

# CALL FOR EVIDENCE FOR AN INITIATIVE (without an impact assessment)

TITLE OF THE INITIATIVE	EU Cardiovascular Health Plan
LEAD DG - RESPONSIBLE UNIT	SANTE – 'Disease prevention and health promotion' unit (SANTE.B4)
LIKELY TYPE OF INITIATIVE	Non-legislative (Commission Communication)
INDICATIVE TIMING	Q4 2025
ADDITIONAL INFORMATION	Public Health - European Commission

This document is for information purposes only. It does not prejudge the final decision of the Commission on whether this initiative will be pursued or on its final content. All aspects of the initiative described in this document, including its timing, are subject to change.

## A. Political context, problem at issue and subsidiarity check

#### **Political context**

Over 1.7 million lives are lost every year because of cardiovascular diseases, which are the leading cause of death in the EU¹. They are also a significant cause of disability, premature retirement, and absenteeism, negatively impacting quality of life, shortening life expectancy and contributing to decreased productivity and economic output, costing the EU around EUR 280 billion annually².

Projections indicate a significant increase in cardiovascular disease prevalence and mortality by 2050, mainly due to the ageing population and other societal trends. Given this increasing impact of cardiovascular diseases on health systems and on individuals, a comprehensive and coordinated EU cardiovascular health plan with impactful actions that have EU-added value could bring significant benefits.

President von der Leyen's <u>political guidelines</u> and her <u>mission letter</u> to the Commissioner for Health and Animal Welfare call for the Commission to step up its work on preventive health, particularly for cardiovascular diseases. This echoes the firm recognition and call for action to tackle this public health challenge by the Council of the European Union<sup>3</sup>, the European Parliament<sup>4</sup> and stakeholders.

The EU cardiovascular health plan aims to improve public health at both individual and societal level and to contribute to competitiveness and innovation, improving EU citizens' quality of life.

## Problem the initiative aims to tackle

Most cardiovascular diseases can be prevented by addressing risk factors. Stepping up actions to improve lifestyles can significantly help reduce mortality rates for all non-communicable diseases.

Early detection and screening programmes can identify both structural and rare heart diseases. Health checks can help identify individuals at high risk of developing or dying from cardiovascular diseases, such as those with high blood pressure, high cholesterol, diabetes and obesity. Studies show that timely intervention for risk factors can reduce the likelihood of heart attacks and strokes, as around 20-40% of heart attacks occur in individuals with undiagnosed cardiovascular diseases<sup>5</sup>.

<u>Inequalities between regions, population groups and genders</u> make the need for health equity more pressing than ever. Cardiovascular disease is often considered a men's issue and more knowledge on women-specific presentation and risk factors is needed. Cardiovascular disease also disproportionately affects vulnerable groups,

<sup>&</sup>lt;sup>1</sup> https://doi.org/10.1787/b3704e14-en

<sup>&</sup>lt;sup>2</sup> European Heart Journal (2023) 44, 4752-4767 https://doi.org/10.1093/eurheartj/ehad583.

<sup>&</sup>lt;sup>3</sup> In December 2024 the Council adopted Council Conclusions on the improvement of cardiovascular health in the European Union.

<sup>4</sup> https://mepheartgroup.eu/

<sup>&</sup>lt;sup>5</sup> Call to Action: Urgent Challenges in Cardiovascular disease, Circulation 2019; 139:00-00, https://doi.org/10.1161/CIR.00000000000000552.

including children, older people, those with pre-existing conditions, and socioeconomically-disadvantaged populations.

A research and innovation gap on cardiovascular diseases means more recent, reliable and comparable data are needed for developing evidence-based policies and high-quality health products. The opportunities offered by new technologies (including digital and artificial intelligence) and personalised medicine and tools will further foster innovation and enhance the uptake of promising prevention, detection, treatment and care approaches.

## Basis for EU action (legal basis and subsidiarity check)

# Legal basis

Article 168(1) of the Treaty on the Functioning of the European Union stresses a high level of human health protection to be ensured in the definition and implementation of all EU policies and activities. Article 6(a) of this Treaty gives the EU the competence to support, coordinate, or supplement the actions of the Member States for the protection and improvement of human health.

The substantial impact of cardiovascular diseases on our society and economy make intervention and coordination at EU level appropriate, as we need to pool resources, expertise and tools at EU level. The EU cardiovascular health plan will complement the policies of Member States and will mobilise available resources towards a common goal, in respect of the subsidiarity and proportionality principles.

### Practical need for EU action

While Member States are responsible for organising and providing health services and medical care, the Commission has actively supported them in reaching the Sustainable Development Goals and particularly SDG target 3.4<sup>6</sup>, by reducing the burden of non-communicable diseases, including cardiovascular diseases.

Developing an EU cardiovascular health plan will further support Member States in reaching SDG target 3.4, in stepping up efforts on prevention, addressing widening health inequalities, and reducing the considerable burden on healthcare and economy.

