EuropaBio®

The European Association for Bioindustries

EVENT REPORT

NATIONAL ASSOCIATIONS COUNCIL SUMMIT 2022

Biotechnology: Delivering Europe's industrial strategy across sector

france biotech
association des entrepreneurs des sciences de la vie

MABDESIGN
THE IMMUNOTHERAPY NETWORK

BIOECONOMY FOR CHANGE
NETWORK & EXPERTISE

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SUMMARY

EuropaBio's National Associations Council (NAC) brings together national and regional biotechnology Associations.

The Council represents biotechnology priorities across Europe from a national and regional perspective, with members working in alignment to build long term economic and societal benefits from biotechnology, focussing into national governments and out to European policy makers and the European ecosystem, including regulators.

The 2022 EuropaBio National Associations Council (NAC) Summit, aligned with the French Presidency, focused on how biotechnology delivers the Industrial Strategy through national development.

National Associations, biotechnology companies, policymakers and other stakeholders gathered to discuss commercial pathways for biotechnology across sectors; for healthcare biotechnology to deliver innovative therapeutics to patients, and for industrial biotechnology to drive economic growth and market development.

HEALTHCARE BIOTECHNOLOGY: INNOVATIVE THERAPEUTICS TO PATIENTS IN EUROPE

INTRODUCTION

We are entering a time of significant legislative change for many aspects of healthcare which will impact Europe on multiple levels. The revision of the pharmaceutical legislation, the Orphan and Paediatric regulations, the establishment of a new European Health Data Space and the latest progress on Advanced Therapy Medicinal Products (ATMPs) will significantly shape Europe's innovative landscape. These developments will influence the translation of science into therapies, the ability of small companies to start and grow, and long-term investment decisions for large companies and countries within Europe.

During this year's edition of the National Associations Council Presidency Summit, EuropaBio gathered National Associations, SMEs and other businesses executives, and policymakers, to discuss how Europe can translate research and innovation into sustainable and accessible healthcare across Europe.

During the event, speakers discussed the impact of national and EU initiatives and policies in moving research advances to patient uptake. They examined what is needed to improve investment into technologies, skills and infrastructure for next-generation therapies and how to enable cross-border innovation and healthcare to improve patients' access to new therapies.

CHALLENGES

These challenges represent an opportunity for Europe to deliver the maximum impact from the capacity created through 27 countries working closely together. Whilst many benefits have been realised over the last decades, Europe can continue to develop, particularly in harnessing the therapeutic power of advancing science and the ability to deliver benefits to more European citizens. Such developments naturally translate into greater competitive advantages as biotechnology SMEs grow into mid and large-sized companies and multi-nationals invest in scale-up, manufacture and clinical trials across Europe.

Developing novel medicines from biotechnology is a long-term, high-risk venture that requires an agile business environment.

The current European regulatory system is not prepared for the latest technologies. EMA authorisation procedures are too complex and have considerable administrative barriers which makes patients' timely access to essential innovative medicines difficult.

In addition to the complexity of the approval procedures, national pricing and reimbursement systems are not adequately catered to new products, such as gene and cell therapies. The lack of interoperability of data and what needs to be generated for HTA processes and regulatory approval poses a significant challenge to European SMEs. It is crucial to harmonise requirements between regulators and HTA bodies across Europe.

Whilst Europe has the financial means to invest in start-ups and SMEs, it is too structurally conservative compared to other global regions (state aid being a direct example). The COVID-19 pandemic highlighted private companies' inability to bear alone all technical and financial risks associated with research, development and prediction of drugs, vaccines and diagnostics. The result of this is that globally impactful innovations emerge in disproportionately higher numbers outside Europe, and the deeper infrastructure and skills development is not developed to enable rapid scientific response or industrial scale up when needed.

Europe is not sufficiently competitive in terms of overall timelines for review and approval of regulatory submissions. This forces European experts to seek innovation-friendlier environments abroad, jeopardising Europe's strategic autonomy.

