# Healthcare& LifeSciences Review

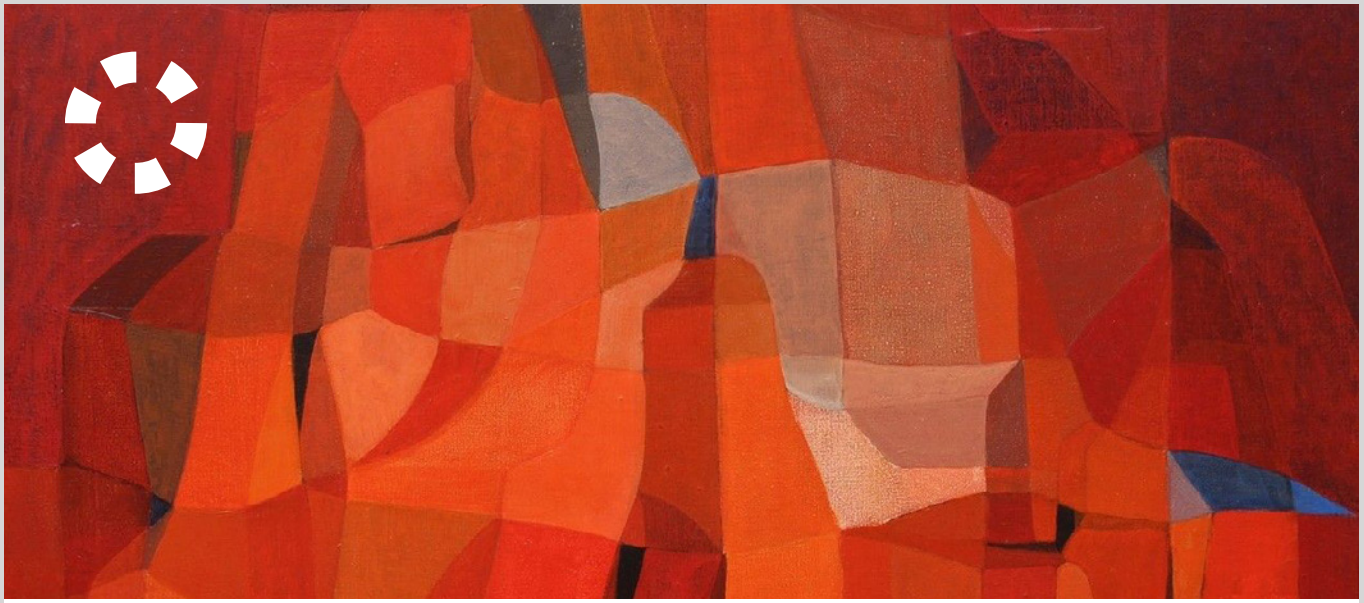
PHARMA BOARDROOM

AUGUST 2023





# BELGIUM



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PHARMA BOARDROOM

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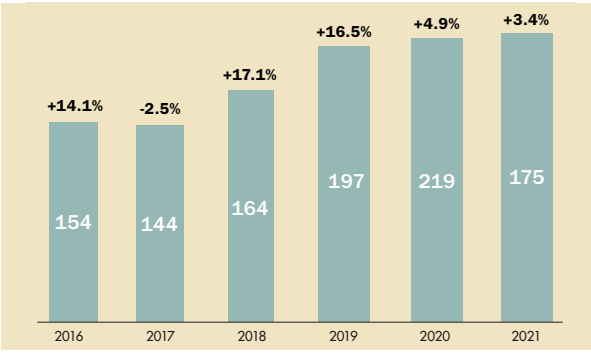








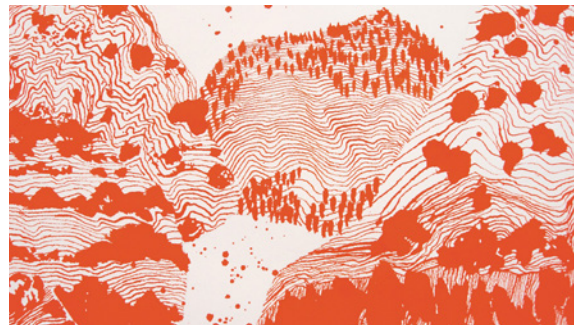



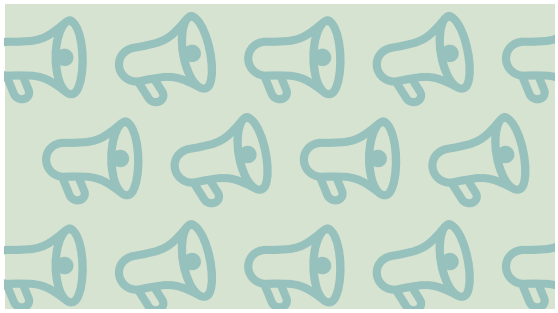





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# Preface

At a time when a comprehensive series of reforms presented as a new 'medicines roadmap' and aimed at addressing access issues while streamlining approval and reimbursement procedures awaits approval from legislators, this new report examines the unique strengths of Belgium's healthcare and life sciences sector and looks at the challenges it will need to overcome in order to maintain its competitive advantage.

While proposed reforms are still in an incipient stage and it remains to be seen what their immediate impact will be, it is undeniable that Belgium holds a strong position as a vibrant life sciences hub at the heart of Europe. Although the country itself represents only a mid-sized marketplace, Belgium boasts a robust environment that fosters multinational drug makers as well as home-grown biotechs and is replete with singular expertise.

From its strategic position at the centre of the European continent, Belgium has consolidated its role as a pharma manufacturer and exporter, trading over EUR 230 million of biopharmaceuticals per day to destinations across Europe and beyond. But apart from production and exports, Belgium also demonstrates its commitment to R&D with an annual investment of over EUR five billion, making it the fourth largest pharma R&D spender within EU.

Belgium has further displayed its prowess in the domain of clinical trials thanks to the nation's speedy approval procedures for clinical trials as well as its superior infrastructure and the formidable level of expertise of its researchers. Meanwhile, the country has also become a European biotech hotbed producing a number of biotech success stories regardless of recent economic downturns.

However, despite everything it has going for it, the Belgian life sciences sector is not without its challenges. Factors such as the rising cost of labour, the equalising effect of new centralised EU clinical trials regulations and the complex and outdated approval and reimbursement processes that slow access to medicines have the potential to sway its competitive edge.

Through in-depth interviews with key stakeholders across the Belgian healthcare value chain – including CEOs, government authorities, industry body representatives, heads of the local affiliates of multinational pharma companies, and representatives of Belgian biotech –, this report provides a comprehensive look at Belgium's healthcare and life sciences ecosystem.

Esteemed members of the global healthcare and life sciences community,

It may sound like a cliché, but our healthcare systems are at crossroads. The fundamentals of our systems often still find their origin in a societal context of 30, 40 our 50 years ago. In the meantime, societies have changed profoundly. The needs of our populations and patients have shifted toward preventive, integrated, and social care. Outcome and experience of care is at the heart of the debate with an empowered patient. Health professionals and providers are under pressure to catch up with growing demands without burning themselves out. Innovation is everywhere but struggles with access and is confronted with authorities that, rightfully, have become more assertive with regard to proof of value and cost-effectiveness.

What can we do when faced with so many challenges; challenges that indicate, rather than an era of change, a change of era? The answer is collaboration and shared leadership to understand these challenges and, of course, invent and design solutions to address them. Sharing leadership also means that authorities and existing engagement models need to open up to new ideas, ways of thinking, policy instruments, and stakeholders. Industry has long been such a stakeholder. Many successful partnerships between authorities and industry can be mentioned. However, there is still room for improvement in the relationship toward more mutual trust and shared responsibility in a sector where most expenditure comes from public means.

Building on the existing partnership and strengthening mutual trust and shared responsibility is at the heart of my professional ambitions. It is my pleasure to introduce this latest version of the Healthcare & Life Sciences Review: Belgium, a multi-stakeholder initiative. I hope it can go some way to capturing the dynamism, expertise, and footprint of this country's healthcare ecosystem, which is all about collaboration.

Words are cheap if not followed by action. The Belgian National Institute for Health and Disability Insurance (NIHDI), which I serve as deputy CEO, is in the midst of rolling out a 52-point action plan to modernize the reimbursement of medicines, which we hope will increase Belgian patients' ability to access cutting edge-medical innovation while maintaining equity throughout the system, ensuring the judicial and efficient use of our resources, and bolstering Belgium's status as the pharma valley of Europe. In some way, the plan is the successor of the Future Pact that was concluded in 2015 and was internationally recognized as an innovative good practice of shared pharma strategy development and delivery. I had the chance to play an active role in both exercises; it has only convinced me more that together we can achieve more. The results do not lie.

May this Healthcare & Life Sciences Review be an expression of the importance of good dialogue and collaboration between authorities, industry, and all stakeholders to give the citizens and patients what they deserve: real access to innovative and need-driven healthcare of high quality.

Best regards,

Pedro Facon
Deputy CEO
National Institute for Health and Disability Insurance (NIHDI)

Distinguished members of the global healthcare and life sciences industries,

As CEO of pharma.be, It is my deep pleasure to introduce this new edition of Healthcare & Life Sciences Review Belgium 2023, a fabulous opportunity to showcase the crucial role that Belgium's innovative pharmaceutical industry plays on a European and global level.

Belgium is indisputably a major contributor to global research in the life sciences, with companies from all over the world choosing to collaborate with our top-class academics and burgeoning biotech sector, as well as take advantage of our first-class infrastructure. We spend more on pharma R&D per inhabitant than any other country in the EU and contribute over ten percent of all EU pharma R&D investment. Moreover, Belgium ranks second in the EU in terms of number of clinical trials per inhabitant and account for almost one fifth of all EU trials in oncology.

Belgium is also a crucial link in the European – and global – pharmaceutical manufacturing supply chain. Despite our country's modest size, we are the fifth largest pharma producer in the EU and the bloc's fourth largest pharma exporter (second per inhabitant). Belgium accounts for a full 13 percent of EU pharma exports and reinforced its position as a major vaccine manufacturer in the wake of the COVID-19 pandemic.

Finally, our industry is a major contributor to the prosperity of the Belgian nation and a cornerstone of the economy. pharma.be's 128 member companies directly employ about 42,000 people (a number which swells to 130,000 when considering indirect and induced jobs) and Belgium ranks third in Europe in terms of both the share of total employment and of employment in the manufacturing industry. The Belgian biopharmaceutical sector's contribution to national income is substantially higher – around EUR 700 million – than expenditure on it.

Despite these many successes, we must guard against complacency and as pharma.be we are actively encouraging a domestic and European policy framework that continues to reward lifesaving innovation and protect the lifeblood of medical R&D – intellectual property.

I invite all stakeholders to read this report and learn more about why Belgium is truly the pharma valley of Europe from the mouths of the enterprising and pioneering people that make up our sector.

Yours sincerely

Caroline Ven
CEO
pharma.be

Dear members of the international healthcare community,

It is my pleasure to introduce this new report, Healthcare & Life Sciences Review: Belgium 2023 as managing director of Medaxes, the Belgian industry association for companies producing generic and biosimilar medicines, as well as other off-patent medicines and self-care products.

And we, as the off-patent industry, have a meaningful story to tell. While the Belgian innovative industry is well-known and plays an important role in our country's healthcare, we are proud to highlight that Medaxes member companies cover over 70 percent of the volume of medicines used in Belgium while accounting for only 25 percent of costs to the health system. Our companies provide a cost-effective solution for medical needs, emphasising the importance of balancing the innovative industry with affordable baseline care. It's a promise our member companies make true every day to the Belgian patients. This is so valuable; we cannot take this for granted.

However, affordable and quality baseline care for the Belgian population can only be safeguarded when a favourable climate for generics and biosimilars exists. After all, healthy competition between several players is a potential answer to the current problem of shortages as our members diversify the supply chain and thus better serve patients. Unfortunately, we still observe that the prescription market share for generic medications in Belgium is dominated by originator brands, and the situation is even worse for biosimilars, with low market penetration compared to other European countries.

Our healthcare system therefore needs a fundamental rethink. Nevertheless, doing so is a real challenge; akin to trying to change a wheel while riding a bicycle. Building a futureproof healthcare model will require stakeholders that are both visionary but at the same time pragmatic; able to deep dive into change without losing sight of the bigger picture.

We believe there is a need for a societal debate on the willingness to pay for healthcare, including medicines. It is crucial to raise awareness that baseline care should not be taken for granted and that investment in our quality of life is essential.

We urge stakeholders to see the off-patent industry as more than just a cheaper alternative. We promote healthy competition, which benefits price dynamics and fosters various forms of innovation beyond new molecules. Moreover, incremental innovations in dosage and other areas within the off-patent and generic sectors can contribute to cost-effective and high-quality medicines.

The OECD recently stated that "the pandemic has also shown that effective health spending is an investment, not a cost to be contained: stronger, more resilient health systems protect both populations and economies."

Indeed. Once we start seeing healthcare expenditure as an investment and not a cost, it opens up our minds to new ideas and can lead to new opportunities. This is our strong belief, our conviction: keeping healthcare accessible and affordable, is a shared responsibility.
I hope this report sheds light on the current challenges we are facing, and what the path towards a more sustainable, future-fit, and equitable healthcare system – with off-patent medicines playing a key role – will look like.

Yours sincerely

Jasmien Coenen
Managing Director
Medaxes

Medaxes
Association for accessible medicines

## MACROECONOMIC SNAPSHOT

**CAPITAL:** Brussels

**TOTAL AREA:** 30,528 km2 (136th largest in world)

**LANGUAGES:** Dutch, French, German

**GDP (USD) - PPP:** 688.48 BILLION (2021)

**TYPE OF GOVERNMENT:**
Federal parliamentary constitutional monarchy

**GDP PER CAPITA (USD) - PPP:** 59,388 (2021)

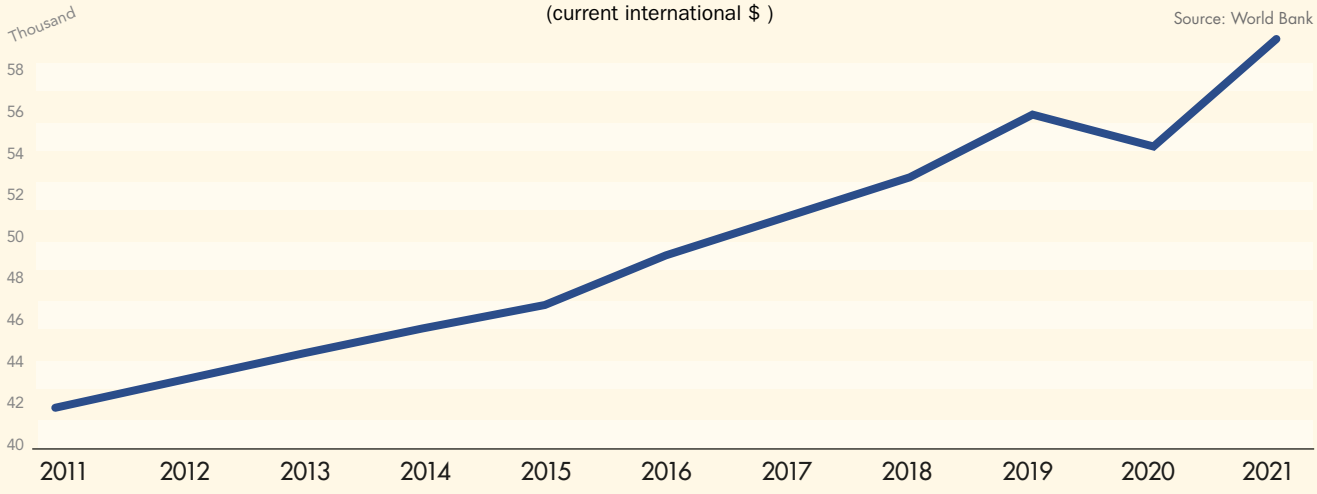
**POPULATION:** 11,697,557(2023)

**GDP GROWTH (ANNUAL %) :** 8.4

Source: World Bank

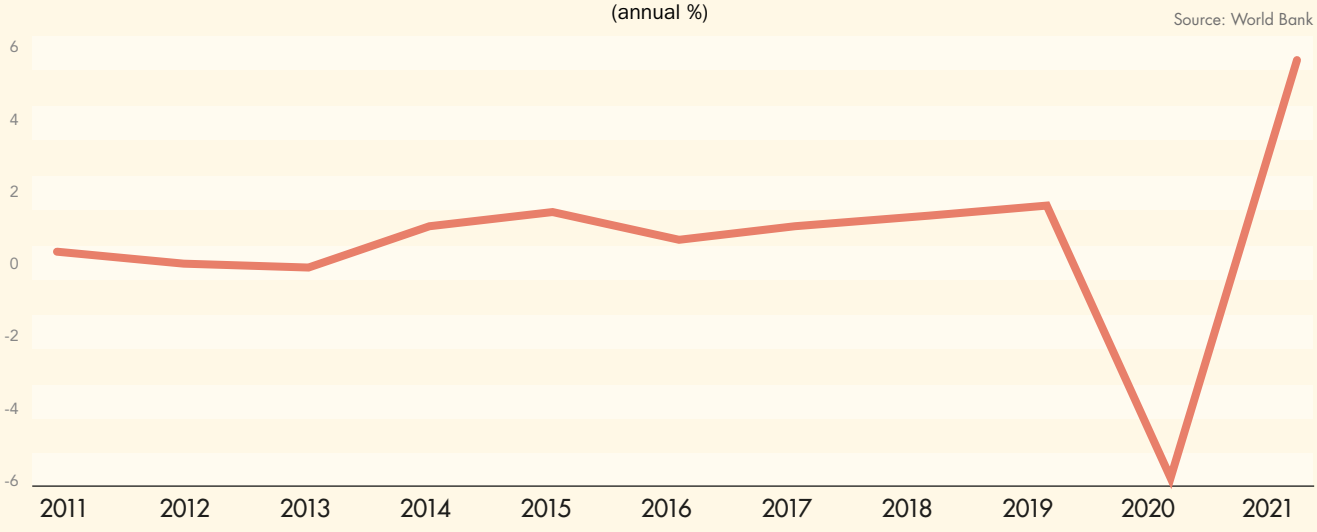
## GDP PER CAPITA

(current international $ )




## GDP PER CAPITA GROWTH

(annual %)



## LEADING CAUSES OF DEATH IN BELGIUM

(2019 and percentage change 2009-2019, all ages combined)

Source: IHME

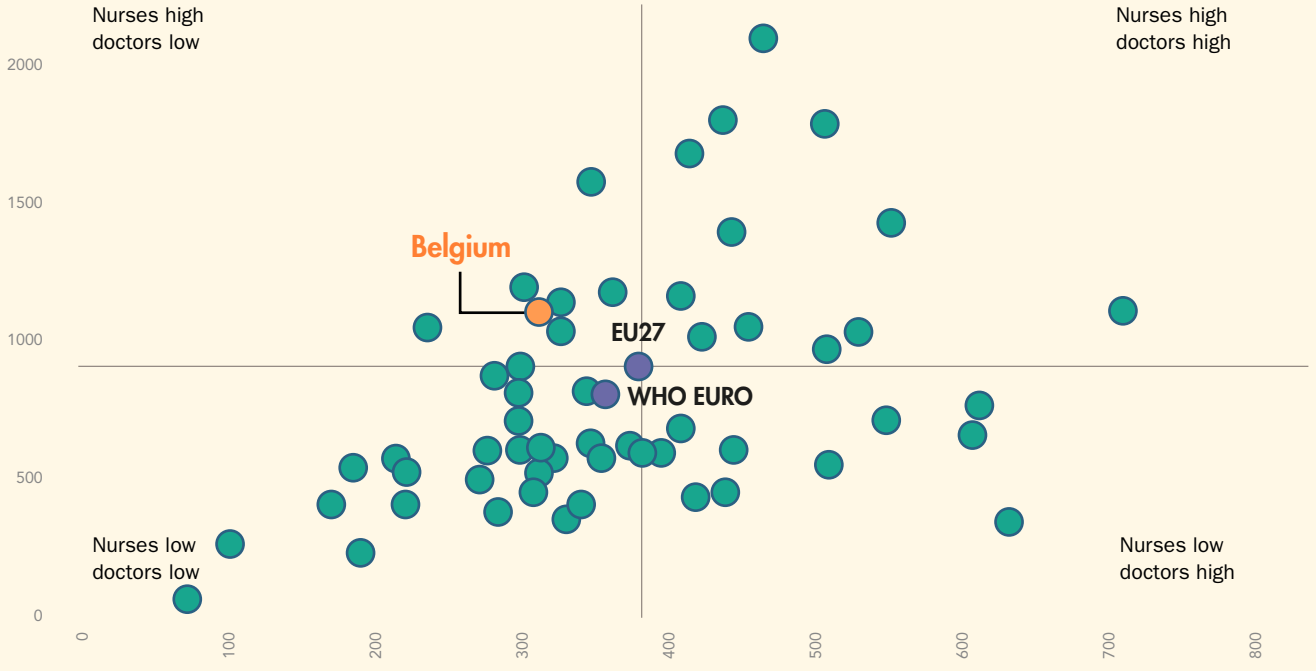
Communicable, maternal, neonatal and nutritional diseases | Non-communicable disease | Injuries

| 2009 | | 2019 | | % CHANGE 2009-2019 |
|---|---|---|---|---|
| ISCHEMIC HEART DISEASE | 1 | 1 | ISCHEMIC HEART DISEASE | -2.6% |
| STROKE | 2 | 2 | STROKE | 2.9% |
| LUNG CANCER | 3 | 3 | LUNG CANCER | 10.4% |
| COPD | 4 | 4 | COPD | 8.2% |
| LOWER RESPIRATORY INFECT | 5 | 5 | ALZHEIMER'S DISEASE | 36.4% |
| ALZHEIMER'S DISEASE | 6 | 6 | LOWER RESPIRATORY INFECT | 18.2% |
| COLORECTAL CANCER | 7 | 7 | COLORECTAL CANCER | 13.0% |
| BREAST CANCER | 8 | 8 | CHRONIC KIDNEY DISEASE | 28.8% |
| FALLS | 9 | 9 | BREAST CANCER | 6.8% |
| SELF-HARM | 10 | 10 | FALLS | 17.8% |
| CHRONIC KIDNEY DISEASE | 11 | 12 | SELF-HARM | -6.4% |

