AseBio and EuropaBio address the challenges of the Pharmaceutical Strategy and NBTs in Europe

- During the Presidency of the Council of the European Union, Spain will lead the dialogue on these critical policies for European patients, food safety, and the green transition.

- "We need to find a path that ensures access for all patients to medications and reduces waiting times," says Ana Polanco, President of AseBio.

- "Europe needs to define a predictable regulatory framework for new genome editing techniques. Only then can we harness our scientific, human, infrastructure, and raw material strengths to build a competitive ecosystem in industrial biotechnology," explains Ion Arocena, CEO of AseBio.

The European Association for Bioindustries (EuropaBio) and AseBio have hosted the Annual Summit of the National Associations Council (NAC) of EuropaBio, held on June 22nd. This meeting takes place within the framework of the upcoming Spanish presidency of the Council of the European Union, from July 1st to December 31st, 2023.

At a **crucial moment for the biotechnology industry**, Spain will lead the dialogue on the **European Commission's proposal on new genomic techniques**

(NGTs) and the **review of the Pharmaceutical Strategy for Europe**, critical policies for European patients, Europe's food safety, and the green transition.

The Summit began by focusing on the process of reviewing **healthcare innovation mechanisms** in which Europe is currently immersed, with European pharmaceutical legislation acting as a central axis. This was the main topic of the first panel held during this event, where participants discussed what this means for patients and Europe's overall competitive position.

Ana Polanco, President of AseBio, highlighted the Spanish biotechnology ecosystem and its strength, two key elements that make it attractive to innovative pharmaceutical and biotechnology companies in this new scenario. In this regard, she shared advancements in regulation that have occurred in countries like the United States and China, with the aim of attracting the interest of pharmaceutical and biotech companies.

"We need to create a better environment that enables **increased competitiveness and autonomy for Europe**", argued Polanco. "We are at a critical moment in Europe. We need to create the right environment to invest in Europe", she expressed, referring not only to the challenge posed by pharmaceutical regulation but also to other challenges such as the European Green Deal.

The President of AseBio emphasized that all the steps being taken should aim to **"facilitate access to innovation in Europe."** She added, "We need to find a path that ensures access for all patients to medications and reduces waiting times", and called for **"all stakeholders to work together"** in order to develop a "real plan for European health" in the face of the current complex system of access to medications.

"Europe needs to recognize the role of the biopharmaceutical industry and create a favorable ecosystem for innovation. **Pharmaceutical legislation is a**

great opportunity to advance both Europe and the biotechnology ecosystem", Polanco concluded.

The European agri-food chain and new genomic editing techniques

The second panel of the day analyzed the challenges faced by the European agri-food chain in terms of resilience, sustainability, and competitiveness in the context of **new genomic editing techniques (NGTs)**. Participants explored European goals in the field of industrial biotechnology innovation and how these goals can be achieved.

Ion Arocena, CEO of AseBio, highlighted the existing competitiveness in both Spain and Europe, not only in the field of industrial biotechnology but also in NGTs. However, in order to translate this into real impacts, **"we need to adapt regulatory frameworks to innovations"**.

"New genomic editing techniques are characterized by their effectiveness. They can be very precise, fast, and relatively inexpensive. Therefore, they have the potential to enable the development of new innovative products more efficiently and with fewer resources," Arocena stated.

This implies a **predictable regulatory framework for NGTs** since the current one is clearly outdated. It also requires regulations that are suitable for the pursued objectives and that enable innovation, as well as a flexible framework that can adapt to the development of new technologies without needing to completely modify the regulations each time a new technology emerges.

"**Europe needs to define a predictable regulatory framework for new genome editing techniques**. Only then can we harness our scientific, human, infrastructure, and raw material strengths to build a competitive ecosystem in industrial biotechnology," argued the CEO of AseBio.
"Regulation is a necessary condition but not sufficient," argued Arocena. "The investment required to scale up industrial biotechnology processes is often

high, and accessing financing for large-scale biofabrication projects can be challenging in Europe", Arocena concluded.

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Who we are
AseBio has roughly 300 members and represents the whole Spanish biotechnology sector. Its mission is to lead the country's transformation, positioning science, innovation and particularly biotechnology as a driving force for economic growth and social wellbeing. Members include companies, associations, foundations, universities and technology and research centres that are directly or indirectly involved in the field of biotechnology in Spain.