When it comes to clinical trials, increased digitalisation could support the efforts to reduce duplication and the administrative burden. Industry, regulators, HTA agencies, payers and other stakeholders must have equal access to critical information and engage in early dialogues on topics as appropriate clinical study design.

The data generated in these clinical trials lack common standards and interoperability. These challenges limit the potential for cross-border collaboration and the search for new medical solutions. Alongside essential data, European citizens also need to cross borders. Europeans have the right to access healthcare in any EU country and be reimbursed for care received abroad by their home country. Therapies such as ATMPs are very specialised treatments that can only be administered in specialised treatment centres that do not exist in every Member State. Support to improve cross-border health for patients who need access to innovative therapies is needed at the EU and national levels.

Furthermore, cross-border patient access can support SMEs that do not have the financial resources to apply for pricing and reimbursement in all European countries. National procedures and timelines are also often opaque to physicians, patients and companies, making cross-border healthcare more challenging.

European Reference Networks (ERNs) have not yet achieved their full potential. Their initial progress in creating networked centres of excellence is primarily focused on public organisations and does not enable EU-wide innovation critical in the understanding and treatment of rare diseases when patient numbers and the critical mass of knowledge are stretched across multiple countries.

RECOMMENDATIONS

01

Create regulatory frameworks suited to accelerating novel technologies to market

There is a clear need for regulatory simplification across markets. EU systems need to become more streamlined and have accelerated approval procedures. Regulatory systems with fewer barriers to market entry will support biotech SMEs, improve Europe's competitiveness and attractiveness, and foster innovation. [1]

02

Improve timelines and procedural transparency for patients to access advanced novel therapies and healthcare across Europe

Timelines and national procedures need to become more transparent for every stakeholder involved in providing care, including physicians, patients and companies, with reimbursement systems better prepared for new therapeutics. [2]

03

Align the information required for regulatory and HTA frameworks

Early dialogue between regulators and HTA stakeholders should improve evidentiary alignment. The information required by regulators and HTA bodies for market access and pricing and reimbursement decisions should be harmonized to allow better access to new therapeutics in a timely and more resource-efficient manner. [3]

04

Review instruments such as state aid to enhance European competitiveness globally for higher-risk investment

European businesses need clear, coherent and innovation-friendly policies. There is a clear need for a holistic approach to European policies, including state aid. Solidarity initiatives and risk-sharing is needed to increase the probability of success and equitable access between the Members States. [4] [5]

05

Enhance national cooperation for alignment of data to enable greater international benefit

There is a lack of interoperability of health data regarding clinical trials. Different protocols, ways of using data, and interpretations of GDPR across Europe make it difficult to use data across borders. Europe needs to enhance the standards for data content and interoperability. [6]

06

Promote industry engagement to strengthen the ability of ERNs within research and innovation for patient benefit

ERNs need an upgraded scope to realize their potential as true hubs for European excellence. All stakeholders, including patients, healthcare providers, and industry, need to engage together to support ERNs' professional network and leverage their ability to support research and innovation for greater patient benefit. [7]

INDUSTRIAL BIOTECHNOLOGY AND BIOECONOMY: GROWTH AND INNOVATION TO MARKET

INTRODUCTION

Industrial biotechnology is a key enabling technology for European competitiveness. It supports the transition toward a circular bioeconomy, transforming manufacturing processes as part of a global shift and contributing toward European Green Deal objectives, reducing production energy, water, and waste.

The session explored industrial biotechnology's economic growth and market development, focusing on how Europe accelerates commercial activities through biomanufacturing and how bio-based innovation is translated into the food chain.

Speakers debated how national initiatives and EU policies and programs enable long term investment into large scale manufacturing and ensure an innovative and competitive next-generation industrial landscape. Regarding food production systems, panellists addressed the core role of innovation for Europe's sustainability and competitiveness, the importance of capitalizing on world-leading research and how the current policies and regulatory frameworks impact investment and market performance.