## PRACTISING NURSES AND PHYSICIANS

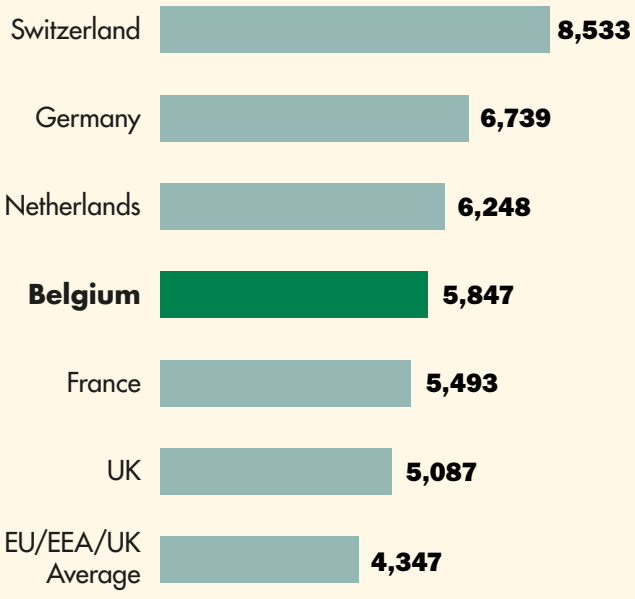
(per 100000 population, 2019)

Source: WHO; National Helath Workforce Accounts (2022)



## CURRENT HEALTH EXPENDITURE PER CAPITA IN LEADING EUROPEAN COUNTRIES

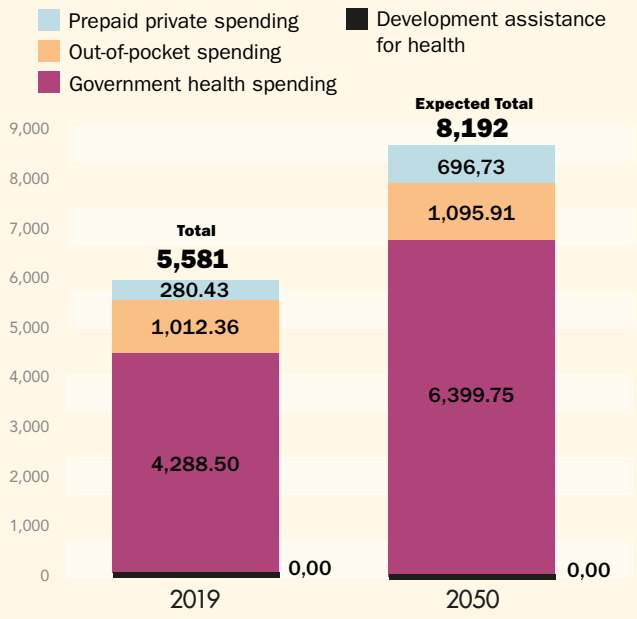
(US$ PPP, 2019)




## HOW MUCH IS SPENT ON HEALTH AND FROM WHICH SOURCES?

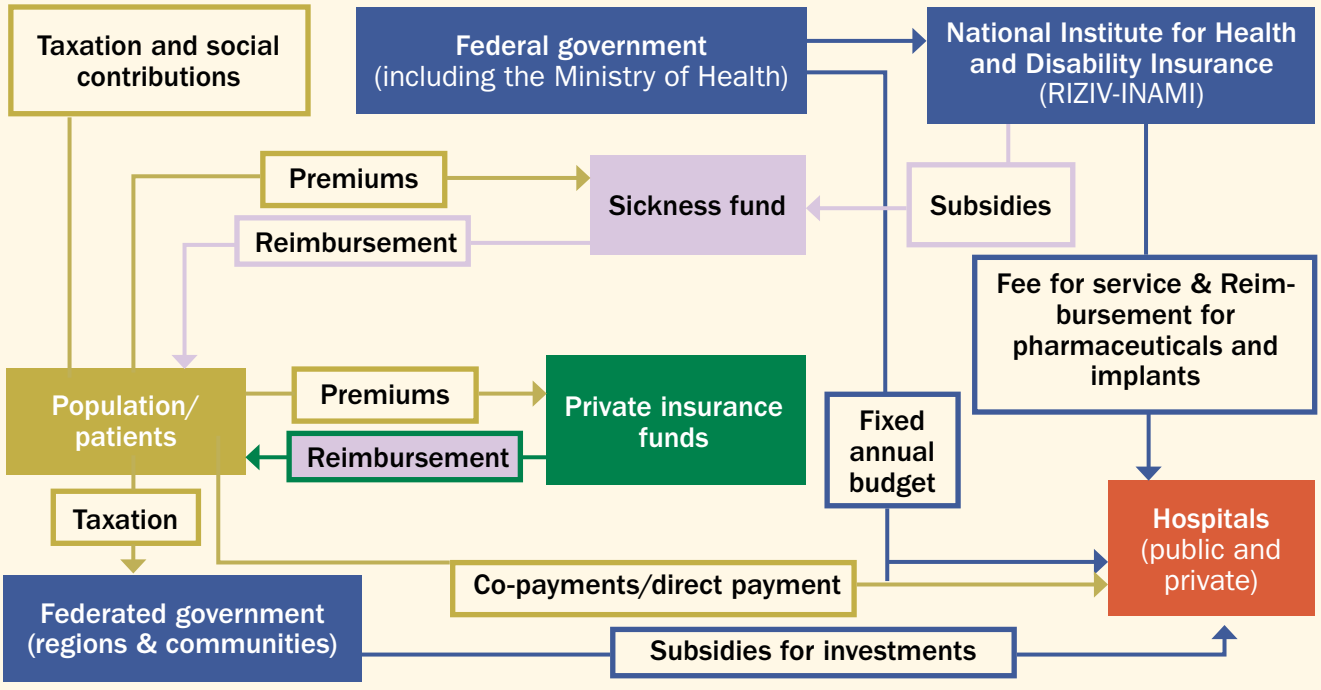
(USD per person, 2021)

Source: Institute for Health Metrics and Evaluation




## HOSPITAL FINANCING SYSTEM IN BELGIUM

(2018-2021)

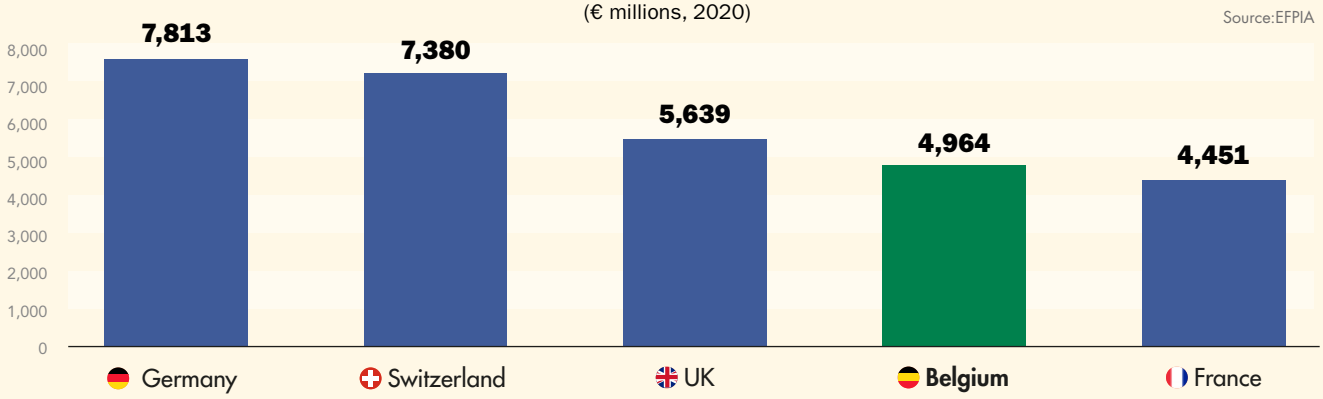



Source: Medicines For Europe : https://www.medicinesforeurope.com/wp-content/uploads/2019/10/20190903_Hospital-Reform-Study_final.pdf

## TOP 5 R&D SPENDERS IN EUROPE

(€ millions, 2020)

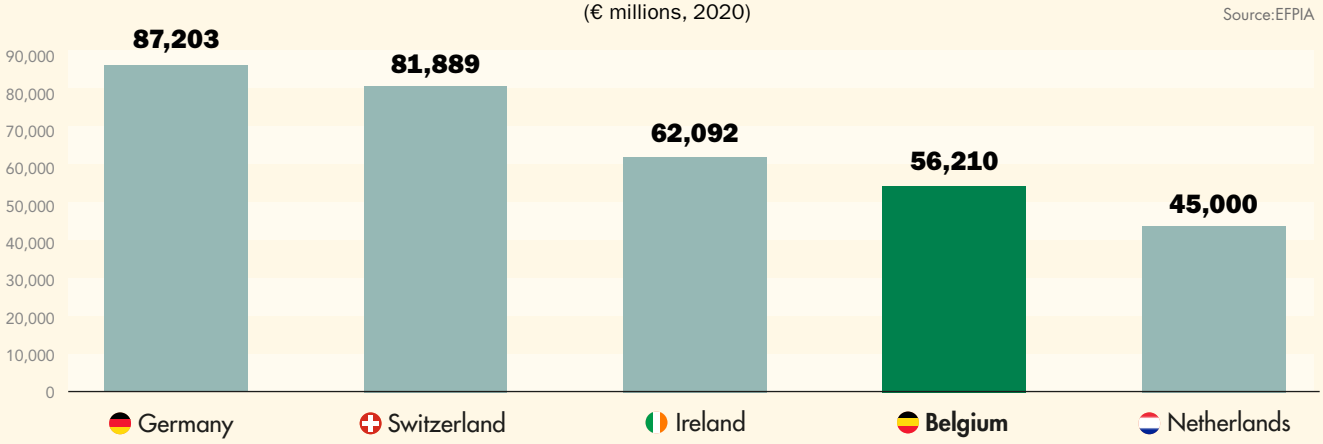
Source:EFPIA




## TOP 5 PHARMA EXPORTERS IN EUROPE

(€ millions, 2020)

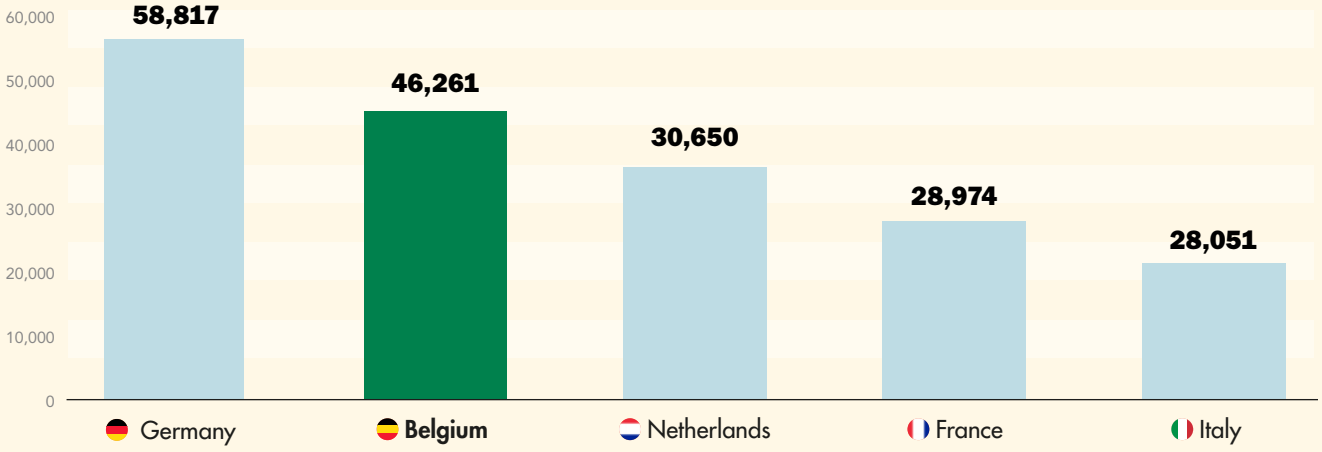
Source:EFPIA



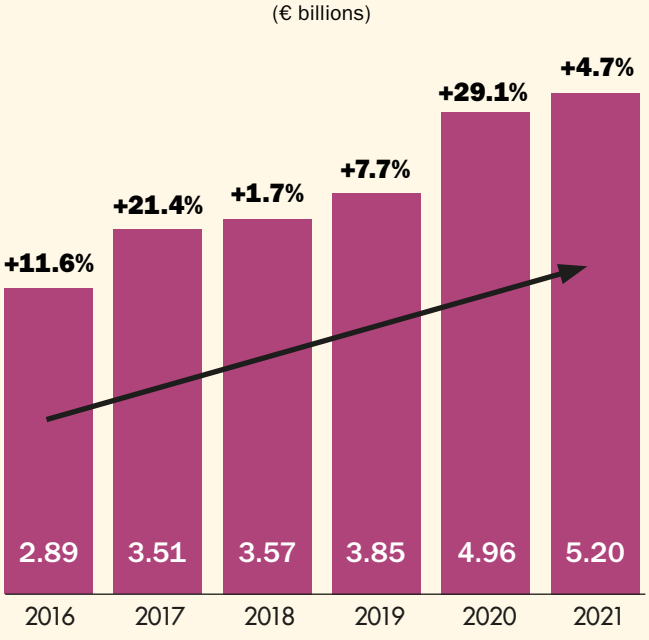

## TOP 5 PHARMA IMPORTERS IN EUROPE

(€ millions, 2020)

Source:EFPIA

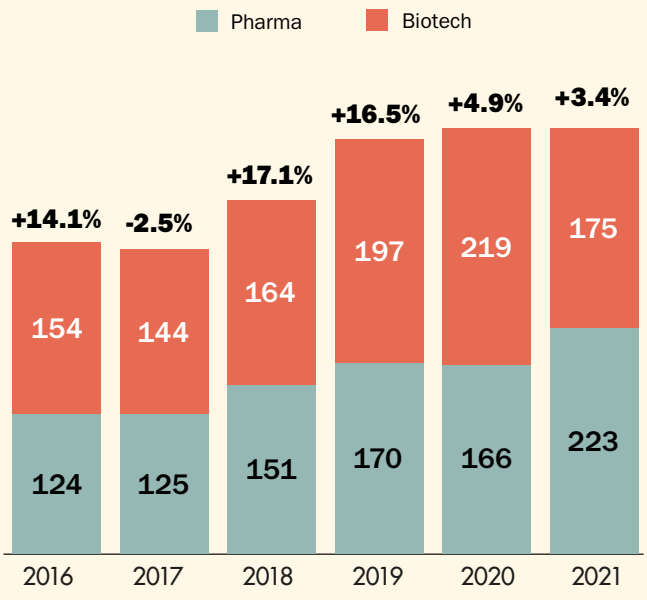


## EVOLUTION OF R&D INVESTMENTS



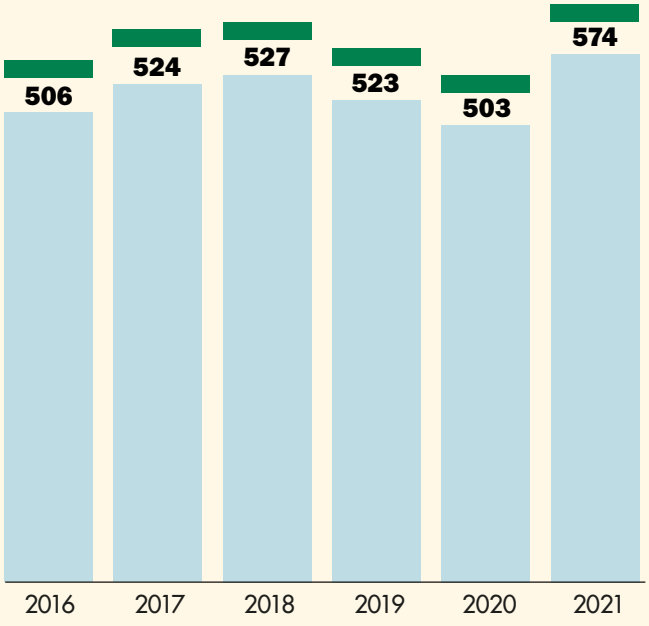

Source: pharma.be

## EVOLUTION OF NUMBER OF PATENT APPLICANTIONS



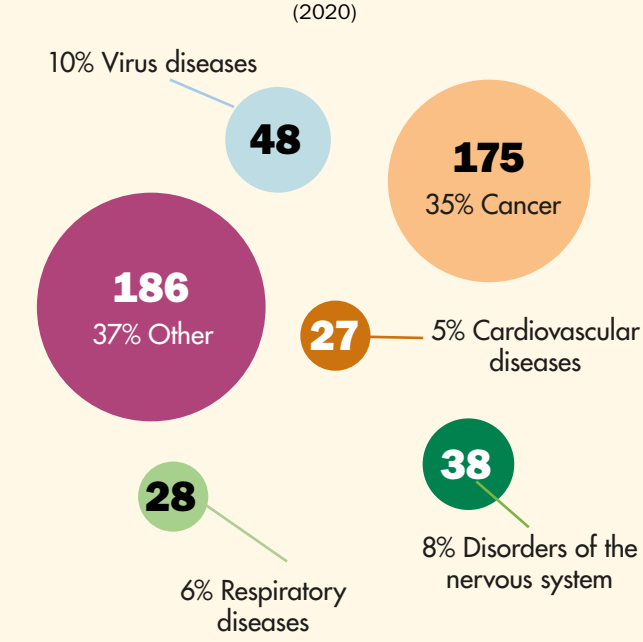

Source: pharma.be

## NUMBER OF AUTHORISED CLINICAL TRIALS




Source: pharma.be

## PROPORTION OF CLINICAL TRIALS AUTHORISATIONS FOR SELECTED DISEASE AREAS



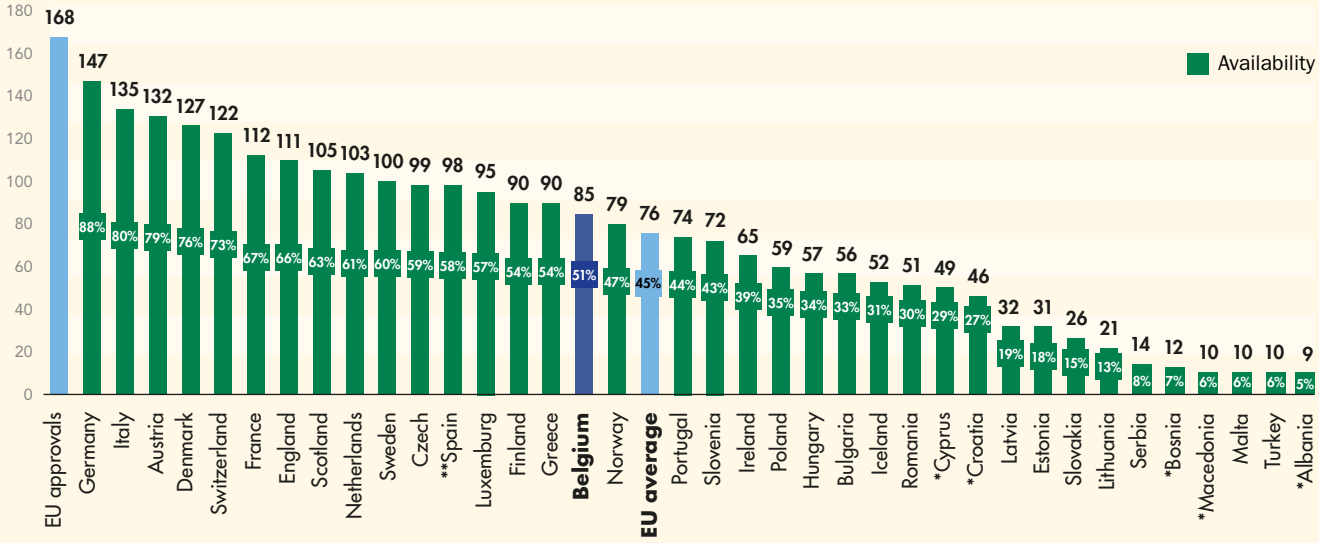

Source: pharma.be

## EFPIA WAIT INDICATOR - RATE OF AVAILABILITY

(2018-2021)

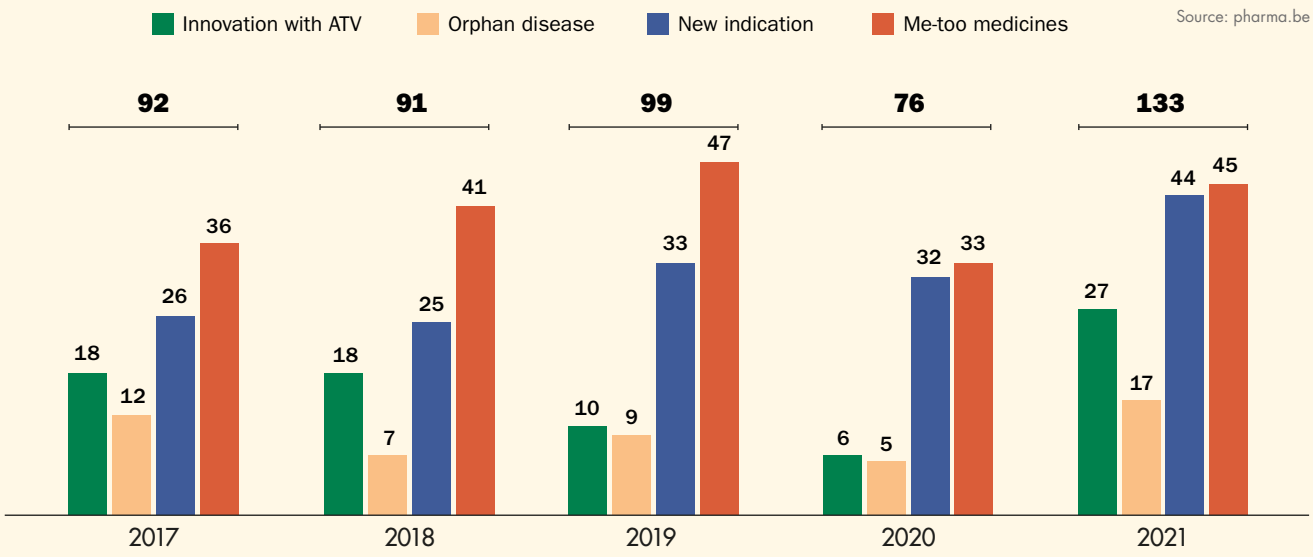
Source: EFPIA

The **rate of availability**, measured by the number of medicines available to patients in European countries as of 5'h January 2023. For most countries this is the point at which the product gains access to the reimbursement list*, including products with limited availability.




