# Stronger together: The impact of Joint Advocacy efforts for European Union and National Cardiovascular Health Plans

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## EUROPEAN SOCIETY OF CARDIOLOGY ADVOCACY AND EU CARDIOVASCULAR HEALTH PLAN

Despite the decline in cardiovascular disease (CVD) mortality in many countries, CVDs remain the most common cause of death within the European Union (EU), comprising 37% of all deaths [1]. More than 60 million people are living with CVD in the EU, roughly 1 in 10 Europeans. The burden associated with CVD is enormous for healthcare systems, society, and for patients and their families. In 2021, in addition to the human costs, CVD was estimated to cost the EU €282 billion [2]. In addition to mortality, morbidity, and costs, the experience of a heart attack or stroke can also have a profound and lasting impact on the quality of life of those affected, as well as their families or caregivers. CVD is very often perceived as a "lifestyle" disease related to modifiable risk factors, such as tobacco use, harmful alcohol intake, an unhealthy diet, and physical inactivity, for which the individuals themselves are to blame. However, many risk factors lie outside the individual's control. Therefore, the issue is much more complex and requires population-level policy interventions and a mindset shift. Many of the modifiable risk factors associated with CVD are also risk factors for certain cancers, and yet cancer and cancer treatment are viewed very differently by laypeople and policymakers. Another common misperception is that CVD is limited to older people. CVD heavily impacts people of all age groups and is the leading cause of mortality in people under 65 years in Europe [3]. While CVDs can occur at any age, their risk and prevalence increase in older people, which is particularly relevant given Europe's aging population. The population aged 65 years or older is predicted to increase significantly in the EU, rising from 90.5 million at the start of 2019 to an estimated 130 million by 2050 [4], and there will be corresponding increases in CVD incidence and its associated burden.

Furthermore, this burden is spread unevenly over Europe. Tremendous inequalities remain in patient access to appropriate cardiovascular (CV) care within and across EU countries. CVD accounts for 50%–60% of all deaths in the Baltic States and Romania, almost two-thirds (65%) in Bulgaria, but in contrast, fewer than one-quarter of all deaths in France (24%) and Denmark (22%) [4]. The higher incidence, prevalence, and disability in lower-income countries confirm the close correlation between health and wealth [5]. In addition, significant sex inequity persists in

cardiovascular care, with longer delays for diagnosis and sub-optimal management evident in females compared to males [6]. The fact that such huge variations exist shows that it is possible to achieve the lower rates of CVD seen in some higher-income countries. Significant interactions were observed between CVD risk factors and overall and CVD-specific mortality during the recent COVID-19 pandemic, clearly demonstrating the need for multifaceted public policies [7].

Such disturbing facts and figures are associated with the lack of clear EU policy on CV health. Everything that we need to improve the care of our patients — whether it is research, education, early diagnosis, or treatment — is downstream from policy. The reality is that where society puts its priorities and spends its resources is determined by policymakers, and it is our mission to ensure that CV health becomes a government priority in every country. In other words, CVD must receive attention and funding proportional to the burden and challenges that it presents to our citizens.

## EUROPEAN SOCIETY OF CARDIOLOGY REGULATORY AGENDA

EU regulatory ecosystem should be efficient, fostering innovation and ensuring timely access to optimal therapies and technologies, thereby addressing the enormous burden of unmet medical needs in CVD. The European Society of Cardiology (ESC) perspective on the European Union's regulatory agenda concerning drugs and medical devices is deeply rooted in its commitment to enhancing patient outcomes through evidence-based cardiovascular care.

