NEWS FROM BRUSSELS

Word from Senior Policy Advisor Dr. Theodoros Koutroubas

Dear Friends,

It seems that the EU has decided to give Healthcare at least a big part of the attention it deserves. As you will see, in this first News From Brussels of the year, the European Commission has recently proposed an ambitious health-related package of measures, and the European Parliament's Public Health Committee has worked on important proposals to enhance availability of key medicines across Member States. In France, the good work of our colleagues of ONI brought fruit with the publication of the decree that restructures and clarifies the scope of nursing practice.

Do come back to us with national news and feedback.

Have a lovely weekend!

Warm regards,

Theo

NEWSLETTER HIGHLIGHTS

New Measures to Make EU Health Sector More Innovative, Competitive and Resilient

The European Commission has recently proposed an ambitious package of measures to **improve the health of EU citizens, while ensuring the long-term resilience and competitiveness of the health sector.**

The package includes a Biotech Act, revised rules for medical devices, and a Safe Hearts Plan, which will:

- strengthen the EU biotechnology sector;
- accelerate the development of innovative new treatments and therapies for patients;
- make rules for the development of medical devices from lab to market simpler and more efficient for EU companies, while ensuring a very high level of patient safety;
- tackle Europe's leading cause of death, cardiovascular diseases, with a comprehensive EU approach to prevent, detect, and treat them in time.

Together, these initiatives will contribute to a **more modern, efficient, and resilient health ecosystem for all EU citizens**, while incentivising growth and innovation in this strategic sector.

Biotech Act

Biotechnology is one of the fastest growing sectors in the EU. It currently accounts for more than 900 000 jobs – 75% of which are in the health sector - and contributes close to **€40 billion to the European economy**. Biotech can revolutionise healthcare, as a source of ground-breaking new treatments and

Itherapies, more precise diagnoses and personalised medicines. However, as clearly pointed out in the Draghi report, the EU is lagging behind global competitors in this area, due to insufficient funding, regulatory bottlenecks and barriers to innovation.

The proposed Biotech Act will increase Europe's biotechnology potential by supporting the transition of innovative ideas from laboratory to market. It will explore new means of funding and investment for biotech companies, through a new health biotech investment pilot to be developed in cooperation with the EIB Group. It will aim to boost bio-manufacturing via targeted support.

The Act will incentivise companies to conduct research and production within Europe, accelerate clinical trials authorisations across countries, and fast-track the development of cutting-edge new therapies using AI, data and regulatory sandboxes. Furthermore, it will simplify EU regulations to reduce costs and burdens for companies. For complex innovative products it will establish single regulatory pathways. Ultimately the Act aims to build a world-leading health biotech industry that delivers for European patients.

Safe Hearts Plan

Cardiovascular diseases are the leading cause of premature death in the EU and they are preventable. They kill 1.7 million Europeans every year. Without urgent action, cardiovascular diseases are projected to rise by 90% by 2050. Furthermore, cardiovascular diseases cost the European economy €282 billion annually.

The Safe Hearts Plan is the **first ever comprehensive EU approach to tackling this immense public health challenge**. It presents targeted measures to improve prevention, detection and treatment of cardiovascular diseases.

The Plan improves heart health by helping individuals with personalised disease prediction tools and therapies, while addressing risk factors like tobacco, unhealthy diets, and alcohol. It seeks to bridge research gaps and integrate data, digital solutions and artificial intelligence to strengthen health systems. With levels of early cardiovascular deaths varying significantly across EU countries, the Plan emphasises reducing health inequalities and improving access to healthcare and therapies. For example, the Commission will support Member States in developing national cardiovascular health plans, establish dashboards monitoring health inequalities, and launch an Incubator to speed up the use of AI. Beyond public health benefits, the Safe Hearts Plan also strives to bolster the EU economy and stimulate innovation in cardiovascular care, with clear goals set for 2035.

Medical Devices

The EU is a world leader in medical devices. The sector employs close to one million people, mostly in small and medium-sized enterprises, and the EU market is worth around €170 billion. However, current EU rules are creating unnecessary costs, bottlenecks, uncertainty for companies, and delays for patients.

The plan's proposals will simplify EU rules for medical devices, support the digitalisation of procedures, and offer a coherent framework so that companies can respond to changing market conditions and patient needs. To speed up access to medical devices and guarantee a continuous supply, timelines to complete conformity assessments will be introduced.

A stronger role for the European Medicines Agency (EMA) will strengthen coordination at EU level while companies will be offered more scientific, technical and regulatory expertise. The EMA will also monitor shortages of medical devices, and a list of critical devices will be created. The reform will ensure that patient safety remains the highest priority, while enabling faster access to safe and innovative devices and strengthening the

EU's competitiveness in this vital sector. Finally, the proposal will ensure uniform and coherent rules for medical devices incorporating AI applications. Altogether, these measures should lead to **overall cost savings of €3.3 billion per year**, including €2.4 billion annual administrative savings.