## NUMBER OF MEDICINE APPROVALS PER YEAR

Source: pharma.be




· According to the biopharmaceutical companies involved, medicinal products **with added therapeutic value** (ATV) offer a higher therapeutic value than standard therapies. In other words, they are more effective in treating the disease.
· Orphan drugs **treat rare diseases**, thus often addressing unmet medical needs.
· **New indications for medicines** that are already reimbursed for a certain indication/condition and for which the company is requesting additional reimbursement for another indication/condition. For example, a drug that is already reimbursed for the treatment of lung cancer but that is now also reimbursed for the treatment of colorectal cancer.
· **Me-too medicines** do not provide a higher therapeutic value compared to existing medicines for the same indication/condition, but they can offer added value to the patient because of an improvement in dosage, dosing times, convenience, or ease of use. Moreover, me-too medicines may guarantee continuity of treatment in case existing medicines are not available.

# SECTOR AGENDA PRIORITIES

REPRESENTATIVES OF BELGIAN ASSOCIATIONS FOR INNOVATIVE PHARMA, GENERICS AND BIOSIMILARS, MEDTECH, OTC, BIOTECH, HOSPITALS, AND MEDICAL PRFOESSIONALS SHARE THEIR KEY AGENDA PRIORITIES. THESE INCLUDE WHERE THEY FEEL THAT CHANGE IS NEEDED TO DRIVE BETTER OUTCOMES FOR THEIR MEMBERS AS WELL AS FOR THE OVERALL HEALTHCARE ECOSYSTEM.

## 1 Innovative Pharma: Building Trust via Dialogue

For pharma.be's Caroline Ven, open dialogue with stakeholders across the healthcare ecosystem as to the value and benefits that innovative pharma brings is much needed. "pharma.be is attempting to engage in more open dialogue with all stakeholders and to explain both our mission and business model," she asserts.

"We need indeed intellectual property (IP) protection, for instance, to make sure that the incentive to invest in a very risky business over a long period of time prior to a positive outcome remains. When we are criticised on this point, I point to the fact that no other actors within the health system are stepping up and doing this; it requires long-term shareholders as it is a long and expensive process with no guarantee of success. Unlike playing up pharma's economic benefits – which is more straightforward and easier to understand – there remains a need to build trust via dialogue about our role in the health system"

## 2 Generics & Biosimilars: In Search of a Future-Proof Model

In the generics and biosimilars space, Jasmien Coenen of Medaxes feels that a more robust marketplace for her member companies to operate would render the Belgian healthcare system more sustainable. "Our association's main focus is to shift the narrative and emphasize the importance of future-proofing the off-patent sector," says Coenen.

"While we recognize the importance of innovation, we also highlight the potential consequences of solely focusing on innovation at the expense of access to basic medicines. This is the message we aim to convey to everyone. Fortunately, we see initiatives emerging that align with our perspective. The recent royal decree on tendering in hospitals, for example, reflects a desire for a competitive marketplace and acknowledges the need for competition to ensure sustainability. We are pleased that our message is being understood, but still, major improvements can be made to render the market sustainable and competitive for generic and biosimilar medicines."

## 3 OTC: A Bigger Role for Consumer Healthcare

Consumer healthcare has a bigger role to place in Belgian healthcare says Marc Gryseels of over-the-counter medicine (OTC) association BACHI. Half of all boxes sold in Belgian dispensaries are OTC products and Gryseels feels that even more medicines should be switched from prescription to OTC.

"A big opportunity is to transition some of the currently reimbursed products to OTC medicines," he begins. "We need to reconsider which products should be reimbursed and which ones should require a prescription. Our focus should be on the process of switching products from prescription to OTC, which currently has a negative connotation. We need to improve this process by changing indications, not ingredients, so that we do not disrupt the balance between products in the market. If we can identify a pathology that allows for self-medication and products that are safe enough for OTC sale, then we should switch it from prescription to OTC. We should not continue to reimburse basic self-care treatments, which can be costly. Changing indications to OTC will allow everyone to access the products and help improve self-care, while also freeing up funds for new drugs. We could when necessary, maintain a negative list of products that should remain on prescription due to safety concerns within that indication."

## 4 Medtech: Towards Value

More needs to be done in terms of value- and outcome-based healthcare, according to Marnix Denys of beMedTech, the association representing the medical devices industry in Belgium. However, Denys warns

MARC GRYSEELS
managing director, BACHI

KAREL VAN DE SOMPEL
director, GIBBIS

MARNIX DENYS
managing director, beMedTech

ERIK PRESENT
president, Healixia

that such a transformation will not happen overnight. "The shift towards value-based healthcare is a complex process," he outlines. "Currently, the healthcare financing system in Belgium does not incentivize healthcare professionals or institutions based on outcomes or results. Instead, they are paid for activities and treatments. This traditional financing model creates a bias and may hinder the adoption of alternative patient pathways that could be more efficient and value-based, such as telemonitoring and homecare.

"The decision-making process for allocating healthcare budgets in Belgium has historically focused on distributing funds among different players, rather than maximizing the health potential of the population within the given budget. To move towards a more sustainable healthcare system, a shift towards value-based healthcare is needed, where the emphasis is on achieving better health outcomes for patients.

## 5 Biotech: Ready for Investment

The Dutch-speaking region of Flanders has long been a hotbed of biotech excellence, with numerous examples of university spin-offs being translated into commercial-stage companies and many of those later acquired by Big Pharma. These include rare disease-focused Ablynx, acquired by Sanofi in 2018; Argenx, one of Europe's most successful biotech companies; Galapagos, which is now entering the CAR-T space; and Oxurion (formerly ThromboGenics), which brought a first-in-class retina therapy from bench to market in Europe and the US.

Wouter Piepers of Flanders.bio urges biotech investors "not to sleep on Flanders and Belgium as the best is yet to come." He adds, "Many new therapeutics and technologies have already emerged from our region, and many more are set to come online in the coming years, across a range of different disease areas."

"The Flanders and Belgium biotech scene is also not afraid to engage in the new model of precision financing, and our biotech talent is not afraid of being scrutinised on science and data, or on the quality of its people. On the contrary, I have always witnessed an attitude of wanting to do better. I can see many of our members that are therefore perfectly aligned with the new normal in funding. We are open for business."

## 6 Hospitals: Time for Change

The hospitals sector in Belgium is facing the triple threat of an aging society with increased healthcare demands, a drop in its attractiveness as a work environment causing many professionals to leave, and several financing issues. For Karel van de Sompel, a 35-year Pfizer veteran who now leads GIBBIS – the pluralistic federation of the public and private social-profit healthcare sector within the Brussels area – the time is nigh for change.

"It is time to act and realise the critical importance of the healthcare sector both from a medical and an economic perspective," he proclaims. "We need to continue to invest and leave space for innovation. It is also time to value, more than ever, the incredible work of care personnel, people who work day in and day out, and make sure we have enough of a workforce. We need to make that job attractive again so that people will join us."

"As a sector, let us be open to continuous change. Our society is changing and will continue to change and advocating for the status quo is not going to help us. I know budgets are limited, but that should inspire us, even more, to do the right thing because we owe it to the patients who are waiting for new treatments."

## 7 Medical Professionals: Pharma Specialisation

Healixia is a three-year old association which brings together medical professionals from across the Belgian healthcare and life sciences ecosystem. For the organisation's president, Erik Present, creating educational pathways for its members to specialise in and engage more with pharmaceuticals is a key agenda priority.

"One area where Healixia is particularly active, which is specific to Belgium, is supporting the recognition of pharmaceutical medicine or clinical pharmacology as a speciality for physicians," he explains.

"Belgian physicians that want to actively engage with the pharma industry or in clinical development currently lack a clear educational track, Healixia is attempting to bring the right stakeholders together on this topic. Estimations show that around 400 to 450 Belgian physicians are active in companies, academia, or authorities around the life cycle of a drug or device."

# PHARMA GIVING BACK

FOUR PHARMA COUNTRY MANAGERS SHARE THE CONTINUED FOCUS OF THEIR COMPANIES ON BUILDING THE WELL-BEING OF THEIR TEAMS AND ON GIVING BACK TO THE COMMUNITY.

## Positive Social Impact

**PIERRE BOYER**
GM BeLux, Servier

"The Servier group's ambition is to make a meaningful social impact for patients and for a sustainable world by 2030. We aim to become an innovative and patient-driven company with a robust pipeline; a resilient, growing and sustainable company balanced on three pillars: specialty care, cardio-metabolic and venous diseases, and generics. We also want to be a company with a measurable positive social impact and an attractive company with passionate employees who take pride in their work."

## Investing in CSR

**RENAUD DECROIX**
GM BeLux, AbbVie

"Our vision of corporate social responsibility makes me very proud. We invest in concrete actions for society. All over the world, for example, we a week during which every employee gives up a workday, financed by the company, to go and work for the benefit of the community. This ranges from rehabilitating shelters to supporting people with disabilities. We have also developed highly innovative initiatives in Belgium, such as healthcare heroes, which encourages students to think about tomorrow's healthcare."

## People Development

**AN VAN GERVEN**
Country GM BeLux, Pfizer

"(Re-)establishing a connection means making sure that people can be themselves at work and grow. We are lucky to have great people at Pfizer and their well-being and ability to grow is the basis for everything else. We have a good set of expert colleagues and good connections across our cross-functional teams. We need to reinforce that and keep on going in that direction."

## Community & Diversity

**GÁBOR SZTANISZLÁV**
GM Belux, Amgen

"In Belgium, Amgen places a strong emphasis on community and diversity especially due to the cultural diversity of the country. One recent example of this is our support of the Special Olympics in Belgium. Amgen not only supports the organisation as a company, but many of our colleagues also volunteer to help organise the national games of the Special Olympics this year. Another way Amgen reflects the importance of community and diversity in Belgium is through its focus on gender balance and cultural diversity of its workforce. We continuously monitor different levels of our organisation to ensure we have the right balance of genders and cultural backgrounds. There is a strong belief that having a diversified workforce brings more value and creativity to the company."

**PEDRO FACON**,
Deputy CEO, NIHDI

# Rethinking The Access Conundrum

AMIDST COMPLAINTS FROM BOTH INDUSTRY AND PAYERS THAT BELGIUM IS FALLING BEHIND ITS EUROPEAN COUNTERPARTS WITH RESPECT TO ACCESS, THE BELGIAN NATIONAL INSTITUTE FOR HEALTH AND DISABILITY INSURANCE (NIHDI) HAS PRESENTED A NEW MEDICINES ROADMAP TO THE COUNTRY'S MINISTRY OF HEALTH. AT THE CENTRE OF THE ROADMAP'S PROPOSED REFORMS ARE WHAT HAVE BECOME KNOWN AS MANAGED ENTRY AGREEMENTS, OR RISK-SHARING CONTRACTS BETWEEN THE GOVERNMENT AND DRUG MAKERS. INAMI DEPUTY CEO PEDRO FACON DISCUSSES THE ISSUES AROUND THESE AGREEMENTS AND HOW THE NEW ROADMAP LOOKS TO ADDRESS THEM.

**Is it sustainable for NIHDI to have such a large proportion of the medicines budget dedicated to these managed entry agreements?**

**PEDRO FACON (PF):** We remain supportive of managed entry agreements in principle. Innovation is coming online more and more quickly and NIHDI aims to give our patients rapid access to this innovation. However, we are frequently confronted with reimbursement procedures that leave unanswered questions regarding both outcomes and budgetary impact.

Managed entry agreements, in and of themselves, are a good tool to diminish uncertainties and prepare fundamental discussions on the permanent reimbursement of medicines. However, several issues have been raised from both NIHDI and the Belgian Health Care Knowledge Centre (KCE), the country's health technology assessment (HTA) body.

Firstly, these contracts are rapidly growing in number, now accounting for almost half of total medicine expenditure, which poses questions about how they, and our classic reimbursement procedures, are managed.
The second issue is the length of the contracts, which diminish uncertainties, but can lead to NIHDI being trapped in a deal for a possibly less effective product for a long period of time. As a payer, we want assurances that these uncertainties will be diminished and that data collection and evidence gathering are done so that we are able to exit these contracts if necessary and as soon as possible.

The third point, which is the cause of much discussion on both societal and political levels, is the confidentiality of the budget chapter of these contracts. A degree of confidentiality is important, given Belgian prices' role in reference pricing systems across Europe, but the increasing negotiated prices are understandably leading to a debate as to the level at which their confidentiality can be accepted.

Fourthly, there are improvements to be made around data collection and analysis. NIHDI has a small expert group of just three people negotiating managed entry agreements, despite the giant budget of EUR 2.5 billion that they represent, meaning that our resources are stretched as this team concludes new contracts while also following up on existing ones.

These four points all form important parts of the new medicines roadmap that NIHDI has recently proposed to the minister following thorough stakeholder discussions

**"Innovation is coming online more and more quickly and NIHDI aims to give our patients rapid access to this innovation. However, we are frequently confronted with reimbursement procedures that leave unanswered questions regarding both outcomes and budgetary impact."**

in the second half of 2022. While some stakeholders feel we should simply stop these contracts altogether or do away with confidentiality agreements, this would be a foolhardy move without a pan-European agreement. European-level solutions are under discussion, but our first priority on a national level should be to ensure financially acceptable access to quality innovations for our patients.

**What kinds of reforms to the current managed entry agreement system is NIHDI proposing within this roadmap?**

**PF:** New propositions include putting the type of risk-sharing agreement we make with the firm in the public part of the contract. This would not include figures, but rather concepts like the architecture of compensation mechanisms. NIHDI is also looking to publish a more profound annual analysis of the way we use these contracts. This involves the creation of a new trial and real-world evidence platform to drive better research design, data collection, and data analysis in collaboration with the KCE and the Federal Agency for Medicines and Health Products (FAMHP), Belgium's drug regulator. Unlike some of the other proposals on the table, this is supported by the pharmaceutical industry and is something I am also keen to discuss further at a European level as Belgium takes on the presidency of the EU Council in 2024.

**Will the creation of this trial and real-world evidence platform mean that the job of collecting data still sits with companies? How will stakeholder responsibilities evolve?**

**PF:** As well as aiming to support the work of the contract negotiation group and the Commission on Reimbursement of medicines, this platform also aims to support companies. They will get feedback from the FAMHP, NIHDI and KCE experts represented on the platform who are very familiar with data research and techniques.

Significantly, we will also include the new Health Data Agency that is being launched. This will be an important tool in strengthening the way that real-world evidence research is designed, how the data is collected, and how it is analysed.

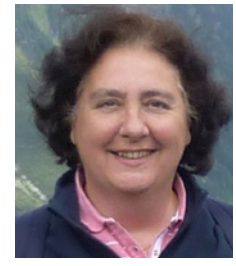
All of this inter-stakeholder effort should hopefully lead to a more value-based discussion on reimbursement, beyond budgetary constraints alone. Today, we often lack the data and insight to really pinpoint value. Companies often complain about being paid too little for their products, but we can also see that reimbursement is being granted to products which finally do not have excellent real-world data despite promising early trials.

**Belgium has historically been one of Europe's leading clinical trial destinations, but the rollout of standardised clinical trial legislation across the EU may serve to diminish the country's competitiveness. Moreover, if the products being trialled are unlikely to eventually reach the market, or will be subject to a long wait before market entry, industry sponsors may think twice about locating trials in Belgium. What do you see as NIHDI's role in addressing these issues?**

**PF:** Belgium has a historical advantage in clinical trials, but the new European regulation will be something of an equaliser. Our new medicines roadmap attempts to help maintain Belgium's competitiveness and attractiveness. The country still boasts solid fundamentals, including the quality of our clinical centres, hospitals, doctors, and training programmes. That said, from the point of view of the payer, it is true that we need to think long-term about early and fast access. The roadmap is not about clinical trials alone, but we need to contribute to a continuously attractive landscape.

# THE NEED FOR A REIMBURSEMENT OVERHAUL

IN THE MIDST OF A LANDMARK REFORM OF BELGIUM'S REIMBURSEMENT PROCEDURE, DIANE KLEINERMANS, PRESIDENT OF THE COMMISSION FOR THE REIMBURSEMENT OF MEDICINES AT BELGIUM'S NATIONAL INSTITUTE FOR HEALTH AND DISABILITY INSURANCE (NIHDI), OUTLINES THE CHALLENGES POSED BY THE CURRENT OUTDATED AND COMPLEX REIMBURSEMENT PROCEDURES AND HOW THE PROPOSED REFORMS ARE SET TO TACKLE THEM.



DIANE KLEINERMANS

President, Commission for the Reimbursement of Medicines, NIHDI

**What are the most significant challenges that NIHDI's Drug Reimbursement Commission is currently facing and how might this upcoming reform help alleviate them?**

**DIANE KLEINERMANS (DK):** It is essential to note that the current procedure has been in place for over 20 years, since 2001. Although there have been amendments and additions to it over time, the procedure has become quite complex. It was adjusted to address new market challenges and emerging technologies. However, its design did not fully anticipate and accommodate the challenges we face today. We need to review and simplify the procedure to ensure it is capable of effectively addressing these challenges, including providing early access to patients in need, particularly for new types of technologies and combination therapies, which our current procedure does not adequately address.

Another important consideration is the "patent cliff" and "biocliff" phenomena in Belgium, where there is a significant decrease in drug prices when patents expire. We are nearing the end of this process, and it is crucial that we improve our ability to respond to this challenge. Funding is necessary not only for innovation but also to ensure comprehensive treatment options can be financed. Simplifying procedures and adapting to changing times is essential.

> **"The current [reimbursement] procedure has been in place for over 20 years, since 2001."**

**There seems to be a larger than average number of managed entry agreements in Belgium. What are your thoughts on this?**

**DK:** There are several factors behind the increase in the number of managed entry agreements in Belgium. Firstly, the early introduction of new technologies to the market has led to higher levels of uncertainty and limited data availability at the time of reimbursement requests. Additionally, there are significant budgetary and financial uncertainties, as well as a rise in the prices of medicines. Managed entry agreements serve not only to provide early access to promising medicines but also as a tool to control budgets.

However, one weakness of the current managed entry agreement system in Belgium is the process of exiting these agreements. Initially, these agreements were intended to have a limited duration of three years, with the possibility of extension. However, some companies have found ways to prolong their presence in these agreements, using it as a strategy to maintain their official prices.

Discussions are underway as part of the reform to find a solution to this problem. It is important to address this issue because it is not reasonable for a drug to remain under temporary reimbursement for an extended period when there is no longer any significant uncertainty.

# An Enduring Commitment to Belgium

RENAUD DECROIX

GM BeLux, AbbVie

Renaud Decroix has built a career at AbbVie and its prior incarnation, Abbott, over the course of almost 20 years, working initially in Belgium and then in France, Portugal and the US before returning to his home country as GM at AbbVie Belgium & Luxembourg. He remarks on what keeps him engaged and motivated, coming back to Belgium after a long stint abroad, and AbbVie's upcoming product launches in Belgium.

**You will be celebrating 20 years in the company next year, congratulations! How has your journey at AbbVie led you to your role today?**

**RENAUD DECROIX (RD):** AbbVie is a great company. It has a very clear mission: to raise the quality of care for patients in its therapeutic areas, to have a positive impact on society that goes beyond the cutting-edge treatments we have been able to develop, and to create a unique fulfilment environment for its employees. We've just celebrated our 10th anniversary, and I have to say that our company has made a remarkable journey for the benefit of patients. AbbVie was born out of Abbott in 2013. I started at Abbott as Marketing Director for Primary Care, here in Belgium. I then moved to France and Portugal before joining our headquarters in the USA. Today, I manage the dynamic teams in Belgium and Luxembourg. These varied experiences, stimulated by our development culture at AbbVie, enable us to develop the skills and agility needed in our sector. I always advise my team members to consider these opportunities when they arise. It's unique!

**You began your career in Belgium, then moved back many years later. How has the market evolved over this period?**

**RD:** As a country, we have an extraordinary healthcare community, and as soon as an innovative product is available, the scientific community is quick to adopt it. Thanks to this ecosystem, AbbVie, which is a global group, conducts around 200 clinical trials here in Belgium.

