REPORT TO SOCIETY 2025

pharma.be
ASSOCIATION GÉNÉRALE DE L'INDUSTRIE DU MÉDICAMENT
ALGEMENE VERENIGING VAN DE GENEESMIDDELENINDUSTRIE

REPORT TO SOCIETY 2025

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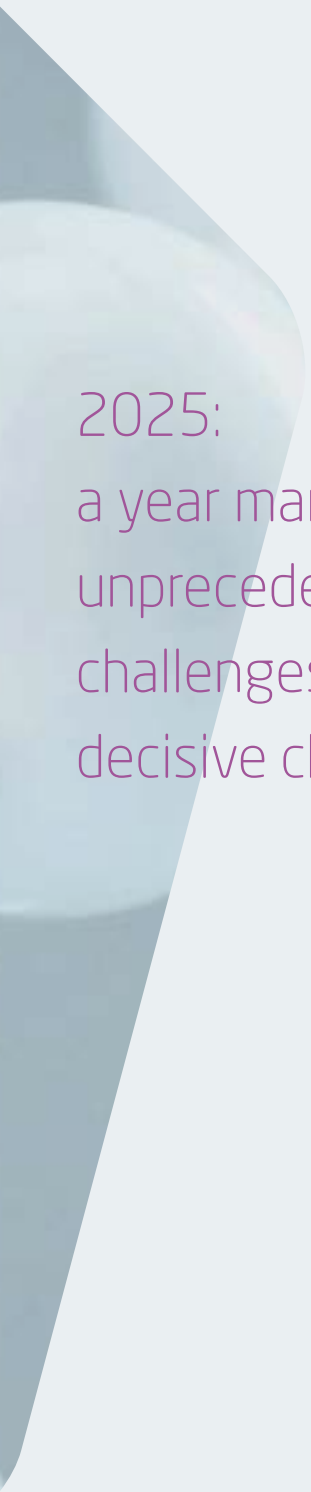
FOREWORD

Caroline Ven
CEO, pharma.be



2025: a year marked by unprecedented challenges and decisive choices

Armed conflicts, budgetary restrictions and new rules imposed by economic partners are putting Belgium under severe pressure. For the first time in years, we are seeing a decline in key areas such as employment, patent applications, investment in research and development, and exports.

The choices we make today will determine our future. The time has come to show vision and determination. Our country is facing important choices.

For example, we must focus more on prevention. HPV vaccination is a good example. It prevents 12 000 premature deaths and 430 000 hours of care in Europe every year. Investing in prevention means investing in well-being and a healthy society.

It is also essential to focus on health in general. Every euro invested in health and new breakthrough treatments yields up to 4 euros in health gains. Smart choices strengthen society, employment, research and economic growth.

Let us also be realistic: life-saving therapies cannot be offered at clearance prices. Investments in innovation deserve our recognition and support.

Belgium and Europe have everything they need not only to maintain their pioneering role in science and biopharmaceuticals, but also to strengthen it. Vision, determination and cooperation will enable us to shape a future where everyone wins within the vast healthcare ecosystem.

Discover the role of our sector in this regard in pharma.be's fifth Report to Society.

01
WHO WE ARE

1.1. MISSION OF PHARMA.BE

AS A **KNOWLEDGE CENTRE AND REPRESENTATIVE ASSOCIATION OF THE INNOVATIVE BIOPHARMACEUTICAL INDUSTRY**, PHARMA.BE ACTS AS A **TRUSTED PARTNER** CONTRIBUTING TO THE **SUSTAINABLE HEALTH OF CITIZENS, PATIENTS AND THE BELGIAN ECONOMY** THROUGH **KNOWLEDGE SHARING, COLLABORATION AND DIALOGUE**.

1.2. FOCUS ON THE PATIENT

PHARMA.BE REPRESENTS INNOVATIVE BIOPHARMACEUTICAL COMPANIES IN BELGIUM AND RESPONSIBLY FOSTERS A SUPPORTIVE BUSINESS ENVIRONMENT. THE AIM IS TO ENSURE THAT PATIENTS HAVE OPTIMAL ACCESS TO THERAPEUTIC INNOVATION. IN THIS WAY, WE ALSO CONTRIBUTE TO IMPROVING THE BELGIAN HEALTHCARE SYSTEM.

THE MANIFESTO OF THE BIOPHARMACEUTICAL INDUSTRY IN BELGIUM

Living your life to the fullest.
Spending time with family and friends. Enjoying good health. We all share these needs. They define the way we live our lives. They drive us in everything we do, every single day.

Together with **more than 120 member companies,** we work every day to make innovative and valuable medicines available to patients in Belgium.

For us, health is central:
we want the best possible life for everyone in Belgium. That is why our mission is to make Belgium the healthiest place to grow up, live, work and spend your later years.

We are deeply rooted in science.
History shows that the most crucial breakthroughs in healthcare happen in laboratories. Breakthroughs that have improved the treatment of breast cancer or turned HIV into a manageable chronic condition.

But science is a means, not an end in itself. Science is our passion, but only because it allows us to make a positive impact on lives. We are the people who care for others.

The world is changing rapidly –
with new diseases and viruses, an ageing population, and ever-advancing digitalisation. And there are numerous new questions. Scientific progress rarely follows a straight line. In our industry, we fail far more often than we succeed. There is nothing we can do about that. But as scientists through and through, we refuse to accept defeat. We never give up. It is our responsibility to continue to strive for the best health for all.

We are not alone.
Together with patients, doctors, hospitals, accredited health insurance funds, pharmacists, universities, research groups, public authorities and the government, we are united by a common goal: the best possible healthcare for everyone in Belgium.

Together,
we make sure
that everyone can
live a healthy life.

1.3. WITH 124 MEMBERS

PHARMA.BE BRINGS TOGETHER 124 BIOPHARMACEUTICAL COMPANIES OPERATING ACROSS BELGIUM. YOU WILL FIND THEM INVOLVED IN EVERY KEY STAGE OF THE BIOPHARMACEUTICAL VALUE CHAIN: FROM R&D AND CLINICAL TRIALS TO PRODUCTION, FROM MARKET LAUNCH TO DISTRIBUTION OF MEDICINES.

GROUP.10: DRIVING INNOVATION AND HEALTH

Within pharma.be, Group.10 brings together more than 70 small- and medium-sized enterprises, start-ups and biotechnology companies. Although these companies differ greatly from one another, they are highly complementary. The group brings together inspiring entrepreneurial stories – from promising start-ups and family-run companies to Belgian branches of international players.

Their specialised focus on specific health domains makes them invaluable to many patients in Belgium. They contribute to the early development of medicines, clinical trials, manufacturing and distribution.

TOGETHER, THEY ACCOUNT FOR:

±10%
of the turnover of the innovative biopharmaceutical industry in Belgium

408 263 euros
added value per employee in 2024

2 471
jobs in 2024

620
medicines on the market in 2024

Source: pharma.be, based on IQVIA and NBB extract

These companies nonetheless face major challenges. Their limited scale makes them particularly vulnerable to changing policy and market conditions. At the same time, they remain a driving force behind innovation and an essential link within our health ecosystem.

ANIMAL HEALTH GROUP: PROMOTING THE WELL-BEING OF ANIMALS AND PEOPLE

Healthy animals contribute to healthy people. They offer companionship, provide us with safe and nutritious food and often play a supportive role – for example, helping people with disabilities or offering comfort to patients. Animals are an integral part of our lives, so it is only natural to take good care of them.

That is why, since its inception, pharma.be has been committed to both human and veterinary sectors. Within this framework, the **Animal Health Group** occupies a key position. Working closely with the authorities and other partners, the group strives to ensure smooth access to innovative, high-quality veterinary medicines in Belgium.

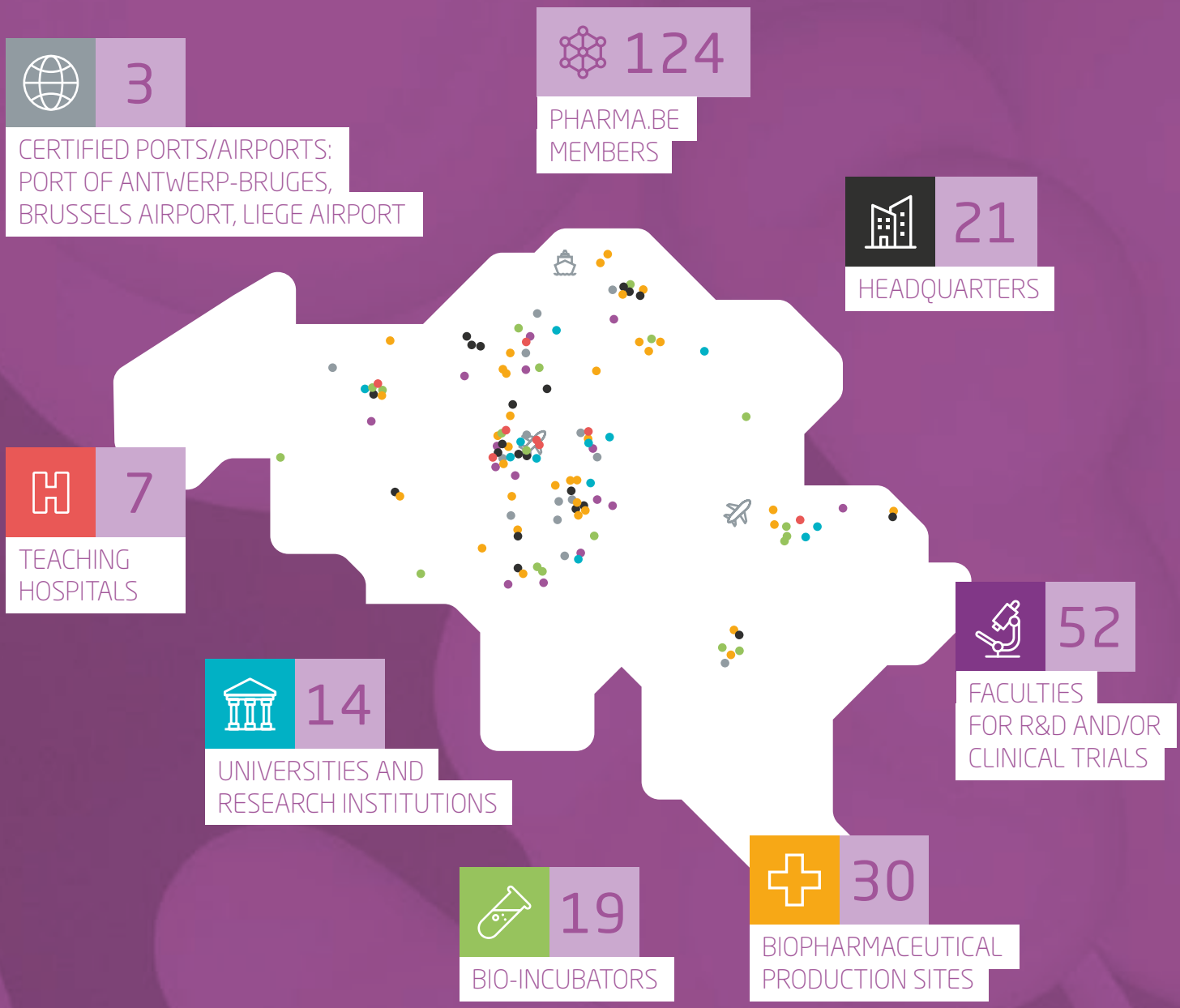
With its 13 member companies, the group brings more than 1 500 products to market, ranging from vaccines to cutting-edge treatments. The companies within the Animal Health Group develop solutions to prevent and treat animal diseases, with particular focus on prevention and vaccination. Their efforts help keep livestock healthy and ensure that companion animals receive the care they deserve.

