

EuropaBio observations in response to Europe's Beating Cancer Plan

EuropaBio welcomes the European Commission's commitment to develop a European plan to fight cancer and is supportive of its overarching approach in tackling all key stages of the disease: prevention, early diagnosis, treatment, and quality of life. Above all, we strongly advocate the employment of supportive measures for health innovation to ensure that novel cancer treatments move from the laboratory to the hospital bedside as swiftly as possible.

In this context, EuropaBio is pleased to share its views and would welcome any opportunity to further discuss these points during a meeting or conference call.

EuropaBio, the European Association for Bioindustries, is the recognised voice of the European biotechnology sector, representing 81 corporate and associate members, and bioregions, and 15 national biotechnology associations which in turn represent over 1800 biotech SMEs.

Our comments are focused on the importance of access to, and uptake of, high-quality innovative therapies, as well as on the challenges related to data and scientific evidence. EuropaBio considers the recommended actions below to be essential for creating a European healthcare environment which accelerates the adoption of high-quality innovative therapies that can meaningfully contribute to a different paradigm for tackling cancer in the future, thereby maximising the impact of cutting-edge science to the benefit of cancer patients.

EuropaBio welcomes the European Commission's intention to develop measures improving prevention, early detection and diagnosis. Additionally, we would like to provide specific comments on the following pillars.

Treatment and care

The Cancer Comparator Report for Europe (IHE, 2019) notes that investment in cancer research has resulted in a growing number of approved cancer medicines. While we have seen more treatments reach patients in the last decade, we have also seen the adoption of innovative approaches such as

targeted immunotherapies which use the body's own immune system to combat cancer.

Advanced Therapy Medicinal Products (ATMPs) are a new generation of innovative medicines based on genes, cells, or tissues. These highly personalised approaches indicate a new wave of treatments which bring the potential to cure diseases, including cancer, and to dramatically improve patients' life expectancy and quality of life. An example of one such treatment, CAR-T cell therapy, is already showing promising results in adults and children suffering from specific types of blood cancer. The CAR-T cell therapy can achieve complete recovery (no detectable cancer) in patients for whom few or no other treatment options available.

While cutting-edge technologies have the possibility of transforming the cancer treatment landscape, related treatments require an environment that is supportive of healthcare innovation. EuropaBio invites the Commission, in collaboration with the European Medicines Agency (EMA), to consider measures to help ensure that treatments can move from the laboratory to the hospital bedside as swiftly as possible:

- The regulatory framework for ATMPs should encourage and facilitate research and development in areas of unmet medical need. To this end, the European Commission should take steps to remove complexity and obstacles which make it more difficult to conduct clinical trials in the EU, including measures to streamline approval processes for ATMPs that contain genetically modified organisms. This would also boost the global competitiveness of the EU.
- Strong intellectual property incentives are vital to foster research and development, and the European Commission should ensure that the strengths of the current incentives' framework are protected and remain a key driver of innovation in areas of unmet medical need.

Access and uptake of these new therapies is strongly dependent on appropriate and modern healthcare systems, services delivery, and health workers skills. As highlighted in the Commission Roadmap, "our healthcare systems were originally designed to treat short-term, acute infectious diseases". Scientific developments and new therapies, such as gene and cell therapies, that hold the potential to revolutionise the way cancer will be treated in the future, require measures that contribute to adapt healthcare systems' models. In this respect, EuropaBio recommends that:

- The EC and Member States should work together and in collaboration with other stakeholders, including industry, to ensure healthcare systems and



health professional skills are adapted to the increased prevalence of cancers to ensure optimal access and use of innovative diagnosis tools and therapies. This requires long-term planning of infrastructure and health professional skills, as well as continuous training in the use of innovative technologies.

Knowledge, data, and scientific evidence

EuropaBio is supportive of the European Commission's intention to explore ways to fill existing knowledge gaps on cancer. Due to their innovative nature, evidence uncertainty is an element that particularly characterises therapies such as ATMPs, some of which are specifically developed to treat cancers. The evolution of technologies and the opportunities provided by digital health tools can contribute to addressing such gaps and reducing the existing uncertainty around scientific evidence.

- There is a significant opportunity for the healthcare sector arising from the development of personalised medicine, genomics, and artificial intelligence, which will have an increasing impact in cancer care and research.
- To maximise the potential gains from these growing areas, the EU must reduce obstacles to the collection, sharing and utilisation of real-world data.
- In particular, there is a need for standardisation of electronic health records, core outcomes sets and registries to ensure that evidence gaps for innovative therapies are reduced, thereby equipping decision-makers to assess their value to patients and the broader healthcare system.
- EuropaBio strongly believes that the Europe's Beating Cancer Plan should be well aligned to complementary initiatives in this area, as is the planned creation of a European Health Data Space.