The ESC strongly advocates for a harmonized regulatory framework across the EU and between different jurisdictions, particularly emphasizing collaboration with American regulators, including the Food and Drug Administration. Fragmented regulations can lead to disparities in patient care and hinder access to innovations. A unified approach would streamline processes, reduce bureaucratic delays, and ensure equitable patient access to advancements in cardiovascular care across all member states. The ESC believes harmonization is crucial not only for maintaining patient safety and efficacy standards but also for fostering a competitive and innovative environment for developers and manufacturers. Collaboration between regulatory bodies, healthcare professionals, industry stakeholders, and patients is of paramount importance to the ESC. This collaborative approach enhances the regulatory process, ensuring it is responsive to the needs of all stakeholders. The Cardiovascular Round Table provides a strategic forum for high-level dialogue between the ESC leadership and healthcare industry partners, addressing key strategic issues for the future of cardiovascular health in Europe [8].

EU pharmaceutical legislation, the most extensive reform in over 2 decades, aims to promote innovation while ensuring timely and equitable access to medicines. The ESC commends the progress made in strengthening the consultation of healthcare professionals in the regulatory process, including the drafting of scientific guidelines addressing unmet medical needs. Regulators and policymakers should proactively identify therapeutic areas where innovation is stagnating despite high disease burdens, such as CVDs. An agile and responsive regulatory system should encourage research and development in Europe.

The ESC recognizes the need for adaptive pathways and accelerated approval processes, particularly for breakthrough therapies addressing unmet medical needs. The society supports European Medicines Agency initiatives such as the Priority Medicines scheme that aims to enhance support for developing medicines offering significant benefits over existing treatments. The ESC stresses the need to tailor priority pathways to appropriately address the unmet needs of patients with cardiovascular diseases [9].

Accelerated approval should be balanced with comprehensive post-market studies to ensure ongoing patient safety and efficacy. Real-world evidence and cardiovascular registries, including those managed by the ESC, can significantly contribute to post-market surveillance, substantiating benefits and mitigating risks associated with new therapies and technologies [10]. Reinforcing public research is key to addressing existing gaps.

