus package at the next Working Group Digital Health meeting, taking place on 5 February 2026, in view of preparing a letter to the European Commission requesting clarification on certain definitions and positions taken in the legislation. CPME also plans to reply to the feedback consultation of the proposals which are open until 5 March (the deadline is being postponed every day until translations in all EU official languages are available).

As first impressions, CPME may analyse the following elements:

- Amendments to the definition of personal data and capacity to re-identify natural persons;
- Broad definition of 'scientific research';
- Expanding automated-decision making, allowing data mining and profiling by default;
- A new legal basis for AI training, using 'legitimate interest';
- Centralised reporting

Environmental Omnibus

On 10 December, the Commission presented a package of measures presented as 'simplification' to amend environmental legislation in the areas of industrial emissions, circular economy, environmental assessments and geospatial data. The key elements of the proposal are:

- Streamlined environmental assessments for granting permits
- Simplified industrial emissions standards for industry and farmers
- More effective digital solutions for hazardous substances in products
- Simplified Extended Producer Responsibility (EPR)
- Facilitated access to geospatial data

The Commission will continue the process of simplification. For example, the Commission is due to publish guidance on the Packaging and Packaging Waste Regulation to provide further clarity and harmonised implementation on issues raised in the call for evidence.

The Commission is also planning to revise the Water Framework Directive (as already announced in the RESourceEU Action Plan), as well as the Marine Strategy Framework Directive, the Water Resilience Strategy and the Circular Economy Act.

To address the decision to prioritise simplification over protection, the EU Health Air Coalition, including CPME, published a letter urging the Commission to uphold and strengthen existing EU air pollution reduction and reporting requirements. The key points in the letter are :

- Air pollution remains a major health crisis
- EU air quality policies work, but more progress is needed
- Prioritise implementation and enforcement—not deregulation

Food and Feed Safety Omnibus

On 16 December, the European Commission published the cross-cutting food and feed Omnibus package which aims to simplify rules and procedures across the EU's applicable legislation, from plant protection products and biocidal products, to feed, official controls and animal health and welfare. It proposes for example making renewal procedures for pesticides and biocides simpler. This paves the way for the continued use of substances contaminating waters and threatening public health. However, the Commission also proposes accelerating procedures for market access for bio-pesticides. The legislative proposal will now be submitted to the European Parliament and the Council for adoption.

Political outlook

EU Health Report: Chronic Diseases and Underinvestment Remain Key Challenges

On 11 December, a new report on the state of health in the EU published by the Commission identified the non-communicable diseases as a cause for most of the preventable illnesses and deaths in the EU.

This report, accompanying the 2025 edition of the OECD Health at a glance shows that Europe urgently needs to invest in its health systems to improve Europeans' healthcare. Four particularly important areas are highlighted:

- Address the major health concern of non-communicable diseases
- Strengthen the backbone of EU health care
- Improve healthcare through technology
- Support EU competitiveness through affordable access to pharmaceuticals and innovation

The report accompanies the Health at a Glance country reports.

Public Health

ECDC Report: Pandemic Experience Offers Roadmap for Future Respiratory Disease Preparedness

On 17 December, the ECDC published a report analysing how public health laboratories (PHLs) in EU/EEA countries performed during the COVID-19 pandemic and what lessons can be used to strengthen preparedness for future respiratory disease outbreaks. The report highlighted the challenges faced by the PHLs during the crisis, like the staff shortage, the intense pressure or the supply chain problem.

However, the report also gave several recommendations for the future:

- Maintain sufficient baseline laboratory capacity even outside emergencies
- Improve digital systems and data sharing to support rapid surveillance and decision-making.
- Have plans to scale up and down capacity as needed.
- Retain and build on pandemic-era advances in sequencing and other diagnostic tools.

