



Accessibility and effectiveness

**Will EU pharmaceutical reform
work for patients?**

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LETTER FROM THE PRESIDENT



Why the independence of the medical profession matters

As doctors, we make daily decisions to protect our patients. These decisions are often complex, pressured by time and resources, and made under conditions of uncertainty. This requires clinicians to weigh evidence, experience, and the unique circumstances of each patient. If doctors and other health professionals are not free to make these clinical judgments without undue outside influence, the integrity of care is at risk.

Beyond doctors' daily role in treating patients, we also have a moral duty to advocate on behalf of our patients and for improving national and European health systems. National medical associations (NMAs) perform this role by providing a collective voice that can defend professional standards, medical ethics, and scientific integrity against political or commercial pressure. By representing doctors as a profession rather than as isolated individuals, NMAs advocate for patient-centred policy and speak publicly when government actions or external interests threaten.

Autonomy is balanced by the need to ensure accountability for a decision to patients and peers. This professional responsibility goes beyond legal liability and has a broader ethical and societal dimension. These principles follow from the lessons of the Nuremberg Medical Trial of 1946–47 and the resulting Nuremberg Code. Therefore, safeguarding the independence of the medical profession is not a luxury privileging doctors, it is a fundamental necessity for the well-being of patients, public trust, and medical ethics, and lies at the core of our democracies and societies.

In this issue, we include examples that illustrate the challenges reported by our members across Europe. As you read the examples, we invite you to consider how we can work together as patients, physicians and policy-makers to defend the medical profession together.

Dr Ole Johan Bakke, *CPME President*

A handwritten signature in blue ink, appearing to read 'Bakke', written in a cursive style.

Will EU pharmaceutical reform ensure equal access to medicines for patients?



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The EU has agreed its most comprehensive and profound pharmaceutical reform in over two decades, with further legislation for the sector now being negotiated.

For European Doctors, this is a critical opportunity to improve the quality of patient care, support the medical workforce, and mitigate the deepening healthcare disparities within the European Union.

A lot happened in the pharmaceutical field in the past year. The reform of the EU's pharmaceutical legislation was agreed in December, and proposals for a Critical Medicines Act (CMA) and the first part of a Biotech Act are currently being negotiated.

These legislations are set to redefine the rules for drug development, authorisation, and access in Europe.

Dr Péter Álmos
CPME Vice President



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A central commitment of the pharmaceutical reform is to ensure access to medicines for every EU citizen.

The disruptions to supply chains in recent years, coupled with the lessons learned from the pandemic, have highlighted the vulnerability of the EU's pharmaceutical supply. It is essential to strengthen secure reserves and enhance Europe's own internal capacity for innovation.

At present, sharp economic disparities between Member States translate directly into clinical practice.

While innovative therapies become available almost immediately in some countries, in others—due to smaller market sizes and price sensitivity—patients often wait years for life-saving preparations.

CPME welcomes the reform's ambition to create a genuine, single EU pharmaceutical market. Reducing bureaucratic burdens and accelerating authorisation procedures are indispensable steps, yet they alone are insufficient to dismantle systemic inequalities.

The new framework seeks to balance the profit-driven innovation needs of the pharmaceutical industry with the public interest, particularly regarding the timely market entry of generics and biosimilars. CPME's stance is firm: incentives must reward demonstrable added therapeutic value.

We need solutions that focus on unmet medical needs.

This is especially true for the fight against antimicrobial resistance, where European doctors agree that a new market model is needed for the development of novel antimicrobials.

However, we have strong reservations about the agreed transferable exclusivity voucher, which could result in a significant extension of the protection period for other more expensive medicines, for example cancer treatments.

We are concerned of a scope-creep where the introduction of the voucher may lead to similar mechanisms being demanded for other types of medicine in future, opening a Pandora's box resulting in higher costs for healthcare systems.

Strategic autonomy, reducing dependence on third countries and increasing European manufacturing capacity, is vital to ensure that the next global crisis does not find the healthcare system in a defenseless position.

The list of medicines defined in the proposed the Critical Medicines Act underscores that organisations representing physicians must be actively involved in regulatory processes, for example the represented at the Critical Medicines Coordination Group.

This is the only way to ensure that, alongside market and national interests, the standards of the medical profession and patient safety are properly upheld. Our interview with Emer Cooke (page 10) explores how healthcare professionals can be a vital partner.

We urge the institutions to improve the proposed Act, for example by ensuring that any public funding granted to pharmaceutical companies should go hand in hand with strong obligations regarding security of supply, affordability and transparency.

These reforms take place in the wider context of the EU looking to enhance its global competitiveness in life sciences and as a whole. Our event report on page 7 highlights our call to safeguard ethics for clinical trials as the Biotech Act looks to streamline approval timelines. We also highly encourage you to read the excellent contribution from ESIP on balancing sustainability and competitiveness in healthcare on page 23.



Overall, the new set of legislation holds immense potential to create a more agile, patient-centered, and resilient system. Its true success, however, will be decided during the implementation.

This requires ensuring healthcare capacities are maintained at appropriate levels and guaranteeing the meaningful, continuous involvement of professional stakeholders. These reforms alone will not completely close the gap to equitable access in Europe for patients to the medicines they need. National policy-makers need to continue to strive to make this ambition a reality.

CPME remains committed to supporting this process with our expertise. Our goal is shared: a regulatory environment that enables physicians to provide the best possible care to patients in every corner of Europe, regardless of their location or social status.

Report: Safeguarding bioethics in clinical trials in a competitiveness-driven EU



From left to right: Claudia Louati, Dr Christofer Lindholm, Dr Otmar Kloiber and Dr Monique Al

© Anantha Krishnan

On 14 January, CPME, together with the World Medical Association (WMA), co-hosted a policy briefing for decision-makers and stakeholders on the revision of the Clinical Trials Regulation proposed in the EU Biotech Act.

The event discussed how to protect patients and uphold medical ethics while adapting to this changing research landscape and regulatory framework.