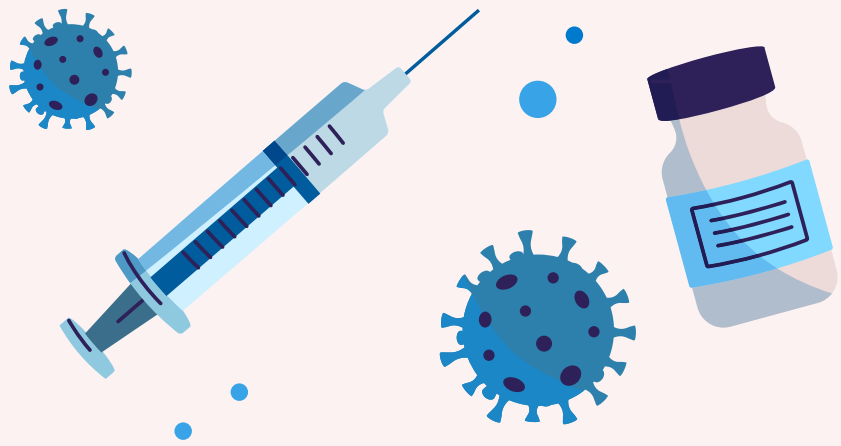
It is one of the best countries in Europe for clinical trials. Belgium is a country with an excellent speed of enrolment and a strong healthcare ecosystem. The level of expertise is high. We have a lot of international experts. We need to preserve this wealth and ensure that this talent remains in Belgium.

**"As a country, we have an extraordinary healthcare community, and as soon as an innovative product is available, the scientific community is quick to adopt it."**

**What are your projections for AbbVie Belgium and Luxembourg in the upcoming years?**

**RD:** In immunology, our ambition is to remain a benchmark. We have launches scheduled for late 2023 and early 2024, and we see the next 12 months as the year of gastroenterology. This therapeutic area is very important in Belgium, and the country has centers of excellence and leading experts in the field.

# Vaccines: Building on a Seismic Legacy



PERHAPS TO THE SURPRISE OF MANY, BELGIUM IS THE WORLD'S SECOND-LARGEST PRODUCER OF VACCINES, BEHIND ONLY THE US, AND – CAPITALISING ON ITS YEARS OF EXPERIENCE IN THE FIELD – PLAYED A VITAL ROLE IN THE DEVELOPMENT, PRODUCTION, AND DISTRIBUTION OF COVID-19 VACCINES OVER THE PAST THREE YEARS. AN ECOSYSTEM OF START-UPS AND SERVICE PROVIDERS HAS EMERGED AROUND THE MULTINATIONAL COMPANIES THAT HAVE CONSISTENTLY INVESTED IN BELGIAN VACCINES OVER RECENT DECADES, BUT THERE IS STILL WORK TO DO TO BRING THE COUNTRY'S DOMESTIC VACCINATION PROGRAMS IN LINE WITH ITS WORLD LEADING R&D AND MANUFACTURING CAPABILITIES.

## COVID-19: A CALL TO ARMS

The rapid development, regulatory approval, and distribution of effective vaccines against COVID-19 stands as one of the life sciences industry's proudest moments in living memory. It allowed countries across the world to safeguard their populations from serious illness and eventually ease the stringent lockdowns and restrictions on personal freedoms that the pandemic precipitated.

As Caroline Ven of innovative industry association pharma.be elucidates, "our members were at the forefront of the production and distribution of COVID vaccines to the rest of the world." The most notable example of how Belgium leveraged its long history in vaccine development and production was at Pfizer's Puurs manufacturing site. Located strategically between Brussels Airport and the Port of Antwerp and operational since 1963, Puurs produces more than 400 million doses of injectable vaccines and medicines in various formats every year for export to over 170 countries.

The site was chosen as one of two to produce Pfizer's BioNTech-partnered mRNA COVID-19 vaccine – a product that brought in over USD 35 billion in profits last year for the second year in a row –, making it Europe's first facility to produce an mRNA vaccine at a large scale.

**"Our members were at the forefront of the production and distribution of COVID vaccines to the rest of the world."**

Puurs has seen its staff numbers swell from 2,800 pre-pandemic to 4,500 today and, as the company looks to expand its vaccine output beyond COVID, it recently announced a further EUR 1.2 billion investment into the site.

GSK, which has three major vaccine sites (in Wavre, Rixensart and Gembloux) and the global headquarters for its vaccines division in Belgium, also stepped up during the pandemic. While its Sanofi-partnered COVID vaccine did not secure EMA approval until November 2022, purchase agreements for the booster shot have now been agreed with more than 20 EU member states as well as the UK and Canada. Belgium played a key role in this belated success with the adjuvant technology behind the shot developed at the company's historic R&D site in Rixensart, while one billion doses of adjuvants are produced annually at Wavre, its largest global manufacturing site.

Other key COVID-19 vaccine-related investments in Belgium include Janssen's R&D centre in Beerse, which worked closely with its global vaccine headquarters across the border in Leiden in the Netherlands on the company's one-shot jab. Moreover, bioprocessing and formulation services for the Oxford/AstraZeneca COVID-19 vaccine were carried out by CDMO Novasep's Belgian plant in Seneffe. Added to these Big Pharma efforts were a host of smaller Belgian investments in COVID-19 vaccine R&D and manufacturing, including at the Rega Institute in Leuven, eTheRNA Immunotherapies in Niel, Ziphius Vaccines in Oostkamp, and myNEO in Ghent.

## KNOCK-ON EFFECTS AND A HOST OF NEW ACTORS

Belgium's significant vaccine manufacturing and export footprint has knock-on effects throughout the value chain, not least in terms of opportunities for logistics and distribution partners. Tom Hautekiet, CCO of the Port of Antwerp-Bruges, outlines that "We are the first port in the world to be certified as GDP-compliant, so we must learn how to operate as such and deliver to new customers that offer a lot of opportunities, especially considering that Belgium is the second largest global vaccine producer, just behind the US."

Smaller vaccine-focused firms are also emerging, drawing on the legacy of Big Pharma's Belgian investments in the field. "The country's positioning as the pharma valley of Europe is justified, and it has a rich ecosystem with companies like GSK that have significant footprints here as well as several prominent figures in the global health sector," begins Hugues Bultot, co-founder and CEO of Univercells, a biomanufacturing specialist that provides technology, CDMO, and advisory solutions to its clients. The firm, founded in 2013, partners with the Bill and Melinda Gates Foundation, the Global Health Investments Fund, and other global health stakeholders on decentralised biomanufacturing solutions to improve access to affordable healthcare in regions like Africa and South America.

**"Belgium's expertise in biomanufacturing and its reputation for quality contribute to the advantages of building a life sciences start-up here."**

He continues, "Belgium has a favourable regulatory environment and infrastructure for clinical trials and advanced manufacturing of therapies and vaccines. The country is a key node in global clinical trial supply chains, which allows for efficient testing and validation of new healthcare innovations. Belgium's expertise in biomanufacturing and its reputation for quality contribute to the advantages of building a life sciences start-up here."

PDC*line Pharma is another younger company leveraging Belgium's vaccine expertise and footprint. The immuno-oncology biotech currently has a therapeutic vaccine to treat patients with advanced-stage non-small cell lung cancer in Phase Ib/II clinical trials. "When I joined as CEO in 2016, we decided PDC*line Pharma should be developed in Wallonia, the French-speaking part of Belgium," says Eric Halioua. "The reason for that decision was that I knew the area and its strong ecosystem already because I had been the CEO of a previous company for six years. It is even stronger now with Big Pharma setting up headquarters here and bringing in a lot of talent. We have benefited from that, and most of our management team came from GSK Vaccines."

He continues, "Financing is one of the other strengths of Belgium to attract biotech. In Wallonia, for example, a lot of government funding is available, and there are also many VC funds present here. In addition, Belgium is very quick for setting up clinical trials."

Not only does GSK Vaccines provide a rich pool of talent for other vaccine-focused outfits to draw from, but the company also partners up with innovative local players, thus further bolstering the ecosystem. "Vaccines are [made] using biological components - which can be

quite complex to produce at large scale," states Jamila Louahed, GSK VP, head of therapeutic vaccines R&D and the Rixensart R&D centre.

"We have developed strategic collaborations to help optimise our production processes, like with imec, a leading nanotechnology research centre with headquarters in Flanders, in order to leverage nanoelectronics to automate and improve control processes in biomanufacturing of our vaccines, including those in development phase. This collaboration contributes to consolidate Belgium's strategic role in vaccine R&D and make Belgium the Health and Biotech valley of tomorrow."

## DOMESTIC IMMUNISATION: NOT A PROPHET IN THEIR OWN LAND?

However, while Belgium's role in developing, producing, and distributing lifesaving vaccines to the world is now better known than ever, pharma industry stakeholders worry that these products remain undervalued at home. "Vaccine hesitancy crept up in Belgium during the pandemic, although not as badly as in some other European countries, and pharma was accused of just wanting to sell vaccines rather than make people better," laments pharma.be's Ven. "There needs to be a greater recognition of the economic cost of a pandemic and people not being able to work versus the costs of vaccines, which is far lower."

Most worryingly for Emmanuelle Boishardy, VP and GM of GSK BeLux, Belgium completely lacks an adult immunisation framework and vaccines' true value on both a health and economic level is not fully appreciated by the Belgian government. "We are pushing to change this," she asserts. "While discussions can be challenging, especially given the differences between vaccines and treatments, vaccines for adults, like for children, are vital tools with a return on investment (ROI) of four euros to every one euro spent," she asserts.

**"Currently, much adult vaccination [in Belgium] depends on the preferences or knowledge of individual patients and doctors, whereas an overarching framework is needed."**

"Not only do vaccines protect individuals against infectious diseases, but they also protect against serious complications and aggravation of underlying diseases. All these benefits ultimately translate in a positive economic and societal impact, not the least on health inequities. However, to many in government, they are still seen as a cost rather than an investment and the pharmacoeconomic assessment of vaccine value is still too narrow. For this reason, we need to continue attempting to educate and inform all stakeholders about the broad value of vaccines, including for adults." She concludes, "Currently, much adult vaccination [in Belgium] depends on the preferences or knowledge of individual patients and doctors, whereas an overarching framework is needed."

GSK

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# The Prodigal Son Returns

BACK HOME IN BELGIUM AFTER A STELLAR STINT IN BIG PHARMA, DR PAUL STOFFELS IS NOW LOOKING TO RE-SHAPE THE FUTURE OF CANCER CARE WITH THE PREVIOUSLY STRUGGLING BIO-TECH HE HELPED CO-FOUND IN 1999, GALAPAGOS.

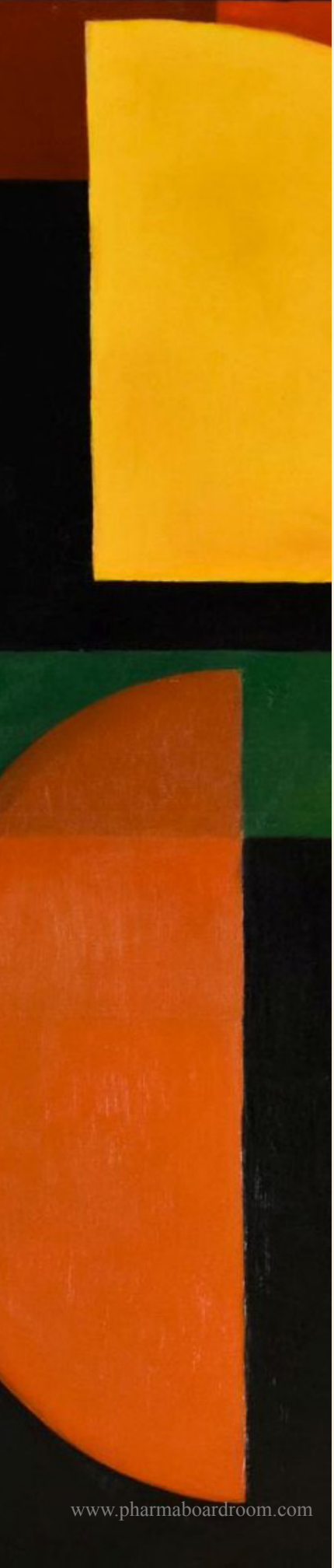
**PAUL STOFFELS**
CEO and chairman, Galapagos

Stoffels is a heavyweight of the global pharmaceutical industry and close ally of the legendary Dr Paul Janssen, under whose tutelage he led the development of several breakthrough prod-ucts for HIV, helping change the treatment paradigm for what was previously a life-ending dis-ease. Having overseen a transformation of J&J's R&D operations as its worldwide pharmaceuti-cals chairman, Stoffels was involved in the launch of 25 innovative medicines at the company – seven of which have since been added to the WHO's Essential Medicines List – and doubled its pharma sales from USD 22.5 billion in 2009 to 45.6 billion by 2020. Immediately prior to re-joining Galapagos, he served as vice chairman of J&J's executive committee and chief scientific officer, notable spearheading the development of its single-shot COVID-19 vaccine within a rec-ord time frame.

The challenges facing Stoffels upon leaving J&J and cutting short his retirement to return to Galapagos last year – ostensibly to be closer to his four children and seven grandchildren in Europe – were significant and differed greatly from those in a Big Pharma behemoth with a stacked pipeline like J&J. Following a string of poor data readouts and the shuttering of projects in osteoarthritis and pulmonary fibrosis, Galapagos' own pipeline was almost bare, leading Stof-fels to embark on what he called in the 2022 annual report, "a year of transformation and change."

This meant moving away from the biotech's historic R&D focus on novel mode-of-action small molecule drugs targeting a broad range of indications to what Stoffels calls "a patient-centric, medical need-driven approach in our key therapeutic areas of immunology and oncology." Cell therapy was selected as the way forward, with Stoffels having been heavily involved in J&J's 2017 licensing deal with Chinese drug developer Legend Biotech for what became Carvykti, still one of only two cell therapies approved in the US for

**"The complexities of conditions like cancer demand a revolutionary solution; that is where CAR-T cell therapy could be a potential game-changer."**



multiple myeloma. "The complexities of conditions like cancer demand a revolutionary solution; that is where CAR-T cell therapy could be a potential game-changer," he says.

However, drawing on his decades of experience, Stoffels is keen to foreground the fact that game-changing innovation means nothing if it cannot be absorbed by healthcare systems due to lack of funds or infrastructure. This is especially pertinent for CAR-T cell therapies, which often come at a cost of hundreds of thousands of dollars due to the need for complex cellular manu-facturing as well as the high level of hospital care necessary post-administration.

He notes that "The true essence of a therapy lies not only in its effectiveness but also in its accessibility, flexibility, and the expansion of its benefits to encompass a broader spectrum of life-threatening diseases. That is where pioneering research and groundbreaking manufacturing solutions could play a significant role." He adds, "Despite the tremendous potential of current CAR-T therapies, long lead times, highly manual central manufacturing, and complex logistics remain the limiting factors for large-scale capacity and broad patient access."

In this spirit of pragmatism with the aim of making a rapid leap forward to develop solutions addressing CAR-T's current limitations, Stoffels has looked towards M&A. In his first year on the job, Galapagos acquired two companies – Cellpoint and AboundBio – which he explains gave it access to both "an innovative, scalable, decentralized, and automated point-of-care CAR-T de-livery model as well as a next-generation fully human antibody-based therapeutics platform."

Being able to administer and monitor CAR-T cells via a machine which sits at a patient's bedside will, in Stoffels' view, have important ramifications on the speed, quality, and cost of the therapy, allowing for administration with seven days and eliminating the need for complex logistics or cryopreservation. Galapagos will install its manufacturing capabilities in ten European hospi-tals in 2023 and up to 20 next year, when it will also launch in the US.

Additionally, while the integration of this new delivery model for CAR-T into healthcare systems will depend upon these systems "recognizing the value of innovation, implementing appropriate reimbursement practices, expediting regulatory processes, and ensuring timely market en-try," Stoffels is optimistic that another career-defining breakthrough is afoot.

**"The true essence of a therapy lies not only in its effectiveness but also in its accessibility, flex-ibility, and the expansion of its benefits to encompass a broader spectrum of life-threatening diseases."**

"Whether we are developing therapies for conditions like HIV or pushing the boundaries of innovative science such as CAR-T, our ultimate goal is to translate scientific discoveries into tangible improvements in the quality of life for those in need," he concludes. "Let us all work together with a shared vision, collaborating to transform scientific discoveries into meaningful healthcare solutions that enhance the lives of patients worldwide."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# Belgium

## One of a Kind

Encircled by heavyweight life sciences powerhouses of the likes of Germany, France and Switzerland, plucky Belgium nonetheless continues to astonish and project considerable influence when it comes to its abilities to develop, manufacture and sell medicines.

Despite representing only a mid-size marketplace from an in-country commercial perspective, the comparatively small European Union member state nevertheless "a thriving and competitive biopharma ecosystem that encompasses the entire value chain, spanning research and development to manufacturing. The industry environment is robust, fostering the presence of both multinational companies and biotechs, with a particular emphasis on biological and vaccine expertise," observes Paul Stoffels, CEO of the renowned homegrown biotech, Galapagos.

Indeed, over the past couple of years, against the backdrop of an increasingly uncertain and volatile global operating environment, Belgium's medicines output has "come on in leaps and bounds."

In the post-COVID period, the country's pharmaceutical exports have skyrocketed from an already high starting base, increasing more than 70 percent, to the point where the multilingual nation state now habitually trades in excess of EUR 230 million worth of biopharmaceuticals per day to export destinations stretching from the European continent's major economies all the way to the megamarkets of China and North America.

## Export Springboard

How can such feats be explained? Part of the reason clearly lies in the country's strong industrial prowess combined with an ever more sophisticated and expansive logistics infrastructure. Courtesy of its strategic placement close to the heart of the European continent and a stellar supporting network of air and sea lanes, the centrepiece of which is undoubtedly Antwerp-Bruges seaport, Belgium "has burnished its credentials as a platform from which it has become pretty easy to import and export products," notes Tom Hautekiet the port's chief commercial officer.

"This is of particular interest and appeal to the (more than 30) pharmaceutical players already possessing production sites in-country as Belgium can nowadays be leveraged as a launchpad for exporting intermediates or finished product and harnessed as a vital node in worldwide supply and distribution chains," he opines.

Such dynamics are immediately apparent in the prevailing strategies of Big Pharma. "In Zaventem, we have established one of the largest Pfizer logistics centres to be found anywhere, handling two-thirds of our global distribution and mobilising air, land, and sea corridors to deliver medicines to more than 170 countries worldwide," confirms An Van Gerven the company's general manger for BeLux.

Meanwhile, the iconic Japanese biopharma player, Takeda, has elected to turn its Belgian operations into a major node for the worldwide production and distribution of its plasma-derived therapies. "Over the last two years, we've invested over EUR 400 million in our Lessines site, expanding the existing site and adding new warehousing and production facilities so we can reliably supply over 80 countries," reveals General Manager Michael Nesrallah, who forecasts yet more growth to come for the site in the years ahead.

Likewise, Sanofi has been placing big-ticket investments in its Geel manufacturing and supply site in Flanders. "This site is essentially tasked with the global production of our blockbuster biologics such as monoclonal antibodies and therapeutic proteins. Last year, executive management took the strategic decision to inject a further EUR 120 million worth of investment into the site for the incorporation of a new global production line for one of our most innovative haemophilia molecules," proudly recounts the French company's country lead and Benelux general manager for specialty care, Johan Heylen.

GSK, for its part, has been assiduously overhauling its vaccine distribution hub in Gembloux where next year it shall be partnering with Yusen Logistics to construct a state-of-the-art, fully GDP certified warehouse and logistics center kitted out with cold chain storage systems, autonomous mobile robots, and automated guided vehicles.

MICHAEL NESRALLAH

general manager, Takeda

JOHAN HEYLEN

country lead Belgium & general manager Specialty Care Belux, Sanofi

"This facility, which incorporates cutting-edge technologies and the very latest, exacting environmental standards, will not only serve to consolidate our incoming material storage, but shall also enable us to distribute millions of vaccines more quickly and more sustainably to people across more than 160 counties while simultaneously reducing our CO2 emissions," enthuses Emmanuelle Boishardy, VP and general manager for GSK BeLux.

That's not to overlook, however, the important contribution that smaller entities implanted within Belgium, such as those producing active pharmaceutical ingredients (APIs), have made to bolster and expand the country's pharma exports envelope. Even prior to Covid-19, Belgium accounted for a deeply impressive 13 percent of the EU's total aggregated pharmaceutical exports, and now that share is likely to be significantly higher with the locally-embedded industry capitalising upon pent-up post-pandemic demand for non-Covid related medical treatments.

"What we've essentially witnessed has been a massive and rapid upscaling, on behalf of both major and minor players, to serve rampant global demand. This has been achieved by leveraging latent capacity within our nation's manufacturing facilities as well as the profound capabilities of world-class logistics partners such as Brussels Airport, Liege Airport, and the Port of Antwerp," elaborates Caroline Ven, CEO of Pharma.be, the association for originator drug developers.

"Many of these are now fully cold chain certified and appropriately equipped to deal with the highly specific

conditions at which many of the new products coming onstream have to be transported," she insists.

## R&D Mega Hub

Belgium's unique life science offering is even more intriguing and multifaceted, however. Despite only ranking as Europe's 34th biggest country by landmass and 13th by population, Belgium consistently manages to find the wherewithal to invest over EUR five billion in pharmaceutical R&D every year, rendering the nation the fourth largest pharma R&D spender within the entire Union, and the first per capita by some significant margin. "This ability to outspend even far larger neighbours such as France is emblematic of Belgium's coming of age as a bona fide, world class pharma hub in its own right," believes Heylen.