As cardiovascular disease is a common challenge in all countries and the worrying trend is projected to persist and increase, action at EU level would have added value, for instance by reducing inequalities between Member States, regions, and population groups. Scarce resources<sup>7</sup> for research, innovation, and developing new interventions also call for coordinated action to achieve economies of scale.

#### B. What does the initiative aim to achieve and how

The EU cardiovascular health plan aims to help Member States reduce the number of people falling ill with cardiovascular diseases and prevent premature deaths for those with existing conditions or risk factors, such as obesity, high blood pressure or related comorbidities that increase their risk of developing heart disease.

The plan will support, coordinate, and complement Member States' efforts, paying particular attention to the division of competencies between the EU and the Member States.

Building on initiatives such as Europe's Beating Cancer Plan, the EU cardiovascular health plan is expected to include three key action areas with the most potential for EU-added value, namely:

- (1) prevention (e.g. by addressing unhealthy behaviours to reduce the risk factors for cardiovascular diseases);
- (2) early detection and screening (e.g. through an EU protocol on health checks for cardiovascular diseases or EU guidance on using digital tools for personalised treatment and remote monitoring);
- (3) management, care, and rehabilitation.

It will examine the opportunities offered by emerging technologies (including digital health tools), data-driven approaches, artificial intelligence and virtual human twins. It will also examine innovative, patient-centred and personalised solutions to help prevent, detect as early as possible, and treat cardiovascular diseases.

The plan will benefit from the transformative opportunities offered by the European Health Data Space to shift from reactive to predictive and personalised cardiovascular care, to tailor interventions to individual risk profiles, to reduce health inequalities, and to foster timely access to innovation.

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<sup>&</sup>lt;sup>6</sup> SDG Target 3.4 | Noncommunicable diseases and mental health: By 2030, reduce by one third premature mortality from non-communicable diseases through prevention and treatment and promote mental health and well-being

<sup>7</sup> ibid

It will also aim to address (i) the current research and innovation gap, in line with the Strategy for Life Sciences<sup>8</sup>, (ii) the gender dimension<sup>9</sup> and (iii) the inclusion of marginalised and vulnerable groups. It will align with the Commission's Vision for Agriculture and Food<sup>10</sup> in Europe.

The EU cardiovascular health plan is expected to also support the development of national plans and programmes dedicated to cardiovascular health through initiatives on prevention, early detection and screening, management, care and rehabilitation, and personalised approaches.

It will contribute to a more resilient and competitive European health ecosystem, empowering individuals to manage their health and strengthening Europe's leadership in responsible health innovation.

#### Likely impacts

The EU cardiovascular health plan is expected to:

- help Member States reduce the burden of cardiovascular diseases on citizens, society and economy;
- help reduce existing inequalities between Member States, population groups and genders, by ensuring the right of timely access to preventive healthcare, medicines and treatment;
- help Member States make progress in reaching the Sustainable Development Goals (particularly targets 3.2 and 3.4.); and
- help make the health and medical technology industry more competitive.

The plan will use the European Health Data Space, the AI Act and the forthcoming Apply AI strategy to position cardiovascular health as a strategic testbed for the responsible scaling-up and clinical integration of AI solutions for non-communicable diseases. It will support the validation, deployment and governance of trustworthy digital and AI tools under EU governance frameworks such as the European Health Data Space and the AI Act.

#### **Future monitoring**

The Commission will set out a monitoring framework and identify relevant indicators.

#### C. Better regulation

#### Impact assessment

Considering the nature of the initiative, no impact assessment will be carried out. The need for an impact assessment on any follow-up measures stemming from the Communication will be assessed as relevant.

#### Consultation strategy

The consultation strategy aims to ensure that all stakeholders concerned and citizens have an opportunity to express their views and share insights on the problem to be solved, the key action areas proposed, and the likely impacts. The input will feed into the development of the actions of the plan.

The consultation is addressed to citizens, non-governmental organisations, national/regional/local authorities, health and medical technology industries, healthcare providers and professionals, research and technology organisations, academia, and relevant international organisations, and any other stakeholders.

This consultation has three main streams:

- 1) a call for evidence for views and contributions from all stakeholder groups, civil society, industry, healthcare institutions and professionals and authorities at national, regional and local level;
- 2) targeted consultations with public health stakeholders and healthcare and medical technology industry (carried out through webinars and meetings); and
- 3) targeted consultations of EU Member States via the Expert Group on Public Health.

A first stakeholder consultation event was held on 16 May 2025. A second one will be held in September 2025. A report summarising the results of all consultation activities will be published on the consultation page once all consultation activities are closed and the plan is adopted.

<sup>&</sup>lt;sup>8</sup> Strategy for European Life Sciences - European Commission

<sup>9</sup> https://commission.europa.eu/document/0c3fe55d-9e4f-4377-9d14-93d03398b434\_en

<sup>10</sup> eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52025DC0075