Recent months have seen much activity on the competitiveness of the EU's life sciences and biotechnology sector. In 2024, Mario Draghi's influential report called for greater use of health data for research purposes. The European Health Data Space is seen as a milestone for the clinical use of patient data and holds potential for further use in research. More recently, the Biotech Act proposal looks at reforming rules to support innovation in Europe, including a revision of the Clinical Trials Regulation.

Alongside the potential benefits for patient care, these developments raise questions about data privacy, ethical safeguards and equitable access to treatments.

In a discussion under the Chatham House Rule, invited stakeholders and the European Commission presented their views. Following the event, we interviewed several speakers for this report.

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Dr Otmar Kloiber (WMA Secretary General)

Competitiveness and bioethics are not opposing goals

Dr Ole Johan Bakke (CPME President) said that there is a legitimate demand for research and innovation to access health data spaces to improve treatments and competitiveness. However, he stressed that medical ethics, scientific progress and patients' rights are not competing priorities, but inseparable.

Dr Christofer Lindholm (Chair of the WMA Medical Ethics Committee) added that it is vital that ethical safeguards are not weakened in the name of innovation.

He emphasised that competitiveness and bioethics are not opposing goals. Ethical rigor is essential to scientific credibility, public trust, and sustainable medical progress.

Declaration of Helsinki

The World Medical Association's Declaration of Helsinki, first adopted in 1964 and recently revised in 2024, is the internationally accepted standard for designing, conducting, recording and reporting clinical trials. The Declaration underlines that rights, interests, and well-being of research participants must always take precedence over scientific and societal interests.

Researchers, ethics committees, and governments around the world rely on the Declaration to guide fundamental ethical considerations and decision-making.

The Biotech Act must safeguard ethical standards in clinical trials

Dr Otmar Kloiber (WMA Secretary General) noted that the Biotech Act introduces new methods and new types of regulations, which in part are experimental, in order to reduce bureaucracy and streamline clinical trials. This comes at a time of increasing use of AI, big data and biobanks which are being used for generating new information.

He called for regulation which does not hinder ethical review and respects the ethical principles laid down in the Declaration of Helsinki (see text box). This provides a protection for the people which are in clinical trials, be they patients or volunteers, and provides safety for the researchers because they know that they do ethical research.

Ethics committees need sufficient training and resources

The speakers explained that ethics committees are independent, multidisciplinary bodies that protect the rights, safety, and informed consent processes for human research participants.

Dr Bakke said that ethics committees need to have decent conditions and be properly financed and staffed, to be able to work with the real ethical problems and challenges.

Dr Monique Al (Co-chair of MedEthicsEU) said she is pleased that role of medical research ethics committees has been strengthened in the Biotech Act. She reiterated the importance of securing sufficient resources to fulfil their roles and responsibilities.

It is essential that patients remain at the centre

Claudia Louati (Head of Policy, European Patients Forum) said that it is essential that patients' safety and needs remain at the heart of the review of the Clinical Trials Regulation. She highlighted the definition of unmet medical needs, involvement of patients in the design of protocols, and in the redesign of the research, and the access to the medicines and innovations that address patients needs.

Dr Christiaan Keijzer (CPME Immediate Past President) said that the Biotech Act has the potential to improve the role of ethics committees, strengthening position of patients. However, he emphasised that we must look closely at the position of patients throughout the negotiations on the regulation.



Claudia Louati (Head of Policy, European Patients Forum)

The Biotech Act sets a useful basis but requires clarifications

Prof. Dominique Sprumont (Council for International Organizations of Medical Sciences) concluded that we are at the crossroads, both at European and international level, on promoting innovation whilst balancing the respect for human rights and the dignity of the participants.

He said that the Biotech Act is setting a useful basis, but further clarifications are needed. For example, improving the recruitment of patients especially in multinational clinical trials must be considered.

Dr Péter Álmos (CPME Vice President) said CPME will continue to be an active partner in the further development of the regulations.

Interview with Emer Cooke

Executive Director of the European Medicines Agency

Following the extension of her term until April 2027, we discuss EMA's extended mandate, future challenges and the role of healthcare professionals

How is EMA's extended mandate progressing and what are the next steps?

We have been operating since 2022 under our extended mandate, which has given us added responsibilities in crisis co-ordination and response. The extended mandate put on a more permanent footing some of the structures and processes established by EMA during the COVID-19 pandemic.

Today, those structures and processes are well in place and running full speed. I'm thinking here, first, of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG). The group's role is to respond to medicine supply issues caused by major events or public health emergencies, and to coordinate swift actions within the EU.



And of course, the Emergency Task Force (ETF), the advisory and support body that handles regulatory activities in preparation for and during a public-health emergency.

Looking ahead, the next item on the cards for us will be the implementation of the reform of the EU pharmaceutical legislation, which has recently been agreed at EU level. This reform is about making life simpler for all parties: enabling a simplified and more integrated regulatory system that is easier to navigate for developers. It is also about making Europe more competitive and more attractive in the global environment.

This will be a unique opportunity to do things differently: work better, work smarter and for EMA to further future-proof its operations.



Emer Cooke during an exchange of views with MEPs / © European Parliament

What are your hopes for a Critical Medicines Act?

EMA has done a lot to help prevent and mitigate medicines shortages, but we can always do more.

Shortages are an area where we need more Europe, to fully seize all opportunities offered through collaboration and move from reactive to predictive approaches, and thus tackle shortages more efficiently.

To complement many of the ongoing initiatives on managing shortages of medicines, the Critical Medicines Act will provide for greater coordination of procurement activities and help us be more agile in improving our manufacturing capacity where it matters the most: critical medicines, whose continuous availability is a priority for patient care.

What are the regulatory challenges of bringing novel antibiotics to market?

Fundamentally, the challenges with bringing new antibiotics to the market are not regulatory ones. At EMA, we have long been encouraging development of new antibiotics and are always ready to engage early with developers to support it. This is also now a task of the ETF, which is looking at any potential new antimicrobial as part of our preparedness activities, with a view to avoid a public health emergency.