Next Steps

The legislative proposals for a Biotech Act and simplification of the Medical Devices and In vitro Diagnostics Regulations will now be submitted to the European Parliament and the Council for adoption.

Critical Medicines: New Measures to Strengthen Security of Supply

European Parliament

On the 15th of December 2025, European Parliament's Public Health Committee adopted its proposals to enhance the availability of key medicines in the EU.

The draft bill, adopted with 27 votes in favour, one against and eight abstentions, aims to **ensure a high level of public health protection for EU citizens by reducing the EU's dependency on third countries and boosting the competitiveness of its pharmaceutical sector.**

Strategic projects and access to dedicated funding

The draft text supports the setting up of industrial "strategic projects'" in the EU to create, modernise and improve manufacturing capacity for critical medicines or their base substances. To promote a coordinated EU approach and to ensure legal certainty for project promoters, MEPs want the Commission to adopt guidelines for the assessment of projects.

The report requires the EU, and EU member states to prioritise financial support for strategic projects, including through regional funding. MEPs also want a dedicated "critical medicines security fund" to be established within the EU's next multiannual financial framework (MFF).

Boost collaborative procurement of innovative, high-cost medicines

MEPs want public procurement procedures to allow for the award of contracts to multiple suppliers for the same product to promote diversification of supply and ensure that production is distributed across different manufacturers and geographical locations within the EU. Contracting authorities should apply procurement requirements that favour producers manufacturing a significant proportion of critical medicines in the EU.

The report highlights the benefits of voluntary collaborative procurements (e.g. three or more EU countries acting together, or joint procurement involving the Commission and at least five or more EU countries) to improve supply, notably for rare diseases medicines, antimicrobials, and other innovative, high-cost, or specialised treatments.

Coordination and redistribution of national stockpiles

MEPs call for the creation of an EU coordination mechanism for national stockpiles and contingency stocks of critical medicines. They also want the Commission to have the power to decide on, as a last resort, the redistribution of medicines from one national stockpile to one or more of other countries, in instances where a shortage or a supply disruption of a critical medicinal product has been identified.

Rapporteur Tomislav Sokol (EPP, HR) said: "*Today's vote is a defining moment for Europe's health security. We are committed to strengthening the availability and supply of critical medicines for all EU citizens. We are tackling persistent shortages and reducing our dependence on a limited number of external suppliers. The report sets out the strategic projects, collaborative procurement, and incentives needed to boost EU pharmaceutical manufacturing, while ensuring fair access to essential medicines like antibiotics, insulin, and pain treatments. It would bring us closer to a resilient, independent, and patient-centric pharmaceutical ecosystem that delivers stability and better care across the EU.*"

Next steps

Parliament's position is expected to be adopted during the January 2026 plenary session, after which negotiations with EU governments can begin.

France Adopts New Regulatory Framework

The Decree on the Activities and Skills of the Nursing Profession was published in the Official Journal of the French Republic on the 24th December 2025. The French National Order of Nurses (ONI) welcomes the publication of this text, which has been eagerly awaited by the profession.

A new decree issued by the French government has changed the official role that nursing practitioners play in healthcare. This text is published in application of the law on the nursing profession adopted last June. Being a result of long-lasting and thorough consultation, it reflects a set of advances and requirements that have been supported for a long time by the our colleagues at ONI, in line with the evolution of our professionals' practices and the health needs of the population.

The decree clarifies and structures the scope of nursing practice. **It clarifies the content of nursing missions, based on nursing reasoning and clinical expertise, prevention, health education, patient follow-up and coordination of care pathways. It explicitly enshrines the recognition of nursing consultation and nursing diagnosis, providing the legal security expected of professional practices.**

It also defines the content of the nurse's own role by clearly affirming the professional autonomy of nurses. It recognizes their ability to take direct care of patients, to initiate, perform and evaluate acts and care within their field of competence, as well as to prescribe, in defined areas, health products and complementary examinations.

Direct Access Recognition

Direct access to nursing care under the specific role is thus explicitly recognized and is part of a coordinated care pathway, based on the traceability of care and interprofessional cooperation, contributing to the strengthening of access to care and the continuity of care. **This recognition is a major step forward for the profession and contributes to improving access to care and continuity of care, particularly in areas of tension.**

Finally, the text explicitly recognises state-certified nurse anaesthetists in an advanced practice logic, with a specific inclusion in the Public Health Code. The terms and conditions relating to other nursing specialties are governed by specific regulatory texts that have not yet been published.

While these changes constitute significant advances for the profession and for patients, their full effectiveness remains conditional on the publication of the implementing decrees provided for by the recently published decree.

The National Council of ONI highlights specifically that:

- the decree relating to the list of acts and care falling within the nurse's own role;
- the decree relating to the nursing prescription,

must be published by June 30, 2026.

ONI will remain fully mobilised and vigilant as regards compliance with the announced timetable and the quality of future texts, and will ensure, as part of its missions, that the implementation of these new provisions is in line with the safety of care, ethics and the interests of patients.