Such R&D largesse has been fundamentally rendered possible by the presence of a fully-fledged landscape comprising all the core ingredients of life-science value creation encompassing top-notch hospitals, institutes, medical universities, small and large enterprises, venture capital and a highly skilled, diverse practitioner and clinical community ready to collaborate.

"Belgium has managed to place itself on the map and assert itself as an extremely relevant and meaningful location for Novartis because of the establishment of the so-called pharma-valley: a well-rounded enabling ecosystem straddling the full product life cycle from development and research, through manufacturing and conditioning all the way to supply chain and distribution," perceives Novartis' Country President Federico Mambretti. "And the confluence of these attributes – skills, expertise, versatility, support structures and incentives – mean companies like ours can comfortably invest, thrive and attain peak performance."

"Historically the Belgian pharma scene has, of course, always boasted an illustrious constellation of home-grown icons like Solvay, Janssen and UCB, but this rich

heritage has also been complemented by concerted efforts to fill in the gaps and entice in companies and investment across the full pharma spectrum," observes Pierre Boyer, general manager for BeLux at Servier. Moreover, over time, this has set in motion a "virtuous circle that is self-perpetuating."

## Blending Breath with Depth

In other words, rather than focusing merely upon the commercialisation segment of the value chain as one might expect from any ordinary small or middling market, Belgium's planners have been sagacious enough to nurture and cultivate a distinctly holistic setting that covers all the main bases. The resulting outcome is a simultaneously well differentiated and compelling offering that makes it that little bit easier to decide to invest further.

At the same time, there are definite cultural characteristics at play that have helped smooth Belgian pharma's ascension. "One nuance I notice in Belgium that stands in stark contrast to other innovation-rich markets such as the United States is the tightness of the community: from academics and entrepreneurs to industry, clinicians and policymakers. There is great deal of connectivity and interaction, and you get a sense that real trust has been forged over time," discerns Takeda's Nesrallah.

ERIC HALIOUA

president & CEO, PDC*line Pharma

"Belgium's biopharma ecosystem is further strengthened by close collaborations among academic institutions, hospitals, spin-offs, start-ups, SMEs, large corporations, and a well-developed logistics network. This collaborative spirit fuels innovation and facilitates the seamless exchange of knowledge and resources, contributing to the overall success of the ecosystem," agrees Galapagos' Paul Stoffels. "This ecosystem thrives on extensive knowledge in pharmaceutical sciences and a pool of experienced professionals. Notably, the biotech sector, especially in the realm of cell therapies, has witnessed significant growth, even comparable to renowned hubs like Boston," he believes.

Wouter Piepers, the CEO of the regional association flanders.bio very much concurs. "Not only is Flanders rapidly turning into a hotbed of biotech where the translation of good science can be converted into high-profile spinoffs, but Wallonia is becoming a pioneer in niche bioprocessing and biomanufacturing for some highly specialised therapeutics…Just consider GSK's development of vaccines, Takeda's plasma therapies, Univercells' activities in the bioreactor space or Becarv's aseptic design and process engineering," he argues.

Belgium's dominance in the vaccines space is already well accepted with companies such as GSK tending to consolidate much of their capabilities in this discipline firmly in the country. "Belgium hosts three of our major vaccine sites – in Wavre, Rixensart and Gembloux respectively – including our company's global headquarters for its vaccines division. All GSK's vaccines that have the '-rix' suffix refer to their connection to the Rixensart site where the majority of our vaccines R&D is conducted," explains Emmanuelle Boishardy.

Some insiders also believe that this space is likely to see a lot more action thanks to the massive attention given over to vaccine development during the global pandemic. "Perceptions about viability have evolved rapidly, and the experience and awareness related to the development of the COVID-19 vaccine has resulted in a palpable boost for cancer vaccines. Big Pharma's appetite and interest in cancer vaccines has certainly been re-stimulated," thinks Eric Halioua, president and CEO of PDC*line Pharma,

a Liege-based outfit deploying a plasmacytoid dendritic cell-line pre-loaded with peptides from target tumor antigens for their core cancer vaccine platform.

Meanwhile the recent decision of Janssen to situate its first ever chimeric antigen receptor T cell (CAR-T) development campus in Ghent's Tech Lane Science Park is seen as confirmation of Belgium's burgeoning preeminence in the field of next generation cell therapies. "We can be immensely proud that our country has been chosen to host to the first cell therapy production site in Europe. It proves that we possess the requisite talent and know how to makes top investments like this possible," declared Belgian Prime Minister Alexander De Croo at the time.

"The most important raw material in Flanders is actually our brains and our staunch commitment to technological innovation, which is why biotech like this has become one of our showpieces," explains Minister-President of the Flemish Government Jan Jambon.

Janssen's own general manager, Maria Fernando Prado absolutely agrees. "I consider that the selection of Belgium [for our new CAR-T production site] represents a watershed moment and is positive testimony of the value of the country in terms of innovation capacity and intrinsic quality of people," she posits. "It is emblematic of the genuine appetite and enthusiasm for development of new technologies here, beyond any additional benefits that might be accrued from its convenient central geographic location."

## Resilient Biotech

With over 140 operating biotech companies representing almost a quarter of Europe's biotech market buttressed by a fully fleshed network of seven academic hospitals, 12 universities and countless research institutes, Belgium boasts a robust biotech landscape seemingly able to withstand even today's febrile economic environment and successive downturns in VC financing.

"Against the backdrop of an economic system under pressure and a myriad of geo-political challenges, we are perceiving a tendency towards precision financing, whereby biotech investors are becoming more discriminate, disciplined, and demanding and there is a need for strong data and efficiency. Money remains available, but only for the right projects," reasons Piepers of flanders.bio.

"What we're noticing is that projects are being de-risked earlier – with a weeding out the good from the bad, and even the good from great – and the cost of money is higher. Moreover, the same shift is simultaneously occurring on the investor side, with highly specialised funds now driving decisions, while the IPO window remains closed for the foreseeable future," he concedes.

And yet, for all of that, he remains optimistic about the staying power and resilience of the country's biotech scene, pointing to the continuous churn out of exciting prospects and impressive track record of spin-offs that have actually made it into the big league.

"When Ablynx was acquired by Sanofi, it had developed a stellar program in rare diseases and in the slipstream of that success, and building on similar yet different technology, Argenx turned into one of the most successful biotech companies on the planet. Galapagos is another fine example, now blazing new trails in CAR-T

MARK DEKKER

general manager
Benelux, Astellas Pharma

therapies, while Oxurion has been successful in bringing a first-in-class retina therapy from bench to market," he recalls.

Belgian innovation is also playing a role within Japanese giant Astellas' global portfolio, as the company's general manager for Benelux, Mark Dekker, explains. "Benelux's global significance to the company and its potential for future innovation investments can best be illustrated by Astellas' upcoming women's health product," he outlines. "The product was developed at the University of Brussels before being spun off into a local company called Ogeda and acquired by Astellas in 2017. Having already obtained FDA approval, the product will soon be launched in the US. It promises to be a game-changer in women's health and is all based on Belgian research."

Even now, there remains a strong pipeline of up-and-coming actors that have already raised funding to bring their promising candidates forward despite the prevailing "tough love" investment climate. Liège-based Imcyse, which develops a new class of active and specific immunotherapies for the treatment of severe autoimmune disease, for instance, recently secured an equity stake from Pfizer, while Leuven-based Flamingo Theraputics, which specialises in RNA therapeutics, announced a merger with France's Dynacure. Ghent-based Confo Therapeutics, a spin out from Vrije Universiteit Brussels, for its part, recently raised a total of EUR 47.7 million in funding over nine rounds for its peripheral neuropathic pain candidate, proving that pathways remain very much open for the finest ventures.



## Mastery in Clinical Trials

Yet another expression of Belgium's innovation propensity can be seen in its longstanding reputation as a clinical trials destination country of choice. From a volume perspective, the country has, traditionally outperformed its peers when it comes to guiding new therapies through the clinical trial process swiftly and efficiently.

For a start, the sheer number of clinical trial applications approved in-country each year has been growing steadily, rising from under 500 in 2015 to 574 in 2021, which has ensured that Belgium has ranked within Europe's top three countries for more than a decade in terms of the number of clinical trials set up per inhabitant. Commercial trials have also tended to exhibit a larger footprint in Belgium compared to other European states. In 2021, 80 percent of the clinical trials applications approved were initiated by biopharmaceutical companies as opposed to emerging from universities or academic institutes.

Some of the key factors underpinning these achievements have been the superior quality of the country's infrastructure — including its research centers and over 70 hospitals— and the level of expertise of researchers and authorities, including the Federal Agency for Medicines and Health Products (FAMHP). "Belgium is blessed with a high level of expertise for conducting trials so we can proceed with confidence that the trials will be carried out properly and that patient enrolment will work well. Additionally, there are therapeutic experts in Belgium who are well-known at a European level and worldwide, which means they can speak about their experiences with our medicines," points out Servier's Pierre Boyer.

Meanwhile, there is ample capacity to provide choice and to not risk encountering delays. "Structurally, it's a really good setup because there is an abundance of

hospitals and clinics that are well organised and well equipped for undertaking large volumes of trials, which from a drug developer perspective means there are a lot of options and possibilities," notes Aspen's General Manager Vanja Hoeben.

Crucially, Belgium also offers a highly favourable regulatory environment, having introduced an important clinical trials law in 2018 to ensure the practical implementation of the EU Clinical Trials Regulation (CTR). Under that law, Belgium has continued to implement its ultra-fast approval procedures for clinical trials, particularly for Phase I trials — a procedure that takes barely 15 days!

"I believe this market to be exceptionally attractive for early-stage trials due to the exceptionally speedy approval process on the part of the authorities combined with the plentiful availability of clinics that are Phase I eligible. Of course, the quicker the process is, the more cost-efficient it becomes so the timeframes do matter," remarks Amgen's general manager for BeLux, Gábor Sztaniszláv.

A further competitive advantage also relates to the presence of expertise in specific therapeutic areas such as oncology and haematology. One of the reasons Bayer prefers to run certain trials in Belgium as opposed to its neighbouring home market of Germany is the superior knowledge vested within certain Belgian hospitals and clinics.

"We maintain a relatively high tempo of trials out here, especially those involving oncology, ophthalmology, or cardiovascular, because the physicians tend to be highly engaged and familiar with the therapeutic areas while the larger hospitals, in particular, are greatly experienced," confirms Werner De Prins, country division head pharmaceuticals & senior representative Benelux.

Cancer research indeed leads in terms of the number of clinical studies carried out in Belgium by therapeutic area, with 175 launched in 2020, accounting for 19 percent of the clinical trials in Europe to test drugs against cancer. Then there is

FREDERIC CLAIS

country manager, Eli Lilly

ISABELLE HUYGHE

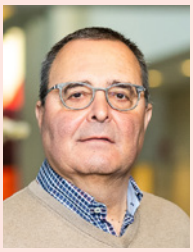
PCRU medical/ scientific advisor, Pfizer

also significant emphasis on viral illnesses (ten percent), and nervous system disorders (eight percent).

Attesting to Belgium's sustained competitiveness as a research focal point, big pharma continues to invest deeply in in-country trials. "Novartis most probably possesses the largest R&D footprint in the Belgian industry with over a hundred active clinical trials at any one moment," declares Novartis' Federico Mambretti.

Meanwhile, Switzerland's other iconic drugmaker, Roche, invested a full EUR 27.7 million into in-country clinic studies in 2021. "Unlike with many of our other European affiliates, for Belgium we've even established our own clinical trial operations unit employing over 30 personnel and conduct the full panoply of trials from Phases I to IV," reveals Marie-José Borst, the company's general manager for BeLux.

Benelux also holds particular resonance for Vertex, the US-headquartered cystic fibrosis innovator, which is now branching out into new therapeutic areas. "Benelux is considered a biopharmaceutical hub with a strong history of delivering clinical trials," explains Paul Newton, senior country manager for Benelux. "Our clinical team reports directly to Boston and runs trials locally, having completed 40 clinical trials in Benelux of which 20 are in Belgium alone. These trials cover not only cystic fibrosis but also other disease areas, where we have been working with CRISPR Therapeutics on gene editing technology that could potentially transform the lives of patients with debilitating illnesses. Belgium is therefore a crucial market for Vertex, and we closely follow any developments that happen in the Belgian environment."



WERNER DE PRINS

country division head pharmaceuticals & senior Bayer representative Benelux

Pfizer too has come up with a bespoke formula for the Belgian market. "With two in-house Clinical Research Units (PCRUs), the company stands apart from many of its peers by keeping phase I research within the business. "We possess two Phase I clinical research centers globally, the first of which is in New Haven, Connecticut and the second of which is right here in Brussels. This demonstrates just how highly we value the Belgian clinical trials environment," explains Isabelle Huyghe, Pfizer CRU medical scientific advisor. "And we've even established a secondary satellite unit in Hasselt where people who come from further away can get initial screening without the need to journey to the capital."

## Linking Health with Wealth

Belgium's local pharma sector has steadily been consolidating its status as a linchpin and dynamo of the national economy, and nowadays accounts for a full five percent of GDP. "From employment to innovation intensity, and especially productivity, pharma has been leading the way lately, and is likely unique in being the only sector to have successfully combined substantial productivity growth with value added and employment growth over the last decade," explains Caroline Ven of pharma.be.

And the sector's impressive track record doesn't end there. Over the past five years, sectoral workforce figures increased by 18.7 percent suggesting real growth momentum. "Ultimately our members contribute a serious volume of highly qualified jobs alongside the creation of a broad array of shorter-skilled positions that comprise maybe around a third of our total employee base," she elaborates.

"In fact, if you crunch the numbers, you'll discover that over 40,000 people are currently employed directly by the Belgian pharma sector with as many as 130,000 indirect jobs sustained on top of that," agrees Sanofi's Johan Heylen. "At the end of the day, Belgium's pharmaceutical industry has an impact on health thanks to our therapies, and simultaneously on the prosperity of the nation by bringing wealth to Belgian society with the value-added jobs we create and the investments we stimulate. These two elements go hand in hand because a society can only be wealthy if it is healthy and the other way round," concludes Pfizer's An Van Gerven.

Eli Lilly, for its part, has even made Belgium home to the company's European Clinical Trial Services (ELECTS) division. "We feel it is important to maintain a strong position in Belgium, both in terms of regulatory compliance from a European level and in terms of access to patients for clinical trials. The ELECTS division coordinates all clinical trials and manages all clinical material across Europe, Africa, and Asia, due to Belgium's long-forged excellence in managing clinical studies," claims Country Manager Frederic Clais.

## The Perils of Complacency

Notwithstanding all this investment and Belgium's clear historical prominence as a clinical trials axis, some stakeholders are beginning to fret, however, that the country risks losing much of its competitive advantage.

The main impetus behind these fears are external factors. Firstly, the rising cost of Belgian labour and its elevating effect on trial fees, and, more urgently, the expected impact from the EU's CTR that came into effect in

## Antwerp-Bruges: The World's First GDP-Compliant Port

Formerly most life science companies tended to lean heavily on the aviation industry for fast and efficient delivery of temperature sensitive medicines such as biologics and vaccines which require optimal conditions during all phases of transport, handing and storage as their potency and effectiveness may be negatively affected if exposed to temperature variations, sunlight, or fluorescence.

Following the supply chain disruption experienced in the wake of Covid-19, rampant price inflation, and rising concern over the need to reduce CO2 emissions, however, the maritime sector is growing in importance within the healthcare supply chain and is increasingly being considered as an alternative modality. Belgium's seaports, therefore, have been quick off the mark to adapt to this new opportunity in container transport with multiple upgrades underway: including the expansion of the Deurganck Dock in Antwerp, additional APM Terminals in Zeebrugge, TriLogiPort in Liège and new sites at the port of Brussels.

**TOM HAUTEKIET**

CCO, Port of Antwerp-Bruges

Blazing new trails, however, has been the port of Antwerp-Bruges Europe's second biggest container port behind Rotterdam, and the number two chemical port globally, second only to Houston. "We have been doing all we can to gain knowledge about concepts such as storage, serialisation and digitalisation, and our terminals have been meeting with quality managers from the pharmaceutical side to better understand how to best respond to their needs," recounts Tom Hautekiet, Antwerp-Bruges Port's CCO. "After all, Belgium ranks as the second largest global vaccine producer, just behind the United States and is an increasingly influential exporter of next generation biologic medicines so it makes sense that Belgian logistics infrastructure should be at the vanguard of pioneering these changes," he reasons.

Consequently, Antwerp-Bruges now enjoys the distinction of being the first global GDP-compliant port with its facilities fully cold chain certified and able to deal with the specific conditions at which many of the new biologics coming on stream need to be transported. This has not just entailed the establishment of digital twins with sensors all around the port infrastructure that measure, monitor and record aspects such as temperature and light levels, but also intricately understanding every step of the process, so that it is possible to control and trace a medicine as it moves across the supply chain.

"It requires a high level of interaction with external stakeholders, who must all understand how GDP works, not only the port and the pharmaceutical companies, but also the terminals, sailing companies and ports on the other side of the world. There are GDP airports in Singapore, Switzerland, and Belgium but no other seaports thus far, so it is a work in progress as we set about instigating and cultivating those alliances," admits Hautekiet.

MARIE-JOSÉ BORST

general manager
BeLux, Roche

January and includes the creation of an EU clinical trials portal and database.

"From a Belgian perspective, a centralised EU clinical trial database potentially levels the playing field in Europe and diminishes one of our main points of competitive differentiation," says Roche's Borst. "Belgium has a historical advantage in clinical trials, but the new European regulation will undoubtedly be something of an equaliser," concedes Pedro Facon, deputy CEO of the National Institute for Health and Disability Insurance (NIHDI), the second largest social security institution in Belgium after pensions.

This new EU uniformity requires policymakers and industry alike to think afresh. "While Belgium may no longer be able to move faster than other EU countries, that doesn't necessarily mean that it still can't differentiate itself. This is a moment for reinvention and a wake-up call if our country seeks to maintain its privileged position at the clinical trials high table," counsels Borst.

Others agree. "It is vitally important to recognise that the achievements of the past are no guarantees of future success. If we maintain business as usual and stand still, then that actually means being overtaken and falling backwards," warns Mambretti.

MICHEL COLLARD

CEO, PharmaScan
BeLux



## Market Access: Ready for a Reboot?

Xavier de Cuyper, CEO of FAMHP, nonetheless claims that the government agency has been conscientiously preparing for the new legislation. "The CTR rollout certainly has had an impact, but our extensive pilot project seems to have paid off in the first year of implementation and companies are still investing in trials," he assures.

De Cuyper cites Belgium's competitive timelines for mono-national Phase I clinical studies and FAMHP's involvement in the European project on Simultaneous National Scientific Advice (SNSA) as a potential way forward within the CTR. "The SNSA pilot has a specific focus on, but is not limited to, multinational scientific and technical/regulatory advice to facilitate and accelerate multinational clinical trials within Europe to the maximum extent possible," he argues.

The local industry itself, has also been identifying additional ideas for potential improvements that could help preserve competitiveness. "We can see merit in bringing individual clinical trial sites together into clinical trial centres which, as research moves into more niche and rare indications, should broaden the catchment area and boost patient recruitment potential," urges Michel Collard, CEO of PharmaScan BeLux, a non-profit organisation established jointly by pharma.be and off-patent association Medaxes to create a comprehensive database on hospital drugs by aggregating shipping units from distributors.

Within Belgium's own pharma market – despite a predictably reliable, albeit unspectacular, compound annual

XAVIER DE CUYPER

CEO, Federal Agency for Medicines & Health Products (FAMHP), Belgium

growth rate of around four percent – there are, however, clear signs of discontent around a deterioration in patients' level of access to innovative medicines.

"The European Medicines Agency (EMA) fast-track procedures and rolling reviews might have helped to improve access, but once you've secure EMA approval, there are still a great many hurdles at the national level to navigate before patients can properly get their hands on innovative therapies," regrets Pfizer's An Van Gerven.

Indeed, the EFPIA's 'WAIT' Indicator demonstrates that Belgian patients are having to wait considerably longer than their counterparts in other high-income European countries to access the same approved medicines. "Right now, we are ranking an appalling 23rd place among member states with the Belgian population habitually facing average waiting times of over 500 days," points out Marie-José Borst.

Moreover, the situation for certain specific therapeutic areas can be even worse. "We've noticed that, owing to the complexity of the system, oncology therapies are taking around 540 days over here compared to only 130 days in neighbouring Germany," observes Servier's Pierre Boyer, while Takeda is reporting having encountered delays of up to 638 days for their orphan drugs.

When it comes to reimbursement there are also formidable obstacles to overcome. The drug reimbursement process has become more and more elongated over time and implies a lengthy approval procedure that must go through both the Commission for the Reimbursement of Medicines (CRM) and the minister of social affairs so can take 180 days. Then, finally, when the decisions eventually get handed out, they are often very disappointing.

"In 2021, Belgium had 21 negative reimbursement decisions, meaning no reimbursement at all, yet 90 percent of those same products were reimbursed in Germany, and 81 percent in markets like the Netherlands, Austria, and Finland…This means that Belgium is experiencing a serious access equity issue and that our patients have fewer options available to them than their equivalents in neighbouring markets," argues GSK's Emmanuelle Boishardy.

Another problem is that, once reimbursed, the approved reimbursement criteria are often much narrower than the product label itself. "A high number of products do get reimbursed, but usually at very low price and with a restricted patient population," notes Amgen's Sztaniszláv.