We are also engaging actively internationally to streamline development approaches. The challenges are more of a financial nature, because a company developing a new antimicrobial will be investing in a medicine which will have to be used very prudently and therefore with a small market.

The revision of the pharmaceutical legislation foresees new incentives for medicines with a potential to combat antimicrobial resistance, to help bridge this gap.



The EMA Healthcare Professionals' Working Party / © European Medicines Agency

How can EMA work with healthcare professionals to tackle medicine and medical device shortages?

We engage closely with healthcare professionals' organisations because their views and practical experience is essential to consider in the complex discussions on medicine shortages.

We are delighted that a representative of our healthcare professionals' working party (pictured above) takes part in MSSG because this means we can get timely input from doctors and pharmacists on their real-life experience.

Because healthcare professionals and patients are on the frontline of shortages issues, we also aim to support them in these often-difficult situations.

We have issued guidance on [best practices](#) for healthcare professionals and patient organisations to help to manage the impact of shortages.

These include suggestions to collect and analyse information on shortages and their early signs, as well as communicating and raising awareness amongst their members on causes of shortages, safe use of alternative medicines, risks of stockpiling and where to find information on ongoing shortages.

Managing medicine shortages isn't the responsibility of one single actor: regulators, healthcare professionals, patients, and industry – we all need to work together to prevent and manage shortages, and ensure patients continue to get the medicines they need.

Recently, we organised a [public webinar](#) to explain how regulators are addressing shortages, and what everyone can do to prepare for and help manage them.

We have also launched an [awareness campaign](#), co-created with both patient and healthcare professional organisations, to explain the role each of these actors plays, under the hashtag #ItTakesATeam.

How can healthcare professionals contribute further to the work of the EMA?

We have long been closely engaging with healthcare professionals' organisations as this is essential in ensuring our recommendations are in phase with the realities of how a medicine will be used in practice.

Looking forward, the environment in which medicine regulators and doctors operate is changing fast, and we will need to further reinforce this dialogue.

It will be essential to ensure new legislation, such as the new pharmaceutical legislation or the European Health Data Space, is implemented in a way which supports the needs of patients and healthcare professionals.

Innovation will continue in fields such as personalised medicines, cell and gene therapies and medical devices. We also see how digital healthcare is creating new ways of treating patients, of using tools like artificial intelligence to capture, use and analyse such data.

Another common challenge today is health misinformation, which many doctors are directly confronted with in their daily practice. I see a lot of possible common areas of work here, to champion science and evidence-based medicine.

In this changing landscape, new expertise will have to be developed and incorporated in the medicines regulatory network, and a lot of this expertise will need to come from healthcare professionals, including younger generations of medical professionals and even current biomedical science students.



In fact, I think it will be essential to ensure that medicines regulation is more present in medical degree curriculum, especially as we see the blurring of lines between medicines, devices and technologies, as well as the opportunities and challenges presented by artificial intelligence.

We will need healthcare professionals' organisations to help us find the right expertise, but also to identify areas of concern and opportunities for further collaboration.

Ultimately, we want to build a bidirectional exchange of information where both EMA and organisations learn with and from each other.

We rely on CPME, as a long-standing member of EMA's healthcare professionals' working party, to help us shape further our dialogue with European doctors.

New European plan to prevent cardiovascular diseases may fall short



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Markus Kujawa
Senior EU Policy Adviser

The European Commission published their EU cardiovascular health plan a.k.a. the Safe Hearts Plan in December.

This first ever comprehensive EU approach is welcomed as cardiovascular diseases still kill 1.7 million Europeans every year.

As we know, cardiovascular diseases are largely preventable through targeted action on key controllable risk factors such as unhealthy diet, tobacco use, physical inactivity, air pollution, and harmful use of alcohol.

CPME has therefore recommended the Commission to prioritise public health when making policies and to deliver the legislative proposals of the 2021 Europe's Beating Cancer Plan to reduce these risk factors.

These initiatives were related to some of the cost-effective, evidence-based WHO's "Best Buys" to prevent and manage noncommunicable diseases such as taxes on unhealthy products, labelling rules for food, health warnings on tobacco and alcohol, as well as stronger restrictions on marketing and advertising.

In this light, European doctors are pleased to see that the European Commission intends to propose a revision of the legislative framework on tobacco control.

This will adapt to new developments and market trends, e.g. by strengthening the rules on novel tobacco and nicotine products. Already prior to the Safe Hearts Plan, the Commission has proposed to update the EU Tobacco Taxation Directive as the latest update to the Directive is from 2010 and the market dynamics have changed significantly since then.

The EU Commissioners for health and taxation have pledged to drive taxes high, but the Commission's trade department has been criticised for undisclosed meetings with the tobacco industry, failing to meet its transparency obligations under the WHO Framework Convention on Tobacco Control. This shows a lack of coherent policy-making.

Unfortunately, the Safe Hearts Plan does not include many other effective legislative proposals to combat cardiovascular diseases.

Proposals for Council recommendations on vaccination against respiratory infections and on promoting health-enhancing physical activity can be seen positive, as well as the trainings to healthcare professionals on the link between vaccine-preventable diseases and cardiovascular diseases.



However, the plan only briefly mentions taxation of alcoholic and sugar-sweetened beverages; climate change and environmental factors, such as air or noise pollution; and health literacy, without proposing any concrete actions.

We sincerely hope that there will be meaningful follow up to some of the new plan's elements such as the study on ultra-processed foods and the intention to evaluate the Audiovisual Media Service Directive, which includes rules to protect minors from harmful advertising.

European doctors remind policymakers that protecting the health of millions of European citizens cannot be done without binding legislative measures.

We hope with all our hearts that this will not be forgotten when the EU cardiovascular health plan is implemented.

Healthcare professionals urge European countries to increase vaccination coverage and tackle misinformation

The Coalition for Vaccination, co-chaired by CPME, calls on European countries to upscale efforts to increase vaccination coverage and continue building on past achievements of vaccination in Europe.