Chapter 4 provides more detail about the Animal Health Group's activities and impact.

Discover our members

1.4. PART OF AN EXTENSIVE ECOSYSTEM

THE MEMBERS OF PHARMA.BE ARE PART OF A VIBRANT **BELGIAN BIOPHARMACEUTICAL ECOSYSTEM**, WHICH INCLUDES UNIVERSITIES AND RESEARCH INSTITUTES, ACADEMIC HOSPITALS, BIO-INCUBATORS, AND LOGISTICS PLAYERS SUCH AS BRUSSELS AIRPORT, LIEGE AIRPORT, AND THE PORT OF ANTWERP-BRUGES.



1.5. DEDICATED LEADERSHIP

THE BOARD OF DIRECTORS IS RESPONSIBLE FOR THE STRATEGIC MANAGEMENT OF PHARMA.BE AND IS COMPOSED OF 17 DIRECTORS. THE CURRENT CHAIR OF THE BOARD OF DIRECTORS IS FRÉDÉRIC CLAIS (ELI LILLY BENELUX). THE VICE-CHAIR IS XAVIER HORMAECHEA (UCB PHARMA). MEMBERS OF THE BOARD OF DIRECTORS SERVE A THREE-YEAR TERM. THEY ARE ELECTED AT THE GENERAL ASSEMBLY.

Frédéric Clais
Eli Lilly Benelux
Chair of pharma.be

Xavier Hormaechea
UCB Pharma
Vice-Chair of pharma.be

Renaud Decroix
AbbVie

Gregory Paton
Almirall

Sara Schaufelberger
Amgen

Angela Thompson
AstraZeneca

Niels Hessmann
Bayer

Paul Lacante
Bristol-Myers Squibb Belgium

Frédéric Martin
GlaxoSmithKline Pharmaceuticals

Roxana Botea
Janssen-Cilag

Katrien De Vos
MSD Belgium

Federico Mambretti
Novartis

Axel De Muyt
Novo Nordisk Pharma

Réginald Decraene
Pfizer

Marie-José Borst
Roche

Bart Vermeulen
Sanofi Belgium

Bruno Rabilier
Takeda Belgium

1.6. A TEAM OF EXPERTS

THE PHARMA.BE TEAM CONSISTS OF **32 HIGHLY MOTIVATED EMPLOYEES** WITH A VARIETY OF SKILLS AND EXPERTISE. THEY PROVIDE SERVICES TO OUR MEMBER COMPANIES, REPRESENT THEM ON RELEVANT COUNCILS, COMMITTEES, AND ADVISORY BODIES, AND PROMOTE THEIR INTERESTS AT VARIOUS LEVELS.

MEET THE PHARMA.BE TEAM:

Caroline Ven
CEO

Ann Adriaensen
Secretary General & Public Health Director

Geert Steurs
Economics and Financial Director

David Gering
Communications Director

Julie Gusman
Market Access Services Director

Patricia van Dijck
Political & Medical Director

Hanne Wouters
Market Access Advisor

Marjan Willaert
Policy Advisor – Market Access & SME Account Manager

Filipo Serra
Market Access Advisor

Magali Audiart
Pricing & Market Access Advisor

Lize Fonteyn
Market Access Advisor

Nathalie Lambot
Public Health & Clinical Trials Advisor

Marie Vande Ginste
Prevention & Sustainability Advisor

Oona Van Nieuwenhove
Public & Animal Health Advisor

Koen Raeymaekers
Public Health Policy Advisor

Karen Crabbé
Economic & Health Data Advisor

Thomas Cloots
Economic Advisor

Tom De Spiegelaere
Healthcare Budget Advisor

Gaspard Toussaint
Economic & Digital Health Advisor

Olivia Geldof
Legal Advisor

Willy Cnops
Life Science Advisor (external)

Armand Voorschuur
European and International Policy Advisor

Laura Van Eeckhout
Policy Advisor

Anne-Sophie Doms
Content Manager

Denise Blockmans
Webmaster

Quentin Vanleeuw
Project & Process Manager

Melanie Balcaen
Finance & HR Manager

Carine Vancutsem
Members, Partners & Office Manager

Annick Vancutsem
Members, Partners & Office Assistant

Chloé Legrand
Members, Partners & Office Assistant

Jennifer Andzouana
Members, Partners & Office Assistant

Guy De Backer
ICT Manager (external)

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1.7. SPECIALISED PARTNERS

BIOPHARMACEUTICAL KNOWLEDGE AND THE REGULATORY FRAMEWORK ARE EVOLVING AT A RAPID PACE, LEADING TO GROWING COMPLEXITY. OUR MEMBERS ARE THEREFORE INCREASINGLY TURNING TO EXTERNAL SERVICE PROVIDERS FOR EXPERTISE THAT HELPS THEM KEEP PACE WITH THE LATEST DEVELOPMENTS.

To promote interaction between members and service providers, we have developed a modular partnership programme. In this way, we help to build an active community, foster exchange and networking between our members and partners, and strengthen the Belgian biopharmaceutical ecosystem.

In 2024, 58 organisations partnered with pharma.be. These organisations operate in a wide range of specialist fields, including pricing and reimbursement, drug registration, pharmacovigilance, clinical trials, legislation, treatment adherence and the proper use of medicines, as well as logistics.

Discover our partnership offering

1.8. INTERNATIONAL REACH

pharma.be is also internationally connected, first and foremost as a member of the **European Federation of Pharmaceutical Industries and Associations (EFPIA).** EFPIA represents the biopharmaceutical industry operating in Europe. Its direct members include 36 national associations, 40 leading biopharmaceutical companies and a growing number of small- and medium-sized enterprises (SMEs). EFPIA's role is to create a collaborative environment that enables its members to discover, develop, and deliver new treatments and vaccines for people across Europe, while also contributing to the European economy.

At the global level, pharma.be is affiliated with the **International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)**, which represents innovative biopharmaceutical companies and national and regional associations worldwide.

pharma.be is also a member of **AnimalhealthEurope**, which champions One Health, innovation and sustainability to advance animal health, make food production more sustainable and keep companion animals healthy.

Finally, pharma.be is also represented at the **Association of the European Self-Care Industry (AESGP)**, which represents the European self-care industry and promotes the responsible use of authorised non-prescription medicines, food supplements and medical devices.

DAVID HAS A PASSION FOR PHARMA

Belgium is not just the land of beer and chocolate. Belgium also has a strong reputation in the field of biopharmaceutical products. We are leaders in clinical research and in the development of innovative medicines and vaccines. Belgium also has a unique ecosystem in which pharmaceutical companies work hand-in-hand with universities, hospitals and other partners.

INTERNATIONALLY, WE ARE KNOWN AS A "PHARMA VALLEY" BECAUSE OUR SMALL COUNTRY PLAYS A VERY BIG ROLE IN GLOBAL HEALTH!

DAVID GERING,
Communications Director

DISCOVER THE PASSION OF DAVID AND HIS COLLEAGUES IN THE BIOPHARMACEUTICAL SECTOR

02 WHAT WE DO

2.1. ACTIVE ACROSS THE ENTIRE VALUE CHAIN

TOGETHER, THE PHARMA.BE MEMBER COMPANIES **HOLD STRONG POSITIONS IN EUROPE IN EVERY KEY ASPECT OF THE BIOPHARMACEUTICAL VALUE CHAIN**, FROM R&D AND CLINICAL TRIALS TO PRODUCTION, MARKET INTRODUCTION AND DISTRIBUTION OF MEDICINES. THIS IS THANKS TO A UNIQUE COMBINATION OF A WELL-DEVELOPED ECOSYSTEM, A HIGHLY SKILLED WORKFORCE, AND STRONG COLLABORATION WITH PUBLIC AUTHORITIES AND RESEARCH CENTRES.

The benefits of an integrated approach to the value chain are significant, not only for patients, their communities, and healthcare, but also for the economy. This became especially clear during the COVID-19 pandemic. The Belgian biopharmaceutical sector was able to rise to the challenge fully, from research and production to the delivery of innovative solutions for patients.

In this section, we take a closer look at the innovation activities of our member companies in Belgium aimed at improving patient outcomes: how much they invest in R&D, the clinical trials they conduct here, and their focus on prevention. We also provide an overview of the new medicines for which our companies have applied for and obtained reimbursement and, finally, address the challenges surrounding rare diseases. In Chapter 3, we then examine the added value of these activities for patients, the healthcare sector, and society, as well as their economic return.

Source: pharma.be

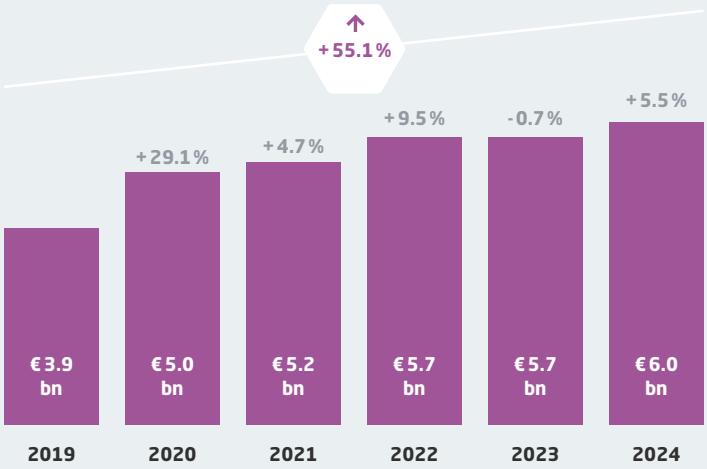
2.2. RESEARCH AND DEVELOPMENT AS A DRIVER OF INNOVATION

2.2.1. INVESTMENT IN R&D IN BELGIUM

BECAUSE BELGIUM HAS NO NATURAL RESOURCES, THE ECONOMY RELIES ON KNOWLEDGE. IN THE EUROPEAN INNOVATION SCOREBOARD, BELGIUM OCCUPIES A RESPECTABLE FIFTH PLACE. THE BIOPHARMACEUTICAL SECTOR HAS EMERGED AS ONE OF THE UNDISPUTED PILLARS OF THE KNOWLEDGE ECONOMY. THE SECTOR INVESTS HEAVILY IN RESEARCH AND DEVELOPMENT, DELIVERING CRUCIAL INNOVATIONS YEAR AFTER YEAR. THESE OFFER ADDED VALUE NOT ONLY FOR OUR KNOWLEDGE ECONOMY, BUT ABOVE ALL FOR OUR HEALTH.

