Dear colleagues

This edition follows our Board meeting held in Brussels on 18 June 2025, when we adopted a statement on the proposed Critical Medicines Act, providing recommendations which were sent to key actors in the ongoing negotiations (see page 6).

Whilst the summer is quickly approaching, we remain as busy as ever. This month included a visit to the BMA's annual representative meeting in Liverpool (see the report on page 7) and I presented at Workshop 'Ethics in the EHDS' TEHDAS2 Joint Action, where we continue to engage.

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 – 18 June 2025

CPME News

Feature

Monitoring

Internal Affairs

Communication review

- The Board reviewed the association's communication activities and discussed action points for a member engagement strategy.

The Board also discussed social media activities and whether CPME should remain on X. It was agreed that X remains a valuable communication channel to EU policy-makers, however the Board noted concerns over the politicisation of the platform and the spread of mis- and dis-information.

Meeting with Belgian Medical Order

- The Board took note of a fruitful meeting between the CPME President and the Belgian Medical Order.

Planning for CPME meetings October 2025

- The Board took note of the draft agenda for the Policy Sessions and General Assembly taking place on 24-25 October.

Request of support from Turkish Medical Association

- The Board approved a letter to the Turkish government, supporting the Turkish Medical Association's campaign to reinstate two doctors who have been dismissed from public service due to statements made.

Financial Affairs

Draft budget 2026

- The Board discussed the next steps for the 2026 budget, agreeing on the need to pursue a balanced budget. A revised draft budget will be presented at the Board meeting in September.

Policies

European Commission proposal for a Critical Medicines Act

- The Board amended and approved the statement as amended (see full details on page 6).

Confederación Estatal de Sindicatos Médicos (CESM) campaign on Spanish reforms

- The Board agreed to politely decline the request a support from the CESM. The Board agreed that while CPME shares the spirit and value of the request, CESM is a member organisation.

FNOMCeO Manifesto on Health as a Strategic Investment

- The Board reviewed the invitation received from FNOMCeO for the launch of the manifesto presented previously.

The CPME President is invited to attend the launch event and speak in a roundtable. (A full report on this will be shared in the next Bulletin).

European Health Data Space

- The Board took note of CPME's current activities contributing to the efforts to prepare the implementation of the EHDS.

The overview included updates on the Joint Actions xt-EHR and TEHDAS2 which are working on the primary and secondary use provisions respectively. In addition, the new i2x project will work towards a consensus on the technical specifications for the EHR exchange format. It was highlighted that the volume of work was very high, and CPME's input was thanks to the generous expertise of WG members and rapporteurs.

Humanitarian situation in Gaza

- The Board agreed to discuss further on the humanitarian situation in Gaza at the meeting in September, prior to the General Assembly in October.

The Board will also seek to clarify with the General Assembly its mandate to act on such topics according to the Rules of Procedure.

European doctors call for Critical Medicines Act to address security of supply, affordability and transparency

The statement provides recommendations on how to improve the proposed Critical Medicines Act, and was published ahead of the discussion in the Employment, Social Policy, Health and Consumer Affairs Council, where the act was discussed.

The availability of medicines has been a long-standing challenge in the EU. National medical associations have reported that the problem of medicine shortages has become systemic across seasons and types of medicinal products, which is impacting patient safety and the practice of healthcare professionals.

The statement includes the following recommendations to improve the proposed Act:

- We stress the need to ensure that any public funding granted to pharmaceutical companies should go hand in hand with strong obligations regarding security of supply, affordability and transparency on the public money granted to companies. Any form of accelerated procedures applied by Member States' authorities should follow this principle.

- Procurement of medicines should go beyond price and follow non-price criteria, such as security of supply, transparency throughout the supply chain and environmental criteria.

- Member States should not generally deviate from applying security of supply criteria in procurement. Exceptions should be limited to specific cases where the application of security of supply criteria would lead to disproportionate prices.

- Healthcare professionals are key partners in mitigating the negative impact of shortages on patient safety and health. Doctors and other healthcare professionals should have a seat at the future Critical Medicines Alliance Coordination Group.