We are concerned that the success of vaccine protection may be in danger, due to vaccine hesitancy, vaccine shortages, misinformation and disinformation, and structural barriers to access within healthcare systems.

Losing protection could have dangerous consequences for individuals and population groups. The Coalition supports the European Commission's continued work, alongside Member States, European Centre for Disease Prevention and Control (ECDC), and European Medicines Agency (EMA), to:

- Provide clear, accessible, and evidence-based information
- Actively counter misinformation and disinformation
- Support national vaccination strategies based on scientific evidence
- Provide adequate education and continuing professional development for healthcare professionals,



- Monitor the performance of immunisation programmes
- Advance a European digital vaccination card
- Improve transparency in vaccine approval processes
- Strengthen independent, national and EU-wide vaccine safety surveillance.

Read the Coalition's full statement [here](#).



Healing the healers: a call to action for Europe's doctors and nurses

**Dr Ledia Lazeri**

*Regional Adviser, Mental Health and Well-being
WHO/Europe*

Dr Tomas Zapata

*Regional Adviser, Health Workforce and Service Delivery
WHO/Europe*

Europe's health systems rely on the skill, dedication and ethical commitment of doctors and nurses.

Yet, our data now clearly shows that the very people entrusted with protecting our health are working under conditions that are harming their own mental well-being.

This is not a marginal issue, nor an individual failing. It is a systemic problem that demands collective, urgent action.

On World Mental Health Day last year, WHO/Europe released the Mental Health of Nurses and Doctors (MeND) [report](#), the largest-ever survey of its kind. Drawing on more than 90 000 responses from doctors and nurses across the European Union, Iceland and Norway, the findings are sobering.

- **One in three doctors and nurses report symptoms of depression.**
- **One in four doctors and nurses report symptoms of anxiety.**
- **One in ten say they have had thoughts of being "better off dead" or of hurting themselves in the past two weeks.**
- **The prevalence of suicidal thoughts among doctors and nurses is double that of the general population.**



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Unsafe work, unsafe systems

Behind these figures are workplaces marked by excessive demands and inadequate protections. One in three respondents experienced bullying or violent threats in the past year, while one in ten reported physical violence or sexual harassment.

Long and unpredictable hours remain the norm: one in four doctors works more than 50 hours per week, and many do so under temporary or insecure contracts.

These conditions are not just associated with distress – they are directly linked to depression, anxiety and suicidal ideation.

For a profession grounded in trust and responsibility, the implications extend far beyond the workforce itself. Poor mental health among doctors and nurses actually has an impact on patient safety and quality of care.

In some countries, up to 40% of health workers with depressive symptoms reported taking sick leave in the past year, and between 11% and 34% said they were considering leaving their jobs altogether. At a time when Europe faces a projected shortage of nearly one million health workers by 2030, this is a risk we simply cannot afford.

And yet, there is also a powerful signal of hope. Despite these pressures, most doctors and nurses report a strong sense of purpose and meaning in their work. They remain committed to caring for patients and serving their communities. What they lack is not motivation, but an enabling environment that allows them to practice safely and with dignity.



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Seven concrete actions to protect those who care

Our MeND report sets out seven concrete, achievable actions that can transform working conditions and protect the mental health of health professionals.

These recommendations are not abstract ideals; they are practical measures that countries can implement by repurposing existing resources.

First, health-care systems must demonstrate zero tolerance for violence, harassment and bullying of any kind. Violence against health workers is not “part of the job” – it is unacceptable and preventable.

Second, shift work must become more predictable and flexible, allowing doctors and nurses to balance professional responsibilities with rest, family life and recovery.

Third, the culture of work-till-exhaustion must end. Overtime should be managed fairly, within legal limits, and embedded in a workplace culture that values well-being as much as productivity.

Fourth, excessive workloads must be addressed. Smarter workforce planning, streamlined workflows and the responsible use of digital tools – including AI – can help reduce administrative burdens and free up time for patient care.

Fifth, leadership matters. Health leaders must be trained and held accountable for creating safe, supportive and inclusive workplace cultures. Well-being should be treated as a core performance measure, alongside patient safety and clinical outcomes.



© WHO / Christopher Black

Sixth, all doctors and nurses must have access to confidential, stigma-free mental health support. Seeking help should never jeopardize a career.

Finally, countries should conduct regular monitoring and public reporting on health worker well-being. What is measured is more likely to be improved.

We believe that for CPME and its member associations, these findings are both a warning and an opportunity.

As the collective voice of Europe's doctors, CPME is uniquely positioned to bring the medical profession's perspective into national and European policy debates, and to advocate for health systems that care for those who care for others.

Supporting the mental health of doctors and nurses is not only a moral imperative; it is fundamental to patient safety, access to care and the long-term sustainability of our health systems.

We hope that the MeND report will serve as a springboard for honest dialogue among policymakers, professional bodies, health leaders and patients.

It should also encourage countries beyond those surveyed to examine the mental health of their health workforce and to act on the evidence.

Healing hands should not come at the cost of hurting minds. The evidence is clear. The solutions are known. What is needed now is the collective will to act.

i2X project is shaping Europe's digital health future: CPME brings doctors' voices to centre stage



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One of the main challenges facing European healthcare is the fragmented nature of digital systems.

In most hospitals and clinics, electronic health records (EHRs) are not easily shared between departments, and even worse, between hospitals or countries. Patient health data is often stored in separate software systems, which requires repeated entry and manual reconciliation, resulting in additional administrative effort.

This fragmentation reduces the time clinicians have available for direct patient care and limits the potential of digital health innovation.

The i2X project (Intelligent Implementations of the European Electronic Health Record Exchange Format), launched in April 2025 with participation from CPME, was established to address this challenge.

The initiative, which is co-funded by the Digital Europe Programme, brings together 38 partners from 12 Member States, including hospitals, technology providers, public authorities and professional organisations.

The aim of i2X is to show how health data exchange can improve the efficiency, safety and quality of care in real-world clinical conditions.