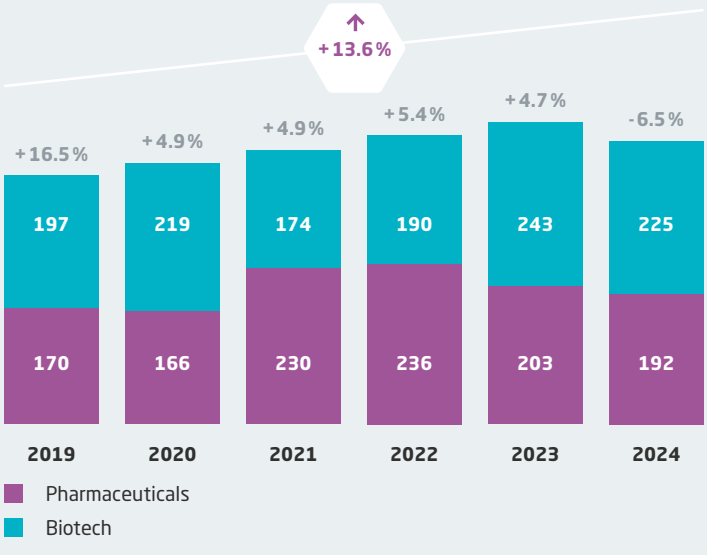
- In 2024, the sector surpassed the **6 billion euro** mark in R&D investment for the first time, representing more than **16 million euros per day**;
- Over a five-year period, R&D investment has grown by more than half. In terms of both absolute investments and growth figures, the biopharmaceutical sector is the **leader in R&D** in Belgium;
- In 2024, on average **more than one patent application was filed per day** in Belgium in the pharmacy and biotechnology fields. These applications are crucial for the sector, as the protection offered by patents is essential for continuing to invest in costly, long-term research programmes;
- Despite the increased investments in R&D, we are seeing, for the first time in years, a decline in the number of patent applications by pharmaceutical companies in 2024. The biopharmaceutical sector remains the national leader, accounting for nearly 16% of all patent filings in Belgium, but innovation appears to be becoming increasingly difficult, and investment remains particularly high-risk.

Evolution of R&D investment in Belgium



Source: pharma.be, survey amongst members

Evolution in patent applications in Belgium



Source: European Patent Office, European patent applications 2015-2024 per field of technology

WOUTER HAS A PASSION FOR PHARMA

Research and development is truly the core of what we do. Every day we work on new solutions to improve – and often save – lives. We invest a great deal of time and expertise in this, and that is precisely why our pharma sector is one of the most innovative in Belgium. And that innovation goes beyond producing new medicines. It also means developing new delivery methods, manufacturing processes, or new uses for existing medicines. Innovation does not stop once a product reaches the market; we continue investing in new possibilities.

THROUGH OUR INNOVATIONS, WE ARE TRULY MAKING A DIFFERENCE WORLDWIDE!

WOUTER VANDAMME,
Medical Advisor

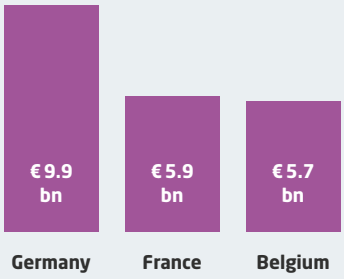
DISCOVER THE PASSION OF WOUTER AND HIS COLLEAGUES IN THE BIOPHARMACEUTICAL SECTOR

2.2.2. INVESTMENT IN R&D COMPARED WITH EUROPE

BELGIUM MAY BE A SMALL COUNTRY, BUT ITS PATIENTS AND HEALTHCARE SYSTEM BENEFIT FROM PROPORTIONALLY HIGH LEVELS OF INVESTMENT IN BIOPHARMACEUTICAL INNOVATION.

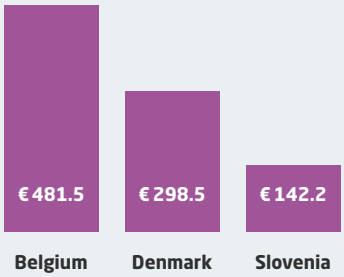
The total amount of R&D investment in the Belgian biopharmaceutical sector is comparable to that of much larger European countries. In terms of R&D investment in 2023 – the most recent year for which European comparisons are available – Belgium ranked behind only Germany and France. Compared with other large countries such as Italy or Spain, Belgium performs much better, with investment that is three and four times higher respectively.
This is a remarkable achievement given that Belgium ranks only eighth in terms of population size.

Total biopharmaceutical investment 2023



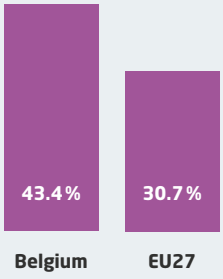
When we look at investment per capita, Belgium is an undisputed leader.
Compared with Denmark, second in the ranking, investment in Belgium is more than 60 % higher.
For Slovenia, the next country in the ranking, Belgium's investment is already three times higher.
These figures clearly demonstrate Belgium's exceptional position in R&D investment.

Biopharmaceutical R&D investment per capita 2023



Between 2019 and 2023, Belgium's per capita R&D investment rose by more than 43 % – roughly one and a half times the growth rate of total per capita R&D investment across the EU-27.
No other country with a significant level of per capita R&D investment achieved such strong growth.
For example, growth in Denmark was limited to 12 %, and Slovenia even saw a decline of 11 %.

Growth in biopharmaceutical R&D investment per capita 2019–2023



Sources: pharma.be, member survey & EFPIA, The Pharmaceutical Industry in Figures, Key Data 2025

These impressive figures show that innovations cannot be taken for granted. New, innovative medicines require an enormous amount of time and resources. The biopharmaceutical sector is therefore the most R&D-intensive industry. Not only in Belgium but across Europe, the Belgian biopharmaceutical sector is playing an increasingly significant role in R&D.

THE IMPORTANCE OF INTELLECTUAL PROPERTY RIGHTS

INTELLECTUAL PROPERTY RIGHTS AS A LEVER FOR HEALTH:
PHARMA.BE ON THEIR VALUE FOR PATIENTS, SOCIETY AND THE SECTOR

What are intellectual property rights?

Intellectual property rights (IPR), including patents, are a cornerstone of our innovation system. They allow companies to protect the inventions behind their medicines for a limited period of time. In return, the invention must be described and published, so that this knowledge is shared with others.

There is a broad system of IPR, with each type of right serving a specific function and helping to protect and valorise innovation. Each component has its own value and purpose, essential to a well-functioning model.

Why are intellectual property rights sometimes questioned?

The justification for IPR in the health sector is sometimes questioned: is it acceptable that life-saving medicines and vaccines are protected by a patent? Are IPR generally appropriate for such a vital industry? Should medicines not belong to everyone?

From its societal role, pharma.be recognises the relevance of these questions and has published a brochure providing context and factual information to encourage an informed discussion.

There are many misconceptions about patents in the biopharmaceutical industry. The most persistent misconception is probably that patents held by biopharmaceutical companies directly lead to limited access to new medicines and disproportionately high prices.

This misunderstanding arises from a backward-looking perspective – assessing the situation only after a new medicine has reached the market. As author Jack Scannell illustrates, this is like focusing only on the winners of a lottery: if you look solely at those who win, it appears extraordinarily profitable – you spend one euro and win a million.

But research and development (R&D) in the biopharmaceutical industry is, by its very nature, forward looking – it takes place at a time when the new innovative medicine does not yet exist. The key question is: how can we ensure that such new and innovative medicines can come into being in the first place? Why would companies still invest such large sums when the likelihood of success is so small? Because if no one is willing to take that risk, there will be no new medicines.

What added value do intellectual property rights bring?

IPR make it worthwhile to take risks, bear costs and invest the time required to develop new medicines. New medicines do not appear by themselves. While developing ideas in other sectors can be relatively fast, in the biopharmaceutical industry it typically takes ten to twelve years before a new medicine reaches patients.

The attrition rate is also extremely high. Of the many promising molecules that are studied, only a tiny fraction ultimately become effective medicines. Behind every successful new medicine lie countless others that did not make it through the various rounds of clinical research.

IPR therefore sustains an innovation ecosystem that enables universities, small biotech companies, and pharmaceutical companies to achieve breakthroughs. In a sector such as the innovative pharmaceutical industry, that is vital. A strong IPR framework forms the foundation of our research-driven industry, enabling the development of medicines that can treat – and sometimes even cure – patients.

A sound intellectual property system allows ideas and innovations to reach the market safely and responsibly, delivering tangible benefits for society and quality of life. New medicines regularly bring breakthroughs in the treatment – and even the cure – of diseases.

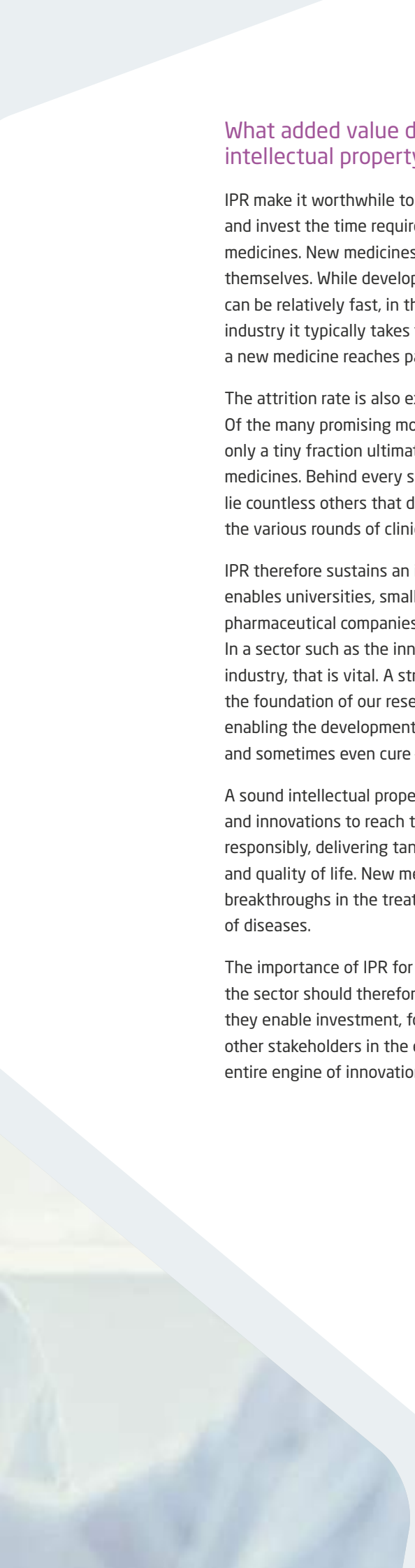
The importance of IPR for patients, society and the sector should therefore not be underestimated: they enable investment, foster collaboration with other stakeholders in the ecosystem, and keep the entire engine of innovation in healthcare running.