CPME attended BMA annual representatives meeting

CPME attended the BMA annual representatives meeting from 22-24 June. Dr Tom Dolphin and Dr Peter Holden, Vice-President of UEMO, were elected council chair and treasurer respectively, while Dr Latifa Patel also handed the position of representative body chair to Dr Amit Kochhar. Dr Mary McCarthy ended her term as president and was succeeded by Dr John Chisholm.

Among the topics featured on the agenda were continued industrial action e.g. for residents/junior doctors' contracts towards pay restoration, and concerns regarding the General Medical Council's functioning as a regulator, in particular in relation to the approach to physician associates. The BMA has launched a professional register and calls for a new regulator.

The meeting also saw extensive discussions on the humanitarian situation in Gaza, with several motions addressing i.a. the BMA's role in speaking out on such topics. There were also emergency motions e.g. calling on the WMA and IMA to condemn the attacks on healthcare, including in Gaza, and proposing suspension of relations with the latter pending a statement. In scientific lunch sessions, there were presentations on the 'Doctors in Distress' project aiming to reduce suicide rates among health professionals, and on obesity prevention and treatment, weighing the policy options available.

The future of EU health research and life sciences strategy

A Strategy for European Life Sciences - Positioning the EU as the world's most attractive place for life sciences by 2030

On 2 July, the European Commission published "A Strategy for European Life Sciences – Positioning the EU as the world's most attractive place for life sciences by 2030." The document outlines the strategic importance of life sciences in strengthening the EU's competitiveness, resilience, and strategic autonomy, while also improving public health.

The goal is to develop a unified strategy at EU level that promotes coordination, sustainable funding, and better integration of research networks. Key priorities of EU Life Sciences Strategy include reforming pharmaceutical and medical device regulations, launching a new Biotech Act, and clinical trials. These initiatives aim to boost innovation, attract investment, and ensure faster access to cutting-edge therapies for all European patients.

Clinical trials

Building on TheACT EU, a joint initiative of the Commission, the European Medicines Agency and the Heads of national Medicines Agencies, the strategy will also look at clinical trials against the background of regulatory and technological innovation, including digital tools and harmonised guidance. CPME strongly advocates that clinical trials must be transparent, and the safeguards of the Clinical Trials Regulation must be upheld, including on patient consent.

Biotech act

The EU Biotech Act is currently scheduled for publication in the third quarter of 2026 and it is a key element of the European Commission's vision to make the EU the world's leading hub for life sciences by 2030. As outlined in the Strategy for European Life Sciences, the Act aims to accelerate the translation of biotech research into practical applications, enhance industrial processes, and bring sustainable, high-impact products to market. CPME provided input in a call for evidence for the Biotech Act.

The next EU research and innovation programme set to take shape

In addition to the life sciences strategy, on 16 July the European Commission will present the proposal for the EU budget from 2028-2034, including the 10th Framework Programme for research and innovation (FP10).

The Commission's draft proposal for FP10 was leaked in early July, indicating that parts of it are to be aligned more closely with a new European Competitiveness Fund (ECF). Whilst FP10 is expected to remain a standalone programme, many other EU programmes, such as EU4Health, are expected to absorbed into the ECF. The leak reveals four pillars: excellent science, competitiveness and society, innovation, and European research area. The competitiveness pillar is expected to support collaborative research and innovation and will be tightly connected to the ECF. Some observers had voiced concern about a rumoured lack of collaborative research.

The draft proposal does not yet include details on the budget. The current programme is worth €93.5 billion over seven years, making it the largest multinational research and innovation programme in the world. The Parliament's Industry, Research, and Energy (ITRE) Committee has recommended a higher figure of €220 billion, however this is unlikely to be achieved in the Commission's budget. The Programme of the Danish EU Presidency (from July to December) highlights that it will commence negotiations on EU research and innovation efforts as well as the Strategy for Life Sciences. Therefore, the strategic priorities of the next research and innovation prigramme will soon start to truly take shape.

