



# Reinforcing Belgium's Position as a Leading Global Biopharma Hub



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# Reinforcing Belgium's Position as a Leading Global Biopharma Hub

**Jonas Geerinck, Johannes Thoms, Tom Brijs, Miet Billen, Bert Simoens,  
and Stephanie Andraos**

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# INVESTING IN MARKET LEADERSHIP

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**The country has substantial strengths on which to build, including a large and vibrant biopharma ecosystem.**

The Belgian government has set a goal of reinforcing its position as a strong “health and biotech valley” attracting a greater share of global biopharmaceutical industry activities such as research, clinical trials, and manufacturing. The country has substantial strengths on which to build, including a large and vibrant biopharma ecosystem. With other countries having similar ambitions and preparing moves to strengthen their own positions in the wake of the COVID-19 pandemic, new collaboration opportunities emerge. Securing Belgium’s place as a global biopharma leader will take concerted effort from the government, public services, the private sector, universities, the research community, and hospitals.<sup>1</sup>

This work is the result of a collaboration with representatives of the Cabinet of the Prime Minister, in the context of its Coalition Agreement of September 2020, to assess the country’s current position and identify the next steps for Belgium to achieve its goals. In the process, we worked closely with the Health, Science, and Technology (HST) Group (including Johnson & Johnson, Pfizer, GlaxoSmithKline, and UCB) and industry associations pharma.be and bio.be. In addition, we exchanged ideas with representatives from the private sector, regulatory bodies, public services, academia, academic hospitals, and selected federations. This report contains a summary of our analysis and conclusions.<sup>2</sup>

Even with its strong starting point and access to the necessary building blocks, our research shows that it is important for Belgium to act in five areas to extend its leading position in biopharma:

- Reinforce its current competitive position in talent and attractiveness to businesses.
- Unlock the potential of Belgium’s rich health data sources, particularly through connecting data sources, improving accessibility, and the use of analytics, to improve patient outcomes and public health.
- Stimulate regional and cross-border collaboration and coordination among businesses, universities, hospitals, and public-private partnerships.
- Deploy an end-to-end approach across the biopharma value chain, from early research to patient access.
- Accelerate Belgium’s involvement in selected innovative platforms (such as cell therapy, gene therapy, digital therapeutics, and mRNA).

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<sup>1</sup> Throughout this report we refer to “biopharma” as the ecosystem involved in researching, developing, and manufacturing biomedical products and vaccines as well as applying those developments in biotechnology for the prevention, diagnosis, and treatment of diseases to improve the quality of life of the human population.

<sup>2</sup> BCG’s support is provided on a pro bono basis.

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Substantial benefits can be realized from acting quickly and decisively. Patients will receive higher quality care and access to innovative therapies. The economy will gain from greater GDP growth, more job creation, and increased workforce productivity. The country will be better able to retain and attract life sciences talent by offering appealing career opportunities, to strengthen its reputation as a global center of excellence in the dynamic and growing biopharma industry, and to make the move towards sustainable biopharma supply chains and manufacturing.

The following pages present a plan for putting these initiatives in action.

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## THE EVOLVING BIOPHARMA LANDSCAPE

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In addition to well-known macro trends, such as an aging population and the accompanying increase in chronic diseases, a number of developments—global, regional, and local—are shaping the evolution of the biopharma landscape.

The first is a distinct move away from a “one-size-fits all” health care model towards more precise, individualized delivery of health care, which is the result of significant advances in the “omics” technologies (such as genomics, transcriptomics, proteomics, and metabolomics), the development of large initiatives to advance personalized health care, and significant progress in innovative therapies. For example, global revenues in the cell and gene therapy market are projected to grow at a rate of more than 90% a year through 2024.<sup>3</sup>

Second, there is a growing attention being paid to value-based health care, propelled primarily by the increasing complexity and costs of current health care systems. Achieving value-based care would translate into long-term benefits across the entire clinical care chain, from disease prevention to diagnosis, treatment and follow-up.

A third critical trend is the rise of digital health and therapeutics, which will contribute to lasting improvements across the health care value chain—in clinical care settings, R&D, and supply chain and manufacturing. In clinical care, these advances may facilitate out-of-hospital medical procedures and also improve clinical applications in disease prevention and diagnostics and treatment selection. In R&D, data, advanced analytics, and digitalization may allow out-of-hospital clinical trials, the shortening of development cycles, and new ways of testing scientific hypotheses on larger datasets. In supply chain and manufacturing, digital tools, automation, and data and analytics can lead to significant efficiency gains (by reducing conversion cost and ramp-up time, for example) and shorter cycles to deliver medicines to patients.

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The rise of novel technologies and therapies such as cell therapies, gene therapies, and mRNA vaccines and therapeutics are mandating a fundamental rethinking of the value chain as traditional boundaries among research, clinical trials, manufacturing, and patient administration blur.

