Belgian biotech for a better world

LET'S STRENGTHEN OUR UNIQUE POSITION TOGETHER



INTRODUCTION

BELGIUM, THE "HEALTH & BIOTECH VALLEY" UNIQUE IN THE WORLD

Innovations that follow hot on each other's heels, new investments in R&D and bioproduction, and a leading position in the world for exports of biopharma products. The spotlights are focused almost every day on our biotech companies in Belgium. Numerous start-ups are feeding a rapidly growing sector in Brussels, Wallonia and Flanders. Everything points to maximum growth potential today. The Belgian Health & Biotech Valley, with more than 600 companies in the biotechnology sector, is creating a strong industrial and innovation-driven dynamic. Over the past decade, the number of direct jobs in the biopharma and biotech industries has risen significantly from 26,000 to around 39,000; exports have almost tripled to over 98 billion euros, and investment in research and development has risen from 2.2 to 5.3 billion euros, more than doubling.

10 Belgian biotech companies are listed on Euronext Brussels with a market cap of €22.8 billion euros and accounting for 75% of the sector's European stock market value.¹ INNOVATION

LOGISTICS

INTRODUCTION

Belgium occupies this unique position in the world thanks to outstanding achievements in all activities of the biotech value chain: from research and development, through (pre-)clinical studies, to sophisticated bioproduction and exports. It is strengthened by a unique ecosystem with close cooperation between universities and colleges, academic centres, international companies, SMEs, spin-offs and start-ups, as well as specific training centres and logistics partners. The long-standing support from our federal and regional governments in terms of innovation through various fiscal measures and subsidies have contributed to achieve this global position. A competitive advantage to cherish.

Countries such as the United Kingdom ⁴ and the Netherlands ⁵ are also playing a full part in strengthening biotech policies. In addition, inflation, higher labour costs, energy costs and raw material costs are putting increasing pressure on our country. Our leading position is not assured. As a country, we cannot stay behind if we want to remain the 'health and biotech valley' in Europe.

JOINING FORCES FOR A STRONGER COMPETITIVE POSITION

Indeed, we have a strong starting position, but now is the time to take decisive steps and structurally anchor this forward-looking sector in our country. This encompasses not only innovation in research, development and bioproduction but also talent development and logistical positioning Let's join forces with federal and regional governments to accelerate growth and remain competitive both in Europe and the rest of the world. This is our vision for the next 20 years.

Belgium. The health & biotech valley. Today & Tomorrow.



GEOFFREY POT Chairman of the bio.be/essenscia board

THE NEED TO MAINTAIN GLOBAL LEADERSHIP

In the wake of the COVID-19 crisis, several regions and countries within Europe have placed an increased focus on the growth of the biotech sector. Just think of the 'Executive Order on Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe and Secure American Bioeconomy' ² launched by the US government in September 2022, or the 'Healthcare Innovation 2030 Plan'³ with an investment of 7.5 billion euros announced last year by the French Government. TALENT

LOGISTICS

PART 1



INNOVATION the key to a sustainable and healthy society

Our innovative biotech processes and products make the difference in the transformation to a sustainable, digital and healthy society worldwide.

- With world-class biopharma (80%), for research and development and bio-production of innovative medicines for the 21st century. These include Advanced Therapy Medicinal Products (ATMP), such as cell therapy, gene therapy and tissue therapy, but also immune therapy, monoclonal and polyclonal antibodies, new vaccine platforms (adjuvant, mRNA, DNA, viral vector), plasma proteins, genomics and radiopharmaceuticals
- With **industrial biotech (15%)**, for the efficient production of bulk and fine chemicals, enzymes, food ingredients, detergents, materials, biofuels, etc. from renewable raw materials
- With **agrobiotech (5%)**, for hybridisation, genetic improvement, use of micro-organisms and innovative management measures to optimise agricultural production.

bioproduction companies remains a challenge. The availability of early stage and late stage venture capital is much lower compared to the US. There is also a decline in the development and production of ground-breaking therapies that Europe once pioneered, namely Advanced Therapy Medicinal Products (ATMPs). There is flat growth in Europe, while growth is skyrocketing in the US and Asia.7 This is no different in Belgium. Our leadership position that we have built over the past 20 years is increasingly being challenged post-COVID, even within Europe. The Belgian tax model serves as an inspiration for many countries. In addition, countries such as France, the Netherlands and the UK have started catching up and are granting generous budgets. With one goal - to accelerate R&D, upscaling and bio-production capacity, thus also attracting foreign investments.