CHALLENGES

The challenges identified within Industrial Biotechnology are a fundamental aspect that Europe must address in responding effectively to climate change, economic recovery and security of supply chains. Industrial biotechnology stands at the cusp of its full potential for Europe and, in line with regions all over the world, Europe needs to enable it for large-scale applications across sectors, moving beyond petrochemical processes and fossil fuels.

Climate change and environmental degradation are an existential threat to Europe and the world, and industrial biotechnology is a core technology that has not yet been fully utilised. The European Green Deal is Europe's response to tackling climate and environmental-related challenges transforming Europe into a modern, resource-efficient and competitive economy. The European Green Deal does not fully support biotechnology research and innovation for innovative sustainable products available to consumers at scale. The potential of market stimulation measures for bio-based products is yet to be fulfilled.

SMEs play a central role in the green transition and economic transformation but need to be supported in achieving their full potential. SMEs face many hurdles in their ability to scale up and gain access to the essential public and private funding that enables them to grow and mature. The ability for European SMEs to access the scale of funding needed for large scale production has not been achieved, but the potential is there.

Open innovation and other platforms enabling scale-up are not visible or accessible enough. Maturing technologies across Europe do not yet have the ease of access that would be required at the frequency, speed and scale that can deliver full benefit from promising technologies.

The current European regulatory framework is hampering innovation and making timely access to the market difficult. European businesses face considerable regulatory challenges that push them to seek markets abroad, damaging Europe's competitiveness and attractiveness. These constraints are illustrated, for instance, by EFSA's lengthy approval time and complexity in the innovative food sector or the EU GM regulatory framework, which is not fit for purpose, particularly when considering new genomic techniques. Whilst large companies will choose to develop technologies outside Europe, SMEs do not have that luxury and either will not be founded or will not reach the market.

RECOMMENDATIONS

01

Promote an evidence-based pathway for environmental, economic and employment benefits in Europe

The European Green Deal ambitions are not limited to only reducing greenhouse emissions but also include targets for a more sustainable, circular society. This approach will secure Europe's competitiveness and resilience. Supporting innovative sectors with the potential to contribute to Green Deal goals, like industrial biotechnology, would create job opportunities and enable a new and independent economy. To unlock investment, scale-up for biomanufacturing in Europe and achieve Europe's Green Deal goals, we need to facilitate evidence-based pathways. [8]

02

Ensure sustainable innovation scale-up and facilitate market access

Public investment plays a crucial role in unlocking investment and scale-up for biomanufacturing in Europe. Public-private partnerships can de-risk and attract investment while simultaneously creating the capacity to bring together the different actors around the value chain and facilitate the transfer and scale-up of technology that is not yet mature. Open innovation platforms also have a crucial role in securing projects' acceleration phase after the proof of concept. [9]

03

Make sustainable choices the most accessible for consumers

Demand outstrips supply for sustainable products in Europe. We need to ensure that the most sustainable choice is always available throughout the value chain. [10]

04

Adopt a product-centric regulatory approach, where requirements are predictable and proportionate to risk

Europe needs a science-based, proportionate and predictable regulatory approach to current and future biotechnology innovation. To keep up with the fast pace of innovation in this sector, the legislation should be based on the characteristics of the organisms (or their products) rather than on the techniques used to develop them. A future-proof, product-centric regulatory framework is imperative for the EU biotechnology sector to secure its global competitiveness, building on the long record of EU excellence in biotechnological innovation, whilst further contributing toward the EU green transition for a more sustainable future.

05

Modernize and accelerate regulatory frameworks for advanced innovation

Innovative products and breakthrough innovations face dense European regulatory frameworks, including complex risk assessment and approval procedures. An agile and adaptable regulatory environment with proportionate and timely risk assessment would speed up entry to market for innovative biotechnology products while also supporting the smaller players in the value chain.