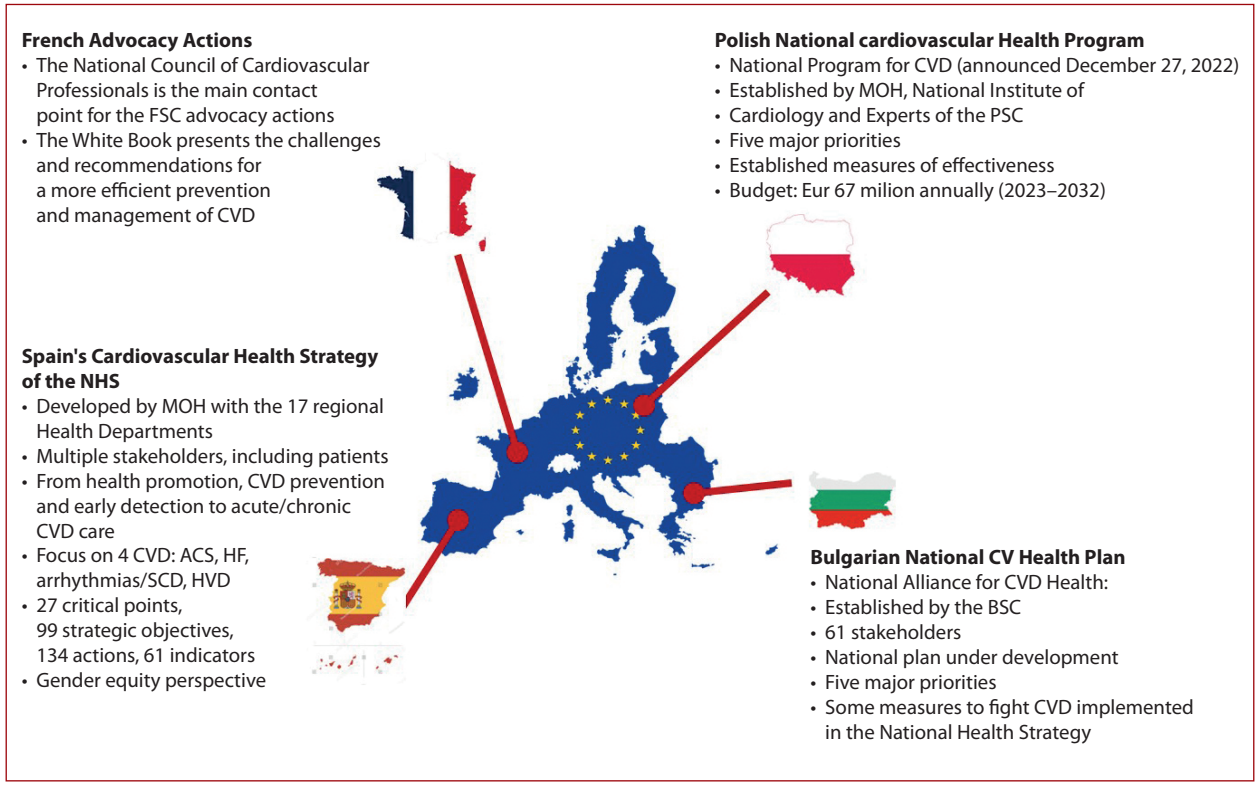
## NATIONAL PLANS FOR CARDIOVASCULAR HEALTH AND EU CARDIOVASCULAR HEALTH PLAN

At the ESC, our specific advocacy goal is to secure an EU cardiovascular health plan together with 27 national plans for cardiovascular health. This is a goal shared by all members of the European Alliance for Cardiovascular Health [11].

Best-practice guidelines on how to apply preventive measures, treatments, and rehabilitation have been developed by medical societies, such as the ESC. Yet, even when access to care is available, implementation, uptake, and adherence are often suboptimal in clinical practice. At this point, cardiovascular plans and advocacy programs are being developed or have been developed in several EU countries, including Bulgaria, France, Spain, and Poland due to outstanding efforts and exceptional engagement of national cardiac societies (Central Figure).

## BULGARIAN PLAN FOR CARDIOVASCULAR HEALTH

According to ESC Atlas, Bulgaria is among the European countries with the highest CVD mortality: 55% in males and 65% in females in 2021 [3]. A considerable proportion of affected individuals are under 65, which highlights the need for effective measures to reduce this preventable premature mortality. Risk factors are more prevalent than in the average European population. Costs incurred due to CVD are also considerable, amounting to EUR 1983 million in 2021, of which 33% were due to informal care costs, morbidity, and mortality losses, and only 37% were direct




**Central Figure.** Cardiovascular plans and advocacy programmes for cardiovascular diseases (CVDs) are being developed or have been developed by Ministries of Health (MOH), in several European Union countries including Bulgaria, France, Spain and Poland with the contribution and/or leadership of Bulgarian Society of Cardiology (BSC), French Society of Cardiology (FSC), Spanish Society of Cardiology (SSC) and Polish Society of Cardiology (PSC)

Abbreviations: ACS, acute coronary syndrome; CV, cardiovascular; HF, heart failure; HVD, heart valve disease; NHS, National Health System; SCD, sudden cardiac death

medical costs [12]. Based on these and other data, the Bulgarian Society of Cardiology (BSC) has recognized the significant societal impact of CVD and the need for rapid action.

Thus, immediately following the establishment of the European Alliance for CV Health in 2021, the BSC closely followed this initiative by establishing the Bulgarian National Alliance for CV Health. The primary role of this alliance is to involve stakeholders from different fields in creating a national plan for CV health. The Alliance and the BSC organized several events to raise awareness among politicians and decision-makers about the country's high burden of CVDs and to call for action aimed at their reduction. As a result of the systematic activities of the BSC, the National Alliance for Cardiovascular Health issued a memorandum signed by 61 stakeholders. This was crucial in providing broad societal support for the National Plan for Cardiovascular Health. The stakeholders' pledge that they assume responsibility for creating, validating, and approving this document was much needed.