CHALLENGES

Belgium is one of the top innovators in Europe.⁶ Despite Europe's strength in science, translating and upscaling new lab innovations into Permanent dialogue with the federal and regional authorities will therefore be needed in order to accelerate and strengthen our international competitiveness in research, development, bio-production, talent development and logistics positioning. **FALEN**

Permanent dialogue

- → Continue the «Biopharma R&D Platform» on the initiative of the Prime Minister with the representatives of the main pharmaceutical investors (HST), the biotech and life-science industry (bio.be) and the pharmaceutical sector
- → Under the umbrella of the 'Biopharma R&D platform', launch regional consultations to stimulate regional economic growth in the biotech sector

Ambitious policy for innovation in R&D and bio-production

- → Competitive and differentiated fiscal policy to ensure Belgium remains attractive for future investments
 - Simultaneous implementation of minimum corporate tax in all countries worldwide
 - A fair implementation of the minimum corporate tax rate , recognising innovation in research and development (R&D) and bioproduction, without creating a competitive disadvantage compared with other countries in Europe, and a flexibility in the existing instruments to support innovation. All in compliance with OECD guidelines
 - Consider introducing additional tools to support innovation after the implementation of the minimum corporate tax
- → Maintain a favourable investment climate for basic research
- → Transition from 'invented in Belgium' to 'invented and made in Belgium'
 - Increase access to early-stage and late-stage venture capital
 - Attract international funds to establish an office in Belgium
 - Boost the availability of local funds by leveraging public funding with other (private) partners
 - Ensure an optimal and attractive investment climate for VCs (venture capitalists)
 - No introduction of an additional tax on venture capital

Belgium, the hub in Europe for the most digital and sustainable factories of the future
Make the most of Belgium's wealth of health data sources by giving the Health Data Authority

- the necessary green light and providing an action plan for each relevant administration by 2025
- Support companies investing in breakthrough technologies and innovative processes that accelerate the shift to sustainable and digital bio-production

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- Belgium, centre of excellence for ATMP research and development (R&D) and bio-production
 - Publish the Royal Decrees executing the «Law of 30 October 2018 amending the Law of 19 December 2008 on the procurement of human body material for the purpose of medical application to humans or scientific research»
 - Further refine the existing law of 30 October 2018 in consultation with industry and university hospitals to further stimulate the research and production of such medicines, such as cell and gene therapy
 - Overcome challenges related to the latest SoHO proposal (Regulation on standards of quality and safety for substances of human origin intended for human application) by introducing:
 - Harmonisation between Member States in order to avoid stricter and different approaches
 - Rules that ensure a sufficient level of data protection when submitting SoHO authorisation files
 - A robust framework that establishes clear principles for allocation and access to SoHOs
 - Belgium, global hub for nuclear medicine
 - Optimal support for nuclear medicine investments in collaboration with universities and research centres
- Set up innovative test environments to design and test the biotech ecosystem of the future, putting out of the box ideas first: e.g. from deep tech and nanotechnology to new techniques for online quality control and delivery of medicines via drones
- Provide support to address the shortage of incubator space for the bio-based economy, possibly through a leverage mechanism
- → Competitive EU bio-production regulatory framework to strengthen Europe's strategic autonomy and resilience
 - Belgium and its regions to take the lead with a coordinated approach to launch these discussions in Europe
 - Set up bio-production targets and developing smart evidence-based legislation to accelerate investment in bio-production capacity and potential

• No gold-plating when transposing European legislation into national/regional legislation

• Update the GMO regulatory framework for new technological developments to provide a transparent and simplified market authorization procedure for products where no non-native genetic information has been introduced

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regulatory jobs.