Unlike earlier research efforts, i2X is an implementation-based project. Its activities will be conducted directly within healthcare institutions — 12 hospitals across Europe — to test how the European Electronic Health Record Exchange Format can work in everyday settings.

The project aims to ensure that interoperability becomes not just a regulatory standard, but a practical reality that supports the medical workforce.

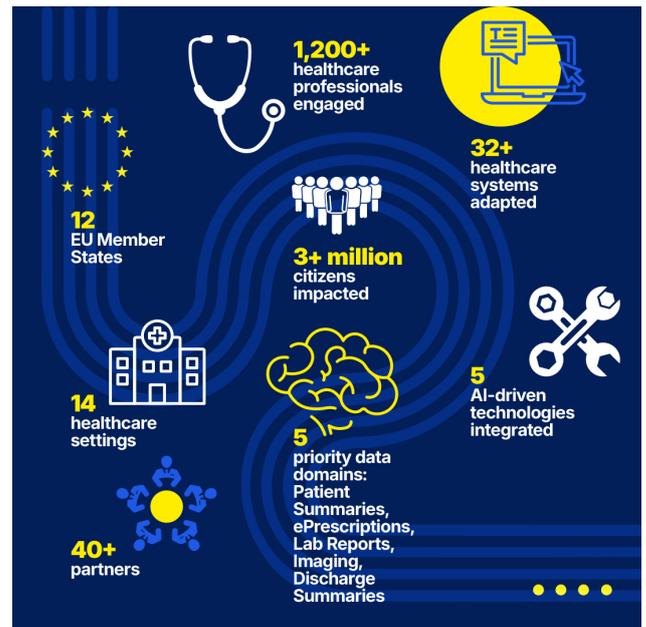
At the centre of this effort is a study coordinated by the University of Thessaly (Greece) in collaboration with CPME. This study marks the first phase of i2X and will gather evidence on the current experience of healthcare professionals using EHR systems.

The study aims to understand how doctors and other healthcare professionals interact with digital tools, the barriers they face and how these systems could be improved to make them more intuitive and clinically useful.

To achieve this, the project has developed the Needs Assessment Questionnaire for Healthcare Professionals. The questionnaire investigates areas such as the usability of existing EHRs, time spent on documentation, duplication of data entry, access to patient information from other institutions, and attitudes toward artificial intelligence (AI) applications such as automated documentation or intelligent search.

It also explores perceptions of interoperability, terminology standards, and information overload, issues that strongly influence the quality of clinical work.

The results will guide the development of innovative tools and methods that help EHR systems become more aligned with clinical workflows. This evidence will also inform recommendations to European policymakers and health authorities on how to implement interoperable solutions that genuinely support care delivery.



European healthcare professionals are encouraged to take part in this survey and contribute their experience. Their insights will help build a European Health Data Space that is technically robust, clinically relevant, and grounded in practical usability.

Click [here](#) for more information and to participate in the survey or scan below:



Sustainability and competitiveness in healthcare: a difficult balance, but necessary



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Europe is entering a defining moment for health policy.

Public health budgets are overstretched and confronted with structural challenges: ageing populations, rising multimorbidities and the growing cost of innovation are all pushing expenditure upward.

At the same time, new geopolitical trends are accelerating Europe's rush to competitiveness, amid global tensions reshaping trade, supply chains and strategic autonomy.

Healthcare sits at the crossroads of these trends: it is both a pillar of social resilience and an increasingly strategic sector for economic security.

Finding the right balance between competitiveness and sustainability lays in this duality.

Strengthening industrial competitiveness in pharmaceuticals and medical technologies can support jobs, innovation and supply security.

Yet competitiveness policies that are designed without regard to the functioning of the welfare state risk eroding the very foundation that makes Europe attractive: a trusted social model supported by stable, predictable funding.

The welfare state is a core element of the European way of life. It rests on a simple promise: access to healthcare and social protection should be equitable and affordable. Preserving this promise requires sustainability, both financially and operationally.

Sustainability is not only about cutting costs: it is about ensuring health systems can continue to deliver quality care, without shifting unsustainable burdens onto patients.



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The tension between boosting competitiveness and safeguarding sustainability has become especially evident in recent years.

In the last year, a plethora of new EU initiatives, revisions and strategic packages were launched.

Many of these proposals aim to attract and retain investment, bolster research and development and secure manufacturing capacity.

Those goals are legitimate and necessary, but they must be pursued with safeguards that prevent unintended consequences for public finances and patient access.

By all means, EU policies should avoid blank cheques in the form of overly generous incentives, poorly targeted subsidies or policy choices that inflate prices without delivering public value.

Whether through extended monopolies or weak conditionalities, incentives should not lead to systematic – yet unsustainable and unjustified – overpaying.

Furthermore, in a context of financial constraints, higher spending in one area may become an obligation to deprioritise others, compromising equitable and affordable access to medicines.

And when budgets tighten, patients face delays, stricter reimbursement criteria, shortages or unequal access between countries and regions.

In short, if affordability erodes, healthcare risks becoming a commodity, available faster, or only, to those who can pay.

This should never be the case in Europe.



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So, what does proper balance look like?

First, competitiveness policies must be fact-based and tied to clear public objectives:

Improved health outcomes, better access, stronger supply security, fair economic returns and financial sustainability of healthcare systems. Incentives should come with conditions and measurable contributions to public health.

Second, EU policies should be designed as a coherent package, not a collection of siloed initiatives.

A 'competitiveness-first' measure in one file can create downstream cost pressures elsewhere.

Third, impact assessments must be non-negotiable.

Every major proposal should be stress-tested for patient access, affordability and sustainability of health systems.

Europe can and must be both competitive and sustainable.

The choice is whether we embed sustainability and equity into competitiveness strategies from the start, ensuring that industrial policies reinforce, rather than erode, the welfare state in Europe.

CPME discussed Greek and European health policy challenges during 100th year of Panhellenic Medical Association



Our General Assembly met in Athens from 24–25 October to discuss the health policy agenda, both in Greece and Europe as a whole, emphasising the need to invest in the health workforce.

