New measures to make EU health sector more innovative, competitive and resilient

The European Commission has today 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 therapies, 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 today's 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.

Today'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. We will also begin work with Member States to start implementing the key deliverables of the “Safe Hearts” plan.

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