Intellectual property in Belgium

Belgium's strong position in the life sciences is made possible in part by robust protection of IPR. But Belgium's position is under pressure. In 2024, for the first time in years, we see a decline in the number of patent applications filed by pharmaceutical companies. While there were 446 applications in 2023, that number fell to 417 in 2024. This marks a clear break from the trend of recent years. Nevertheless, the biopharmaceutical sector remains a national leader.

The current federal government recognises the crucial role of IPR in our sector and explicitly affirms in its coalition agreement that Belgium stands for a strong IPR policy that supports developers while balancing social interests.

pharma.be actively contributes to shaping this policy in practice, to ensure Belgium remains a leader in biopharmaceutical innovation and that citizens and patients continue to have access to effective and safe new treatments.



Read the brochure

2.3. CLINICAL TRIALS AIMED AT DEVELOPING NEW TREATMENTS

CLINICAL TRIALS ARE ESSENTIAL FOR THE DEVELOPMENT OF NEW MEDICINES AND VACCINES. THEY ENABLE RESEARCHERS NOT ONLY TO TEST WHETHER A MEDICINE IS EFFECTIVE AND SAFE BUT ALSO TO GAIN VALUABLE INSIGHTS INTO THE TREATMENT AND PREVENTION OF DISEASES. CLINICAL TRIALS ALSO OFFER PATIENTS FREE ACCESS TO THE LATEST TREATMENTS EVEN BEFORE THEY REACH THE MARKET. A STIMULATING RESEARCH ENVIRONMENT IS THEREFORE ESSENTIAL FOR MAKING PROGRESS IN HEALTHCARE AND MEDICAL SCIENCE.

BELGIUM REMAINS A LEADER IN CLINICAL RESEARCH, BUT ITS POSITION IS UNDER PRESSURE

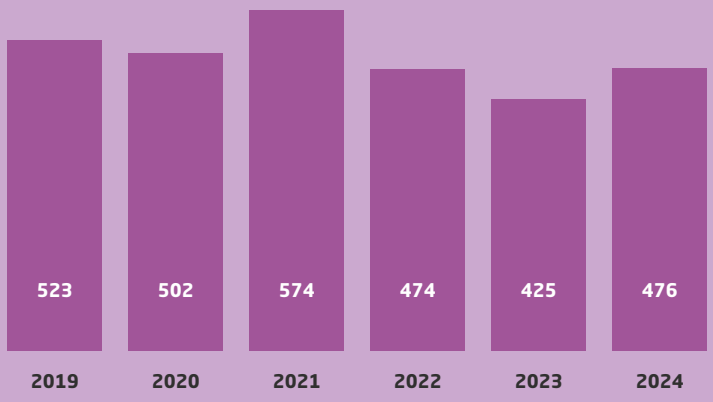
With 476 approved applications, Belgium once again ranked among Europe's top countries in 2024 for the number of clinical trials per capita. Biopharmaceutical companies accounted for more than three quarters of these applications.

Our leading position is the result of a dynamic ecosystem supported by the strong presence and expertise of biopharmaceutical companies, the high quality and knowledge of our academic sector, state-of-the-art research centres and hospitals, and the in-depth expertise of the competent authorities – in particular the Federal Agency for Medicines and Health Products (FAMHP).

However, this position is under pressure. If we look at the number of approved applications in Belgium between 2019 – the year before the coronavirus pandemic – and 2024, we see a decrease of 9%. In the broader European and global context, a recent report by EFPIA and IQVIA shows that Europe is increasingly losing market share to Asia, which is becoming the preferred region for launching clinical trials.

TO REMAIN COMPETITIVE AND ATTRACTIVE, IT IS THEREFORE CRUCIAL THAT BELGIUM INVESTS IN INNOVATIVE TECHNOLOGIES, RESEARCH METHODS, AND ORGANISATIONAL MODELS, AND CREATES A REGULATORY FRAMEWORK THAT EVOLVES WITH THE CHANGING CONTEXT.

Number of approved applications for clinical trials in Belgium



Source: FAMHP

DISCOVER THE PASSION OF MIEKE AND HER COLLEAGUES IN THE BIOPHARMACEUTICAL SECTOR

MIEKE HAS A PASSION FOR PHARMA

If we want to maintain our leading position in clinical trials, we must focus on speed – starting trials quickly, recruiting patients efficiently, and embracing new research methods and technologies.
Thanks to our clinical trials, Belgian patients often gain early access to innovative new treatments.

THROUGH OUR CLINICAL RESEARCH, WE AS AN INDUSTRY TRULY MAKE A DIFFERENCE!

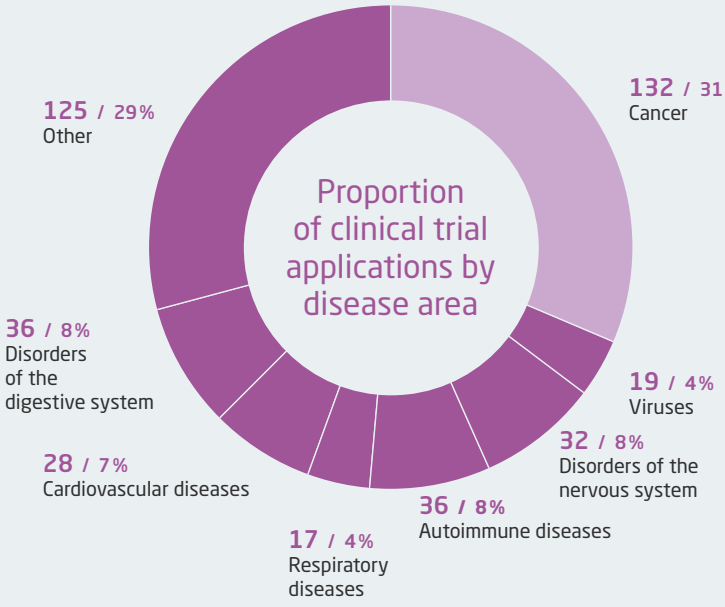
MIEKE VANCOILLIE,
Clinical Operations Head

CLINICAL RESEARCH ACROSS THERAPEUTIC AREAS

The consistently high number of clinical trials launched each year shows that biopharmaceutical companies remain committed to investing in Belgium, with the goal of developing new treatments in a wide range of fields.

With a share of 31 %, research into cancer treatments remains number one. In 2023, 132 trials for cancer treatments were launched in Belgium. These accounted for 18 %, or just under one in five, of all clinical trials conducted in this field across Europe.

THIS CLEARLY ILLUSTRATES BELGIUM'S VITAL ROLE IN CANCER RESEARCH.



Source: Deloitte report 'Belgium as clinical trial location in Europe - key results 2023'

UNIQUE EXPERTISE IN EARLY-PHASE TRIALS – AN ASSET TO PROTECT

IN RECENT YEARS, BELGIUM HAS BUILT STRONG EXPERTISE IN THE EARLIEST PHASES OF MEDICINE DEVELOPMENT, SUCH AS FIRST-IN-HUMAN (FIH) TRIALS. THIS SUCCESS IS DUE TO SEVERAL FACTORS:

- A tailored regulatory framework with shorter timelines for the assessment of Phase 1 trials conducted exclusively in Belgium;
- Specialised expertise at the FAMHP;
- An outstanding ecosystem, with:
  - Numerous specialised Phase 1 units, both commercial and hospital-based, with expertise in trials involving healthy volunteers and patients;
  - Centres capable of conducting first-in-human trials;
  - Clinical sites with highly trained professionals at all levels: investigators, physicians, nurses, laboratories, pharmacists, etc.

In 2023, as many as 21 % of approved studies in Belgium were Phase 1 trials, and 14 % of these were first-in-human studies. Much of the information found in a medicine's patient leaflet is based on the results of Phase 1 trials.

Percentage of clinical trial applications by phase in Belgium compared with a selection of nine European countries* (2023)

Belgium

Selection of 9 European countries

* Denmark, Germany, Estonia, France, the Netherlands, Poland, Spain, United Kingdom and Sweden

Source: Deloitte report 'Belgium as clinical trial location in Europe - key results 2023'

It is vital that Belgium maintains and strengthens this unique position in early-phase research. Doing so will help attract not only crucial Phase 1 studies but also the subsequent Phase 2 and Phase 3 studies that are essential for developing new medicines.

DISCOVER THE PASSION OF FRANCINE AND HER COLLEAGUES IN THE BIOPHARMACEUTICAL SECTOR

FRANCINE HAS A PASSION FOR PHARMA

WHEN INNOVATION STARTS HERE IN BELGIUM, IT IS NO COINCIDENCE - AND IT SAYS A LOT!

Thanks to our recognised medical expertise, strong infrastructure, and effective legislation, Belgium truly excels in this field.
That unique combination inspires confidence among other pharmaceutical companies worldwide. And that is exactly why so many Phase 1 clinical trials start here.

FRANCINE METELO,
Senior Clinical Services Manager

BELGIUM'S AMBITION TO STRENGTHEN ITS ROLE AS AN INNOVATION HUB FOR CLINICAL TRIALS

To achieve this, Belgium must continue to stand out by:

- Guaranteeing the quality of data and the safety of patients;
- Ensuring rapid start-up after approval;
- Maintaining an efficient, diverse, and fair system for patient recruitment.

Collaboration between researchers and clinical teams across institutions and regions is essential. Only then can we efficiently share knowledge and good practices and make maximum use of available resources and infrastructure. Equally vital to maintaining our competitive position is close cooperation with the competent authorities to ensure that applications are handled smoothly.

> It is crucial to build connections. This way, all partners understand not only each other's limitations and challenges but also each other's strengths. That is how we can continue to build and invest together – across academia, regulatory bodies, sponsors, the pharmaceutical industry, and other partners – to keep Belgium attractive and competitive for clinical trials.

MARIE-THÉRÈSE MARTIN,
VP Head Vaccines Clinical Sciences, GSK

BELGIAN PEDIATRIC CLINICAL RESEARCH NETWORK (BPCRN)

THE BELGIAN SOCIETY FOR PAEDIATRICS (BVK) FOUNDED THE BELGIAN PAEDIATRIC CLINICAL RESEARCH NETWORK (BPCRN) IN 2009 WITH THE SUPPORT OF PHARMA.BE. IN 2024, THIS NETWORK GAINED NEW MOMENTUM UNDER THE UMBRELLA OF THE BELGIAN ACADEMY OF PAEDIATRICS.

The perspectives of industry, government, and regulators are always different, but what I have really noticed is how much overlap there is and how often we work towards the same goals. We share the same interests and can achieve much more by working together. So I mainly see a lot of similarities.

Dr LEVI HOSTE,
Clinical Specialist,
Paediatric Department
and Paediatric Medicines
Research, Ghent University
Hospital (UZ Gent)

The BPCRN plays a key role in facilitating paediatric research in Belgium, with maximum attention to children's safety and data reliability. Thanks to this network, children gain faster access to innovative treatments, and healthcare professionals can continuously develop their skills. It also raises the visibility of paediatric research in Belgium, both nationally and internationally.