The meeting was kindly hosted the Panhellenic Medical Association during its centenary year, with anniversary celebrations culminating in December.

The meeting kicked off with a [video message](#) from Dr Dimitrios Vartzopoulos (Deputy Minister of Health of Greece), who said:

“The challenges we face are not confined by national borders. They are systemic challenges to the European social states themselves.

“We stand at a critical junction defined by complex and interactive threats for collective well-being, demographic, age and mobility.

“In Europe, we have a unique opportunity to transform a chronic problem into a model of effective social policy by creating a model universal and sustainable system built upon the unshakeable principles of dignity, social justice in European solidarity.”

These challenges were illustrated in short videos recorded by Greek doctors, who shared personal and powerful experiences from the frontline of Europe's health workforce crisis as part of CPME's #DoctorsVoice campaign.

The testimonies report excessive working hours, understaffing, financial challenges, exhaustion and effects on mental health, including burnout. The doctors highlighted that the working conditions affect their well-being and personal relationships, and urged policymakers to listen to their voices and provide "protection and respect".

The pressures on health professionals' mental health was underlined by Dr Tomas Zapata of the WHO Regional Office for Europe, who presented sobering results on the Mental Health of Nurses and Doctors in EU, Norway and Iceland survey (see page 17).

These discussions led into one of the main discussions of the meetings, the preparation of a policy which aims to guide reforms in response to growing workforce and efficiency pressures. This policy will be finalised at the upcoming CPME General Assembly in March.

In other policy areas, the General Assembly adopted a response to the European Commission questionnaire on the future Biotech Act, stressing the need to maintain high standards on clinical trials and ensure effective implementation of the Clinical Trials Regulation, aligning with the WMA Declaration of Helsinki and Declaration of Taipei (see page 7).

On digital health, the European Union Agency for Cybersecurity (ENISA) updated on the EU Action Plan for the cybersecurity of hospitals and healthcare providers.



Former President of the Panhellenic Medical Association Dr Athanasios Exadaktylos and CPME President Dr Ole Johan Bakke

Additionally, a response to a consultation on the proposal for a Council Directive on tobacco taxation was adopted. CPME supports the Commission's proposal to increase the minimum tax and extend the scope of the directive to new tobacco and nicotine products. The response also highlights the need to counteract the tobacco and nicotine industry tactics to interfere in policy-making.

In December, CPME President Dr Ole Johan Bakke attended the 100th anniversary celebration of the Panhellenic Medical Association (PhMA) and presented our congratulations and gratitude. PhMA has been a CPME member since 1981, making an invaluable contribution, notably through figures such as Dr Emmanuel Kalokerinos, CPME President from 1995 to 1997.

The event reflected on the history of the PhMA, and the crucial role it has played in the development of Greece's health system.

Independence of the medical profession under threat

Increasing challenges to the independence of the medical profession have been reported by national medical associations across Europe. This causes a threat to doctors, patients, and society as a whole, if independence is not safeguarded and reinforced.

The challenges take many forms. Individual doctors have faced governmental pressure to break patient-doctor confidentiality and report names of patients seeking their care.

Financial actors without medical background or mandate are accessing the ownership and governance of medical facilities as capital investors, skewing patient care to maximise profit and restricting doctors in their clinical practice.

Organised representations of doctors voicing their opposition to government policy have faced retaliation, such as the loss of mandatory membership, dismissal of their leadership, or in the most extreme cases even imprisonment. In addition, restrictions on collective action seriously limits the ability to take industrial action.

The examples on the following pages illustrate that the independence of Europe's national medical associations is increasingly at risk, whether from political, commercial, or regulatory pressures.

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Physician Associates in United Kingdom

Physician Associates and Anaesthesia Associates are healthcare professionals who support doctors under supervision, trained through postgraduate courses, rather than a medical school.

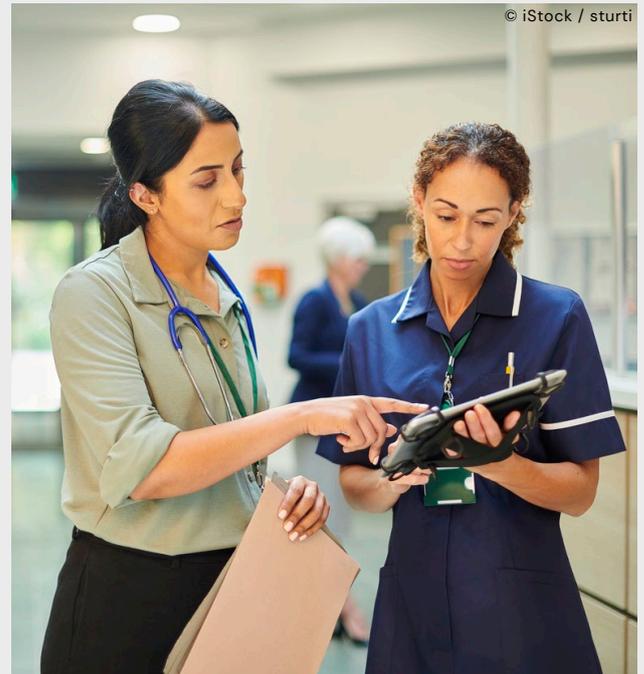
Physician associates (PAs) were introduced in the UK in 2003 to address staffing shortages and reduce the burden on doctors.

This is an example of task shifting, when clinical tasks traditionally performed by doctors are redistributed to non-doctors.

High-profile negligence and misconduct cases have raised concern about the roles, such as illegal prescription practices and six deaths of patients who were misdiagnosed by PAs.

A survey by the British Medical Association (BMA) in 2023 found that 87% of doctors said the way PAs worked in the National Health Service was always or sometimes a risk to patient safety, and highlighted concerns that PAs are being deployed beyond their training.

The BMA does not oppose PAs outright but demanded strict safeguards to ensure patient safety, clear professional boundaries, and appropriate oversight.