Next, the rise of novel technologies and therapies such as cell therapies, gene therapies, and mRNA vaccines and therapeutics are mandating a fundamental rethinking of the value chain as traditional boundaries among research, clinical trials, manufacturing, and patient administration blur. We see greater benefits from more coordination and collaboration at various steps in the value-chain. Managing the shortening value chain demands careful planning and coordination. Countries need to coordinate through the full value chain, rather than focus on one or more individual links, to be able to attract investments in these new platforms.

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<sup>3</sup> Evaluate Pharma and BCG analysis



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Fifth is an increased focus on supply resilience in the wake of COVID-19. The pandemic spotlighted the potential vulnerabilities. To better safeguard public health, many countries are investigating how they can ensure secure access to critical materials and medicines in the event of future health crises. They are seeking to balance greater sovereign control over critical supplies (for example through strategic stockpiles, local production, and redundancy in supply chains) with continued openness to international trade and collaborations.

Last, environmental sustainability efforts are driving other changes in supply chains and manufacturing approaches, with the aim to reduce greenhouse gas emissions, raw material consumption, and waste generation.

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## BUILDING ON BELGIUM'S STRENGTHS TO MEET THE CHALLENGES AHEAD

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The country has a solid R&D base and a strong focus on innovation, ranking as one of the “innovation leaders” in the EU’s European Innovation Scoreboard.<sup>5</sup>

Belgium is well positioned today. It has a solid pool of talent. The number of life sciences employees (3.2 per 1,000 inhabitants) is more than twice the European average. With 12 universities (two of which are in the top 100 in Reuters’ ranking of the most innovative universities) and seven university hospitals, Belgium has a strong pipeline of skills coming to the marketplace, including about 2,600 life sciences graduates per 1 million people (compared with an average of 1,400 for the EU).<sup>4</sup> It has a productive workforce (#5 according to the OECD), well-established workforce experience in specific platforms (such as vaccines), and a network of successful biotech entrepreneurs.

The country has a solid R&D base and a strong focus on innovation, ranking as one of the “innovation leaders” in the EU’s European Innovation Scoreboard.<sup>5</sup> Belgium ranks among the highest in Europe in the absolute value of biopharma R&D investment. In 2020, there was €5 billion of R&D investment. Investment grew at about 14% a year from 2015 through 2020.<sup>6</sup>

Belgium also has a strong track record in clinical trials. It is known for its high number of clinical trial authorizations (about 525 in 2018, #2 in EU per capita) and its strong reputation for the quality of clinical trial centers and expertise of trial investigators. It is also among the fastest countries in Europe for trial protocol approvals.

The strength of Belgium’s supporting ecosystem is exemplified by the presence of incubators (such as the Wallonia Biotech Coaching (WBC) Incubator); accelerators (such as Bio Accelerators in Ghent and Leuven); research centers (such as Vlaamse Instelling voor Technologisch Onderzoek (VITO), Vlaams instituut voor Biotechnologie (VIB), and IMEC); science parks (such as BioPark), and innovation clusters (such as BioWin and flanders.health), all of which boost research innovation and commercialization. There is strong industry presence with the leading global biopharma companies active in Belgium (including Johnson & Johnson, Pfizer, GlaxoSmithKline, and UCB) and more than 300 biotech firms. Belgium is home to close to half of life sciences companies listed on Euronext by market capitalization.<sup>7</sup>

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<sup>4</sup> Eurostat

<sup>5</sup> European Commission

<sup>6</sup> pharma.be

<sup>7</sup> Euronext



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Belgium has major expertise in selected platforms. It is a powerhouse in vaccines, with extensive research, development and manufacturing capabilities. Belgium is also a leader in vaccine exports by trade value.<sup>8</sup> In addition, Belgium has been successful in attracting cell and gene development (it ranks #2 and #3 globally in trials per capita, respectively) and companies (about 9% of EU cell and gene therapy companies are headquartered in Belgium).<sup>9</sup>

Belgium ranks third worldwide in biopharmaceutical exports per capita (with about €54 billion exported in 2020).<sup>10</sup> With a central location in Europe, Belgium also has a strong logistics network, including airports recognized by government and industry authorities for key biopharma capabilities, the port of Antwerp and Zeebrugge, and the continent's highest density of motorways and rail lines.

## THE CASE FOR CHANGE

Belgium's strong biopharma system benefits patients locally through high-quality care and access to innovative therapies. It aids patients globally as well, as evidenced by vaccine innovation, production and exports during the pandemic.

The sector is a significant contributor to the national economy. The biopharmaceutical positive trade balance was about €9 billion in 2020, representing 44% of the country's total positive trade balance. The sector employs an estimated 34,000 people directly and a similar order of magnitude of workers indirectly at other sectors and industries.

