A global Europe the role of transformative legislation

EuropaBio National Associations Summit 2023
Spanish Council Presidency – event report

Summary

Spain assumed the Presidency of the Council of the European Union in the second half of 2023, from July 1 to December 31, in a period of significant challenges for the Member States and the European Union.

The Spanish Presidency has established several priorities for its semester, including fostering and promoting the agri-food technologies essential to the transition towards a more sustainable production model, enabling climate change preparedness and reducing Europe's dependence on imports in an unstable geopolitical scenario.

Likewise, the Presidency continues the work set in motion by the COVID-19 pandemic response. It is focused on strengthening the EU's health autonomy through EU-based innovation and reduce dependence on third countries.

To mark the Spanish Presidency of the Council of the European Union, EuropaBio National Associations, with the support of AseBio - the Spanish Association of Biotechnology Companies, hosted an online summit centred on two fundamental policy proposals for Europe's socioeconomic ambitions and global position - the revision of the general pharmaceutical legislation (GPL) and the proposal for a regulation on plants obtained by certain New Genomic Techniques (NGTs).

This executive report highlights some of the key takeaways of the discussion with additional feedback from biotechnology developers, associations and attendees.

Participants

Healthcare session

- MEP Dolors Montserrat (ES, EPP)
- Ana Polanco, AseBio Chair of the Board, Head of European Government and Public Affairs and Market Access and Pricing at Merck
- Jessica Martinsson, Director General at SwedenBio
- Maria Pascual, Chief Regulatory Officer at Minoryx Therapeutics
- Moderation: Vlad Olteanu, Healthcare Public Affairs Director at EuropaBio

Industrial Biotechnology session

- Ana Judith Martín de la Fuente, Head of Area/Secretary of the Interministerial Council of GMOs at the Spanish Ministry of Agriculture, Food and Fisheries
- Ilaria Ciabatti, Team Leader Biotechnology Unit, European Commission DG Santé
- Ion Arocena Vélez, Director General at AseBio – the Spanish Association of Biotechnology Companies
- Elke Duwenig, Senior Expert Global Regulatory / Public & Government Affairs Biotechnology, Nutrition & Health at BASF
- Oana Dima, Executive Manager of the EU-SAGE network, Science Policy Manager at VIB Ghent University Center for Plant Systems Biology
- Tomasz Zimny, Assistant Professor at the Institute of Law Studies, Polish Academy of Sciences, Warszawa, Poland
- Moderation: Anne-Gaelle Collot, Industrial Biotechnology Director at EuropaBio

Innovation for European patients a balanced ecosystem

Biotechnology has transformed the life-sciences and pharmaceutical industry in the last two decades, delivering breakthrough life-changing therapies for patients and society. Economically, the biotechnology sector has been a national and regional development engine, responsible for over €34.5 billion in direct GDP contribution and 1.1 million jobs in Europe in 2021.

The continent has a diverse and rich biotechnology ecosystem. Europe hosts 42 of the world's top 100 universities for life sciences, has world-leading research centres, established companies and emerging smaller innovators - with the latter responsible for over two-thirds of the research and development pipeline that will become tomorrow's medicines.

Nonetheless, Europe is not realizing its scientific excellence. The continent's research and clinical trials have declined, leading to slower access to innovative therapies. In 2000, the amount of R&D investments made by US and European pharmaceutical companies differed by only €2 billion. In 2020, the difference had increased to almost €25 billion. The United States has outpaced Europe, and China will soon follow.

The March 2023 proposed revision of the Pharmaceutical Legislation risks aggravating these investment trends. The published proposal will negatively impact the biotechnology industry environment and the predictability and stability of Europe's incentives regime. Investors will continue to seek other regions with less fragmented markets, faster approval times and fewer regulatory hurdles.

The industry shares the purpose of improving patient access to innovative therapies. Nevertheless, access to medicines is often determined by complex Member State-level factors that are often beyond the control of marketing authorization holders. Developers, particularly smaller companies, are unable to launch in all EU member states.

SMEs, the main drivers of innovation, have fewer resources. As often as every two years or less, they need to raise capital to conduct clinical trials. The proposed change in the incentives framework will hurt their ability to attract investment, forcing them to sell their assets early in the value chain - leading to a loss of assets to other markets, reducing the return of often public investment and increasing the likelihood of a new therapeutic option not reaching the market.

Stable and predictable regulatory incentives and intellectual property rights are critical to de-risk therapeutic development. The biotechnology ecosystem functions as a whole. Any change in one of its parts will inevitably hinder Europe's ability to innovate and deliver the next generation of therapies for European patients.

Recommendations

1) **Ensure an adequate and balanced incentives framework** that does undermine intellectual property and does not reduce and condition incentives to access requirements unattainable for smaller companies. Europe's incentive frameworks must reflect its current high-risk investments, promote innovation and improve its global competitiveness.

2) Any conceptualization of **Unmet Medical Needs should be non-legislative and agreed upon in a multi-stakeholder patient-centric approach**. Any concept or definition should promote innovation and not exclude any patient population from future therapies that may improve their quality of life.