The BMA has advocated for name change, proper regulation, a defined scope of practice, and moratorium on expansion without sufficient governance. CPME issued a statement noting concern and opposition to the trend of physician substitution and the implications for patient safety with uncertain and potentially severe health implications.

The government ordered a review led by Prof Gillian Leng, which was published in mid-2025, advising reforms including renaming PAs as 'physician assistants' and that PAs should not see undifferentiated patients. The BMA has argued that the report does not go far enough, urging for authoritative, nationally-agreed scopes of practice.

This case highlights the need for a carefully thought-out approach when integrating new roles like physician associates into a healthcare system.



"Professor Leng succeeded in exposing how NHS England introduced these roles and encouraged their expansion without any robust evidence of their safety. The report revealed inadequate national leadership, no accountability and no attempt to listen to the concerns raised by doctors, patients and coroners.

"While the diagnosis was strong, the prescription had significant gaps. Stronger patient safety recommendations, such as the introduction of nationally agreed safe scopes of practice, should have been included but were missed out.

"Despite clear evidence concerning how these roles present a real and ongoing risk to patient safety, the implementation of Professor Leng's recommendations is moving at a glacial pace. We will continue to push for greater protections for patients and an end to the blurring of the lines between qualified doctors and their non-medically trained assistants.

"The WMA recently issued a statement of concern about doctor substitution, and the medical profession worldwide needs to be alert to governments and healthcare providers trying to replace doctors with cheaper, less well-trained non-doctors."



Dr Tom Dolphin
Chair of BMA Council

CPME cautions against unregulated task shifting in Europe

Task shifting describes a situation where a task normally performed by a doctor is transferred to a health professional with a different or lower level of education and training. While task shifting has traditionally been associated with low and middle income countries facing significant shortages of resources and qualified professionals, several European countries have pursued task-shifting initiatives as part of broader health system reforms.

CPME cautions that such measures cannot replace comprehensive workforce planning and investment to ensure adequate and equitable supply of doctors. Task shifting can only be implemented under structured and formal arrangements that prioritise patient safety, safeguard professional accountability, and uphold the quality of care.

The increasing financialisation of healthcare provision in France

France is seeing a gradual but clear increase in the involvement of private capital and investors in the provision and organisation of health services.

French healthcare is increasingly shaped by financial actors that align investment goals with care delivery.

Private investors, especially private equity and investment funds, are acquiring stakes in practices, laboratories, and other care providers, potentially exerting influence over clinical decision-making.

This trend forces healthcare to compete as a public good or as a source of financial return, risking prioritising profits over patient care.

Such pressures undermine the professional autonomy of medical practice in France.



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Regulatory responses have struggled to keep pace with these developments, raising questions about the quality, equity, and long-term accessibility of care for patients.

The French Medical Council has called for urgent legislative measures to curb financialisation, arguing that non-professional investors in medical practices jeopardise doctors' independence and patient well-being.

The Council advocates banning third-party ownership in medical practice companies and limiting external financial control to safeguard the integrity of medical practice and protect public health interests.



“The French Medical Council notes that the process of financialisation of medicine is accelerating, leading to a loss of independence of professionals and to degraded care of patients.

“In 2024, the Council's request to remove the possibility for non-professional third parties to acquire a stake in a medical professional company was not granted. The law in France, today, authorises external shareholding up to 25%. This ownership threshold allows financial groups to take control of a professional practice company through the implementation of complex arrangements. This phenomenon is particularly visible in certain specialties such as medical imaging, biology, and ophthalmology.

“Profitability then becomes the only goal sought, to the detriment of public health and the independence of practitioners. The ambiguity is that financial actors are within the framework of the law, even if they divert its spirit, which aimed precisely to preserve the professional independence of physicians while allowing them to retain decision-making power.

“Our challenge is to involve all stakeholders in solutions that preserve doctors' control over their medical practice and support ethical financialisation in France and Europe.”



Dr Lucie Jousse
*CNOM Vice President
responsible for the mission
on financialisation*

Financialisation of healthcare: a trend across Europe

The trend of financialisation is not only evident in France, but has developed gradually in Europe over recent decades. Financial actors without medical background or mandate are accessing the ownership and governance of medical facilities as capital investors to skew patient care to the maximum economic profitability of services and restricting doctors in their clinical practice.

Escalating governmental pressure on the Hungarian Medical Chamber

In February 2023, the Hungarian Parliament passed legislation rescinding compulsory membership of the Chamber in order to practice. In 2025, a government representative for health publicly questioned the Chamber's very existence.

After the 2023 legislative change, doctors were no longer required to be members of the Chamber to practice, and had to submit a written declaration within 30 days if they wanted to stay, otherwise, their membership was automatically terminated. Despite the measures, roughly 70% of the membership of the Chamber renewed its membership.

In a letter to Prime Minister Viktor Orbán, CPME called on the government to recognise the value of the Chamber for the organisation and delivery of high-quality healthcare as well as broader societal benefits, to support their activities, and to consult them throughout the policy process. CPME has since exchanged with the ministry and clearly expressed concerns and disagreements in a meeting with the Minister of the Interior.



Patient safety is in danger as the pillars of the profession have been compromised, including ethics, licensing and professional guidelines.

Since 2007, many pillars of the independence of the Chamber had already been lost. For example, the responsibility for licensing, drafting ethical codes and overseeing disciplinary actions was removed from the Chamber and transferred to the Medical Research/Health Sciences Council, an entity under the interior ministry, which is responsible for health. The legal changes were passed without any public discourse.

The changes mean that neither the Chamber, nor the ministry, have reliable numbers of doctors, and is not in a position to defend medical ethics. The ministry does not have proper protocols, for example there is no procedure to retract the certification to practice. Without such procedures, the safety of patients is in danger.



“Recent actions taken against the Hungarian Medical Chamber have clearly demonstrated that limiting the autonomy and self-governance of the medical profession ultimately harms patients most.

“Professional self-regulation is not an abstract privilege for doctors, but a core safeguard of high-quality patient care. Whether through maintaining accurate professional registers or addressing ethical issues, these functions primarily serve patients’ interests.