NEW COMPETENCIES FOR THE CLINICAL RESEARCH OF THE FUTURE

EMERGING SOCIAL TRENDS AND NEW TECHNOLOGIES ARE TRANSFORMING THE RESEARCH LANDSCAPE. ARTIFICIAL INTELLIGENCE, BIG DATA, PRECISION MEDICINE, WEARABLES, AND GENOMICS – AMONG OTHERS – ARE ENABLING REAL-TIME DATA PROCESSING AND 100% PERSONALISED PATIENT RESEARCH. CLINICAL TRIALS ARE THUS BECOMING INCREASINGLY EFFICIENT AND PATIENT-FRIENDLY.

However, this shift also demands a wide range of new skills. We therefore need not only clinical expertise but also deep knowledge of data science; we must take new ethical issues into account, while collaboration and coaching are becoming increasingly important.

It is therefore crucial that:

- The biopharmaceutical sector and hospitals train their staff in emerging technologies;
- The authorities provide a robust yet flexible regulatory framework;
- Universities invest in multidisciplinary programmes;
- Ethics committees that assess clinical trial applications continue to specialise – for example in early-phase trials or vaccine research – and refine their approach to reflect new developments.

The key prerequisites are strong collaboration between all stakeholders and continuous investment in innovation. A concrete example is the recently launched master's programme in clinical pharmacology and pharmaceutical medicine for physicians.

DURING ITS ANNUAL FORUM ON CLINICAL TRIALS IN JANUARY 2025, PHARMA.BE BROUGHT TOGETHER THE VARIOUS ACTORS IN CLINICAL RESEARCH TO DISCUSS THESE DEVELOPMENTS AND PREREQUISITES IN DEPTH.

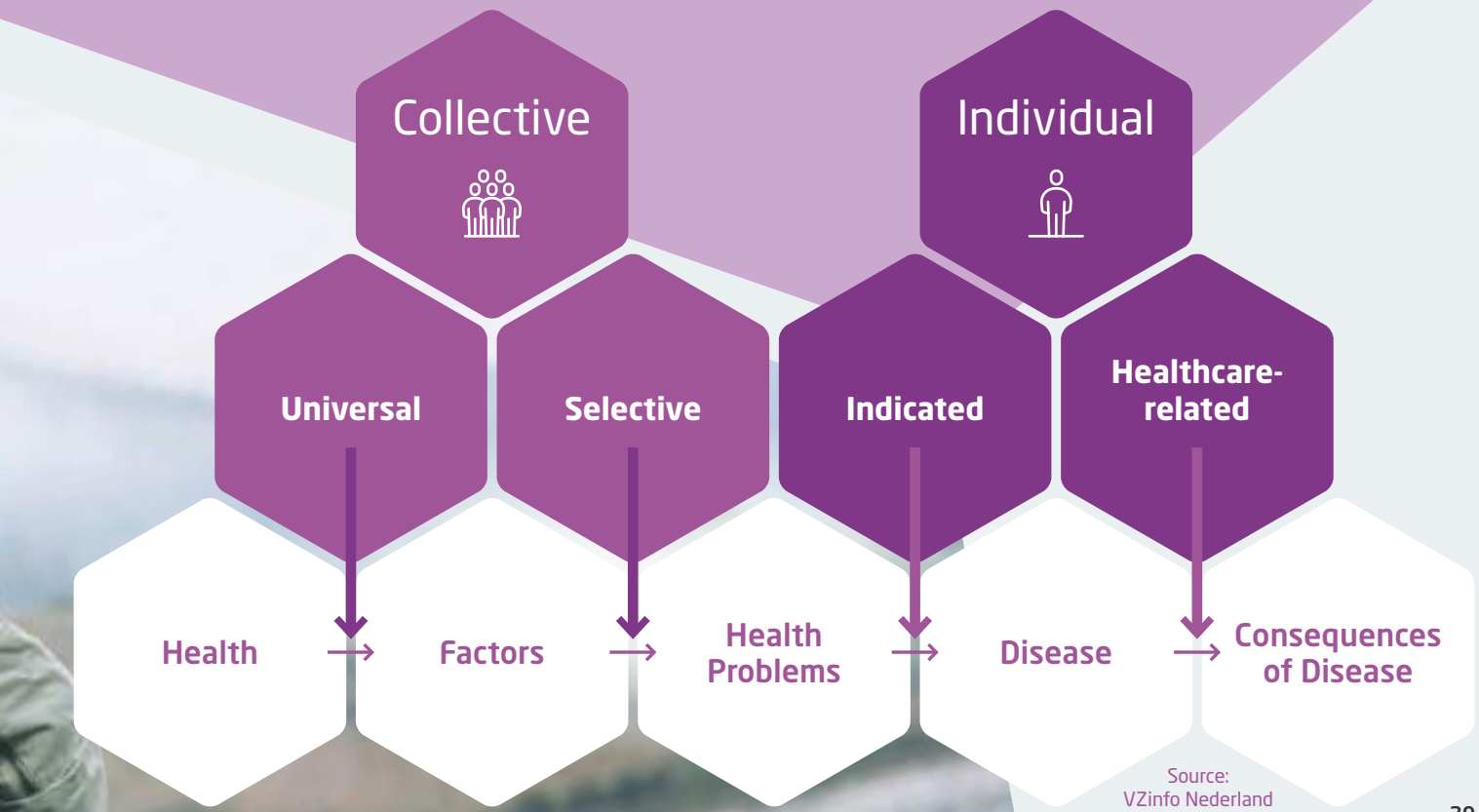
2.4. PREVENTION AS THE KEY TO A HEALTHY FUTURE

WHAT EXACTLY DOES PREVENTION INVOLVE?

PREVENTION MEANS TAKING PROACTIVE MEASURES TO STOP OR SLOW THE ONSET OF DISEASE. WHILE WE OFTEN FIRST THINK OF VACCINES, PREVENTION ALSO INCLUDES CAMPAIGNS PROMOTING HEALTHIER LIFESTYLES OR MEASURES TO IMPROVE AIR QUALITY.

Preventive actions can be viewed and categorised from various perspectives, for example based on the stage of the disease. At pharma.be, we categorise prevention according to target groups, distinguishing four main types:

- **Universal prevention**
  These actions target the entire population and are intended to reduce risk factors, improve overall health and prevent the onset of disease. One example is a broad campaign to promote health literacy;
- **Selective prevention**
  This type of prevention targets subgroups at increased risk of developing a specific disease. The focus is on detecting or preventing the disease in question. An example is encouraging breast cancer screening among women aged 50-69;
- **Indicated prevention**
  These measures are intended to prevent a condition or to improve the health of people who are at high risk and already have observable symptoms in a timely manner. For example, cholesterol-lowering medicines reduce the risk of cardiovascular disease in people with elevated cholesterol;
- **Care related prevention**
  In this type of prevention, a condition has already been diagnosed, but preventive measures are needed to prevent the condition from worsening, or the patient from developing complications or needing readmission. For instance, training on living with diabetes can help people with diabetes to stabilise and improve their health status.



Source:
VZinfo Nederland

THE BIOPHARMACEUTICAL SECTOR AS A PARTNER IN PREVENTION

PREVENTION IMPROVES PUBLIC HEALTH, HELPS TO ADDRESS HEALTH INEQUALITIES AND REDUCES PRESSURE ON OUR HEALTHCARE SYSTEM. IT IS THEREFORE A FUNDAMENTAL PART OF THE MISSION OF THE BIOPHARMACEUTICAL INDUSTRY.

The sector contributes to every type of prevention, through awareness-raising campaigns, the development of vaccines and preventive medicines, and support for patients with chronic conditions.

At the same time, we recognise that preventive actions are only successful if they are broadly supported. Given challenges such as an ageing population and growing pressure on healthcare budgets, it is essential to embed prevention structurally within health policy. Prevention is not a side issue, but a strategic investment in public health.

THERE ARE ALREADY PROMISING INITIATIVES IN WHICH DIVERSE PARTNERS JOIN FORCES. DRIVEN IN PART BY PHARMA.BE, THE INDUSTRY AIMS TO STRENGTHEN THIS COLLABORATION FURTHER.

VACCINATION, A PARTICULARLY EFFECTIVE FORM OF PREVENTION

VACCINATION PROTECTS NOT ONLY INDIVIDUALS BUT ALSO ENTIRE COMMUNITIES BY BUILDING HERD IMMUNITY. THANKS TO BASIC VACCINATION PROGRAMMES, GLOBAL CHILD MORTALITY RATES HAVE DROPPED SIGNIFICANTLY. SMALLPOX WAS ERADICATED WORLDWIDE IN 1980, AND POLIO HAS DISAPPEARED FROM EUROPE THANKS TO VACCINATION.

There is currently no clear framework for adult vaccination in Belgium. Yet high adult vaccination coverage brings significant socio-economic benefits in addition to individual health gains:

- There is reduced pressure on general practitioners, emergency departments and hospitals; Healthcare professionals can then focus on other urgent needs;
- At the same time, employees maintain their income and routine, while families face fewer disruptions or unpaid leave. This improves well-being and societal stability;
- For employers this translates into less absenteeism and higher productivity, which benefits business continuity and competitiveness.

DISCOVER THE PASSION OF BOUCHRA AND HER COLLEAGUES IN THE BIOPHARMACEUTICAL SECTOR

BOUCHRA HAS A PASSION FOR PHARMA

OUR MISSION IS TO BUILD A HEALTHIER AND BETTER PROTECTED SOCIETY.

Vaccines not only protect, they also reduce the burden on healthcare. Vaccine hesitancy, misinformation and limited knowledge about vaccination make our society vulnerable. To improve access to vaccination, we work closely with policy makers, healthcare professionals and researchers. This allows us to strengthen understanding and highlight the importance of vaccines.

BOUCHRA HATHOUT,
Public Affairs Manager

CONCRETE POLICY PROPOSALS RESULTING FROM BROAD DIALOGUE

PHARMA.BE TOOK THE INITIATIVE TO DEVELOP CONCRETE POLICY PROPOSALS FOR ADULT VACCINATION, TOGETHER WITH STAKEHOLDERS IN THE FIELD. THIS INVOLVED BILATERAL MEETINGS, EXPERT PANELS, A LARGE-SCALE SURVEY, AND SEVERAL IN-DEPTH INTERVIEWS.

This process led to five detailed policy proposals, tailored to the Belgian context. Each proposal contains actions to increase vaccination coverage among adults and older people. They also include a possible allocation of roles and responsibilities for public health agencies, healthcare professionals and other stakeholders.

The proposals are structured around five pillars - governance, planning, budget, data and communication:

- Develop a strategy and framework for adult vaccination aligned with objectives based on a population health approach;
- Shorten the time between recommendation and administration of vaccination across all life stages with a clear funding pathway;
- Increase the budget for prevention and vaccination to meet Belgium's targets for adult and older people's vaccination;
- Roll out robust data recording to support better policy-making;
- Set up tailored campaigns to effectively increase public awareness and understanding of vaccination.