The share of health-related research has steadily decreased from 12% to just over 8% over the last 3 programmes, with some advocates calling for that trend to be reversed, as well a stronger strategic planning to meet health policy objectives. Horizon Europe currently contains five flagship 'missions', including cancer, and the future of these missions will be hotly debated. Ursula Von der Leyen and Emmanuel Macron recently underlined science as a pillar of European democracy and prosperity, and launched the Choose Europe for Science initiative to attract and keep top researchers in Europe.

We will provide a full review of the EU's budget proposal in the August bulletin.

Political Outlook

Employment, Social Policy, Health and Consumer Affairs Council (Health)

On 20 June, the Employment, Social Policy, Health and Consumer Affairs Council held a meeting in Luxembourg, where Ministers of Health discussed key public health challenges, focusing on mental health, medicine availability, disease prevention, and youth protection.

- **Mental Health of Youth in the Digital Era:** The Council adopted conclusions aimed at protecting children's and adolescents' mental health in the digital age. With a main focus on promoting safe digital use and creating age-appropriate, supportive online environments.

- **Critical Medicines Act (CMA):** Ministers discussed the proposed CMA to address medicine shortages in the EU. Key points included support for strategic projects, joint procurement, and contingency stock planning. While generally supportive, Member States raised concerns about financing and the need to respect national competences.

- **Prevention Measures (Tobacco and Alcohol):** Ministers emphasised revising tobacco legislation and welcomed plans for an EU cardiovascular disease action plan. There was a strong focus on protecting youth from tobacco and alcohol products.

- **Other Issues Discussed:** Disinformation in health, regulation of sperm/egg donor limits, impact of wastewater regulations on medicine supply, pandemic preparedness negotiations, incoming Danish presidency's work programme

2025 European Semester Spring Package sets out guidance to boost EU competitiveness

The 2025 European Semester Spring Package provides tailored policy guidance to strengthen EU competitiveness, prosperity, and resilience amid current trade and security challenges. Drawing on the five-year Competitiveness Compass roadmap, it includes country-specific recommendations (CSRs) to close innovation gaps, advance decarbonisation, reduce strategic dependencies, improve defense capabilities, and promote skills and quality jobs with social fairness. For example, the CSR report on Bulgaria highlights the current crisis faced by the healthcare sector including shortages as well as an uneven repartition of healthcare professionals.

Additionally, it assesses the Recovery and Resilience Plan (RRP) aiming at implementing reform to improve shortages in healthcare sectors. Moreover, the Cohesion Policy implementation urges Member States to accelerate reforms before the RRF ends in 2026.

2026 annual budget to fund EU priorities addressing global challenges

On 4 June, the European Commission released a draft for the 2026 budget and include an estimated €22 billion budget under 'Single Market, Innovation & Digital' to modernise healthcare through expanded digital-health tools interoperable electronic health records, AI diagnostics, telemedicine platforms and to accelerate pharmaceutical R&D and vaccine development (including next-generation mRNA and high-throughput screening capacity).

Moreover, "Natural Resources & Environment" (€57 billion) supports cleaner hospital waste treatment to remove pharmaceutical residues and incentivises greener production processes in the pharma sector, reducing environmental risks to public health. Altogether, these allocations aim to strengthen EU health systems by enhancing vaccination capacity, fostering pharmaceutical innovation and embedding digitalisation in care delivery.

The draft budget will have to be formally adopted by the European Parliament and Council before the end of the year.

Public Health

The climate crisis is a health crisis – and the European Region is in the hot seat

On 10 June, the WHO launched the Pan-European Commission on Climate and Health (PECCH) to address the growing health threats caused by climate change. The PECCH will focus on reducing emissions, making health systems resilient, and involving diverse voices from science, policy, and civil society.

Clean Industrial Deal must marry industrial competitiveness with climate action

On 19 June, the European Parliament adopted a resolution supporting the European Commission's Clean Industrial Deal, calling for stronger alignment between climate goals and industrial competitiveness. MEPs emphasised the new Industrial Decarbonisation Bank as crucial for scaling up clean technology investments based on carbon impact, scalability, and supply security.
The resolution welcomes efforts to promote lead markets for European-made clean, circular, and low-carbon products and calls for stimulating demand through public and private procurement.