IVAN PERRICHON

general manager, Théa Pharma BeLux

He identifies the need for practical mechanisms to ensure earlier access to breakthrough therapies and laments that the prevailing system is too rigid to allow for temporary or partial reimbursement before the official reimbursement decision is made. "I believe that involving specialty professionals would allow a more accurate and objective evaluation of whether a product has a significant added value compared to the standard of care…. This would enable high-potential products to enter discussions on agreeing on a price, whereas, under the current system, products frequently

PAUL NEWTON

senior country manager
Benelux, Vertex Pharmaceuticals

never reach this stage, resulting in many promising products falling out of the system too early," he reasons.

Ivan Perrichon, general manager for French ophthalmology specialist Théa Pharma in BeLux, worry that the authorities' tough bargaining on pricing may come back to bite it if it leads to therapies which impact public health not being launched. "Approvals are no simpler in ophthalmology than in other areas," he begins. "But we do aim to partner with local authorities to face upcoming challenges, like progressive myopia, which is a public health matter, not just for Théa. It is a societal issue that must be addressed today if we want to prevent the cost in the next 20 years because of the associated pathologies that will arise. This also raises the question of sanitary dependence that might impact the healthcare system even more."

Nor is incremental innovation sufficiently recognised by the reimbursement system according to Van Gerven. "If we develop a new application for an off-patent product, the authorities do not recognise it as an innovation. However, a posology of one tablet per day to treat a chronic disease like hypertension instead of several tablets per day is an innovative solution that will genuinely improve the quality of life of the patient, their adherence to the treatment, and will bring positive health, and ultimately economic, outcomes. It is short-sighted to ignore this," she contends.

ISABELLE DE WALSCHE

managing director
Benelux, Gedeon Richter

Others, such as Isabelle De Walsche, managing director for Benelux at Gedeon Richter, want to see more clarity and certainty. "In a market like the Netherlands, you can have pre-meetings, which have no impact on the outcomes, but at least you can get a feel for the state of mind of the commission. Personally, I like that, because you can get an idea of the objectives of both sides and a sense of where you stand well in advance of a formal decision being made. I very much miss that in the Belgian system," she admits.

Paul Newton of Vertex – which has achieved reimbursement for all four of its cystic fibrosis therapies in Belgium and which can treat approximately 85 percent of CF patients in the country – is rather more sanguine. "The Belgian authorities are open to engaging in dialogue with the pharmaceutical industry," he opines. "I have seen signals that they are listening to our concerns, and I hope that this continues. I believe that if we listen to each other, we can work together to create a sustainable healthcare system that benefits patients, healthcare systems, and society as a whole."

Mark Dekker of Astellas is broadly in agreement. "In terms of the reimbursement negotiations for our oncology portfolio, when NIHDI recognises the value or benefit of a product, they will find a way to get it to patients. This has been the case for our therapies in refractory acute myeloid leukaemia (AML) and metastatic bladder cancer, which achieved reimbursement in 2021 and 2023 respectively."

Dekker does however caution that "there is room for improvement in terms of adequately valuing what innovations like these offer patients and the overall healthcare system. Not all innovative medicines make it to Belgium and the gap between approval and availability is 534 days, far behind Germany (133 days) and the Netherlands (294 days)."

What then are the potential consequences of a dysfunctional market access process like this where only 50 percent of EMA-approved innovative products are reimbursed, fewer than in Greece, and where the timeframe to market can be often slower than Albania? "If such a scenario endures long-term, this might ultimately dampen the enthusiasm for innovative pharma to invest in R&D and clinical trials," warns Borst, "because the bridge from having a fantastic portfolio to ensuring patient access cannot be taken as a given in Belgium and our innovation is only worthwhile if patients can gain access to it."

"Though Amgen tries to participate in as many trials as possible, Phase III trials, especially for chronic diseases, present a big ethical dilemma because we have patients who are treated with our Phase III trial, but then, after the marketing authorisation is granted, we often have to wait too long for reimbursement. In some cases, we are asked to provide the product for free post-approval, and this can be challenging to sustain," explains Sztaniszláv. "Additionally, the unpredictability of whether the product will be reimbursed or not makes it difficult to decide if we should bring certain trials to Belgium at all. Some manufacturers have even halted clinical trials in Belgium because of this, which is a concerning tendency," he notes.

## A 'Medicines Roadmap'

To their credit, the Belgian authorities freely acknowledge the existence of market access challenges and the need to enact sweeping reform to correct the perceived obsolescence of the prevailing approval and reimbursement procedures. "It's important to recognise that the current procedure has been in place for over two decades and that, although there have been plenty of incremental modifications over the years, the procedure has actually become rather complex and unwieldy," admits Diane Kleinermans, president of the Commission for the Reimbursement of Medicines at NIHDI.

"The fundamental issue is that the original design did not fully anticipate the challenges we face today or accommodate next generation technologies or ATMPs such the new types of cell and gene therapies now coming on-stream. As such it is no longer completely fit-for-purpose," she explains.

Additionally, uncertainty about the financial impact or performance of many new products has led to an overuse of managed entry agreements whereby risk is shared between government and industry. As NIHDI's Pedro Facon explains, "These agreements, primarily for innovative medicines in areas like cancer and immunology, already account for EUR 2.5 billion of the EUR six billion medicines budget. While managed entry agreements, in and of themselves, are a good tool for diminishing uncertainties and preparing fundamental discussions on the permanent reimbursement of medicines, having so many of these early-on agreements outside of the standard permanent reimbursement model has become a real challenge."

Minister of Health, Frank Vandenbroucke, consequently last year tasked the NIHDI with conducting a 20-month consultation process with several stakeholders including industry, patient communities, insurers, and the Federal Public Service Economy, the findings of which were subsequently presented in the form of a 'medicines roadmap,' which is still pending approval by legislators.

Under the proposed amendments, reimbursement procedures would be streamlined, and patients should gain access to innovative drugs sooner. For an innovative medicine, the adjudication period would be reduced to four months by allowing a drug's manufacturer to submit a request for reimbursement as soon as it obtains approval from the EMA. Moreover, for drugs that had demonstrated particularly promising potential but were not yet approved, the procedure could be accelerated to just two months.

## NIPRO's Digital Dreams

**SERGE KEMPS**
CEO, Nipro Europe

Japanese-headquartered Nipro is one of the largest companies in the global dialysis industry and bases its EMEA operations out of Mechelen, between Brussels and Antwerp. The firm's Europe CEO Serge Kemps explains how a Belgian acquisition is driving the digital transformation of care for dialysis patients, and why Nipro has made digitalisation a priority area.

The collection and utilisation of data are commonly accepted as crucial to the future of healthcare, and digital solutions that facilitate this data push are therefore increasingly important for global pharma and medtech. To this end, in 2019 Nipro moved to acquire Flanders-based Nephroflow, a start-up focusing on the digitisation of treatment processes for patients with kidney disease; thereby reducing the potential for error and data loss inherent in paper-based systems. Emanating from a structural collaboration with the AZ Sint-Lucas hospital in Ghent, Nephroflow grew to supply the dialysis software to most hospitals in Belgium.

Now rebranded as Nipro Digital Technologies, the firm has become Nipro's software R&D arm, with the hope that further digital solutions can be generated, including how big data can better inform medical professionals which kinds of treatments work best for different types of patients.

"If you look towards digital healthcare, it is all about data and many medical device companies are working towards how we can utilise data to measure and predict the outcomes of a treatment," says Kemps. "Standardizing the definition, measurement, and collection of outcome data enables more effective comparisons across providers and health systems."

He is positive on current uptake in Belgium and the potential for wider rollout. "Digitally, Belgium is moving ahead quite well, though is still behind some other European nations," he admits. "For example, our software is installed in quite a significant number of hospitals. Medical professionals are valuing our systems as the nurses can better treat the patient and nephrologists can monitor and adjust the treatment of patients from a distance. This data will then be able to be used further down the line to establish value-based healthcare."

Kemps concludes, "Digitalisation will result in elevated patient care, as well as fewer human errors, and more time for the patient; something especially relevant at a time when human resources are becoming increasingly scarce."

ALEXANDER ALONSO

general manager, BD Benelux

One of the more eye-catching proposals on the NIHDI's roster of propositions has been to limit the duration of reimbursement contracts to three years, renewable only once for an additional period of three years, when there is no current limit for the duration of contracts. This is designed to safeguard the public purse and prevent instances of being locked-in to disadvantageous agreements long-term.

"The brute reality is that, right now, we often lack the data and insight to pinpoint value. Companies often complain about being paid too little for their products, but we can also see that reimbursement is being granted to products which finally do not have excellent real-world data despite promising early trials. So, we want to iron out these discrepancies," reasons Facon.

The monitoring of evidence on the real value of medicines is also set to be reinforced with an independent 'Real World Evidence' platform that will monitor the use and effectiveness of drugs under contract. "We want the decision to reimburse a medicine to be based more on scientific knowledge and accurate and up-to-date data. Companies themselves should also make more efforts to scientifically clarify the beneficial effect of their medicine," declares Facon.

What's more, alongside measures to improve access to medicines, the reforms also contemplate increased patient participation in the drug reimbursement approval process. "We want to actively involve patients in CRM. Today, insurance companies are the voice of patients. In the future, we will also want patient associations to have a seat at the table," he envisions.

## No Quick Fix

So far, industry's response to the proposals has been mixed with stakeholders from R&D-driven drugmakers and medtech applauding the suggestions for increased RWE and greater patient involvement, but many fretting that changes to contract terms might entail further cost-cutting. "We welcome this initiative and recognise the ambition, yet we believe the suggested reforms are insufficient to close the gap and could even put our system even further at risk if implemented as currently suggested," warns Borst.

Smaller specialty players are particularly concerned. "From an SME perspective, we are fearing the prospect of stronger price cuts because this can be lethal for smaller, pure-play originators," admits Gedeon Richter's De Walsche. "If you have few products and have to face price cuts of say 30 percent, then that's a killer. Usually, bigger companies can diversify their products and compensate for the price cut with the sale of another. However, at our scale, we don't have that luxury," she contends.

Others are sceptical of the federal government's ability to honour its commitments or even to be around long enough to implement them in the light of Belgium's current messy politics comprising upcoming general elections next May and an incumbent governing coalition composed of no less than seven different parties that, last time around, took 494 days to form!

"Those in power have the right vision, but it is exceedingly difficult under the current political circumstances

to move initiatives forward. Processes and protocols are structured in a way that requires considerable effort to change anything. My fear is that although there are a lot of plans for reform now, elections are coming up in under a year and that may change everything," confides Alexander Alonso, Benelux general manager at medical device company Becton Dickinson (BD).

"Frankly the situation was better in the past when we were able to sign an industry pact – the so-called 'Pact of the Future' – which handed us the stability and the sure-fire certainty of being able to plan for a five-year period," nostalgically muses Pierre Boyer.

Meanwhile, many believe that the real issue that need addressing lies outside the scope of the reform plans and concerns the paucity of public expenditure on medicines. "Pharmaceuticals actually comprise a relatively small part of the big picture in terms of overall Belgian health spending. The share of medicines within the NIDHI healthcare budget accounts for a mere 16 percent. Therefore, whilst a 52-point roadmap about negotiating medicine costs may trigger some benefit, it ultimately impacts less than one-fifth of the total budget," reminds Sally Ann McNab, general manager and vice president for Benelux at BMS.

VANJA HOEBEN

head of Benelux, Aspen

"Let's be absolutely clear, pharmaceuticals are not the cuckoo's egg in the healthcare budget," agrees Caroline Ven. "Healthcare expenditure is rising, but this is predominantly going towards infrastructure and staffing. Medicine expenditure is not increasing at anywhere near the same rate, and innovative medicine relative expenditure is actually diminishing."

That drop in Belgium's overall healthcare budget and the decrease in the share of medicine budget can be attributed to various factors according to Lilly's Clais. "The automatic increase in salaries due to inflation is one such element that impacts our budget share. However, this decrease indicates that there may be an inclination towards perceiving innovation as a cost element rather than something to invest in… Real reform will only be possible when we can turn around that mindset," he declares.



## Generics: What Role?

With the Belgian marketplace registering generics penetration of only 16 percent, the second lowest in Europe, many market watchers eye an opportunity for the off-patent industry to be mobilised in helping the country better rationalise its public healthcare spending both by ensuring smarter apportionment of funds and in securing better value for monies expended.

"Currently, the prescription market share for generic medications is dominated by originator brands, and the situation has been even worse for biosimilars. Traditionally physicians have not been incentivised to prescribe off-patent products due to the price decreases which originator products are subject to once the patent expires. With prices of the originator and the biosimilar more or less the same at that point, physicians are instead more inclined to stick with the products they have been using for the past ten or 20 years," notes Bayer's Werner de Prins.

Vanja Hoeben, head of Benelux for South Africa-headquartered Aspen sums up the challenges facing generics companies in the Belgian market today thusly. "Belgian healthcare is under huge pressure to balance the costs associated with new innovations, but continual price cuts for generics are threatening the system's sustainability and eventually these products' availability for patients," he states. "We are advocating for a more sustainable model, which automatically influences prices. Currently, once a product becomes off-patent, its price immediately reduces. Then, when there is a budget overshoot, we as generic companies are forced to pay the bill back via clawback. Moreover, in the last two years, and especially last year, inflation has risen, so there is greater pressure than ever on profit margins."

"While originator products are important, especially for niche markets and unmet medical needs, relying solely on innovation without considering the importance of baseline care is neither a sensible nor sustainable approach. It is essential to create awareness that the off-patent sector plays a crucial role in providing access to basic medicines, particularly as the population grows and ages," points out Jasmien Coenen, general manager of Medaxes, the association for the off-patent industry.

She perceives that, in Belgium, there has been a focus on paying for everything within a closed budget envelope that has neglected the real role of off-patent drugs in supporting the cost of innovation. "We urge stakeholders to see the off-patent industry as more than just a cheaper alternative. We promote healthy competition, which benefits price dynamics and fosters various forms of innovation beyond new molecules. Incremental innovations in dosage and other areas within the off-patent and generic sectors can contribute to extensive cost-effective and high-quality medicines," she argues.

This especially the case for the genericised version of biologics where there is bountiful scope for identifying enhancements. As

Nicolas Van Gelder, country manager for Celltrion, expands, "Whereas a biosimilar is a medicine that is similar to the reference biotherapy, we are intent on creating biobetters which is a modification of a biotherapy that has already been approved, with the aim of improving its efficacy, safety or patient comfort." He gives the example of Infliximab IV which was launched as a subcutaneous formulation and has led to an improved version of the molecule that has been welcomed by healthcare professionals for its improved clinical features and by patients for its convenience.

Van Gelder also believes that the time is ideal for Belgium to start making use of these opportunities. "The blockbuster biologics developed 25 years ago, and which have driven industry growth over this period have all gone off-patent in the last five to seven years, meaning that the time is now for a rethink of where healthcare budgets can best be used and how authorities, academics & industry can come together to ensure that innovative medicines are made available to patients," he muses.

At the same time, generics firms look set to receive a bounce with the news that the EU is intent on abbreviating intellectual property (IP) protection timeframes on originator drugs. "The possible reduction in IP protection for innovative medicines from ten to eight years in Belgium would be positive for the generic and biosimilar medicine companies alike. It would enable them to have quicker market access without hurdles such as backup patent linkage. This could well be the boost our members need to start contributing fully to this marketplace," thinks Coenen

FEDERICO MAMBRETTI

country president, Novartis BeLux

Naturally not many R&D driven drugmakers are convinced. "Restricting IP may seem like a bright solution to reduce costs, but it is not the right approach. IP is crucial for investment, especially for chronic diseases, and any restrictions on it may put the EU at a disadvantage in attracting investments compared to the rest of the world. Dropping the patent period might drive companies out of Europe and into the arms of more welcoming markets such as US, Japan, and China to invest their R&D," warns Lilly's Frederic Clais.

"The premise is that reducing IP periods will bring more innovation, when in fact the opposite is true. Periods of exclusivity and the stimulation of clinical research by laboratories are closely linked. IP provides reassurance in relation to the risks and costs involved in pharmaceutical R&D. If we create uncertainty and a less stable framework for recovering investments and freeing up margins for reinvestment, we risk breaking the virtuous circle of innovation in Europe," frets AbbVie's general manager for Belux, Renaud Decroix.

Nonetheless, the outlook for Belgium's off-patent segment is decidedly looking brighter. "We've been noticing tangible progress of late," says Stefano Christoffersen, country manager for BeLux at the Indian generics player

Accord Healthcare. "Looking back five years ago, the overall penetration of biosimilars was pretty slow, but recently we've witnessed a real shift in the mindsets of healthcare professionals in hospitals and our strategy is beginning to bear fruit. Currently we possess four possess four biosimilars that have achieved reimbursement in Belgium and of which we have launched two. Already one of those has reached a significant market share in hospitals so there's much optimism," he admits.

## Rethinking Healthcare

What is becoming increasingly clear is that systemic root and branch rationalisation across the entire Belgian care continuum will be required if Belgians are to gain easy and equitable access to next generation medical science. "Whether we are talking about pharma, medtech or hospitals, we all have to rethink the way we fund and find innovation. We know that the innovation of tomorrow will become more personalised and specialised and to finance it all within the existing structures simply isn't feasible. Both from a payer perspective, but also from a pharma industry perspective, we need to reconsider that model fundamentally in a way that is value-based, which brings us back to data, results and proper accountability," thinks Karel Van De Sompel, director of GIBBIS, a pluralistic federation of the public and private social-profit healthcare sector within the Brussels area.

Stefan Gijssels, chairman of the Patient Expert Center, mirrors these sentiments. "By adopting a more integrated and process-driven approach, we can significantly improve the system, generate better health outcomes, and reduce costs," he predicts. "This is an area with immense potential for improvement. Belgium already invests a significant portion of its GDP in healthcare, and the system is well-equipped with advanced medical technology and highly educated healthcare professionals. In general, there is adequate funding in the system, however, one challenge lies in the design of the healthcare system itself, which is heavily influenced by the suppliers of services, such as hospitals, doctors, and insurers," he argues.

For Marnix Denys, managing director of medical device association, beMedTech, the need to realign incentive structures and address power imbalances is especially pertinent. "Presently, the healthcare financing system in Belgium does not incentivise healthcare professionals or institutions based on outcomes or results. Instead, they are paid for activities and treatments and this traditional financing model creates a bias and may hinder the adoption of alternative patient pathways that could be more efficient and value-based," she posits.

"Game-changing medical technologies often require a shift in the healthcare process, such as introducing home care or point-of-care testing. This poses a challenge within the current financing system, which primarily rewards activity rather than outcomes. The existing system may even create disincentives for healthcare professionals to embrace new methodologies and technologies. To overcome these hurdles, it is essential to involve health economists in the decision-making processes, alongside healthcare professionals," advocates Denys.

Federico Mambretti concludes with a call for collaboration to ensure continued success for Belgium. "Externally, the future of Belgian healthcare and its global attractiveness is now on the table," he proclaims. "Belgium is a country with a glorious life science history that has learnt how to punch far above its weight and thrive in the face of adversity. Now we must rekindle that original spirit and band together – industry, policy makers, practitioners, healthcare providers, payers and patients – in ensuring that this hard-earned competitiveness is maintained, and that tomorrow's innovative therapies and medical advancements can be fully harnessed," he declares.

# Janssen: BUILDING THE FUTURE FROM BELGIUM

JANSSEN HAS THE LOFTY AIM OF REACHING USD 60BN DOLLARS IN SALES BY 2025, AN 8BN INCREASE ON THE 2021 FIGURE, DESPITE SOME HIGH-PROFILE LOSSES OF EXCLUSIVITY AND THE SPIN-OFF OF ITS CONSUMER HEALTHCARE BRANCH. THIS MASSIVE GROWTH PLAN INVOLVES BOTH EXISTING PRODUCTS AS WELL AS NEW CAR-T AND AUTOIMMUNE DISEASE THERAPIES WITH BELGIUM – THE HOME COUNTRY OF COMPANY FOUNDER DR PAUL JANSSEN – HAVING A HUGE ROLE TO PLAY. THE COUNTRY WILL PLAY HOST TO JANSSEN'S FIRST CAR-T MANUFACTURING CENTRE IN EUROPE, LEVERAGING PREVIOUS INNOVATION INVESTMENTS AS WELL AS THE COUNTRY'S BIOPHARMACEUTICAL AND HEALTHCARE ECOSYSTEM TO PROPEL THE FIRM INTO A NEW ERA.

> "By investing so much in the Belgian ecosystem, we can be an important player on several fronts, leveraging the voice of the innovative industry."
>
> **MARIA FERNANDA PRADO,** managing director, Janssen Benelux

## A Strong Footprint

Janssen, which employs 5,000 people in Belgium, has two international distribution facilities in the country as well as a clinical pharmacology unit, and the Janssen Belgium campus (Janssen Pharmaceutica) boasts global expertise and capabilities across R&D, manufacturing, and new product launches.

"Janssen has a strong footprint here, with a clear investment end-to-end, from discovery and development to commercialization of its innovative treatments," begins Maria Fernanda Prado, the firm's managing director for Benelux. "By investing so much in the Belgian ecosystem, we can be an important player on several fronts, leveraging the voice of the innovative industry."

This investment covers a network of partnerships with local actors, including universities, hospitals, research centres and companies and since 2015, Belgium has hosted Europe's first JLABS, a Janssen-sponsored life science start-up incubator.

## Building a Talent Pipeline

With a broad therapeutic area focus and a stacked product pipeline across neuroscience, oncology, immunology, infectious diseases, cardiovascular and metabolism and pulmonary hypertension,


Prado underlines the importance of building teams that are future fit and capable of delivering for patients.

"I am proud that we were able to compose new leadership teams, extremely talented and diverse, to drive the organization to new heights on our way forward," she starts.