Given this importance, there is an urgency for Belgium to consider the changes taking place and determine how best to further strengthen its ecosystem so that it remains an attractive market for activities such as R&D, clinical trials, the manufacturing of medicines, and the introduction of innovative medicines. The urgency is heightened by the fact that the pandemic will lead many other countries to strengthen their local biopharma ecosystems so that they are better prepared and more resilient in the event of future health crises. In addition, there is an opportunity to implement lessons learned from COVID-19. These include the benefits of fast approvals (such as through rolling reviews for vaccine clinical trials), deeper public-private collaboration (among industry, academia, and regulators), rapid innovation and scale-up of manufacturing capacity, and agile repurposing and tech-transferring.

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<sup>8</sup> World Integrated Trade Solution

<sup>9</sup> EvaluatePharma; Cell and gene therapy innovation summit; BCG analysis

<sup>10</sup> Nationale Bank van België

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Finally, Belgium must respond to an evolving European and global context. There are a number of European and international initiatives being launched for which Belgium needs to decide how it wants to participate and contribute. They include, for example, the Important Projects of Common European Interest (IPCEI) and the HERA (Health Emergency Preparedness and Response Authority) incubator. Other countries are revising their strategies to strive for similar ambitions, and they can challenge the strong position Belgium has today.

There are big benefits from getting all this right. Extending Belgium's position as a leading biopharma hub will lead to:

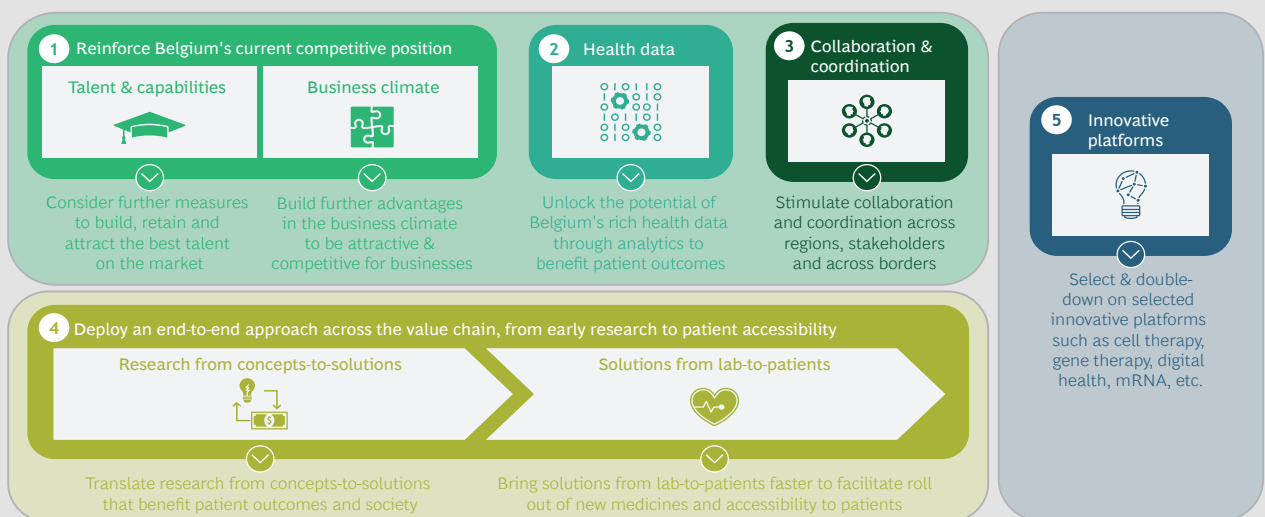
- Patient benefits, such as higher quality of care, equitable access to innovative therapies, and improved quality of life by preventing diseases and prolonging lifelong health.
- Economic benefits, including GDP growth, job creation and increased workforce productivity, broader industry and manufacturing development, positive trade balances, and an increased attractiveness for international investment.
- Broader societal and indirect benefits, such as the ability to retain local talent and attract foreign talent by offering attractive career and development opportunities, and the strengthening of Belgium's reputation and position on the global stage, putting it in a stronger position to engage in international partnerships.

## A FIVE STEP PLAN

Our work shows that, even with its strong starting point and available building blocks, Belgium can take further steps to extend its leading biopharma position. These include steps in five areas. (See Exhibit 1.) As other countries may consider similar areas of focus, Belgium can differentiate itself by building on its unique starting position, by making rapid progress in all five areas as a whole, and by executing the plan with intensity and ambition.

Belgium can take further steps to extend its leading biopharma position.

**Exhibit 1: Belgium can take further steps along 5 areas to pursue its ambition of a "health and biotech valley"**



### Talent and Attractiveness to Business

Belgium has a large pool of biopharma talent and skills; it needs to continue to build on this base. It has demonstrated itself to be an attractive place for biopharma businesses, a position it must also safeguard. These are the table stakes moves for Belgium going forward.

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The measures that Belgium should consider to further build its talent base include the following:

- Developing pre-university orientation programs to encourage enrolment in STEM and life sciences programs.
- Improving coordination among Belgium's universities to avoid fragmentation in terms of capital and expertise.
- Stimulating the entrepreneurial and commercial mindsets of life sciences students and researchers (for example, through immersion programs and business courses).
- Nurturing and extending global partnerships with leading institutions to share expertise and offer attractive international career mobility to local talent.
- Designing programs that build new skills for the future (such as the EU Biotech School & Health Hub initiative).
- Facilitating the exchange of talent within the ecosystem (for example across academia, research institutes, industry, and public sector).