3) Improve the **cross-border healthcare framework** to ensure early access to innovative treatments, particularly for rare disease patients. Not every European country has a specific rare disease population, the medical infrastructure and knowledge to provide care or has completed health technology assessment at the payer level. It is crucial that rare disease patients are not discriminated against and can access care in a different European country.
Boost the clinical research environment.

4) **Boost the clinical research environmen**t. Build on the current work of the European Medicines Agency and Member States to create an environment that encourages clinical trials in Europe. Facilitate streamlined regulatory processes with national expedited procedures, regulatory flexibility for clinical trial design and decentralized clinical trials. Improve patient engagement and recruitment and promote knowledge translation between academia, research centres and industry. Support the uptake of the new clinical trials regulation.

"*It is time for Europe to regain its historical leadership in medicines' innovation and achieve Strategic autonomy. The revision of the general pharmaceutical legislation needs to support SMEs' cutting edge research and make Europe an "attractive hub" for the entire pharmaceutical innovation ecosystem*."
Ana Polanco Alvarez, Merck and AseBio

"*The revision of the general pharmaceutical legislation will profoundly impact the biotechnology sector and its ability to innovate. Europe must remain globally competitive so that society can benefit from our excellent science*."
Dr Jessica Martinsson, SwedenBIO

"*There are currently scientific, regulatory and economic barriers to developing therapeutic alternatives for orphan diseases of unmet need, further aggravated by market access uncertainties. Understanding these challenges is instrumental to developing appropriate policies that boost the efficient development of medicines and make rare disease research more attractive to the industry*."
Dr Maria Pascual, Minoryx

Keeping pace with science new genomic techniques for a sustainable and global Europe

The European Commission defines new genomic techniques (NGTs) as techniques capable of changing the genetic material of an organism and that have been developed since 2001 when the existing EU legislation on genetically modified organisms (GMO) was adopted.

NGTs can deliver crops with improved traits faster than conventional breeding, benefitting farmers, consumers and the environment. NGTs can also be used to improve microorganisms for diverse applications, transforming manufacturing processes across sectors. These techniques can contribute to addressing critical challenges in the agri-food system, including food security, a priority of the Spanish Council Presidency.

Globally, several markets with commercial ties to Europe (including the United States of America, Canada, United Kingdom and Japan) have enacted pragmatic, science-based legislation allowing NGT products to access the market. Despite its strong position in research and development, the EU is not a trendsetter when it comes to enabling frameworks for innovation.

In July 2023, the European Commission published its proposal for a new Regulation on plants produced by certain NGTs (targeted mutagenesis and cisgenesis). The proposal's scope is limited to plants, whilst other sectors that use industrial biotechnology could use new genomic techniques for significant advantage, as is already the case in other global markets. In this regard, the Commission has mandated the European Food Safety Authority (EFSA) to develop a scientific opinion on new developments in biotechnology in microorganisms, laying the groundwork for further proposals.

As the EU modernizes its GMO Framework, it must urgently assess and consider scientific and technological developments in all GMO-related legislation across sectors, which will inevitably be impacted. By addressing genetically modified microorganisms in the GMO framework, the EU can develop a pragmatic and timely approach to novel products that will grow the EU's resilience and competitiveness.

Recommendations

1) **Ensure regulatory certainty for product authorization**. Guarantee a proportionate, product-centric, future-proof and harmonized framework that allows developers to direct investments, providing the industry with a reliable and straightforward approval system for bringing products to the market.

2) Foster an **informed and continuous discussion between legislators, industry and civil society** on NGTs and GMM. The GMO debate is often polarised and based on non-scientific evidence. Promoting a constructive discussion to address citizens' concerns and explain these products' benefits is essential.

3) Include in the NGT legislation a commitment for the European Commission to publish a **proposal for additional policy actions on genetically modified microorganisms** by 2024, building on the European Food Safety Authority (EFSA) to develop a scientific opinion on new developments in biotechnology in microorganisms.

4) **Accelerate the overall revision of the GMO framework across sectors beyond plant**s to align with existing scientific advances - including a further proposal for microorganism products.

"*We encourage working together towards a regulatory framework for novel genomic techniques that provides maximum guarantees of protection while allowing to benefit from scientific and technological progress*"
Ana Judith Martín de la Fuente, Spanish Ministry of Agriculture, Food and Fisheries

"*The European Commission follows the continuous progress in modern biotechnology to consider how the EU can benefit from innovation in the food and agricultural sector while maintaining high safety standards*."
Ilaria Ciabatti, European Commission

"*The current EU GMO legislation is over twenty years old and no longer fit for purpose. Europe needs to support the fast-paced scientific innovation by developing a regulatory framework that fits today's and tomorrow's technologies*."
Ion Arocena Vélez, AseBio

"*For sustainable solutions, we need all tools available, including new genomic techniques for optimizing our microorganisms and production hosts. Easy and timely access to the market for these kinds of products is key to success*."
Dr Elke Duwenig, BASF

References and further readings

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About EuropaBio

EuropaBio, the European Association for Bioindustries, promotes an innovative and dynamic European biotechnology industry. EuropaBio and its members are committed to the socially responsible use of biotechnology to improve quality of life; to prevent, diagnose, treat, and cure diseases; to improve the quality and quantity of food and feedstuffs and to move towards a biobased and zero-waste economy.
EuropaBio represents corporate and associate members, plus national biotechnology associations and bioregions.

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