Currently, the National Plan for Cardiovascular Health is in the preparation phase. The BSC has issued a document describing the concept to be implemented in the plan and outlining the significant groups of priorities as the plan's backbone. Apart from the "horizontal" actions directed towards establishing collaboration with the ESC and the other ESC member countries, the plan contains five major "vertical" actions that represent major priorities. These are

- Primary prevention to reduce the burden of CVD among the Bulgarian population. This priority is meant to identify the most effective policies and measures to identify the highest-risk groups at the population level.
- Secondary prevention by early screening and precise diagnosis in patients with established CVD to prevent progression,
- Early diagnosis and providing access to the most effective treatment, keeping with the principles of personalized and high-quality, evidence-based medical care.
- Early rehabilitation is aimed at accomplishing an early and complete functional recovery of CVD patients.
- Introduction of patient-reported outcome measures to assess the management of cardiovascular disease.

A working group of experts is currently mapping the areas in which strategic measures are needed for each of the major priorities. Once these are identified, the working group will propose concrete and detailed strategic actions that will be incorporated into the final document.

Since early April 2024, some of the main priorities mentioned earlier have also been included in the National Health Strategy 2030, which has been ratified by the Parlia-

ment. This will also make the decision-makers approve, support, and implement the measures meant to be included in the Bulgarian Plan for Cardiovascular Health. A challenge for the implementation and execution of the plan is the frequent change in governments and ministers reflecting the political instability in the country in the last years.

## ADVOCACY FOR A NATIONAL CARDIOVASCULAR PLAN IN FRANCE

Every year in France, 140 000 citizens die from cardiovascular causes. It is estimated that more than 15 million citizens are at risk of developing cardiovascular conditions; this number is steadily increasing by 2.5% every year, especially due to population aging. Despite this dramatic burden of CVDs on the country's public health, no specific national plan is yet available. One of the most concerning aspects is the age demography of cardiologists in France, with more than 25% being older than 60 years and with concerns about the future: while 240 cardiologists retire every year, only 200 young physicians get qualifications in cardiology [13]. Hence, the advocacy for a national CVD plan is essential to improve all aspects of CVD management [14].

Such advocacy in France is supported by several stakeholders, including not only the French Society of Cardiology (FSC) but also the French Federation of Cardiology (public-oriented) as well as patient associations. The National Council of Cardiovascular Professionals is the main contact point for the government and is composed of 4 entities: the FSC, the Hospital Council, the Private Council, and the Private Cardiologists Union. The good relationship among these entities has been instrumental in organizing advocacy actions, with the publication of a White Book to present the challenges and recommendations for more efficient prevention and management of CVDs in this country. This document emphasizes the importance of improving access to care for individuals with, or at risk of, CVDs, as well as the need for more investment in research in cardiology and promotion of CVD awareness. The ESC has directly supported the FSC in this mission. However, the relative instability of the government (with 4 health ministers in 2 years) has made this endeavor more difficult. Recently, contacts have been made with MPs to propose a law on cardiovascular care, with a special focus on measures for better prevention, but the current political instability in the country is an additional challenge.

## SPANISH NATIONAL CARDIOVASCULAR HEALTH PLAN

Although survival rates are improving progressively, CVD was the first cause of mortality in Spain in the last decades, particularly among women up to this year [15, 16]. The Interterritorial Council of the National Health System of Spain, which has a decentralized model composed of 17 regional health systems, approved the Cardiovascular Health Strategy of the National Health System (ESCAV: *Estrategia de Salud CArdioVascular del SNS*) on April 27, 2022 [17]. Contrary to National Plans, National Strategies are not supported by specific allocated budgets.

The main aim of ESCAV is to improve the cardiovascular health of the Spanish population, reducing inequities in cardiovascular health and, at the same time, streamlining care delivery across the regions. ESCAV will support regional health systems to ensure continuity of care for all CVD patients, from prevention, acute pathology care, chronic care continuity, and effective and safe rehabilitation. Specific aims of ESCAV include 1) promoting the adoption of healthy lifestyles, 2) fostering cardiovascular prevention, 3) improving cardiovascular care through early CVD detection and interdisciplinary and coordinated acute and chronic CVD care, and 4) adopting safe, efficient, and sustainable measures.