AN HAS A PASSION FOR PHARMA

PREVENTION IS NOT JUST SMART, IT IS ESSENTIAL.

Belgium shows ambition in preventative healthcare by investing in smart technologies, preventive therapies, vaccines and healthy nutrition, because prevention is far better than cure. And yes, the pharmaceutical sector plays an active role in prevention. It is our mission to work on solutions that help prevent diseases, slow diseases down and keep people healthy for longer. Through prevention, we not only improve individual health but also reduce inequality and relieve pressure on the healthcare system.

AN CLOET,
External Affairs Director

DISCOVER THE PASSION OF AN AND HER COLLEAGUES IN THE BIOPHARMACEUTICAL SECTOR

WITH THESE WELL-SUBSTANTIATED AND WIDELY SUPPORTED POLICY PROPOSALS, PHARMA.BE AIMS TO CONTRIBUTE TO A STRUCTURED AND EFFECTIVE APPROACH TO ADULT VACCINATION IN BELGIUM. ONLY THROUGH JOINT EFFORTS CAN WE ACHIEVE CLEAR POLICY AND PLANNING, TARGETED FUNDING, EFFICIENT DATA SHARING AND INCREASED AWARENESS. THIS WILL STRENGTHEN BELGIUM'S PREPAREDNESS FOR FUTURE DISEASE OUTBREAKS, CONTRIBUTING TO A HEALTHIER SOCIETY AND A BETTER QUALITY OF LIFE FOR ALL.

Read the full report

JONAS HAS A PASSION FOR PHARMA

PREVENTION AND CURE GO HAND IN HAND MAKING OUR HEALTHCARE SYSTEM MORE RESILIENT AND MORE EFFECTIVE!

By detecting diseases early, we can treat patients faster and in a less invasive way, saving time, energy and resources for our healthcare system.
As a pharmaceutical industry we work together with doctors, researchers and patients to promote prevention and early detection so symptoms can be recognised in a timely way.

JONAS VAN RIET,
Policy Manager

DISCOVER THE PASSION OF JONAS AND HIS COLLEAGUES IN THE BIOPHARMACEUTICAL SECTOR

2.5. NEWLY REIMBURSED MEDICINES FOR PATIENTS

THE R&D ACTIVITIES OF OUR MEMBER COMPANIES, AND THE CLINICAL TRIALS THEY CONDUCT IN BELGIUM AND AROUND THE WORLD, LEAD TO THE DEVELOPMENT OF NEW MEDICINES.

To make these available to patients in the European Union, a marketing authorisation (MA) is first applied for at the European Medicines Agency (EMA) or from one or more national authorities in Europe. Companies in Belgium then apply for pricing and reimbursement approval, respectively from the Federal Public Service (FPS) Economy and the National Institute for Health and Disability Insurance (NIHDI), so that patients do not have to bear the full costs themselves.

Below we provide information on the number of medicines newly authorised by the EMA and the number of reimbursed medicines in Belgium in 2024.

2.5.1. NEWLY EMA-APPROVED MEDICINES

In 2024, **65 new innovative medicines were approved by the EMA**.

In its annual report, the EMA highlights that these newly authorised medicines will deliver significant progress in the following areas[1]:

- Haemophilia B, a rare hereditary bleeding disorder;
- Treatment of infections caused by bacteria that are resistant to many current treatments;
- Peripheral thyrotoxicosis in patients with Allan-Herndon-Dudley syndrome, a rare, chronic and severely disabling disease caused by mutations in the gene encoding the MCT8 protein, a thyroid hormone transporter;
- Emergency treatment of anaphylactic (allergic) reactions;
- Paroxysmal nocturnal haemoglobinuria, a rare and potentially life-threatening genetic blood disorder that leads to premature breakdown of red blood cells by the immune system;
- Chikungunya;
- Amyotrophic lateral sclerosis (ALS), a rare and often fatal condition that causes muscle weakness and paralysis;
- Mild cognitive impairment (memory and thinking problems) or mild dementia due to Alzheimer's disease (early Alzheimer's);
- Treatment of tumours associated with Von Hippel-Lindau disease, a rare genetic condition that causes cysts and tumours, and advanced clear-cell renal cell carcinoma;
- Pulmonary arterial hypertension, a rare, long-term, disabling and life-threatening disease in which patients have abnormally high blood pressure in the pulmonary arteries.

The table below summarises the **therapeutic areas** (Anatomical Therapeutic Chemical, ATC) in which the EMA authorised new medicines in 2024.

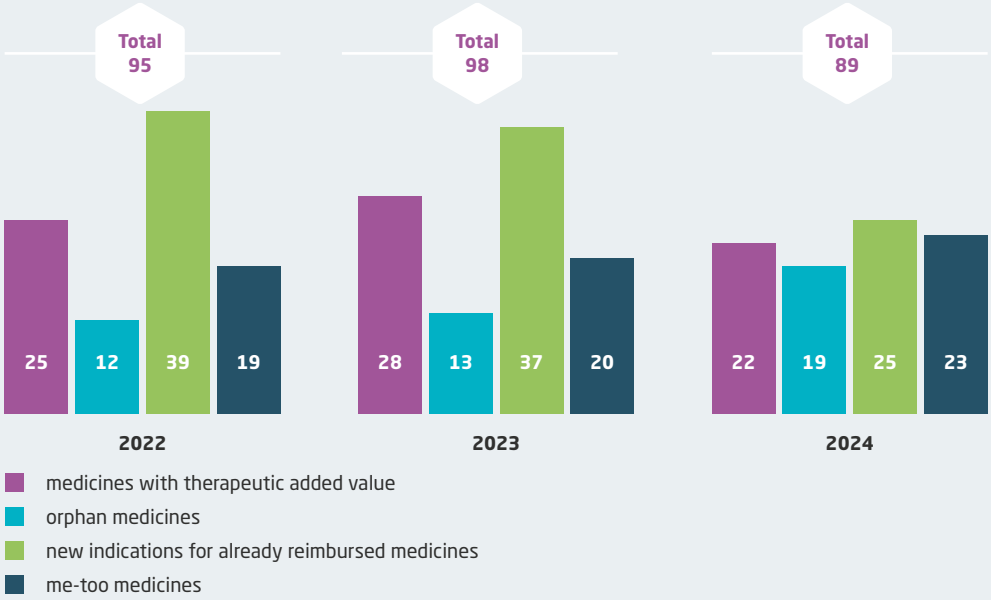
ATC code	Number of newly authorised medicines*	ATC main group	Examples of pathologies
A	4	**digestive system and metabolism**	**Alagille syndrome; primary biliary cholangitis**
B	6	**blood and blood forming organs**	**Congenital thrombotic thrombocytopenic purpura (cTTP); hereditary angioedema; haemophilia**
C	7	**cardiovascular system**	**Transthyretin amyloidosis with cardiomyopathy (ATTR-CM); anaphylaxis; pulmonary arterial hypertension; immunoglobulin A nephropathy**
D	2	**dermatology**	**Eczema; atopic dermatitis; prurigo nodularis**
G	1	**genitourinary system and sex hormones**	**Overactive bladder syndrome**
H	2	**systemic hormonal preparations (excluding sex hormones and insulins)**	**Hypoglycaemia; monocarboxylate transporter 8 (MCT8) deficiency**
J	11	**anti-infectives for systemic use**	**Pneumonia; urinary tract infections; meningitis; respiratory syncytial virus (RSV) infections; influenza; COVID-19**
L	21	**antineoplastic and immunomodulating agents**	**Lung cancer; Merkel cell carcinoma; colorectal cancer; urothelial cancer; breast cancer; oesophageal cancer; gastric cancer; follicular lymphoma; Von Hippel-Lindau disease; kidney cancer; anaemia; neutropenia**
M	0	**musculoskeletal system**	
N	3	**nervous system**	**Alzheimer's; transthyretin amyloidosis with polyneuropathy (ATTR-PN); amyotrophic lateral sclerosis (ALS)**
P	0	**antiparasitic products, insecticides and repellents**	
R	0	**respiratory system**	
S	3	**sensory organs**	**Acanthamoeba keratitis; age-related macular degeneration**
V	4	**miscellaneous**	**Alzheimer's imaging; tuberculosis diagnosis; radiopharmaceuticals**
Not yet assigned	1		**Chikungunya**

* CHMP positive opinions for new (orphan) medicines (n = 63) and hybrid medicines with an orphan status or with new indications (n = 2). Not included: other hybrid medicines, generic and biosimilar medicines.

Source: European Medicines Agency (EMA)

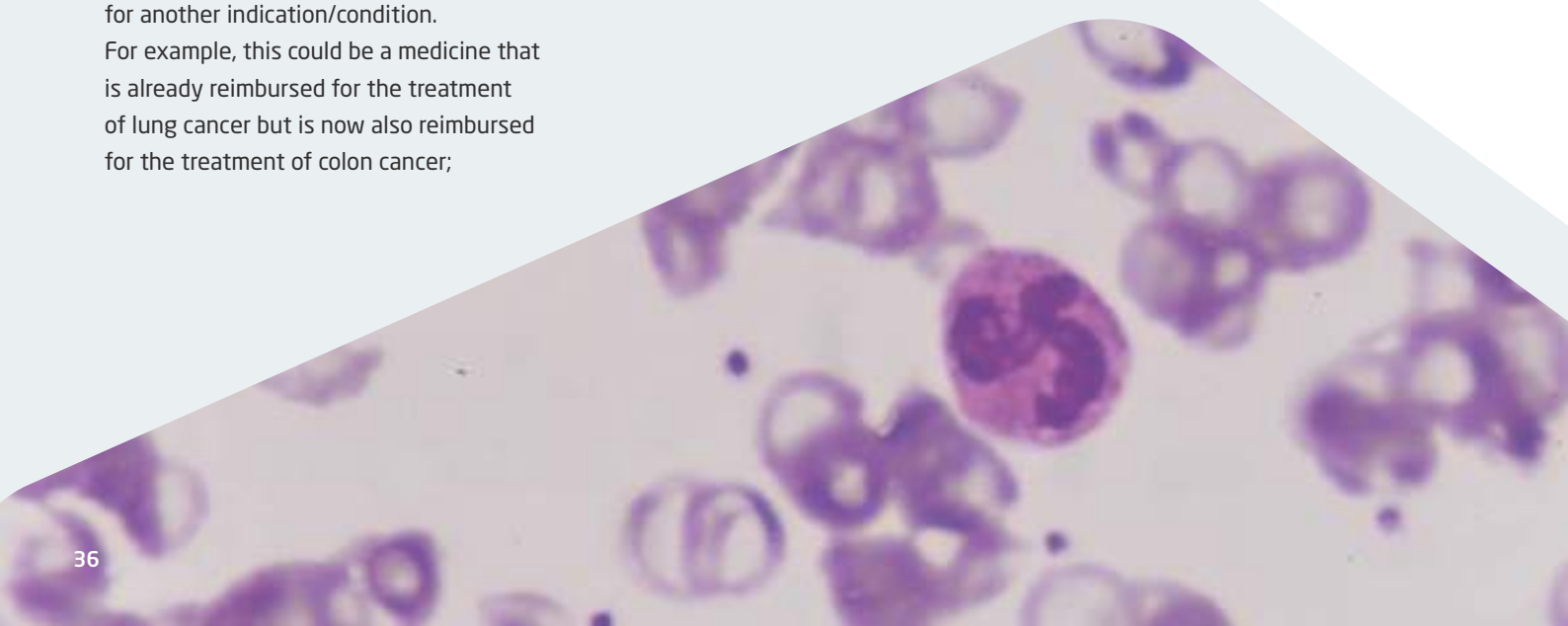
2.5.2. NEWLY REIMBURSED MEDICINES IN BELGIUM