"One of our key priorities, beyond launching our amazing product pipeline is to form a great leadership pipeline. For that, we prioritize our people's development and talent management. We have the luxury of having very qualified, engaged, and passionate people, which makes our ambition of having the best team in the country easier. We have initiatives that allow short-term assignments, to boost the experience of our professionals, according to their development plan, combined with mentoring and coaching programs."

## CAR-T Manufacturing

In a noteworthy recent move, Janssen announced that the Tech Lane Science Park in Ghent will be the location of the company's first European facilities to produce CAR-T cell therapy. A breakthrough blood cancer treatment, CAR-T therapy uses patient's own t-cells, which are genetically modified in a lab, expanded into large numbers, and then reinfused back into the patient. The facilities are being developed in cooperation with Chinese company Legend Biotech for European supply.

On the announcement of the new facility Janssen Pharmaceutica CEO Kris Sterkens said "This is an important investment that confirms our ongoing commitment to research and development in Belgium and Europe to improve the lives of patients around the world."

Prado adds that "the choice of Belgium as the European CAR-T production centre is a positive testimony of the value of the country in terms of innovation capacity and quality of people. There is an appetite for the development of new technologies here, beyond the fact that geographically Belgium benefits from its central location."

**"Having the CAR-T campus in Belgium is an opportunity for us to gain experience, optimize process timelines and collaborate with the local ecosystem."**

It may also have positive knock-on effects on the in-country commercial operations that Prado oversees. "Having the CAR-T campus in Belgium is an opportunity for us to gain experience, optimize process timelines and collaborate with the local ecosystem" she notes. "More importantly, we will be able to gain traction to address the overall unmet need in the European market."

# A Mid-Cap Destination of Choice?

ASIDE FROM THE INNOVATIVE PHARMA GIANTS OF THIS WORLD, ANOTHER BREED OF COMPANIES HAS OPTED FOR BELGIUM AND BUILT A STRONG PRESENCE IN THE COUNTRY. DESPITE SOME INITIAL CHALLENGES. AMONG THEM ARE THE SOUTH KOREAN GENERICS AND BIOSIMILARS MAKER CELLTRION, FINNISH MIDCAP ORION PHARMA AND THE BUDAPEST-HEADQUARTERED WOMEN'S HEALTH FIRM, GEDEON RICHTER.

## Overcoming Belgian Challenges

"In 2019, Celltrion announced that they would launch affiliates over almost all of Europe. The southern part of Europe, including Belgium, has had a more difficult adoption [of biosimilars]. Despite this slow biosimilar adoption, our group quickly understood the importance and influence that Belgian scientists could have. Over time, [adoption] has significantly improved thanks to lots of political initiatives. Especially when former Minister of Health Maggie de Block mandated a relaunch of biosimilars in Belgium," says Nicolas Van Gelder, country manager, Celltrion Healthcare Belgium

**NICOLAS VAN GELDER**
country manager, Celltrion

"[The product launch process] has never been an easy process [in Belgium]. There are a lot of factors to consider and evaluate before you go on the market. However, once the analysis is done and approved internally, the Belgian process is relatively defined. You know how long it will take; you know you have about a year for reimbursement, which is crucial for the vast majority of our portfolio. From the industry side, it is not an easy process," asserts Isabelle De Walsche, managing director Benelux, Gedeon Richter

**STEPHAN VAN NIEUWENHOVE**
country manager, Orion Pharma Benelux

## Team Effort

"In Finland, Orion Pharma has been the established market leader for years while in the more recently founded affiliates, like Benelux, we have to act as challengers to the main players. A big portion of entrepreneurial spirit, dedication and ambition is needed to succeed. The colleagues that are working here have lived this journey and inspired the newcomers to live the Orion values. Most employees working for Orion Pharma Benelux have previously held positions in big pharma companies and are bringing in a lot of expertise. One of the reasons they come to us is that they want to take ownership of their activities and want to be multifaceted. We look to empower our employees and make sure they feel proud, responsible, and part of the success of Orion in Benelux," claims Stephan Van Nieuwenhove, country manager, Orion Pharma Benelux

## Strategies for Market Penetration

"Here in Belgium, our strongest branches are Respiratory (Asthma & COPD) and CNS (Parkinson's Disease). We also have a legacy in Critical Care, for instance, dexmedetomidine, coming from our own R&D, was an important drug in ICUs during the COVID period. You need to know the local market well, especially for us as when we started off, we were starved of large resources, unlike the established companies present in the [Belgian] market for a long time. Therefore, we launched first into niche areas where we could gain larger market penetration with limited staff. Next to that, finding synergies and partnerships with other companies is helping us to bring our medicines to larger target groups. We are collaborating for 8 years with EG (Stada) for our asthma and COPD therapies and this partnership has yielded impressive results, coupled with our global collaboration with Bayer, this helps us in increasing our footprint in Belgium," says Van Nieuwenhove.

## Making a Name in Belgium

"At the beginning of my 11 years [as Managing Director Benelux at Gedeon Richter], no one had heard of Gedeon Richter, and now all Gynecologists and GPs in Benelux know who we are, and what products we have, and I am proud of that," states De Walsche.

"It has been a busy three years [since setting up the Belgian affiliate], because it was the start of a new story. We have a good footprint after three years, with six products launched and five more to come. Celltrion is not just a standard generic and biosimilar company. We are not only replicating what already exists, and making sure that we make it affordable. But we also try to improve whatever we do and aim to make it at least as good or better than the originator by developing biobetter products," confirms Van Gelder.

## Becoming a Top European Contender

"Gedeon Richter aims to be in the top three pharmaceutical companies for women's health in Western Europe. Currently, we are at number three in Belgium for OC, so we are on our way. We are still aiming for double-digit growth every year. Last year, we brought in five new products. One of our products will have a new indication of endometriosis, which will be a significant launch, and there will be a few to follow," says De Walsche.

# ONCOLOGY CLINICAL TRIALS: MAINTAINING LEADERSHIP

DR EVANDRO DE AZEMBUJA OF THE JULES BORDET INSTITUTE IN BRUSSELS IS ONE OF BELGIUM'S LEADING BREAST CANCER SPECIALISTS AND HOLDS ROLES IN BOTH THE BELGIAN SOCIETY OF MEDICAL ONCOLOGY (BSMO) AND ITS EUROPEAN EQUIVALENT (ESMO). AT BORDET, HE IS RESPONSIBLE FOR THE CONTINUOUS SUPERVISION OF SIX RESEARCH FELLOWS AND THE MEDICAL SUPERVISION OF LARGE PHASE III CLINICAL TRIALS. HERE HE ASSESSES THE LEVEL OF TRANSLATIONAL SCIENCE IN EUROPE TODAY, HOW LARGE PHASE III CLINICAL TRIALS HAVE EVOLVED POST-COVID, AND HOW BELGIUM CAN IMPROVE ITS CLINICAL TRIAL LANDSCAPE AND THE CARE PROVIDED TO ITS CANCER PATIENTS.

**EVANDRO DE AZEMBUJA**
Jules Bordet Institute

**What is your assessment of the level of translational science in Europe today and the potential for European oncology innovation to make it all the way to patients?**

**EVANDRO DE AZEMBUJA (EA):** There is plenty of potential in Europe. There is a tendency to assume that the grass is always greener elsewhere, but all geographies come with both challenges and opportunities. Belgium in particular has huge potential, with a significant number of trials per capita in cancer and other diseases, and I feel that the country is performing well.

In terms of the barriers to situating even more clinical research in Belgium and in Europe, obtaining grants is important. Researchers are almost constantly begging for money, and the application processes have become quite painful and time consuming. I myself spent almost all of a recent week's holiday on the phone trying to convince EU backers to release funding!

Another key challenge is regulation; I feel that the current regulatory frameworks in both Belgium and Europe are not particularly facilitative to research. There are so many forms of consent that patients need to fill out, for example, that serve to protect the sponsor more than the patient. Additionally, the existing patient monitoring requirements mean that a huge amount of data is requested from patients and their caregivers, much of which is never used. In an environment where research nurses, for example, are totally overloaded, only data that is needed and which will be used, should be given.

> "The current regulatory frameworks in both Belgium and Europe are not particularly facilitative to research."

**How has the conduct of large Phase III clinical trials evolved in the past few years, and what**

**impact did the COVID-19 pandemic have?**

**EA:** Since starting to work on phase III trials back in 2003, there has definitely been an evolution, which COVID only served to accelerate. The pandemic taught us that on-site monitoring is unnecessary, leading to more distance monitoring, which cuts down on traveling and environmental pollution. However, the outset of COVID brought some major challenges in terms of continuing to conduct clinical trials, given the fact that patients could not enter hospitals, and many trials had to be paused. Despite these challenges, we adapted and managed to find ways to continue patients' treatments. By the second wave of COVID, we already understood what we had to do, and the process was much smoother.

Other geopolitical situations and natural disasters – such as the war in Ukraine and the Turkish earthquakes – have also presented challenges. Against these backdrops, patient monitoring – either remotely or via hospital visits – often becomes difficult if not totally impossible. Moreover, in Turkey many physical patient records were destroyed by the earthquakes, foregrounding the importance of digital data collection. Now, most of the case report forms (CRFs) for our European-level cancer trials are digital.

**Belgium is one of Europe's leading countries in terms of trials per capita, but where is there scope to improve the country's clinical research landscape?**

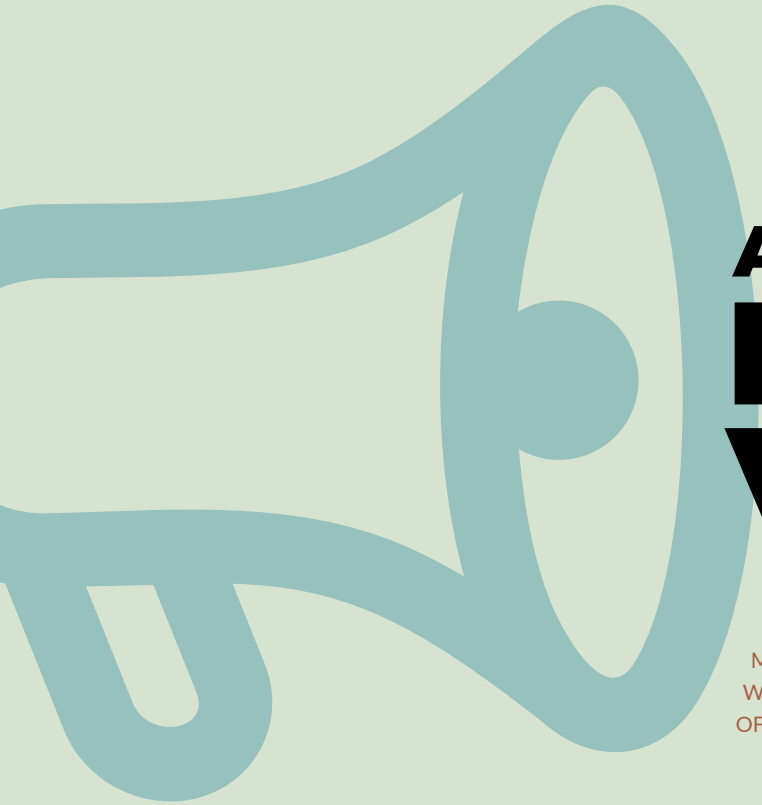
**EA:** Belgian patients have a good level of awareness of clinical trials and often ask their physicians about potential participation. However, Belgian physicians often to do not act quickly enough and start their patients on a new course of treatment which must be completed before they can participate in a trial. Frequently, once that course of treatment is over, the trial is already closed. Moreover, we are sometimes seeing the same trials replicated in different hospitals, all of which suggests that better collaboration and communication across the healthcare spectrum – from patients, to physicians, hospitals, and industry sponsors – is needed.

**How can the overall clinical trial process be improved and what would your message to industry and governmental stakeholders in Belgium be?**

**EA:** We must find a way to reduce the burdens of conducting clinical trials that currently exist. Just as importantly, there needs to be a real push to reduce the costs of drugs. Drug development is an expensive process, but the prices of the new treatments coming online are extreme. Given the aging population and the rising incidence of cancer, using these high-priced therapies will soon become financially untenable for healthcare systems. There needs to be better patient population selection as well as an understanding on the part of the industry of the need for reasonable pricing.

On the government side, I would like to see greater consultation with expert physicians in particular fields of oncology when making their pricing and reimbursement decisions. Many of the committees making decisions on oncology drugs currently lack the much-needed input of expert oncologists; a situation which needs to change. These experts can better discern the clinical utility of drug, and what its benefits (marginal or otherwise) may be.

> "Drug development is an expensive process, but the prices of the new treatments coming online are extreme."



# AMPLIFYING THE PATIENT VOICE

BELGIAN HEALTHCARE PERFORMS STRONGLY ACROSS MOST METRICS AND INTERNATIONAL COMPARISONS, BUT – AS ELSEWHERE – THERE REMAINS ROOM FOR IMPROVEMENT IN TERMS OF INTEGRATING PATIENT FEEDBACK AND EXPERIENCE INTO THE CARE CYCLE.

## ROOM FOR IMPROVEMENT

This became apparent to Stefan Gijssels – a 20-year pharma veteran whose last position in industry was as VP Communication and Public Affairs for Janssen's EMEA operations – during his own personal experience of cancer. Despite his long-term connection to healthcare, Gijssels "was surprised to see that certain aspects of care were completely overlooked, regardless of the overall outcome. Despite receiving treatment at one of the top cancer hospitals in Europe with excellent survival statistics, I personally encountered several areas where things could have been significantly improved, such as diagnosis, patient information on nutrition, on physical exercise, on access to reimbursement and social services, and on the availability of supportive care."

He laments, "Patients are often left to navigate these challenges on their own, without a system in place to guide them through their journey and address their holistic needs, including relationships, employment, nutrition, and physical activity."

For Eva Schroeters, director of RaDiOrg – Belgium's main rare diseases association – this is a scenario keenly felt by rare disease patients. "We have been repeating over and over again the need for our patients to have quick and correct diagnosis, so shortening this diagnosis period is essential. This can be achieved, for example, through organised neonatal screening programs."

She adds, "Secondly, we have some patients with the correct diagnosis but without the expert care that they require. Sometimes this is not available due to the small size of Belgium, but even when we have the dedicated experts here, patients are sometimes not being referred to them. We also see that there is inequality in the quality of healthcare for certain complex rare diseases. For some there is a multidisciplinary approach where post diagnosis they interact straight away with a centre and a whole program is set up with dietary, psychological and social support. The majority of rare diseases that are equally as complex do not have these structures available, and so we have been advocating to have integrated care for all conditions."

Belgium's Patient Expert Center – where Gijssels now serves as chairman – aims to address some of these issues by training patients to become experts in their own disease area. The organisation hopes that its six-month training course for patients – covering everything from the healthcare system to patient rights, psychology, legal responsibilities, disease knowledge, treatment options, research updates, living with the disease, social services, nutrition, physical aspects, and mental well-being – allows them to be better advocates for their illness in front of authorities

EVA SCHOETERS

Director, RaDiOrg

as well as consulting and guiding individual patients and their families.

## DATA IS KEY

Patient association stakeholders are broadly aligned in identifying data as a key factor in improving Belgian patients' treatment experiences and outcomes.

"An important part of our advocacy at the Belgian Diabetes Forum (BDF) [a multi-stakeholder initiative focused on driving better diabetes policy, prevention, and care – Ed.] is the need for better data to understand the true impact of diabetes in Belgium," says the organisation's president, Dr Frank Nobels.

To this end, the Belgian government's move to institute a Health Data Agency is music to Nobels' ears. "Belgian healthcare is strong in many aspects, but we lack vast and accurate data," he states. "We have health records with diagnoses at the level of physicians, and we know the nomenclature of all treatments (without diagnoses) at the social security level, but we do not have a system that links the two. Having advocated for the establishment of a Health Data Agency of the kind that already exists in Denmark and Sweden, we were happy to see the recent announcement that such an agency is finally being created."

However, determining which data should be collected and analysed will be a challenge, according to Frederic Clais of Eli Lilly, an active participant in the BDF. "Digitalization and data registration are key areas of focus for the forum," he opines. "While connected care is important for individual patients and healthcare providers, broader data collection efforts and the creation of worldwide evidence should also be considered."

"It is important to gather data from the patients and have a well-structured database," agrees Stefan Joris, director of the Belgian Cystic Fibrosis Association (BCFA). "Sweden has a good system in place in which the patient associations and healthcare professionals work together and there is an application for patients to use. We should look towards a similar model in Belgium, informing the patients that we are collecting and storing data and where we are using it. Giving them this information builds trust throughout the healthcare network."

Gijssels adds that "the current healthcare system tends to overlook the bigger picture and lacks a holistic mindset. There is often a lack of attention to the broader patient journey which leads to inefficiencies and wasted resources within the system. A systematic approach is needed to capture and analyse patient data, with the aim of improving the overall patient experience and achieving better health outcomes at lower costs. Currently, much of the valuable information about what patients go through remains hidden and underutilized."

Collecting and utilising patients' personal data is, however, no easy task, as Joris explains. "We have built a database that looks at quality of life through a new questionnaire, PRO-CF, that was developed at the European level. We are building a validation study for this system as well as a paediatric version. Furthermore, we are looking to collect data from medical professionals and store it. I would say we have underestimated the importance of patient trust as they have fears about the government having certain information and many are not ready to have their confidential information in the hands of someone they do not know."

## FINDING THE FUNDING

A similarly significant area is financial support, whether from public or private sector organisations, for the work of patient associations. This is especially important given these organisations' concerns about being perceived as in the pocket of the pharmaceutical industry.

"Ideally, government strategies and patient organisations should work together in a collaborative and coordinated manner," begins Gijssels. "The government can provide support and funding to patient organisations to carry out their important work. This is the case in the Netherlands and Belgium ought to follow suit. In fact, from 2024 the Netherlands will double

STEFAN GIJSSELS

chairman, Patient Expert Center

its subsidies to patient groups to reach EUR 46 million. I hope that the Belgium government can come to realize the opportunity to work together and give proper support for the value groups like the Patient Expert Center can bring."

He adds, "the relationship between the industry and patient organisations is indeed an area for concern for the [Belgian] government, but they should increase their own financial support towards patient organisations if they have concerns about industry funding. The existence of patient organisations highlights the gaps and flaws in the healthcare system. If the healthcare system was truly effective in accompanying, supporting, and guiding patients, the need for patient organisations would be minimal… The paid interactions we have with industry are all based on generating better understanding and outcomes, but without any conflicts of interest and in full compliance with all legislation."

> "If the healthcare system was truly effective in accompanying, supporting, and guiding patients, the need for patient organisations would be minimal"
>
> **Stefan Gijssels**, Patient Expert Center

Isabelle de Walsche, managing director Benelux for European women's health-focused mid-cap Gedeon Richter addends, "I agree with the regulation that companies should not have direct contact with patients, but unfortunately for some smaller diseases, there are no patient associations, so there is no one to defend the patient. So, I think we must be aware of that, and try to gain some perspective of their needs and sorrows."

The BDF's Nobels highlights the importance of bringing together a host of different stakeholders to drive positive change. "Private companies are also members of the Forum, and we have a relationship with many different firms, so we are not influenced by just one voice," he begins. "We all have common goals; that is to have better data, screening to diagnose undiscovered patients, early treatment with the correct medication, good follow-up, etc. These goals are mutual with the patient. When we discuss with the government, we let them know we are working also with the industry. We are very transparent in our relationship, and we find the equilibrium between being supported by the private sector and maintaining a strong neutral voice."

## A STRONGER VOICE IN REGULATORY DECISIONS: THE PATIENT COUNCIL

One positive step forward in terms of the relationship between the Belgian government and patient associations is the creation of a patient council within NIHDI's 52-point 'new medicines roadmap', aimed at reforming the country's access to innovation scenario. At a continental level, the European Medicines Agency (EMA) and patients have been actively interacting since the creation of the Agency in 1995, with the Agency now engaging in "systematic patient input along the medicine lifecycle."

The BCFA's Joris feels that Belgium's new patient council is "a major step forward." He adds that "In the past, our voice was only heard in the process if we were invited by the pharmaceutical company, which was not an option as we did not want to be perceived as defending their interests. We have been trying to explain that there are three parties that need to be included in any reimbursement decision: the payer, the pharmaceutical company, and the patient."

"Another point is that if the government stakeholders making the decision do not have the expertise on the disease, they should go and seek it. Patients are the true experts as the only actors that know what living with a condition is like and the impact of a treatment on how they feel. Doctors are seeing this now and are asking for patients' opinions, and so should the

FRANK NOBELS

president, Belgian Diabetes Forum

STEFAN JORIS

director, Belgian Cystic Fibrosis Association (BCFA)

reimbursement body. Therefore, this move to include the patient voice is a welcome one if it happens, but we are not there yet."

Gijssels adds, that "government strategies, like the patient council, play a crucial role in setting the overall direction and framework for healthcare policies and initiatives. They have the power to shape the healthcare landscape, allocate resources, and implement systemic changes. The Patient Council, specifically, can serve as a platform for representing patient perspectives and ensuring that their voices are heard in policy discussions and decision-making processes. It can provide a formal mechanism for patients to engage with policymakers, share their experiences, and contribute to the development of patient-centred policies."

## A COLLABORATIVE APPROACH

For an industry that constantly trumpets its impact on patients, pharma has historically been a little slow to incorporate patient insights into the drug development process, especially at its earliest stages. However, given Belgium's role as an R&D and clinical trials hub, some of the companies implanted in the country are today keen to highlight how they are working to better integrate patient input in their operations.