CHALLENGES

TALENT developing and strengthening the skills for the future



employment. If we also look at indirect and induced employment, this number triples. These 1500 annual employees are roughly divided into 450 for R&D functions, 675 for production, 120 for Data Sciences, 150 for Quality Assurance and 105 for The need is broad, covering PhDs and graduate

research jobs, as well as technical and specific professional job descriptions. The latter have so far hardly been able to flow into the sector. Moreover, it is also noteworthy that women and young people with a migrant background, in particular, are almost completely absent from the influx into the sector, which means that opportunities offered by greater diversity are being missed.

Over the next 5 years, it is estimated that around 1500 new workers will be needed in the biotech

sector each year. This refers only to direct

Not only is there a potential numerical shortage of employees, but also the skills for the future pose a challenge. Multidisciplinarity, knowledge of automation, and digital skills will become standard requirements for future employees in the sector. Efforts need to be made in this regard, both for new and existing employees in the industry.

To address this shortage, additional efforts will be necessary to transform Belgium into the talent growth hub of biotech in Europe.8/9

Short term (< 2 years)

- → Strengthening and retaining local STEM talent
- Establish an integrated STEM strategy by region.
 Introduce early career counseling in education
 Increased focus on dual learning and internships
 Up-to-date digital infrastructure in schools
 Consider shorter (graduate degree) training programs bridging secondary education and the ecosystem
 Recognition of the Biomedical Sciences degree as a medical qualification
 Attracting and retaining international talent
 - A welcome policy for international talents
 - Administrative simplifications
 - Accept legal and social documents in the English language to expedite the relocation of foreign workers.
 - Introduce the 'Trusted Partner Model' (recognized sponsorship) similar to the implementation in the Netherlands and Denmark, where recognized partners conduct posteriori checks instead of a priori checks.
 - Revise the special tax status, lifting the restriction of 150km from the border and 90K salary for international researchers
 - Restore bilateral agreements with the Netherlands, France and Germany for cross-border workers, allowing for more flexible remote work rules
 - Extend visas to 2 years for international life sciences graduates
 - Organize «aftercare» for international students (similar to the decentralized model in the Netherlands)

| Research more flexible language arrangements in higher education | * 🗳 |
|---|-------|
| • Implement a recognised referral system and a network of Expat Centres | * 🚳 📀 |
| Facilitate inter-regional exchange of Postdocs and PhD students | * 🗳 |

→ Preparing existing talent for the future

🕺 FLANDERS 🚳 WALLONIA 📀 BRUSSELS 🕟 BELGIUM -

- Accelerate the roll-out of existing strategic initiatives such as ViTalent, aptaskil and the EU Biotech Campus
- Organise reverse mentoring between industry and students
- Ensure structural alignment of the Lifelong Learning offerings with industry needs
- Introduce a simplified and centralized incentive framework to further promote upskilling and reskilling without compromising the existing employment contracts
- Develop interdisciplinary training programmes for bio-economy regulation aimed at public sector employees involved in bio-based products

SOLUTIONS

Medium term (<5 years)

- → Strengthening and retaining local STEM talent • Play-based introduction of STEM in primary school · Greater focus on teachers' knowledge of STEM · Continued emphasis on dual learning and promotion of longer internships for a wider range of fields of study • Establish a legal framework and provide appropriate funding to facilitate talent exchange between academia, industry, and the public sector (secondments), as well as fair compensation for interns · Additional support for higher education institutions aligning programs with industry needs → Attracting and retaining international talent Accelerate different procedures to attract international talent - Establish a separate status based on specific criteria for certain companies to speed up the transfer of their international talents to Belgium - Streamline the administrative process for a Single Permit by entrusting this authority to a single responsible agency for both work permits and residence permits • An international internship programme for Belgian and EU students, and Belgian companies wishing to expand their activities internationally be Facilitate inter-regional mobility · Faster acceptance of relevant foreign workers' skills and diplomas → Preparing the existing talent for the future
 - Accelerateg the upskilling and retraining of biopharma sector workers
 - A coordinating role for ViTalent and aptaskil
 - Provide a more integrated overview of all possible incentives for Lifelong Learning and Career Guidance or implement a simplified system
 - Make the EU Biotech Campus the leading multidisciplinary and specialized competence center in Europe in the field of advanced bioproduction processes and their digitalization

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the link that connects the world with our biotech solutions

CHALLENGES

The logistics partners are an important link in the Belgian biotech eco-system. In recent years, these partners have optimised their activities and made investments to strengthen Belgium's biotech valley. Brussels Airport was the first airport to receive the CEIV «Centre of Excellence in Pharmaceutical Logistics» accreditation worldwide; Liège airport was voted the best cargo airport in 2020 and the Port of Antwerp-Bruges was the first seaport in the world to transpose GDP (Good Distribution Practices) rules to the maritime sphere to ensure that the entire logistics chain complies with these European GDP rules. Our strategic location and excellence are also recognised worldwide and all eyes are on Belgium. It is therefore important to support these partners in the sustainable development of their future.