In 2024, **89 new innovative medicines or indications were reimbursed in Belgium.**



Notes:

- A **medicine with therapeutic added value** is one that, according to the pharmaceutical company concerned, offers greater therapeutic benefit than an accepted standard treatment. This means the disease is better treated with this medicine;
- An **orphan medicine** is a medicine for the treatment of a rare disease and therefore often provides a solution to an unmet medical need;
- A **new indication** refers to a medicine that is already reimbursed for a particular indication/condition and for which the company is now seeking additional reimbursement for another indication/condition. For example, this could be a medicine that is already reimbursed for the treatment of lung cancer but is now also reimbursed for the treatment of colon cancer;
- A **me-too medicine** does not offer a higher therapeutic value than existing medicines for the same indication/disease but may add value to the patient because of improvements in dosage, administration schedule, comfort or ease of use. An additional advantage of these medicines is the greater assurance that a treatment can be continued in the case of unavailability of the existing medicines.



The table below shows an overview of the **therapeutic areas** (Anatomical Therapeutic Chemical, ATC) in which new medicines were reimbursed in 2024. Around half relate to new medicines, indications for cancer or immunomodulating agents (ATC L). There was also a relative increase in new medicines for neurological diseases (ATC N), for the digestive system and metabolism (code A), and for infectious diseases (ATC J).

ATC code	Number of newly reimbursed medicines/ indications	ATC main group	Examples of pathology
A	8	**digestive system and metabolism**	**Alagille syndrome; Fabry disease; metachromatic leukodystrophy (MLD); Niemann-Pick disease**
B	6	**blood and blood forming organs**	**Hereditary angioedema; anaemia**
C	3	**cardiovascular system**	**Obstructive hypertrophic cardiomyopathy**
D	6	**dermatology**	**Atopic dermatitis**
G	0	**genitourinary system and sex hormones**	-
H	2	**systemic hormonal preparations (excluding sex hormones and insulins)**	**Endometriosis**
J	8	**anti-infectives for systemic use**	**CMV prophylaxis after organ or stem cell transplantation; RSV prophylaxis; rabies prophylaxis**
L	41	**antineoplastic and immunomodulating agents**	**Lung cancer; breast cancer; uterine cancer; prostate cancer; cholangiocarcinoma; diffuse large B-cell lymphoma; mantle cell lymphoma; marginal zone lymphoma; multiple myeloma; acute myeloid leukaemia; myasthenia gravis; Epstein-Barr virus-positive post-transplant lymphoproliferative disease; polycythaemia vera**
M	2	**musculoskeletal system**	**Spinal muscular atrophy**
N	9	**nervous system**	**Migraine; epilepsy; depression**
P	0	**antiparasitic products, insecticides and repellents**	-
R	2	**respiratory system**	**Asthma**
S	0	**sensory organs**	-
V	2	**miscellaneous**	**Methotrexate antidote**

THE GALIEN PRIZE (PRIX GALIEN) HONOURS BIOPHARMACEUTICAL INNOVATION

The Galien Prize, often described as the 'Nobel Prize for biopharmacy', is among the most prestigious distinctions in healthcare. Since its creation in 1970, the prize has annually honoured therapeutic innovations and scientific breakthroughs with major public health impact. The prize is awarded in 17 countries. In Belgium, it has been organised by ArtsenKrant/Journal du Médecin since 1982, with the support of pharma.be. Prizes are awarded in three categories:

- Best innovative medicine;
- Best pharmacological research project;
- Awards for medical devices and innovative start-ups.

A catalyst for biopharmaceutical research

The significance of the Galien Prize goes beyond mere symbolic recognition. The prize recognises biopharmaceutical research and development in Belgium and showcases groundbreaking treatments, advanced medical devices and digital solutions in healthcare. The prize stimulates creativity among researchers and encourages laboratories to invest in ambitious projects, strengthening Belgium's competitiveness and appeal as a life sciences hub.

Innovation in the biopharmaceutical sector is the result of a long and demanding process. Breakthroughs rarely stem from a single brilliant idea; they are the outcome of years, sometimes decades, of rigorous research and tireless teamwork across academia, industry, and healthcare organisations. Sustained support from investors, shareholders and public funding for fundamental research is also crucial. It is this combination of vision, perseverance and collaboration that enables the progress recognised and celebrated by the Galien Prize.

Tangible impact for patients and society

This progress is anything but abstract: it translates into tangible benefits for patients and society. For patients, the Galien Prize symbolises real progress: behind every innovation lies the will to improve quality of life and address unmet medical needs. For society, the prize reflects the value of new medicines not only through clinical benefits, but also through socio-economic impact, such as easing the burden of chronic diseases and advancing personalised medicine.

The laureates of the Galien Prize embody this mission. Their innovations are not theoretical: they change lives. Think of COVID-19 vaccines, gene therapies for rare diseases, and targeted treatments for cancer and autoimmune diseases. The award-winning innovations of the past five years, now reimbursed in Belgium, are not only scientific milestones; they also pave the way towards more personalised and accessible medicine, in which every discovery represents a concrete promise of hope for patients.

Year	Company	Product	Indication
2024	**VERTEX PHARMACEUTICALS**	**Casgevy®**	– **Sickle cell disease** An inherited blood disorder in which red blood cells take on a sickle shape, leading to blockages in blood vessels and chronic anaemia. – **Beta thalassaemia** An inherited blood disorder in which the body produces insufficient or no haemoglobin, leading to severe anaemia.
2023	**BRISTOL-MYERS SQUIBB**	**Camzyos®**	– **Hypertrophic obstructive cardiomyopathy** An inherited heart muscle disease in which the heart muscle thickens and blood outflow from the heart is impeded.
2022	**ARGENX**	**Vyvgart®**	– **Generalised autoimmune myasthenia gravis (with antibodies against acetylcholine receptors)** An autoimmune disease in which signals from the nerves are not properly transmitted to the muscles, causing muscle weakness. – **Chronic inflammatory demyelinating polyradiculoneuropathy** A rare autoimmune disease in which the protective layer around nerves is damaged, causing muscle weakness and sensory disturbances.
2021	**GILEAD**	**Trodelvy®**	– **Triple-negative breast cancer** An aggressive form of breast cancer lacking oestrogen, progesterone or HER2 receptors, more common in younger women. HER2 is a protein that stimulates cell growth. – **Hormone receptor-positive and HER2-negative breast cancer** A less aggressive form of breast cancer in which the tumour grows due to female hormones.
2020	**PFIZER/BIONTECH**	**Comirnaty®**	– **Prevention of COVID-19** An infectious disease caused by a virus that primarily affects the lungs, with symptoms such as fever, cough and fatigue.

Source: Galien Prize and EMA

By supporting these breakthroughs, Belgium reaffirms its position as a strategic hub for biopharmaceutical research and health innovation.

Prevention is an investment, primary care is a lever for change and innovation is a promise for the future. This vision cannot be realised without researchers, healthcare professionals, patients, the innovative biopharmaceutical sector and engaged citizens. Together we make health not a luxury, but a right. Not a burden, but an opportunity.

YVES COPPIETERS,
Walloon Minister of Health, Environment, Solidarity, Social Economy, Equal Opportunities, and Women's Rights

2.6. FOCUS ON RARE DISEASES

RARE DISEASES: A HIDDEN CHALLENGE FOR PATIENTS AND CARE

Rare diseases are conditions that each affect fewer than 1 in 2 000 people. Although each disease is uncommon, together there are an estimated 6 000-8 000 different rare diseases worldwide. In Belgium, more than 660 000 people are thought to live with such a condition. These diseases are often severe, chronic and genetic in origin; 75 % affect children and 30 % of patients die before their fifth birthday[2].

The challenges are enormous: obtaining a correct diagnosis takes an average of five years, specialised expertise is scarce, and effective treatments are often lacking. This has a huge impact on the quality of life of patients and their families.

WHY RESEARCH IS CRUCIAL

The biopharmaceutical industry in Belgium continues to invest in research into innovative therapies and orphan medicines. In 2023, 20 % of all clinical trials in Belgium focused on rare diseases.

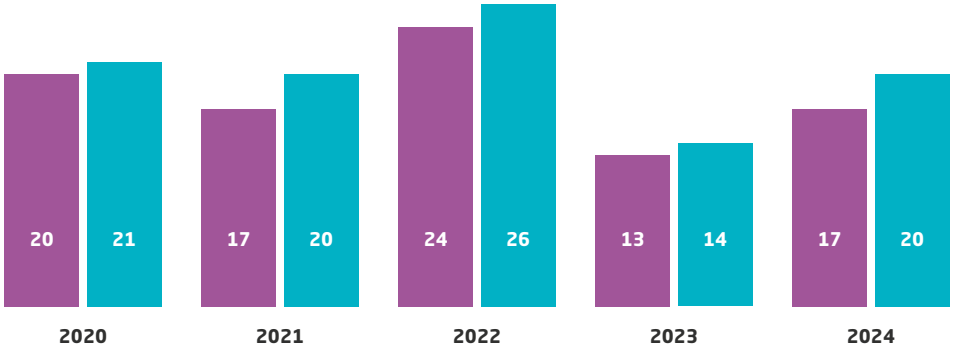
To strengthen Belgium's research and development ecosystem for rare diseases, collaboration at national and international level is essential. That is why pharma.be joined the recently established Belgian mirror group of the European Rare Disease Research Alliance (ERDERA). This group brings together Belgian stakeholders – including industry representatives, research institutions, patient organisations, and public authorities – with the aim of coordinating and strengthening Belgium's contribution to European research initiatives. Through this collaboration, Belgium can respond more effectively to European calls and projects, while promoting knowledge and expertise exchange. This contributes to a stronger and more innovative R&D ecosystem, enabling patients with rare diseases to benefit sooner from new scientific insights and innovative treatments.

RD MOONSHOT: ACCELERATING RESEARCH INTO RARE AND PAEDIATRIC DISEASES

To address unmet medical needs more rapidly, nine partners from industry, government, patient organisations, and research institutions have joined forces in the European initiative Rare and Paediatric Disease Moonshot (RD Moonshot). The goal? To improve patients' quality of life and accelerate the development of innovative medicines and technologies for rare and paediatric diseases, especially where no treatment currently exists.