The rise of new technologies and therapies, together with increasing demand and competition for certain technical and analytical skills (such as data analytics and Artificial Intelligence), will require stimulating workforce reskilling and “upskilling” programs. These efforts should include accelerating internal training programs, leveraging external training centers (such as Cefochim and ViTalent), and establishing public-private post-graduate degree programs.

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**Belgium can attract more foreign talent (and business) by increasing international awareness of the country's strong biopharma position and attractive job opportunities.**

Belgium can attract more foreign talent (and business) by increasing international awareness of the country's strong biopharma position and attractive job opportunities. It can further improve its desirable working climate by simplifying administrative procedures, among other moves. Belgium is already recognized for its attractive incentive schemes for business today (especially those important to R&D, such as innovation income deduction and R&D payroll tax exemption), but it needs to ensure that its incentive climate remains sufficiently attractive to both large biopharma and SMEs. The government needs to define which value chain activities and therapies should be areas of focus for further incentives, while also providing transparency and predictability on the conditionality of incentives.

To advance the country's ease of doing business, the government can recalibrate and modernize how it manages industry relations, building closer relationships with industry decision makers, helping them navigate the local political and regulatory environment (which is often perceived as complex), and assisting in making connections with nearby EU institutions.

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Belgium also needs to take measures to maintain its position as a leading logistics hub. In addition to continuing to invest in logistics and industrial infrastructure, this means providing predictability, stability, and simplicity in fiscal and regulatory frameworks (such as permits and intellectual property protection).

## **Better Patient Outcomes through Health Data and Analytics**

Belgium has a set of high-quality data assets in its health care system of over some 11 million people. For example, electronic health datasets linked on the COZO (Collaboratief Zorgplatform) platform (one of the hubs in Belgium related to eHealth), patient data biobanks from Sciensano, the Belgian cancer registries, and the IMA/AIM (Intermutualistisch Agentschap/Agence Intermutualiste) databank. But fragmentation and regulatory complexity prevent the Belgian health care system from taking full advantage of the richness of this data, that is collected over time, to generate insights that benefit the patient population.

The government and the broader biopharma ecosystem need to invest in data assets, digital platforms, and advanced analytics to generate insights (consistent with good privacy practices and regulations) in research, clinical trials, and overall patient care and public health. For example, in research, this will allow new ways of testing scientific hypotheses, while in clinical care, deploying advanced analytics (such as predictive modelling) will strengthen disease prevention, diagnostics, and treatment selection.

**Harnessing Belgium's health care data and putting it to effective use involves actions in three areas.**

**Connecting Data and Ensuring Data Exhaustiveness.** Going forward, Belgium should facilitate the connection of data sources by investigating how it can engage in the complex effort of standardizing formats across legacy data sets, and by bringing standardization to new data collection. In addition, Belgium can expand its intake of valuable data by facilitating efficient coordination across the various clinical trial steps, exploring secondary participant data use, exploring anonymized data sharing with third parties, and capturing real-world treatment regimen information. The government and the biopharma industry can also explore international collaborations to enrich national datasets and further improve the quality of insights.

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### **Streamlining Data Access and Ensuring Privacy, Integrity, and Security.**

Simplifying access-approval schemes for stakeholders while creating frameworks to ensure data privacy protection, integrity, and security, and building stakeholder trust with regards to sharing of health data.

**Strengthening Analytical Capabilities.** Developing digital and AI infrastructures and hubs and fostering multi-disciplinary collaborations are key steps to generating useful insights from data.

### **Stimulating Collaboration and Coordination Among Regions and Stakeholders.**

Belgium has all the fundamental ingredients close at hand but needs to focus more on bringing individual stakeholders (public and private) together and on incentivizing collaboration and coordination. As a small country situated at the heart of Europe and European initiatives, Belgium should also leverage international partnerships to augment and complement its own strengths.

We see value in acting in the following areas.

**Internal Coordination.** The government should explore incentivizing closer collaboration and coordination across different regions, among academic hospitals (on research, data, and trials), among universities (on both education and research), and with industry. To stimulate the next wave of life sciences innovation, Belgium also needs to further facilitate multidisciplinary cross-pollination in life sciences, data science, engineering, and other relevant fields (for example, *flanders.healthTech* can stimulate innovation in the biotech, medtech, and nanotech domains).

**International Collaboration.** The government and the biopharma ecosystem can work together to identify the areas in which Belgium needs to collaborate more broadly to fill gaps, where it risks missing out on valuable opportunities, and where it can bring significant value to others and open new opportunities. This process should include exploring alliances to create "hubs" with neighboring nations or countries with common interests and complementary strengths.

