European Hematology Association (EHA) recommendations for the upcoming Biotech Act

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The European Hematology Association (EHA) is the leading representative of hematology and hematology professionals in Europe. We are a not-for-profit, public-benefit organization with over 10,000 members and an annual congress welcoming around 18,000 stakeholders each year. EHA supports career development and research, develops and harmonizes hematology education, and advocates for enhanced, affordable and equitable access to innovative therapies for patients with hematological disease across Europe.

EHA recommendations to deliver a fit-for-purpose Biotech Act:

EHA finds the Commission's announcement regarding a Biotech Act extremely timely and necessary. Biotechnological products hold unprecedented potential to improve diagnostic and treatment options for patients, ensuring better health outcomes. From precision diagnostics to advanced therapies, biotech solutions are already reshaping the healthcare landscape. However, it is crucial that these products reach the end-user without unwarranted delays. The Biotech Act must therefore place patients at the center — ensuring equitable access to high-quality, safe and effective biotechnologies across the Union.

1. An adequate regulatory framework

Simplified and streamlined

A simplified and harmonized regulatory framework is necessary to allow the sector to flourish. The high administrative burden and discrepancy between national regulatory approaches gravely hinders (timely) access to innovation. A streamlined, predictable, and science-based regulatory environment applicable across the EU will accelerate the development and market entry of biotech solutions, to the benefit of patients and healthcare systems.

Future-proof

Over the past decade, the medical and life sciences landscape has undergone transformative change. From the advent of CAR-T cell therapies to the integration of AI in diagnostics, innovation has redefined what is possible in patient care. The Biotech Act must be designed to support and adapt to healthcare innovation in the coming decades. Innovators need a future-proof regulatory framework – one that is continuously informed by scientific progress. This stability fosters long-term investment, accelerates the development of new treatments, and ultimately delivers a net gain for all – including patients.

2. Public investment with public return

Public investment in biotechnology must be accompanied by tangible public benefit. EHA advocates for EU (and national) funding mechanisms that guarantee transparency, and promote affordability and reinvestment in public health. This includes conditionalities that ensure publicly-funded innovation is accessible and contributes to sustainable healthcare delivery.

Transparency

EHA strongly supports funding transparency. Manufacturers should disclose the complete funding history of biotech products —regardless of geographic origin, as well as any funding associated with acquired biotech products. This information will be crucial for Member States whilst negotiating fair prices for their health systems. It will furthermore ensure that public and non-profit investment is recognized and reflected in pricing strategies and market access.

Stimulating competition

Public investment should also be deployed with a view to facilitate real competition – not just among the bigger companies. Academic institutes and SMEs should receive support in order to be able to make valuable contributions to the sector. Studies show that investments in health research have an internal rate of return of 10%, i.e., every invested euro yields €0.10 annually in perpetuity, thereby positively impacting the country's GDP for the foreseeable future[1].

3. Equitable access to biotech products

Disparities in access to biotechnological products between the Member States must be tackled by the legislation. EHA therefore urges the Commission to include mechanisms in its proposal with a view to improve access. One example could be joint public procurement, as incorporated in the recently proposed Critical Medicines Act. Under-resourced health systems need support.

4. Impact assessments

Ultimately, the success of the Biotech Act should be measured by its contribution to better health outcomes. EHA encourages the Commission to embed health impact assessments into the legislative framework, with particular regard for patient-reported outcomes.

5. Systematic stakeholder input

EHA asks the Commission to include, in its proposal, a stakeholder network or forum, as it has done in the HTA Regulation and the European Health Data Space, respectively. Such an avenue will be crucial to enable exchanges among relevant stakeholders regarding the

[1] Health Economics Research Group, Office of Health Economics, RAND Europe. Medical Research: What's it worth? Estimating the economic benefits from medical research in the UK. London: UK Evaluation Forum; 2008. Page 42.

implementation and application of the legislation. This forum should entail diverse stakeholder representation, including health professionals and patients, and foster a regular and transparent dialogue. The forum could jointly develop Key Performance Indicators (KPIs) to monitor implementation progress and accountability.

Any governance frameworks set up at EU and national level should likewise involve relevant health stakeholders.

6. Interaction with other EU legislation

The Biotech Act will interact with other pieces of legislation, such as the European Health Data Space (EHDS) and the Medical Devices (IVDR and MDR) regulations. It is important that the Commission's upcoming proposal takes these interactions into account, and includes the necessary specifications to allow for clarity and legal certainty.