ESCAV was developed by a committee composed of nearly 100 members, including health and non-health professionals from 16 different disciplines, decision-makers, and patients. Its structure includes 27 critical points, 99 strategic objectives, 32 general objectives, 67 specific objectives, 136 actions, and 61 indicators articulated under three overarching axes: continuity of care, safety, and use of information systems to guide and monitor changes and six common approaches within each axis: 1) health promotion, CVD prevention, and early detection; 2) citizen empowerment and participation; 3) equity (particularly gender equity); 4) comprehensive management of patients with acute CVD; 5) comprehensive management of patients with chronic CVD; 6) knowledge management, research, and innovation.

The scope of ESCAV spans from tackling social determinants of health to the creation of specific regional care networks for complex CVD cases, such as cardiogenic shock. Four cardiovascular syndromes were selected according to their prevalence or social impact: ischemic heart disease, heart failure, arrhythmias (including sudden death), and heart valve disease.

Currently, the actions taken to develop the multiple tasks include:

- Communication and dissemination of the strategy through national and local meetings.
- Open call to share best practices in ESCAV-related activities for all regional health systems as the first step towards building a continuous and transparent repository of selected best practices evaluated by expert groups.
- Forming strategic alliances with healthcare professional associations, in particular with the Spanish Society of Cardiology and the Spanish Society of Quality in Healthcare, to advance the development of ESCAV. Spanish Society of Cardiology is providing scientific support to launch the programs to develop regional networks for the management of cardiogenic shock (Shock Code), extension of regional networks for acute myocardial infarction to manage also patients with non-ST-segment elevation acute myocardial infarction, and the National Cardiac Arrest Plan. The Spanish Society of

Quality in Healthcare led the scientific management of good practices.

The strategy incorporates key aspects such as fostering research and technological innovation to address healthcare needs from the perspectives of individuals and families and prioritizing information systems and data sharing to achieve improvement.

## POLISH NATIONAL CARDIOVASCULAR HEALTH PLAN

Poland belongs to the group of countries with a high cardiovascular risk, which translates into a 2.5 times higher risk of developing symptomatic atherosclerosis compared to European countries with low risk [18]. On December 27, 2022, Poland established the National Program for Cardiovascular Diseases (NPCVD), which is expected to receive funding of up to EUR 67 million per year in the years 2023–2032 [19]. The aim of the NPCVD is: 1) to reduce the incidence and mortality of CVDs, including the reduction of excess mortality of men of working age (25–64 years) and to bring health indicators closer to the average rates in the EU-27; 2) reducing regional differences in morbidity and mortality and availability of healthcare services; 3) reducing the severity of classic risk factors for CVDs; 4) improving the organization of scientific research and innovation. The five main fields to be funded under the program are investments in medical personnel, investments in education, prophylaxis and lifestyle, investments in patients, investments in research and innovation, and investments in the cardiac care system. Polish Cardiac Society (PCS) experts, including former PCS Presidents, participate in the work of the National Council of Cardiology, the advisory body of the Ministry of Health, which supervises the program. In the current year, several main tasks, among others, will be financed: investments in equipment for non-invasive and invasive diagnostics, new programs for post-graduate cardiology fellowships (specialization), system of new screening programs (i.e., screening of lipid disorders of 8-year-old children), establishing standards of care in selected fields (heart failure, hypertension, valvular heart disease, cardiac arrhythmias and others gradually joining), establishing a uniform system for collecting data in medical registries, multicenter trials on CVD epidemiology. The Polish Cardiac Society developed several position papers and expert opinions, including those on structural heart disease interventions, mechanical cardiac support, therapeutic targets for low-density lipoprotein cholesterol in secondary prevention of myocardial infarction as well as inherited cardiovascular disease, including their therapy in Poland, to provide specific, precise data on the goals listed in the section on the Polish plan [20–24].