SPEAKERS


AFYREN


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BIO
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Española
de Bioempresas


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We create chemistry


Bio Base Europe
Pilot Plant


BIO.BE
Belgian life sciences industry association
Part of
essenscia


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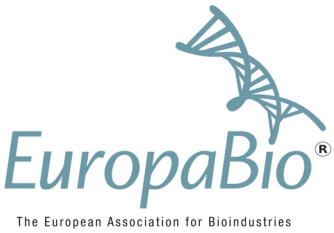
FOR CHANGE
NETWORK & EXPERTISE


Circular
Bio-based
Europe
Joint Undertaking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therapeutics

Endnotes

1 “System of medicines regulation needs to become more streamlined and more expedited, the pathways to accelerate its approvals. Crucially, we need a rating through a system that’s acceptable for SMEs.” (Seán Byrne, EuropaBio)

2 “ It’s already starting to become very challenging, for a small and mid-sized company to go through every country to do a whole pricing and reimbursement application for such a small patient population. So if that can be avoided through cross-border access that would be already helpful. And I think one of the short term solution is to make the procedures a bit more transparent. .“ (Thomas Bols, PTC Therapeutics)

3 “When have an approval and you need to get your pricing to reimbursement, the systems of the pricing and reimbursement are not on not really cater for gene therapies or cell therapies with their unique characteristics, and are more t set up for what I would call more traditional medicine.“ (Thomas Bols, PTC Therapeutics)

4 “Europe has (...) more money than other parts of the world. However, we’re very conservative on where and how we spend our money ... I think we definitely have to change the framework and convince the ecosystem that it needs to invest more money and take high risks.” (Stami Kritas, HBio)

5 “The COVID 19 pandemic crisis has taken all nations and challenged the organisation of the health care system. And this context amplified that we need to strengthen the strategic role of Europe in this field. We have to note that private companies could not bear alone all technical and financial risks associated with research, development and prediction of drugs, vaccines and diagnostics to protect its global population ... solidarity initiative and risk sharing are needed to increase the probability of success and equitable access between states members to get needed vaccines and treatments as soon as possible.” (Frédèric Druck, Bio.be)

6 “When you speak of clinical trials, one big problem that we are facing now is the lack of interoperability of health data. This is something that has been discussed in Europe, a lot. So if you you have different protocols, different ways of using data, different interpretations of GDPR, it’s very hard to use this data in a cross-border setting as it covers different member states. What we are still waiting from the Commission is the health data space regulation which should resolve this issue.” (Tomislav Sokol, European Parliament)

7 “It’s really important that the European Commission makes sure that the European legislation can support cross-border health for rare disease patients who want to have access to innovative treatments. European reference networks that are established and working really well should probably be upgraded in terms of their responsibilities and activities and involvement, also in cross-border health, which I think until now it is rather limited.” (Thomas Bolss, PTC Therapeutics)

8 “The demand is much bigger than the offer, so let’s be optimistic. Be evidence based on what you can bring with all of the project on the environment, on the unemployment and revenues. For the companies, your project can be funded with the support of the French government but also with Europe.” (Mathieu Brandibat, SGPI)

9 “We have to work together and that the public investment has a role to play to ensure that the company becomes solid, stable and that they can attract investment from venture capitalists and from other mechanisms because we are believing in this challenge and these come from the public sides and especially the European Union.” (Virginia Puzzolo, Circular Bio-based Europe Joint Undertaking)

10 “To truly benefit from innovation for health and sustainability, Europe should make the sustainable choice the easiest choice all along the long route from bench to consumer. One of the major bottlenecks that just touched upon already is the GMO legislation. I think we really need a paradigm shift in the way we approach biotech. We shouldn’t discriminate a products for the way it’s made and we should look at the product itself regardless of whether it’s GMO or not.” (Wieteke Wouters, HollandBio)

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