As part of this process, Belgium should assess its participation in existing initiatives at the European and global levels, including initiatives related to governance (EU Health Union, European Medicines Agency (EMA) and European Center for Disease Prevention and Control (ECDC) expansion, HERA), research (Horizon 2020, VACCELERATE, DigitalEurope), European

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and state-level financing (IPCEI), bilateral collaboration (BeNeLuxA+), cross-regional collaboration (ACT-Accelerator, Team Europe, European and Developing Countries Clinical Trials Partnership (EDCTP), and global collaboration (OECD, WHO)). The government and industry can further promote Belgium's strategic priorities, strengths, and growing ecosystem to various stakeholders and in external marketing.

## An End-to-End Approach

The value of an end-to-end approach lies in aligning incentives among participants in different steps of the biopharma value chain, lowering or removing barriers between steps, and prioritizing which challenges to address first. There are two end-to-end processes of focus for Belgium. They are related but each has its own requirements.

**From Concepts to Solutions.** The first is translating research from concepts to solutions that benefit patient outcomes and society. Belgium has a strong track record in research (about 1.5 life sciences publications per 1,000 inhabitants versus an average of about 0.7 for Europe), driven by the highest biopharmaceutical R&D expenditure per capita in the EU (about €5 billion total in 2020) and a large set of qualified R&D employees (about 6,200 in total, more than twice the European avg per capita).<sup>11</sup> In addition, Belgium has strong supporting institutions that translate this research into applications. For example, VIB's success formula is cited by many biopharma stakeholders in Belgium as a key differentiator. Still, Belgium needs to look into scaling up these capabilities. It can boost its relatively low patent-to-publication ratio (about 1.5% versus a 6.6% average in Europe).<sup>12</sup> (See Exhibit 2.).

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Belgium has strong supporting institutions that translate research into applications. For example, VIB's success formula is cited by many biopharma stakeholders in Belgium as a key differentiator.

Today's innovators in Europe face lower venture capital availability than ventures in markets such as the US. Even though the capital attracted for biopharma in Europe grew at a rate of 10% a year from 2015 to 2020, it is five times less than the US, with the gap continuing to widen. Between 5% and 10% of the European share flows to Belgium. Large sums for later-stage funding remain especially challenging to secure. Belgian companies completed only two funding transactions of €100 million or more in the last five years.<sup>13</sup>

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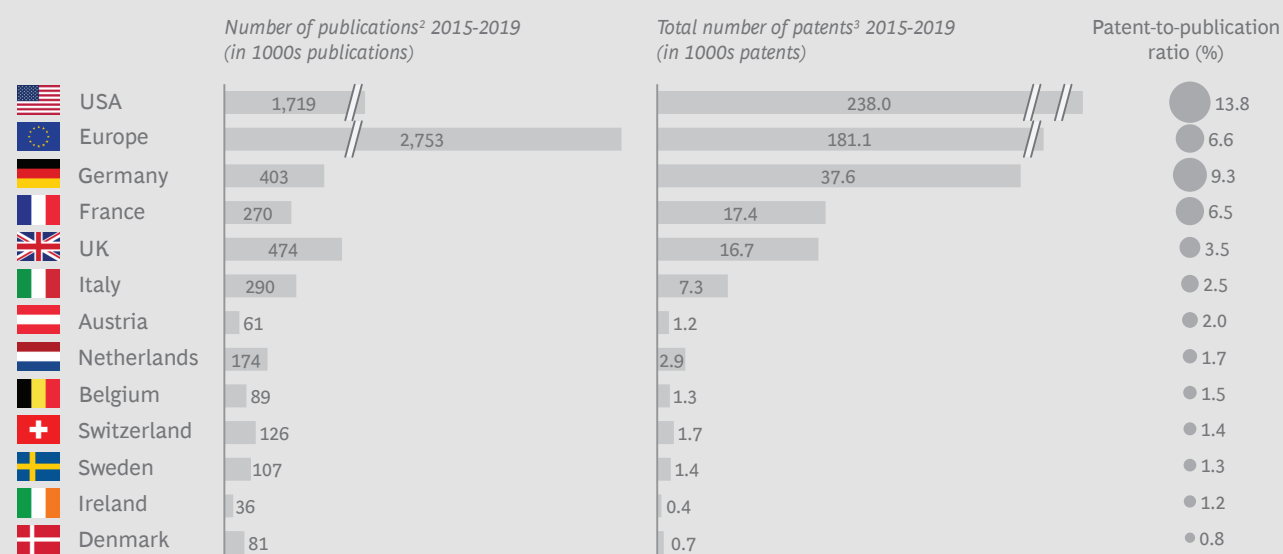
<sup>11</sup> Calculated from Scimago Journal & Country Rank; Pharma.be; EFPIA 2020, Statista, China Statistical yearbook