MEPs support Citizens' Initiative to Improve Access to Abortion Care in Europe

On 17 December, MEPs endorsed a European citizens' initiative to improve access to abortion care for women in Europe through a voluntary opt-in financial solidarity mechanism. Adopted by 358 to 202 and with 79 abstentions, the text calls to establish an opt-in financial mechanism open to all EU countries on a voluntary basis, supported by EU funding. This financial mechanism would enable an EU member state to provide access to the safe termination of pregnancies in accordance with their domestic laws for anyone without access

World Leaders Commit to Expanding Mental Health Care and Reducing NCD Burden

On 16 December, leaders from across the world at the Eightieth United Nations General Assembly (UNGA) adopted the political declaration to combat noncommunicable diseases (NCDs) and mental health challenges through a fully integrated approach.

This declaration is the first addressing NCDs and mental health together, and marks a unique opportunity to accelerate global progress with a set of specific global targets for 2030:

- 150 million fewer tobacco users;
- 150 million more people with hypertension under control; and
- 150 million more people with access to mental health care.

ECDC to lead the integration of wastewater-based surveillance into infectious disease surveillance at the European level

On 10 December, the ECDC published a new framework detailing its strategy to incorporate wastewater-based surveillance (WBS) into infectious disease monitoring throughout the EU/EEA. The document explains upcoming actions and provides guidance for policymakers, public health authorities, and stakeholders involved in wastewater surveillance.

The ECDC is proposing to:

- Create a European WBS network
- Offer support and capacity-building activities
- Organise stakeholders and experts to identify pathogens suited for routine WBS
- Support data integration across countries
- Assess possible database and reporting options

Serious Listeria infections rising in Europe, EU report warns:

On 9 December, the EFSA and ECDC published an article addressing the rising number of cases of Listeria in the EU. According to EFSA, changing diets and an ageing population may be contributing to this phenomenon. The report shows that while food safety standards in Europe remain high, foodborne diseases continue to affect people across all age groups, especially those most vulnerable to severe illness, even though many of these diseases are preventable.

In 2024, it caused the highest proportion of hospitalisations and deaths among all foodborne infections reported in the EU. About 7 in 10 people infected with Listeria needed hospital care, and 1 in 12 people died.

This report is also based on the One Health 2024 Zoonoses Report.

Public hearing of ENVI Committee: Food safety risks linked to energy drink consumption in minors

On 3 December, the ENVI Committee held a public hearing on the risks associated with energy drink consumption among minors. This discussion gathered MEPs, doctors and policy advocates from various backgrounds. The event highlighted:

- The energy drinks industry specifically targets children in their promotion campaigns
- Too few European countries took measures to prevent children buying such products (only Latvia, Lithuania, Poland, Romania and Hungary)
- Many studies link the consumption of energy drinks to cardiovascular issues

Representants of the industries were present during the discussion.

Since 5 January, the UK implemented a ban on food and drinks high in fat, salt and sugar (HFSS) being advertised on TV before 21:00 and at any time online. In January, Norway aslo introduced a ban on marketing of unhealthy food and drinks towards children.

WHO updates guidance to better inform decisions on clean air and climate change mitigation policies:

On 27 November, WHO Europe published a new guidance which provided updated evidence and methodological advice to improve health risk assessments of air pollution and enable policymakers to make better-informed decisions on clean air and climate change mitigation policies.

The guidance relies on the review of a large body of new evidence, consolidated in the last 12 years, on the association of key air pollutants with both mortality and morbidity outcomes. It updates the results of the first iteration of the HRAPIE project, released in 2013, which provided a valuable resource for health risk assessment practitioners, technical experts, researchers and, ultimately, for policy development in the Region.

Professional practice

Home care workers at risk: findings of a new EU-OSHA report highlight safety and health concerns

On 27 November, EU-OSHA examined a recently published report entitled: "Home care workers: a comprehensive overview of occupational safety and health risks". The report identified risks such as musculoskeletal disorders , psychosocial challenges and poor working conditions, highlighting the importance of prevention and worker participation.

