



EHN feedback: Revision of the EU general pharmaceuticals legislation

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The European Heart Network (EHN) welcomes the patient-centred approach of the Pharmaceutical Strategy for Europe, including the revision of the EU general pharmaceuticals legislation, with a view to foster patient access to innovative, safe, available and affordable medicines.

EHN represents heart foundations and cardiovascular patient associations dedicated to improving cardiovascular health in Europe. Cardiovascular disease (CVD) remains by far the leading cause of death in the European Union (EU) and it impacts the lives of more than 60 million EU citizens, both young and old. Around 20% of all premature deaths (before the age of 65) in the EU are caused by CVD. Many cardiovascular conditions are inherited (such as certain cardiomyopathies and arrhythmias) but they do not necessarily manifest themselves until adulthood. Risk and prevalence of CVD increase further with age. This is of utmost relevance in view of Europe's ageing population. In 2040, 155 million Europeans will be over 65. Whilst Europe is still amid the management of the COVID-19 pandemic, the repercussions of the pandemic on CVD mortality and morbidity will continue to increase and further impact the resilience of healthcare systems. Without decisive action, the number of citizens suffering from CVD and the burden of disease will invariably increase dramatically.

Investment in CVD research is particularly low compared to the disease burden and innovation is lagging behind other clinical areas. The role of and access to innovation in cardiovascular medical technologies and medicines should be recognised. This can help close the gap in investment in CVD research.

Several pharmaceutical companies have moved out of the cardiovascular field. In the past five years, about a dozen CVD treatments have been approved by the European Medicines Agency (EMA), yet the vast majority were generics or biosimilars. Challenges that have a negative impact on innovation in CVD include:

- Clinical trials (CTs) on CVD therapies are more expensive compared to other disease areas. They tend to be very large and lengthy to include the most robust measures of mortality (cause of death CVD or non-CVD related), while in other areas surrogate endpoints are more accepted (e.g. progression-free survival in oncology).
- There is a strong focus on 'unmet need'. However, the concept merits a much clearer definition considering the variety and diversity of needs across disease areas and more importantly what patients need. For example, for some CVD patients, the ability to breathe unrestrictedly is more important than limited additional life expectancy.

Quality-of-Life and patient-reported outcome measures in CVD clinical trials could be more prominent.

Shortages of cardiovascular medicines have become increasingly common. [Surveys](#) by the European Association of Hospital Pharmacists show a worrying upward trend of CVD shortages. Given few therapeutic alternatives to drugs in short supply, these shortages pose a major challenge and have heavy consequences on CVD patients' health.

Digitalisation is steering medicine towards real-time data extraction (real world data) and analysis of various sources, such as electronic health records, wearable devices and registries. Big Data and artificial intelligence (AI) hold great potential to boost clinical and pharmacological research in CVD by improving the design, speed and efficacy of more targeted and multi-country clinical trials at lower cost and less time, without compromising safety of patients. Real world data can provide important information, complementing clinical trial data: on the natural course of a disease, on patient characteristics, on therapeutic gaps and quality of life. It can also serve as an external reference for determining comparative effectiveness of medical technologies and medicines. Interoperability, data standards, quality controls and independent scientific and regulatory validation are key to foster reliability in digital technologies and important for patients to trust them. Clear rules on data ownership, including data transfer to third parties and withdrawing consent, need to be covered by legislation.

Recommendations:

- Views of CVD patients on 'unmet need', 'innovation' and value assessment must be central to decision-making.
- The diminishing pipeline of new CVD treatments needs to be tacked by placing a greater emphasis on matching discovery science to unmet clinical needs and by modernising clinical trials to fit the digital era.
- A balanced, regulatory approach weighing digital innovations against protection of personal data is needed.

Additional sources:

EHN ESC 'Fighting cardiovascular disease – a blueprint for EU action', June 2020, <https://ehnheart.org/eu-action-on-cvd.html>

EHN paper 'What is the value of digital tools for cardiovascular patients?', July 2020, <https://ehnheart.org/publications-and-papers/publications/1285:digital-tools-cardiovascular-patients.html>