<sup>12</sup> Scimago Journal & Country Rank; WIPO IP Statistics Data Center

<sup>13</sup> Pitchbook 2021



## Exhibit 2: Belgium Trails Europe<sup>1</sup> and Neighboring Countries in the Patent-to-Publication Ratio



1. Selection of European countries; 2. Calculated as the total number of publications in 3 disciplines: Medicine, Immunology & Microbiology, and Biochemistry, Genetics & Molecular Biology for 2015-2019; 3. Extracted as total number of patents by filing office for 3 disciplines: Pharmaceuticals; Biotechnology; and Medical Technology for 2015-2019; Europe includes EU27+Norway+Switzerland+UK; Note: Patents published at the European Patent Office allocated to European countries according to the ratio of country-published patents to total European patents; Source: Scimago Journal & Country Rank; WIPO IP Statistics Data Center

We recommend actions in three areas to improve the translation of research from concepts to solutions.

### To stimulate further advances in research:

- Ensure a sufficient and varied mix of public and private funding.
- Incentivize academic hospitals to put sufficient focus on research activities next to clinical care.
- Provide support to researchers to navigate administrative requirements (such as GDPR regulations for accessing patient data).

### To translate research into products and solutions:

- Investigate how to further scale VIB's success formula and the successful Tech Transfer Offices' life science programs (such as CD3 and PharmAbs at KU Leuven).
- Further promote academia-industry partnerships, building on existing initiatives (such as Baekeland mandates, VLAIO (Vlaams Agentschap Innoveren en Ondernemen), and Innoviris).

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- Provide support to early-stage entrepreneurs, including targeted courses, assistance in navigating administrative procedures, and access to resources to anchor them in Belgium.

To expand access to capital:

- The government can stimulate local capital investment in the higher-risk later-stage funding rounds by facilitating the matchmaking process between biotech firms and investors and by ensuring that industry experts are involved in life science funds to solidify their decision-making processes. The government can also play a role in boosting the availability of local funds by leveraging public funding in cooperation with financial institutions and other partners.
- To attract foreign funds, government and industry need communication strategies that put the Belgian biotech firms on the international map. They can also actively seek out foreign funds through targeted missions. The government can take actions to encourage international funds to set up local offices, potentially in cooperation with neighboring countries.

**From the Lab to Patients.** The second area of focus is bringing solutions from the lab to patients faster by facilitating the roll-out of new medicines and their accessibility. Belgium is a frontrunner in clinical trials (especially Phase I-II), with a strong reputation in the quality of clinical research centers and the extensive expertise of clinical trial investigators, as well as a centralized ethics committee.<sup>14</sup> Belgium is among the fastest countries in Europe for clinical trial approvals (#2 in Phase I and #1 in Phase II-III).<sup>15</sup> In addition, Belgium has a strong manufacturing footprint and production capabilities.

Belgium nonetheless needs to consider further actions to strive for greater speed and excellence through the lab-to-patient journey—in clinical trials and authorizations, speed of market access, reimbursement for and access to innovative therapies, and manufacturing and supply chain innovation. Patients' access to medicines (and the speed with which medicines are available) in Belgium, for example, is just above the European average but lower than in several neighboring countries. (See Exhibit 3.)

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Belgium is among the fastest countries in Europe for clinical trial approvals and has a strong reputation in the quality of clinical research centers and the extensive expertise of clinical trial investigators.

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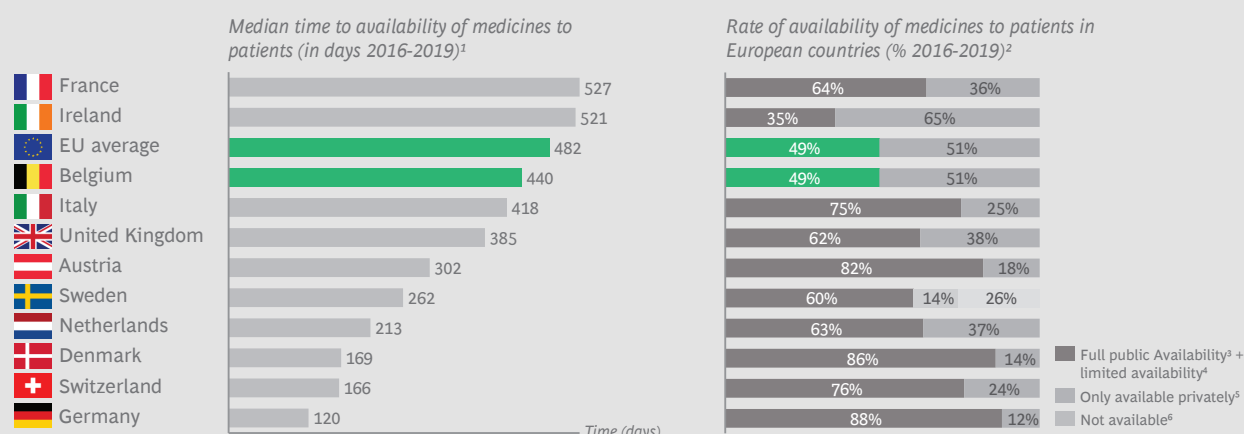
<sup>14</sup> With multiple clinical trial centers being AAHRPP (Association for the Accreditation of Human Research Protection Programs) accredited