It is highly important to make the new diagnostic and treatment modalities available for patients to make the care more effective. The PCS advocated for the reimbursement of new cardiology interventions. As of January 1, 2024, the catalog of guaranteed services includes 4 more procedures: leadless pacing of selected patients, rhythm monitoring using implantable loop recorders, treatment of tricuspid regurgitation using the edge-to-edge method, and mechanical support of left ventricular function as a destination therapy. Since 2023, telemonitoring of implantable devices has been introduced as part of outpatient care. PCS experts, together with representatives of other national scientific societies, prepared position papers. They are taken into account in ongoing reimbursement processes. New drugs for the treatment of rare diseases were included in the reimbursement list (ATTR — tafamidis, HOCM — mavacamten). A stepwise liberalization strategy allowed a change of the criteria for enrolling patients in the second important program: the use of proprotein convertase subtilisin/kexin type 9 inhibitors or inclisiran in patients after myocardial infarction at very high cardiovascular risk, which is financed by the National Health Fund. From April 1, 2024, the Ministry of Health has decided to reduce the low-density lipoprotein cholesterol entry threshold in this program from 100 to 70 mg/dl (2.6 to 1.4 mmol/l). The integrated part of the NPCVD is the "Country Cardiac Network," which was introduced as a pilot on May 11, 2021 [25]. In the beginning, it covered only the Mazovian province, but since November 10, 2022, was expanded to 6 more regions (Greater Poland, Lesser Poland, Lower Silesian, Łódź Province, Pomerania and Upper Silesia). So currently, the program is implemented in 7 out of 15 country's provinces and covers 2/3 of the Polish population. It is expected that in 2026, after evaluation of the results of the pilot phase, the "Country Cardiac Network" is going to be extended to the whole country. The program provides unlimited financing of services in 4 selected areas: secondary and resistant hypertension, heart failure, arrhythmias, and valvular heart diseases. The goal of the program is to make the final cardiovascular diagnosis faster — within 30 days after reporting to the centers participating in the pilot. It also sets up cooperation between various levels of care (primary care, outpatient cardiac services, hospitals). Besides making the diagnosis faster, the program established pathways from in-hospital care to outpatient services, which is particularly important for patients with heart failure. The next important NPCVD activity is the development of electronic individual treatment plans for every CVD patient entering the Country Cardiac Network and making them available online for all physicians at different levels of care.

## SUMMARY AND CONCLUSIONS

Effective policy and healthcare planning are crucial for tackling CVDs. The ESC advocates for an EU-wide cardiovascular health plan and corresponding national plans. Several EU countries have already made progress. Bulgaria has established a National Alliance for Cardiovascular Health, emphasizing prevention, early diagnosis, treatment, and rehabilitation. France faces challenges due to a shortage of cardiologists and political instability but has organized advocacy actions and proposed laws for better cardio-

vascular care. Spain's Cardiovascular Health Strategy aims to reduce health inequities and improve care continuity despite lacking specific funding. Poland's National Program for Cardiovascular Diseases, funded until 2032, focuses on investments in medical personnel, education, prevention, patient care, research, and innovations, with the pilot "Country Cardiac Network" aimed at expediting diagnosis and treatment.

In conclusion, despite significant strides in CVD mortality reduction, the EU faces significant challenges due to the lack of a clear CV health strategy. National and EU-wide cardiovascular health plans are essential for mitigating the disease burden, coordinating policy efforts, securing adequate funding, and creating comprehensive strategies for prevention, early detection, and equitable access to care across member states.

## A CALL TO ACTION

CVDs remain Europe's leading cause of death and impact all domains of life and human activity, such as environment, climate, employment, demographics, infrastructure, and research [26]. Neglect and lack of public investment in cardiovascular health threaten to undo hard-fought efforts to reduce the CVD burden. We call for urgent and bold EU action to address the overwhelming burden of CVD. Each member state should have a cardiovascular health plan.

### *Article information*

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