“Weakening professional autonomy undermines standards, accountability, and trust – key elements without which safe, effective, and ethical healthcare cannot exist.”



Dr Péter Álmos
*President of the Hungarian
Medical Chamber*

Existence of robust organisations representing the medical profession strengthens democracy

Independent medical associations are key in making patients’ right to health a reality and safeguarding the highest quality of medical practice and autonomy.

We reiterate that if clinical decision-making is undermined by administrative interference with this role of the doctor, the rights of patients to have doctors responsible for their high-quality healthcare could be seriously threatened. Unfortunately, this could also include reduced trust in treatment, decreased compliance and loss of social trust in healthcare.

Sustained judicial pressure on Turkish Medical Association

In the last decades, members of the Turkish Medical Association (TMA) have been subjected to forms of judicial harassment, including arbitrary detention and politically motivated trials, unlawful office searches, threats and imprisonment.

The first lawsuit filed against TMA executives followed a 2018 press release titled 'War Is a Public Health Problem'. The charges brought against the executives included 'inciting the public to hatred and hostility', as well as 'spreading terrorist propaganda'. The High Criminal Court sentenced the TMA's Central Council members to prison.

Upon the TMA's appeal to the higher court, all Central Council members were acquitted of all charges. However, as the prosecutor appealed this acquittal, the case is currently under review by the Court of Cassation.

The second case was filed in 2022 on the allegation of 'engaging in activities outside the organisation's purpose'. The lawsuit argued that an assessment made by the then-Central Council President, Prof. Dr. Şebnem Korur Fincancı, to a media outlet in her capacity as a forensic medicine expert, was binding for all Council members.



Members of the TMA Central Council in court © Turkish Medical Association

A civil court in Ankara arbitrarily dismissed the eleven doctors from their elected positions on the TMA Central Council. An appeal to the Court of Cassation deemed the initial ruling unlawful, citing procedural irregularities, the absence of the initiating prosecutor at the hearings, and the violation of the Council members' right to a fair hearing. The retrial has commenced in the Civil Court.

Concurrently, in a separate case filed against Prof. Dr. Fincancı on charges of 'spreading terrorist propaganda', a prison sentence of 2 years, 8 months, and 15 days was handed down. This decision has been appealed, and as the case is currently under review by the Court of Cassation, the verdict is not yet final.

During this same period, the TMA initiated legal proceedings citing the raid on Dr. Fincancı's residence, the live broadcasting of footage from within her home, and insults and threats issued by political figures. The case is set to be lodged with the European Court of Human Rights.



“Physicians must be able to speak out on public health issues, defend ethical standards, and provide impartial medical care without fear of retaliation.

“Attempts to criminalise legitimate professional activities or to interfere with the democratic governance of a medical association threaten not only doctors but the health and safety of the population.

“Medical neutrality and professional self-governance are foundations of any functioning health system.”



Dr Otmar Kloiber
*Secretary General of the World
Medical Association*

Judicial interference in the work of medical doctors is unlawful and unethical

CPME, alongside other international medical associations and human rights organisations, has repeatedly expressed concern about pressure on members of the TMA for simply exercising their professional and ethical responsibilities, and attended numerous trials as an observer. European doctors call on the Turkish authorities to unconditionally safeguard the autonomy and independence of the Turkish Medical Association.

Infringements of medical neutrality provide a further worrying trend, where medical personnel, facilities, and patients are harmed, obstructed, or punished during armed conflict or political violence, in violation of international humanitarian law, including the Geneva Conventions. In this context, CPME recently [called for](#) access to Gaza for medical and humanitarian aid.

Israeli judicial reform and its implications for the health system

In March 2025, the Israeli parliament passed a law expanding elected officials' power to appoint judges, in defiance of a years-long protest.

The proposed changes seek to change the composition of the Judicial Selection Committee, giving a majority of votes to the government and thus giving the government control over the selection and dismissal of judges in all courts, including the Supreme Court.

The proposed changes seek to curb judicial review over legislation, including by legislating against the Supreme Court's exercise of judicial review of Basic Laws.

Simultaneously, the coalition has put forward laws, which could change control of media and academia and, some will have a direct impact on the healthcare system.

Although an apolitical, pluralistic organisation representing physicians from all sides of the political spectrum, the Israeli Medical Association (IMA) is concerned about the potential implications of the reform on the health system.



Doctors protest in Israel © Israeli Medical Association

This could include potential infringements to the right to health and the quality of medicine, medical specialisation as well damage to labour relations, by, for example, limiting the right to strike.

Feeling that the IMA could not stand idly aside, President Zion Hagay issued a statement, which was accepted by the majority of IMA General Assembly delegates.

A functional, ethical health system must be based on democracy and a strong, independent judicial system that ensures that the rights of patients, physicians and the health system will not be harmed.



“Thanks to sustained public pressure and the clear stance taken by the medical community, the most far-reaching elements of the proposed judicial reforms have, for now, been held back.

However, this does not mean the danger has passed. We remain deeply concerned and alert, as the underlying agenda is still very much alive. Recent attempts by the government to assert political control over independent bodies, such as the Council for Higher Education, demonstrate that the same logic continues to guide policy initiatives.

Any erosion of democratic checks and balances ultimately threatens professional autonomy, the quality of medical education, and patients’ rights. The IMA will continue to monitor developments closely and act whenever these core principles are at risk.”



Adv. Leah Wapner
*Secretary General of the Israeli
Medical Association*

Doctors’ right to protest and strike must be protected

The Israeli example demonstrates the vital role of medical associations in public dialogue. However, restrictions on NMAs’ ability to take collective action can seriously limiting the ability to protest and take industrial action.

European doctors reaffirm that all doctors deserve decent and lawful working conditions. Where this is not achieved, doctors have the right to call for the restoration of such conditions. Regulations foresee that this can be implemented without unduly compromising patient safety.

We call on all national governments to ensure doctors can exercise their social rights, including the right to strike as guaranteed under international law.

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