<sup>15</sup> Country clinical trial regulatory websites

The first step is to evaluate and prioritize the axes for action cited above according to where the biggest impacts can be made and then to launch targeted actions in each area:

**Clinical trials.** New trends in trial designs (such as adaptive trials) require developing new expertise and possibly revised approaches in regulatory oversight and approval. Belgium can strengthen collaborations between hospitals and clinical trial centers (CTCs) in trial set-up, establish simple and standardized trial procedures to enable multi-center clinical trials, and create specialized trial networks dedicated to specific therapeutic areas. A platform for trial participant identification and follow-up (similar to the NHS DigiTrials in the UK) can accelerate participant recruitment and engagement as can encouraging clinician patient referrals by engaging clinicians in the trial process.

### Exhibit 3: Market access of medicines to patients in Belgium just above European average but lower than several neighboring countries



1. The time to availability is the days between marketing authorisation and the date of availability to patients in European countries. For most this is the point at which products gain access to the reimbursement list, except for hospital products in DK, SE some products are not covered by the general reimbursement scheme and so this shorter delay is artificially declining the median; 2. The rate of availability is the number of medicines available to patients in European countries. For most countries this is the point at which the product gains access to the reimbursement list. This includes all medicines status to provide a complete picture of the availability of the cohort of medicines studied. 3. Reimbursed through the 'normal' reimbursement system and/or automatically reimbursed or financed by a different budget (e.g., hospital) or managed entry; 4. Reimbursed on an individual basis, and/or to a subpopulation, and/or in some cases whilst reimbursement is pending; 5. Available only within the private market at the patients' expense; 6. Not reimbursed, or pending reimbursement (excluding availability at the patients' expense). Note: Europe is EU27 + UK + Switzerland + Iceland + Norway + Turkey. Source: EFPIA Patients W.A.I.T. Indicator 2020 Survey (April 2021).

**Market access and reimbursement.** Belgium can expedite access for patients by reducing the time lag across all stages of the process from trial readout to full patient access. First, trial readout for regulatory approval by EMA-FAGG/AFMPS (Federaal Agentschap voor Geneesmiddelen en

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Gezondheidsproducten/Agence Fédérale des Médicaments et des Produits de Santé) can be accelerated through early alignment discussions during the trial process with the developers and facilitated by empowering FAGG/AFMPS to play a lead role. Second, regulatory approval by RIZIV/INAMI (Rijksinstituut voor Ziekte- en Invaliditeitsverzekering/Institut National d'Assurance Maladie-Invalidité) for reimbursement can be optimized through fully exploiting the International Horizon Scanning Initiative (IHSI) and stimulating parallel reviews by regulatory and payer organizations. Finally, full patient access can be enhanced by applying innovation uptake metrics.

**Manufacturing and supply chain efficiency.** Stimulate digital factory and supply chain innovations to further increase speed and quality of delivery at lower costs. Avenues for exploration include leveraging innovation centers for an end-to-end integrated pharmaceutical manufacturing ability (the Centre of Excellence in Sustainable Pharmaceutical Engineering (CESPE) is an example); best practice sharing across industries for leveraging data, automation, and AI; adding a life sciences focus to existing analytics initiatives such as AI4Belgium; providing support in developing life sciences industrial digitization roadmaps; and involving regulators closely to facilitate quality-controlled process automation.

## Identify and Emphasize Innovative Platforms

Belgium should look to leverage its considerable strengths in emerging platforms, such as cell therapy, gene therapy, digital health, and mRNA, that will shape the future of the industry. For example, Belgium is already among end-to-end leaders in vaccines, with unique research facilities (Vaccinopolis, the only human challenge study center in the EU, and the Institute of Tropical Medicine); a dedicated center of excellence in vaccinology at the Belgian regulator; and strong manufacturing capabilities, including contract development and manufacturing and contract manufacturing organization (CDMO/CMO) facilities. For example, Pfizer's Puurs manufacturing site was the first to produce a COVID-19 mRNA vaccine at large-scale in Europe.<sup>16</sup>

This success story should serve as an inspiration for how Belgium can build similar positions in other innovative platforms, leveraging its unique starting position. Executing the first four identified next steps in this report will establish the basis for success.

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Belgium is an end-to-end frontrunner in vaccines, with unique research facilities, a dedicated center of excellence in vaccinology at the Belgian regulator and strong manufacturing capabilities.

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<sup>16</sup> European Commission statement by the President von der Leyen, April 2021

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Potential platforms of focus could include digital health, digital therapeutics, cell therapy, gene therapy, mRNA technology, and other next-generation vaccine platforms

To put Belgium at the forefront of new technologies and innovative platforms, the government should also consider the following set of actions.