More than 20% of Europeans exposed to harmful noise pollution levels

On 24 June, the EEA published the report 'Environmental noise in Europe 2025', presenting the latest data and analysing noise pollution and its effects on human health and the environment across Europe. Noise pollution causes serious health problems, negatively impacting wildlife, and disrupting marine life through underwater noise. Additionally, the economic cost of transport noise in Europe is estimated at €95.6 billion per year, or 0.6% of GDP. Despite some progress, exposure to harmful noise has only decreased by 3% since 2017, making the EU's goal to reduce noise disturbance by 30% by 2030 unlikely without stronger action.

Pharmaceuticals & Healthcare

Pharma package: Council agrees its position on new rules for a fairer and more competitive EU pharmaceutical sector

On 5 June 2025, the Council agreed its negotiating mandate on the pharma package, which is composed by a Regulation and a Directive, with the aim to reform the EU general pharmaceutical legislation.

Key points of the Council position include:

- **Regulatory Data Protection (RDP)**: under the Council's mandate, companies producing innovative medicines will be able to prevent competitors from accessing the data used to develop those medicines for eight years
- **Regulatory Market Protection (RMP)**: in addition, producers of innovative medicines will benefit from one year of regulatory market protection, extendable to two years if certain pre-defined key objectives are achieved
- **Obligation to supply**: a new article (56a) has been added to the directive, giving Member States the power to oblige the marketing authorisation holder of a medicinal product to make that product available in sufficient quantities to cover the needs of patients in the Member State.

CPME pushed for a mandatory obligation to file medicines for pricing and reimbursement in all Member States, which has been reflected in this obligation to supply.

In order to support earlier market entry of generic and biosimilar medicinal products, the Council's mandate further clarifies the scope of the so-called 'Bolar exemption' and expands it to include submissions for procurement tenders

Despite CPME's opposition, a Transferable Exclusivity Voucher (TEV) for novel antimicrobials is included. The Council added a provision that it can be used only in year 5 of RDP and only for products whose annual EU sales did not exceed €490 million in any of the previous four years.

The CPME Secretariat is further analysing the Council position and will continue its advocacy on the topic.

The European Parliament adopted its position on the pharma package on 10 April 2024. With both Council and European Parliament with their positions defined on the file, the negotiations between the EU institutions are set to start before the summer break.

Digital Health

EU adopts blueprint to better manage European cyber crises and incidents

On 12 June, the EU adopted a new cyber crisis management blueprint to enhance its collective resilience against large-scale cybersecurity incidents and crises. Approved by telecom ministers, the blueprint outlines how EU Member States should detect, respond to, and recover from major cyber threats, fostering greater coordination and preparedness. Building on the 2017 cybersecurity framework and integrating recent legislation like the NIS2 Directive and the Cyber Solidarity Act, the new guidance seeks to address the EU's increasingly complex threat landscape. It highlights the importance of unified action, clarifies crisis triggers, and defines the roles of key actors such as the European Union Agency for Cybersecurity (ENISA).

The EU Delivers Regulatory Clarity for Digital Health and App Stores

The Medical Device Coordination Group published its latest Guidance on Medical Device Software Apps, a document that provides long-awaited regulatory clarity for digital health and app store ecosystems in the EU. This decision makes app stores active players in the medical device supply chain, not just neutral platforms. For the first time, Apple and Google are officially named as Medical Device Software Distributors. This means they are now legally responsible for the apps distributed through their app stores, including checking documentation and ensuring compliance.

AI-driven Innovation in Medical Imaging

On 25 June, the European Commission published a report exploring how Artificial Intelligence (AI) and Deep Learning can achieve innovation in healthcare. AI and Deep Learning are increasingly used to support the prevention and diagnosis of non-communicable diseases. This report reviews key AI methods in medical imaging and their readiness for clinical use, with examples from lung cancer and cardiovascular disease, demonstrating how AI can be integrated into healthcare. The report also highlights challenges like data quality and clinical validation, offering recommendations for safe and effective AI adoption in EU healthcare projects.

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