In conclusion, the review of the research literature on occupational and safety healthcare (OSH) of home care workers reveals limitations of the existing body of research. Overall, there is limited evidence on OSH risks and related health and safety outcomes of home care workers in the EU. This can be attributed to the small sample sizes and the geographical concentration of most studies, as well as the under-representation of specific categories of home care workers who have been gaining greater significance within the total home care workforce.

Digital Health

The Commission and the European Investment Bank Group team up to support AI Gigafactories

On 4 December, the European Commission, the European Investment Bank and the European Investment Fund signed a memorandum of understanding to support the development and deployment of AI Gigafactories across the European Union. The agreement establishes a framework to accelerate the financing and development of the AI Gigafactories that will anchor Europe's future AI infrastructure. This memorandum is being carried out under the InvestAI initiative, announced by President Ursula von der Leyen at the AI Action Summit in Paris in February 2025. InvestAI mobilises a €20 billion facility to support up to five AI Gigafactories - large-scale computing facilities dedicated to the development and training of next-generation AI models.

Preparing the EU public administration for the AI Act

On 4 December, the EDPS published the High-Risk AI Systems Mapping Report in European Institutions, Agencies and Bodies. The report found key findings on guidance needed by the EU institutions, agencies and bodies (EUIs) and was produced by the new EDPS "AI Unit", following the entry into force of the EU Artificial Intelligence Act (AI Act):

- No EUI declared use or planning of prohibited AI practices
- However, many institutions reported AI systems that may qualify as "high-risk" under the Act, though there is widespread difficulty among EUIs to interpret what qualifies as high-risk
- The most frequent types of AI systems in use or planned: generative-AI solutions, machine-learning-based tools, as well as AI used in recruitment
- In terms of sectors: according to the mapping, institutions working in "Area of Freedom, Security and Justice" are among those with the highest number of self-assessed high-risk AI systems.

This mapping does not particularly address the issues of healthcare or Social Protection yet.

New digital health projects

On 3 December, new projects funded under the 2024 EU4Health calls for proposal aimed at improving digital healthcare across the EU started.

- COMPASS-AI aims to overcome barriers to safe and effective implementation of AI in healthcare, with a focus on cancer care and remote regions. The project will gather a multidisciplinary community of experts to identify and validate best practices of AI in healthcare through real-world pilot studies.
- Nine other new initiatives facilitate the implementation of the eHealth Digital Service Infrastructure (eHDSI) across the EU.
    - The objective of DVKA ePrescription B is to support Germany's efforts to be part of a secure peer-to-peer network of governments across EU countries
    - Through FLaReS, Finland will be developing and deploying a Laboratory Result Report Service to enable cross-border laboratory data exchange in Europe
    - The project LT NCPeH eLAB is dedicated to extending cross-border laboratory results services in Lithuania under MyHealth@EU
    - MH4EU-ES-LR aims to improve MyHealth@EU services in Spain by enabling the secure cross-border exchange of laboratory results and reports.
    - MyHealthCY advances Cyprus's integration into MyHealth@EU, focusing on cross-border healthcare delivery through secure exchange of ePrescriptions, and expanding services to include laboratory results and medical imaging
    - Setup BE-NCPeH PS-A prepares Belgium to connect its eHealth ecosystem to MyHealth@EU
    - RO-MI-LR-DR (starting in 2026) aims to develop services for medical images, laboratory results and discharge reports in Romania
    - EHDSIDenmark (starting in 2026) aims to establish Denmark's National Contact Point for eHealth to implement, test and launch Patient Summary and ePrescription services
    - Preparing Ukraine for integration into the MyHealth@EU network, EU HEALS addresses technical and regulatory gaps, facilitating pilot activities for cross-border healthcare data exchange as part of Ukraine's EU candidate status.

EDITORS

Calum MacKichan, Ph.D.
Communication Officer

Achille Vergain
Policy Intern

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