**Ecosystem Scanning.** The government can align with the ecosystem on the platforms of focus by leveraging existing or establishing new monitoring capabilities to follow ongoing global changes in health, research, industry, and policy, and report to the appropriate governance structure. Potential platforms of focus could include digital health, digital therapeutics, cell therapy, gene therapy, mRNA technology, and other next-generation vaccines platforms.

**Multi-Stakeholder Clusters.** As the UK demonstrated with its catapult network of technology and innovation centers, governments can bring stakeholders from across the value chain together in a development “cluster” to test, improve, and scale new ideas and technologies and build new capabilities. Belgium could build on initiatives such as the Advanced Therapy Medicinal Products (ATMP) hub.

**Innovation Test Environments.** Belgium can build selective plug-and-play infrastructure, accessible to different stakeholders, in which industry and research (academia and hospitals) can co-develop and test innovative technologies and methodologies at cost or under licensing agreement to advance on new manufacturing and research modalities.

**Regulatory Centers of Excellence.** Centralizing and building expertise at regulatory bodies on selected high-priority platforms, can speed the research, development, and market access for new treatments. These centers act as single gateways for industry (from start-ups to large biopharma) to navigate the regulatory landscape and foster a culture of exchange with private partners without compromising regulatory oversight.

## HOW TO GET MOVING

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Belgium has an opportunity to advance, but to focus on the right opportunities, there must be a comprehensive and united approach across private and public sectors. Below, we listed practical next steps for each of the principal groups of stakeholders. In addition to the individual recommendations, all stakeholders need to collaborate in the overall drive to move quickly, stimulate innovation, and achieve results.

### Government

1. The government should hardwire the approach and establish a clear process for how to periodically refresh this view in order to confirm current or identify new areas of focus and drill into these insights to develop concrete policy recommendations.
2. While all stakeholders should be actively involved in recommending the measures needed for Belgium to succeed, it is the policymakers' responsibility to translate these recommendations into a coherent set of policy measures, recognizing that some measures will have an enabling character while others will be more directive.
3. Belgium should view this effort as a transformation in which the solutions require the active involvement of multiple stakeholders. Just like any transformation, we recommend establishing a central coordinator to oversee and track progress, report back to the government and coordinating stakeholder group, and communicate accomplishments to broader audiences.

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### Public Services

1. The government and administrative bodies such as FAGG/AFMPS and RIZIV/INAMI need to determine the roles each should take as part of the hardwiring effort, especially the translation of strategic recommendations into concrete measures and actions.
2. Regulatory bodies must focus on both their oversight responsibilities and stimulating and facilitating innovation and economic activity in partnership with the industry.
3. All public service entities should seek to provide a stable, predictable, and transparent regulatory and financing climate so that the private sector can take a long-term perspective in pursuing opportunities.

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collaboration to get the most  
out of available expertise

## Private Sector

1. Industry should continue to engage in a true partnership spirit with the public sector as part of the hardwiring effort, providing clear input on what they observe in terms of market trends, opportunities, and gaps, as well as on what they need from the public sector to succeed.
2. Companies should identify how to best draw on current policies and regulations to make further progress on achieving the strategic recommendations in this report and take responsibility to act on new policies once they are implemented.

## Education and Research Community

1. Universities and hospitals need to work with existing coordinating bodies (for example VLIR (Vlaamse Interuniversitaire Raad), ARES (Académie de Recherche et d'Enseignement Supérieur), and RUZB/CHAB (Raad Van Universitaire Ziekenhuisen/Conférence des Hôpitaux Académiques de Belgique)) to act firmly and decisively on the recommendations herein.
2. Institutions should communicate clearly with public- and private-sector partners on where they need top-down steering and support to move forward.
3. Hospitals and universities should look for ways to drive further coordination and collaboration to get the most out of available expertise and resources, keeping the country's overarching objectives in mind.



## About the authors

**Jonas Geerinck** is a Managing Director and Partner in the Brussels office of BCG. You may contact him at: [geerinck.jonas@bcg.com](mailto:geerinck.jonas@bcg.com).

**Johannes Thoms** is a Managing Director and Partner in the London office of BCG. You may contact him at [thoms.johannes@bcg.com](mailto:thoms.johannes@bcg.com).

**Tom Brijs** is a Project Leader in the Brussels office of BCG. You may contact him at [brijs.tom@bcg.com](mailto:brijs.tom@bcg.com).

**Miet Billen** is a Consultant in the Brussels office of BCG. You may contact her at [billen.miet@bcg.com](mailto:billen.miet@bcg.com)

**Bert Simoens** is a Senior Associate in the Brussels office of BCG. You may contact him at [simoens.bert@bcg.com](mailto:simoens.bert@bcg.com).

**Stephanie Andraos** is a Senior Associate in the Brussels office of BCG. You may contact her at [andraos.stephanie@bcg.com](mailto:andraos.stephanie@bcg.com).

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## For further contact

If you would like to discuss this report, please contact one of the authors.



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