In addition, the biotech supply chain is facing a revolution. Transport needs to be preserved, shorter and faster chains are crucial for certain medicines such as ATMP, more and more cold-chain transports are needed, and new forms of smart mobility are emerging.

If Belgium wishes to maintain its leadership position as a logistical hub in Europe in the future, the shift towards forward-looking thinking will have to be made. INNOVATION

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- → Enable every opportunity for our airports and seaports to become the most innovative and sustainable biotech logistics partners of the future in Europe
- → Maintain night flights at Brussels National Airport
- → Make tax and regulatory licensing frameworks predictable, stable and simple
- → No ban on import/exports. Safeguard logistical efficiency at all times, even during crisis periods, to ensure the flow of imports and exports
- → Introduce pilot projects around new forms of mobility and adapt the regulations accordingly, e.g. supply of medicines via drones

EUROPE

→ Develop ideas for smart mobility together with the biotech sector and translate these into concrete recommendations by 2030



Let's create, connect and communicate, together!

bio.be/essenscia is the federation for Belgian companies active in life sciences and biotechnology. It represents and advocates for the interests of its members in legislative and regulatory matters, both at the Belgian (federal and regional) and European policy levels. bio.be is part of the umbrella organization essenscia. Its mission includes the establishment of a stable legal framework that promotes innovation and industrialization in biotechnology. bio.be provides access to specialized advice and expertise within an extensive network of partners, both in Belgium and abroad. bio.be is also a member of EuropaBio, the European biotech federation, and the ICBA, the International Council of Biotech Associations.

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JSR Micro → 3001 Heverlee Kaneka Eurogentec → 4102 Ougrée Kiomed Pharma → 4040 Herstal Kitozyme → 4040 Herstal Legend Biotech Belgium → 9050 Gentbrugge Lonza Verviers → 4800 Verviers Merck Chemicals → 1560 Hoeilaart Mithra Pharmaceuticals → 4000 Liège MSD Belgium → 1170 Bruxelles NCardia Belgium → 6041 Gosselies **Novadip** → 1435 Mont-Saint-Guibert Novartis Pharma → 1800 Vilvorde Oleon → 9940 Ertvelde **Oncodna** \rightarrow 6041 Gosselies Pall Artelis → 3320 Hoegaarden **PDC *line Pharma** → 4000 Liège Perseus → 9830 Sint-Martens-Latem Pfizer → 2870 Puurs Pharmacobel → 1070 Bruxelles PhysIOL → 4031 Angleur **Prothya Biosolutions Belgium** → 1120 Bruxelles **Quality Assistance** → 6536 Donstiennes Realco → 1348 Louvain-la-Neuve **Roche** → 1070 Bruxelles **Roche Diagnostics Belgium** → 1831 Diegem **Rockwell Automation** → 1831 Diegem Sanofi Belgium → 1831 Diegem Schepens → 3560 Lummen SCK-CEN → 2400 Mol SGS Lab Simon → 1301 Bierges Syngenta Crop Protection \rightarrow 9052 Zwijnaarde Takeda Belgium → 7860 Lessines Telix Pharmaceuticals Belgium → 4040 Herstal **Tosoh Europe** → 3980 Tessenderlo UCB \rightarrow 1070 Bruxelles **UCB Pharma** \rightarrow 1070 Bruxelles UCL – Administration de la recherche → 1348 Louvain-la-Neuve Unid Manufacturing → 4102 Ougrée **Univercells** \rightarrow 1160 Bruxelles Vesale Bioscience → 5310 Eghezée Xpress Biologics → 4041 Herstal



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