"In the past doctors were a priority, but for the last several years we have worked to integrate the voice of the patient at every stage of the medicine's life cycle," says Pierre Boyer, general manager of Servier BeLux. "We value their opinion and contribution as we believe their knowledge of their illness and treatment is essential to further research and innovation. In oncology, there is an emotional shock when these diseases are diagnosed and afterwards, they become a part of a patient's life. Therefore, it is important not only to improve treatment but to improve the ecosystem around the patient."

He continues, "We did a lot of research on patients suffering from cancer in Belgium and are offering several services to deal with the psychological aspects of the disease. For example, we have a specific educational programme LEA "Listen, Explain and Act" in oncology, developed in collaboration with a patients' association, for patients, families, and healthcare practitioners. We have also a lot of programmes for patients in the cardiovascular disease area and in diabetology about prevention and adherence to treatment."

For Roche, this bolstering of patient input has dovetailed with the company's extensive clinical trial operations in Belgium, as the company's Belux General Manager Marie-José Borst explains. "Patients are central to our discussions and decisions. We work closely with various patient organisations and have co-created several excellent initiatives with them. Patients and patient representatives can express what is most important to them, which we can then incorporate in our operations. In clinical trials, for example, we bring in patient input on both a local and global level to adapt the amount of information given to trial participants."

She goes on, "Additionally, in 2020 Roche Belgium established the Belux Experience Exchange for Patient Organisations (BEEPO), a learning and networking program that brings together Belgian and Luxembourg patient organisations to exchange experiences, knowledge, and best practices. This is a local counterpart to the international IEEPO network. BEEPO discussions are ongoing, and our annual meetings are a great source of patient insight into how we can do things differently.

> "It is important not only to improve treatment but to improve the ecosystem around the patient"
>
> **Pierre Boyer**, Servier BeLux

"One BEEPO discussion centred around the need for easily accessible information on clinical trials. This became the starting point of a larger initiative led by Patient Centrics to co-develop clinical trial.be, a clinical trial portal for Belgium that is already partly live ahead of a full launch in May 2023. Many patient organisations are planning to integrate the tool into their own websites, which lists the 260,000 clinical trials in Belgium by therapeutic area and patient profile. This will be a huge benefit for patients, for Roche, and for the wider ecosystem."

# BENELUX: DISTINCT STRATEGIES NEEDED

AFTER HOLDING A NUMBER OF LEADERSHIP ROLES ACROSS EUROPE AT GSK AND BMS, 28-YEAR INDUSTRY VETERAN SALLY ANN MCNAB IS NO STRANGER TO THE PARTICULARITIES OF EUROPE'S DIVERSE HEALTHCARE SYSTEMS. HAVING JOINED BMS BENELUX AS GENERAL MANAGER AND VP IN 2021, SHE SPEAKS ABOUT WHAT BROUGHT HER TO THE CLUSTER, THE SINGULARITIES OF THIS UNIQUE GROUP OF COUNTRIES AND THE DIRECTION OF EUROPEAN INNOVATION.

SALLY ANN MCNAB

general manager and vice president, Bristol Myers Squibb

**What made you take on this Country General Manager role?**

**SALLY ANN MCNAB (SAM):** I had always wished to have the opportunity to become a General Manager. What is exciting about my role is that it encompasses three countries: Belgium, the Netherlands, and Luxembourg. This has an interesting effect on how we work as a team, how we get diversity into our thinking, and how we can challenge each other. I have always enjoyed change, and diversity keeps me on my toes.

**Belgium and the Netherlands are markets with different dynamics, with the latter often described as quite generics-driven. How would you characterise the Benelux organization for BMS?**

**SAM:** I would not define the Dutch market in that way. As an example, yesterday afternoon, I was in Amsterdam, talking to two fabulous experts – a surgeon and an oncologist – about the future of the way they work and the healthcare system. The Dutch system is both interesting and innovative.

There are a lot of partnerships, and opportunities for new innovative therapies of course have a key place in the Netherlands.

Understanding the healthcare systems and access situations across all three countries is crucial, as they can differ significantly. I have fabulous access teams that know how things are done and are agile and adaptable to the varying situations with which they are faced.

There are also significant cultural differences both between Belgium and the Netherlands, as well as within Belgium itself in terms of language, education, politics, and the different regions there. This diversity is positive but leads to a fair amount of complexity.

**Having worked in several European countries and now sitting in the continent's administrative and political heart, do you feel confident about the future of European innovation?**

**SAM:** I think that when you are inside a system, you tend not to see it for what it is and value the chance that you have. So many European countries have fantastic healthcare and access to amazing physicians in a way that other countries do not have. We can take that for granted.

Healthcare is often considered as a cost but in fact, it is an investment. There is a need for an environment where companies can be confident that they can partner with governments to have the value of their innovative medicines recognized in a timely manner.

> "Understanding the healthcare systems and access situations across all three countries is crucial, as they can differ significantly."

# All Roads Lead to Belgium

HAVING LED GSK'S CZECH REPUBLIC AFFILIATE AND TAKE ON A SIGNIFICANT GLOBAL MARKETING ROLE, GSK VETERAN EMMANUELLE BOISHARDY RECENTLY BECAME VP & GM OF GSK BELUX. SHE REVIEWS THE CAREER PATH THAT BROUGHT HER TO BELGIUM TO HEAD UP THE COMPANY'S STILL BURGEONING EFFORTS IN ONCOLOGY AND HAEMATOLOGY.

EMMANUELLE BOISHARDY
general manager, GSK Belgium

**This is not your first country manager position, having previously served as GSK's Czech Republic lead as well as the firm's global marketing director for vaccines. Can you talk us through this career trajectory?**

**EMMANUELLE BOISHARDY (EB):** My work as GM of GSK Czech Republic between 2017 and 2020 was a career highlight as a professional that loves hands-on roles. This should be no surprise, given my background in marketing, sales, and commercial excellence. I still enjoy being on the field with medical reps, facing the reality in front of physicians, payers, and area experts to better understand how to support them in protecting people's lives.

On finishing my assignment in the Czech Republic, my initial ambition was to take on another GM position in a larger market but realised it would be more beneficial to first gain some global experience. I therefore took up a new role as global marketing director for vaccines; a field I had limited experience in prior to the Czech Republic despite spending over 20 years with GSK. While in Prague I led the team which gained reimbursement for GSK's meningitis B vaccine after two years of hard work, which was an incredibly rewarding and ultimately emotional experience, given the effect this disease has on patients' lives.

Having started my global role with responsibility for GSK's hepatitis vaccines, after six months I took the lead on our combined Diphtheria, Tetanus, and Pertussis (DTP) portfolio, a USD one billion product with a global reach across the US, Europe, and emerging markets.

**How did the opportunity to become GSK's Belgium general manager come about, and why was it the right career move for you in December 2022?**

**EB:** During my global work, I still harboured the ambition to get back to the market. Belgium has the added interest of being a significant country for GSK, with R&D, manufacturing and distribution operations, and political relevance as the base for European Union headquarters. While GSK does carry out some clinical trials in the Czech Republic, Belgium is on another level in terms of global significance to the company.

> "Belgium [is] a significant country for GSK, with R&D, manufacturing and distribution operations, and political relevance as the base for European Union headquarters."

**How have the recent shifts at GSK filtered down to Belgium and what are your priorities in the country today?**

**EB:** We have four main areas of focus, [vaccines, specialty care, general medicines] and the final area of focus is oncology and haematology, which is still being built up. In 2019 GSK bought oncology-focused biotech TESARO, which already had a product on the market, and our teams are still working hard in this area. Our reputation in the country is still largely as a respiratory disease company, as well as a vaccines leader. And it is fantastic that Belgium now also plays host to many of GSK's oncology and haematology clinical trials. One of my key priorities is to balance our operations and reputation more evenly across our four areas of focus.

GEERT REYNIERS, CEO, Multipharma

# The Pharmacy of the Future

ONCE PRIMARILY ASSOCIATED WITH DISPENSING MEDICATIONS ALONE, MANY PHARMACIES HAVE NOW EVOLVED INTO DYNAMIC HEALTHCARE HUBS. OFFERING A DIVERSE RANGE OF SERVICES THAT EXTEND FAR BEYOND TRADITIONAL PRESCRIPTION FILLING. SIMILARLY, PHARMACISTS HAVE EMERGED AS CRUCIAL MEMBERS OF THE HEALTHCARE TEAM, PLAYING INTEGRAL ROLES IN PATIENT CARE, MEDICATION MANAGEMENT. AND PROMOTING OVERALL WELLNESS.

At the forefront of this transformation in Belgium is Multipharma, a co-operative that today stands as the country's largest pharmacy network, counting on 245 pharmacies and 1,800 employees, 624 of whom are pharmacists. As the company's CEO Geert Reyniers explains, "we are much more than mere suppliers of pill boxes. Instead, we have the far broader and more important remit of providing valuable health and pharmaceutical care."

## PHARMACISTS' EXPANDED ROLE

This broader remit in overall healthcare provision was especially apparent during the COVID-19 pandemic, when Multipharma stepped in to offer much-needed testing and vaccination services in its pharmacies. In 2021 alone, the chain conducted 95,000 antigen tests, sold 600,000 self-testing kits, and by 2022 Multipharma pharmacists themselves were able to administer vaccines, thus relieving pressure on overburdened primary care centres and physicians.

Reyniers, himself a qualified pharmacist with a background working for a host of leading global pharma and medtech firms, has prioritised the evolution of the pharmacist's role since assuming the position of Multipharma CEO back in 2021. "We have developed the role of 'advisor-coordinating pharmacist' with the aim of optimising the therapeutic regimens of patients in collaboration with physicians," he states.

Data from a Multipharma-commissioned 2022 survey conducted by research agency iVOX seems to show that this shift is in line with the demands of the Belgian public. 51 percent of survey respondents visited pharmacies for advice about health problems, and 85 percent had loyalty towards a particular pharmacy. While GPs remain the first port of call for health information, the increased importance of pharmacies within Belgian primary care is hard to argue with.

"Even in today's digital age, professional advice and personal contact remain paramount for most patients," says Reyniers. "Pharmacists are important and accessible primary care providers, trained to provide advice and personalised pharmaceutical care to all patients, especially those who need additional guidance." In this vein, Multipharma has prioritised its advice and support services in areas including smoking, early detection of diabetes, pregnancy and early childhood, and diet.

## COMPANY EVOLUTION

Guided by a board mandate for sustainable growth, in 2019 Multipharma also moved to establish a new distribution centre to supply its pharmacies. "This state-of-the-art facility currently supplies just under ten percent of all medicines sold in Belgium," proudly states Reyniers. "We have also invested heavily in sustainability, with complete recycling of all the cardboard and plastic that pass through it as waste, as well as installing 1,680

solar panels," he adds. "Embracing sustainability is a very important component in our mission."

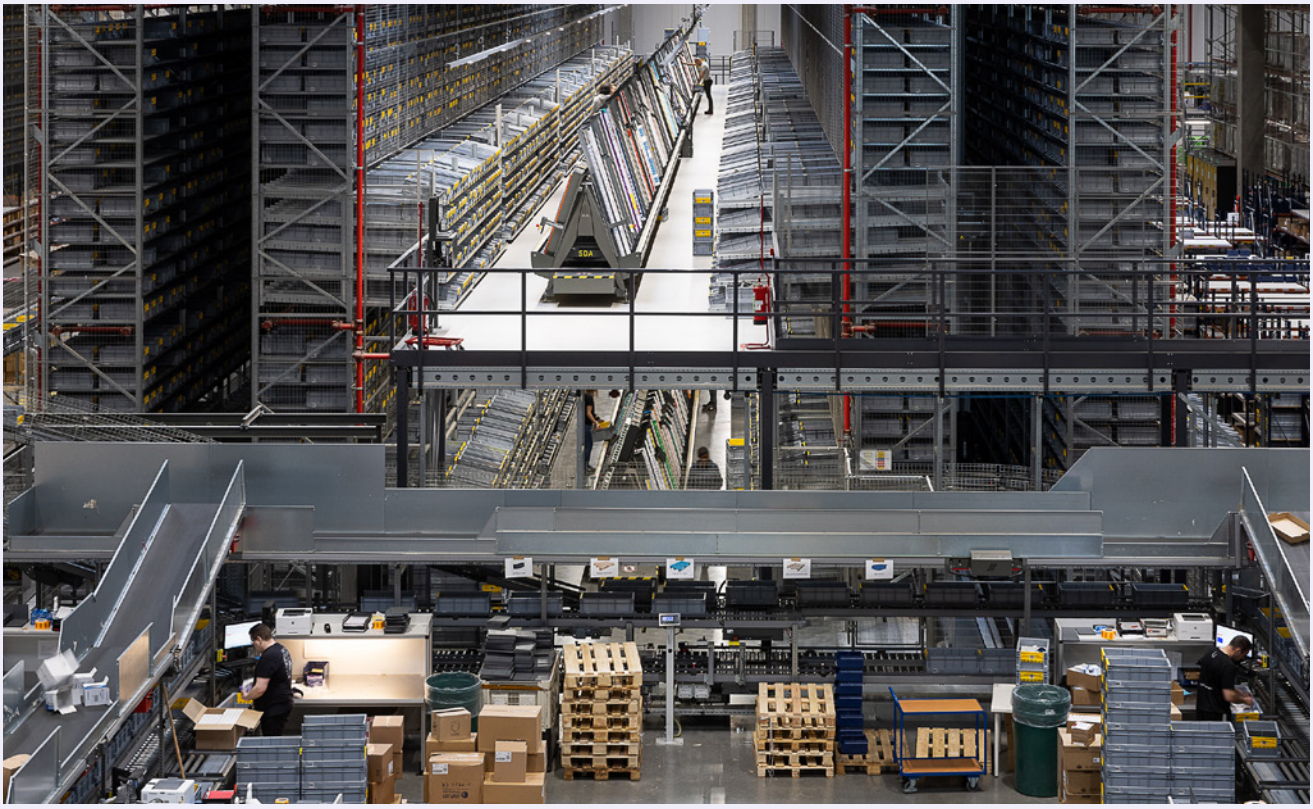
Another key service occurs in two specialised pharmacies where medicines are packaged together for individual patients. "This service not only makes life easier for care homes and their residents but can also be used for ambulatory care and for patients in their own homes who know precisely what they should take and when," says Reyniers.

It is this kind of diversification, with a continuing focus on prescription medicines, that Reyniers feels best sets up the firm for future success. "More than 60 percent of our turnover still comes from prescription drugs, with about 20 percent from non-prescription drugs," he outlines. "A relatively small amount of our turnover is derived from cosmetics and parapharmaceuticals, where price competition from online pharmacies is incredibly fierce. Instead, we double down on our core business of pharmaceuticals and services around them."

## "We are much more than mere suppliers of pill boxes."

That does not mean that Multipharma is eschewing the digital space, but Reyniers instead views the company's online offering as "a digital showcase where we try to offer the same service as in our pharmacies. For example, you can now send prescriptions via our app and chat with the pharmacist of your choice. We also offer our products online at the same prices as in the pharmacy, because we do not want to profile ourselves as a discounter but rather as a healthcare provider."

Although the pharmacy sector in Belgium has experienced significant consolidation in recent years, Reyniers still sees opportunities for growth domestically, building on the group's EUR 473 million annual turnover. "While the number of active pharmacies in our country has declined to 4,675, we still boast one of the highest rates of pharmacies per capita in the EU and there is still room for further consolidation," he notes. "For this reason, we are not looking to expand internationally, but rather stay and take advantage of the opportunities that remain in Belgium, where we are well established as a strong healthcare partner and have a good understanding of the local market."



# A BROADER SCOPE FOR BELGIAN HEALTHCARE

Luc Van Gorp, president of the Christian Mutuality, Belgium's largest health insurance fund, discusses some of the key themes from his 2021 book 'Human Scale: A Plea for Imperfection' ('Mensenmaat: Een Pleidooi Voor Imperfectie' in Dutch), including why innovation in healthcare needs to go beyond medication. He also touches on the acute staffing challenges facing Belgian healthcare, the role of digitalisation in bolstering they system's sustainability, and his hopes for the change patients and a new generation of healthcare professionals can drive.

LUC VAN GORP

president of the Christian Mutuality

## Broadening the Scope of Healthcare

Drawing on his eight years as president of the Christian Mutuality as well as his background as a practicing nurse, Van Gorp is keen for the definition and provision of healthcare in Belgium to be broadened beyond its current levels.

He states, "If a health system cannot support patients psychologically, existentially, and socially – in addition to physically – then it is not serving its purpose, regardless of how well it is funded." Van Gorp points to the only 2 percent of the total healthcare budget in Belgium that is spent on prevention. "With a greater focus on prevention and a more holistic approach to care the number of people who are sick and unable to work could be significantly reduced," he adds.

Many of the Belgian pharma industry stakeholders that PharmaBoardroom has spoken to in recent months have bemoaned the proportion of the budget dedicated to innovative medicines, but Van Gorp offers a stern rebuttal to this criticism, asserting that "We will pay for innovation." He adds, "However, innovation is not limited to medicines or technical solutions. There is also innovation in how we work and live, which is missing from our definition of the term within healthcare."

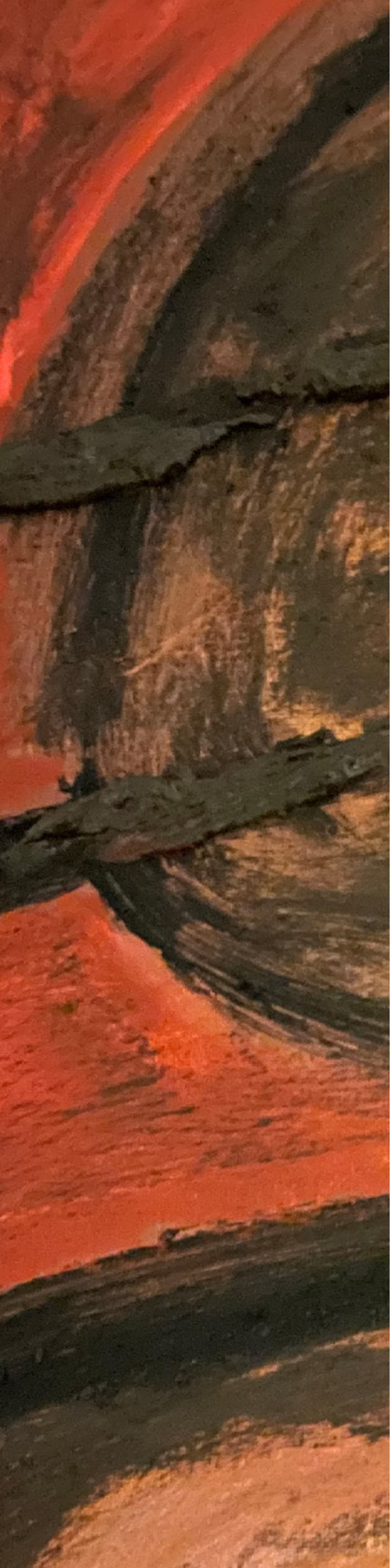
Van Gorp continues, "We are of course in favour of innovation, but only on the condition that the new medicines actually offer added value for patients. Therefore, as the Christian Mutuality, our big question is about how much quality of life an innovation can bring. For those medicines that truly improve quality of life, we have no problem with paying for it as quickly as possible."

> "Innovation is not limited to medicines or technical solutions. There is also innovation in how we work and live, which is missing from our definition of the term within healthcare."

## Staffing in Belgium

A key issue within Belgian healthcare, as across much of Europe, is the attraction and retention of healthcare professionals, according to Van Gorp, who notes that even at Belgium's best hospital – the University Hospital of Leuven – hundreds of beds have been cut in recent years.

He feels that much more should be done to reduce the shortage of doctors and especially nurses. Van Gorp claims that nurses are underpaid in Belgium, especially compared to doctors, given their key patient-facing role and the importance of the connections they are able to build with patients.



"As was made apparent during the COVID-19 pandemic, doctors and nurses do not have a problem with hard work. The issue is not necessarily money, but respect from society. Currently, too many people are saying goodbye to the sector." This is little wonder, with sometimes a culture of stress-filled 70-hour working weeks the norm.

"Just like a school without teachers cannot be called a school, a hospital without doctors and nurses cannot be called a hospital," he concludes.

## Digitalisation

While the incursion of digital solutions into healthcare has been touted by some as a potential fix for these staffing woes, as well as overall system sustainability, Van Gorp is circumspect on their current impact in Belgium. "Whether an interaction is digital or physical, building connections is the most important thing," he proclaims.

He also criticises the reluctance of Belgian doctors to embrace digital solutions which could help build these connections with patients. Citing the example of the Doktr app, which allows patients to have consultations with their healthcare professional, Van Gorp notes that many doctors – worried that such a system will eventually render them obsolete – have only been willing to use this system for patients with which they have a prior relationship. "This is such a shame" he exclaims. "People cannot find help due to lack of doctors and eventually go straight to Accident & Emergency without having established any communication with their general practitioner."

## Agents of Change

Despite these myriad challenges currently plaguing Belgian healthcare, Van Gorp is optimistic about the future. He identifies a key agent of change as the new generation of healthcare professionals now coming through. "This cohort has a different approach to those which went before on everything from health to healthcare, society, and work-life balance. Moreover, there is a far stronger female influence today with a less linear approach to money and growth."

Van Gorp's second agent of change is patients themselves. "Patients today are taking ownership of their own bodies and making decisions about their own health, from homecare adoption to healthy lifestyles, and disease prevention." He adds that "previously, the sole decision maker was the doctor, but we are moving towards a more collective approach with a stronger role for the patient, which can only be positive in terms of the care that is provided."

"Previously, the sole decision maker was the doctor, but we are moving towards a more collective approach with a stronger role for the patient, which can only be positive in terms of the care that is provided."

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