NEW TREATMENTS BRING HOPE FOR PATIENTS

This collaborative effort leads to the development of biopharmaceutical products for the diagnosis, prevention, or treatment of rare diseases for which no alternatives exist. In 2024, the European Medicines Agency (EMA) approved 17 new orphan medicines. This brings the total number of EU-authorised orphan medicines since the introduction of the EU Orphan Regulation to 261.



Source: EMA 'Annual report on the use of the special contribution for orphan medicines 2024'

A NEW BELGIAN NATIONAL PLAN FOR RARE DISEASES

IN FEBRUARY 2025, THERE WAS GOOD NEWS FOR PATIENTS WITH RARE DISEASES: THE 2025-2029 FEDERAL COALITION AGREEMENT EXPLICITLY COMMITS THE NEW GOVERNMENT TO FURTHER DEVELOPING A BELGIAN 'PLAN FOR RARE DISEASES'[3]. THIS PLAN FOCUSES ON:

- Faster diagnosis and referral to recognised expert centres;
- Well-coordinated multidisciplinary care tailored to the specific needs of patients and their families, including case management in complex situations;
- Simplified administrative procedures and easier access to medicines, treatments and devices that address highly specific needs;
- Maintaining smooth access to clinical trials in Belgium;
- High-performance data recording and follow-up;
- Special attention to the transition from paediatric to adult care.

With these measures, Belgium aims not only to improve patients' quality of life but also to strengthen cooperation among the sector, healthcare providers, researchers, and policymakers.

2.7. MEDICAL EXPERTS ON THE ADDED VALUE OF INNOVATIVE MEDICINES

THANKS TO INVESTMENT BY THE BIOPHARMACEUTICAL SECTOR, INNOVATIVE TREATMENTS ARE INTRODUCED EVERY YEAR THAT SIGNIFICANTLY IMPROVE BOTH SURVIVAL AND QUALITY OF LIFE FOR PATIENTS.

WE SPOKE WITH TWO ONCOLOGY EXPERTS ABOUT THE KEY BREAKTHROUGHS, THEIR IMPACT IN THE FIELD AND THE ROLE OF THE BIOPHARMACEUTICAL SECTOR. WE ALSO ASKED THEM WHICH CHALLENGES AND OPPORTUNITIES THEY STILL SEE FOR OUR SECTOR TO FURTHER IMPROVE CANCER CARE IN BELGIUM.
A THIRD EXPERT SHARED INSIGHTS INTO RECENT ADVANCES IN ASTHMA TREATMENT AND THEIR TRANSFORMATIVE IMPACT ON PATIENTS' LIVES.

IN CONVERSATION WITH PROF. DR. AHMAD AWADA

Prof. dr. Ahmad Awada has over 25 years' experience as an oncologist. Throughout his career, he has been actively involved in the clinical development of various innovative cancer treatments and has built extensive expertise in the treatment of solid tumours. Since mid-2024 he has been Director of the Chirec Cancer Institute (CCI), the largest private cancer centre in Belgium. As Chair of All.Can Belgium, he works with patient organisations, healthcare professionals, experts, policy makers and companies to make cancer care in Belgium more efficient, more patient-centred and more innovative.

What breakthroughs have you seen in oncology over the past five years?

In recent years, oncology has once again taken major strides forward. Numerous new treatments have been introduced, which have not only improved survival rates but also patients' quality of life. Cancer care is becoming increasingly multidisciplinary, addressing not just the disease but the whole person. Today, cancer care is truly personalised, fully tailored to each patient's unique situation.

How do you see the role of the biopharmaceutical sector in this evolution?

Without the biopharmaceutical industry's investment in research and development, many of today's innovative treatments simply would not exist. The sector also plays a vital role in ensuring patients gain faster access to effective new therapies.

What are the biggest challenges in oncology today? Where do you still see opportunities for improvement?

One of the main challenges remains rapid access to innovation. In addition, we really need to carry out a thorough revision of Belgium's 'Cancer Plan', which dates back to 2008, so that it aligns with the reality of oncology today. Our healthcare system currently struggles to keep pace with the rapid developments in our field. There is still a great deal of structural work to be done here.

How can the biopharmaceutical sector help address these challenges and accelerate innovation?

You cannot ensure smooth access to innovation in cancer care if the parties involved – pharmaceutical companies, healthcare professionals, regulators and patients – do not engage in open and trust-based dialogue. Through All.Can, we are working on initiatives that enable precisely that dialogue.

We also need clear minimum criteria for assessing innovative treatments – criteria that ensure they are both clinically and statistically meaningful. These criteria should take into account, among other things, factors such as tumour type, clinical context, and the urgency of the need for innovation.

Which factors could contribute to a broader roll-out of promising therapeutic innovations in Belgium?

At All.Can we are currently exploring this question in depth. It is clear that the quality of clinical studies must be excellent at every stage, from design to execution and follow-up. It is also important that the primary endpoint of the research delivers a clearly demonstrable clinical benefit. This benefit should be maintained – and ideally increase – as the study progresses. We should also aim for an acceptable threshold for discontinuation of treatment due to adverse events (for example no more than 15 %).

We should also aim for fewer distant metastases at early stages, fewer hospitalisations, and stable or improved quality of life for patients with metastatic cancer.

IN CONVERSATION WITH PROF. DR. EVANDRO DE AZAMBUJA

Prof. dr. Evandro de Azambuja is a medical oncologist at the Jules Bordet Institute in Brussels, an integrated multidisciplinary centre dedicated entirely to cancer care. He specialises in breast cancer treatment, clinical trials and cardio-oncology. He is currently President of the Belgian Society of Medical Oncology (BSMO) and Director of Membership at the European Society for Medical Oncology (ESMO).

What breakthroughs have you seen in oncology over the past five years?

The widespread adoption of immunotherapies, such as checkpoint inhibitors and CAR-T cell therapies, and the expansion of targeted treatments based on molecular tumour characterisation have transformed cancer care. Advances in radiotherapy now allow greater precision and better preservation of healthy tissue. In addition, digital health technologies and artificial intelligence are increasingly transforming diagnostics, treatment planning and patient follow-up.

These innovations make cancer treatment more personalised and more effective, with fewer side effects. This leads to a substantial improvement in quality of life. Telemedicine and remote monitoring are also making care more efficient. Treatments thus become more accessible and can be better coordinated within multidisciplinary teams.

How do you see the role of the biopharmaceutical sector in this evolution?

Through strong investment in R&D, the biopharmaceutical sector has played a key role in recent breakthroughs in immunotherapy, targeted therapies and precision medicine. Collaborations with academic institutions and clinical research networks have accelerated the discovery and approval of new cancer treatments. Biopharmaceutical companies have also contributed significantly to digital solutions that improve patient follow-up and treatment adherence.

What are the biggest challenges in oncology today? Where do you still see opportunities for improvement?

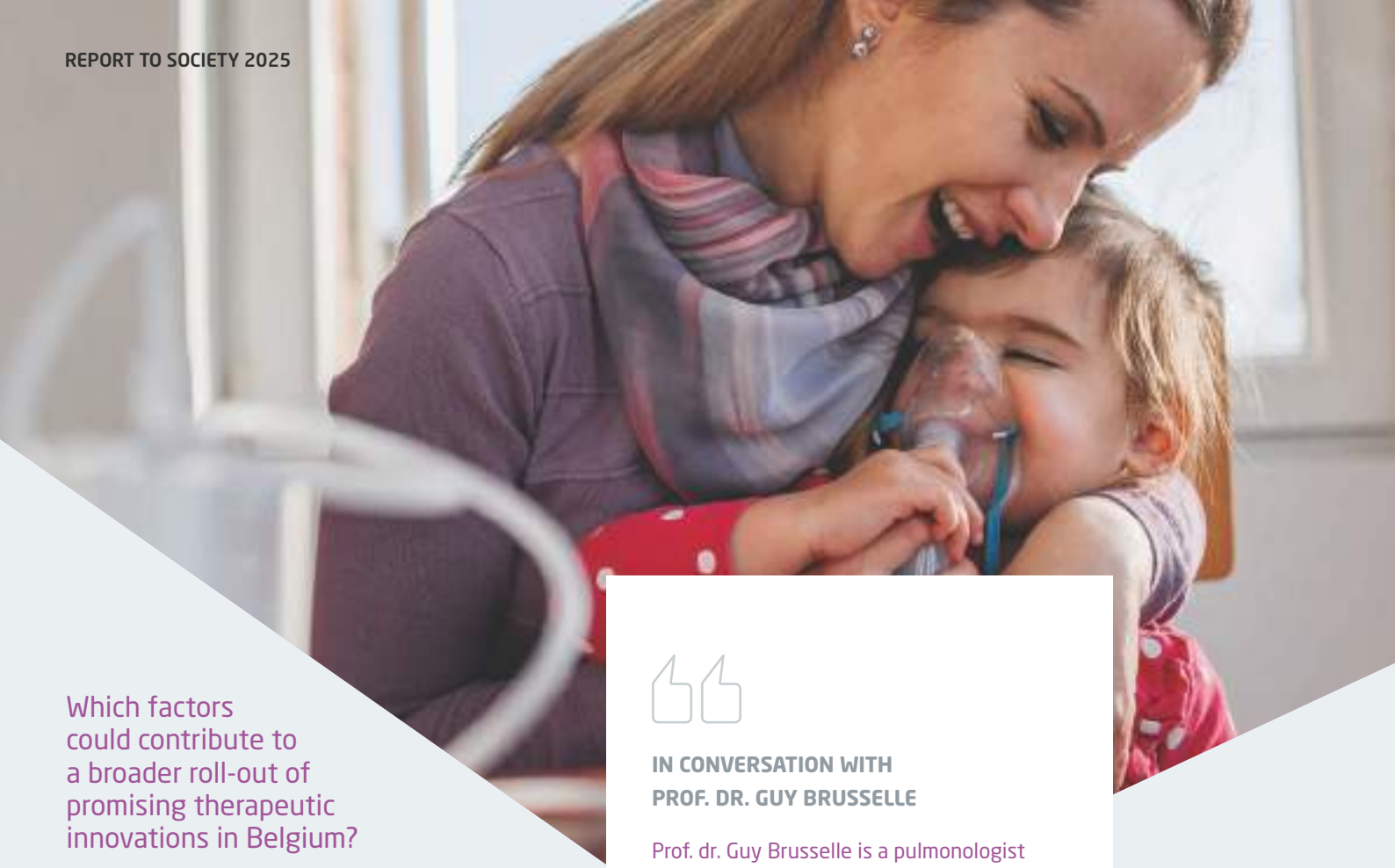
Despite remarkable progress, there are still considerable challenges. Treatment resistance and disease recurrence still limit long-term outcomes. Access to advanced therapies also still depends heavily on region, available care infrastructure and socio-economic factors. Managing side effects, especially in older and vulnerable patients, also remains a concern.

There are clear opportunities to enhance early detection and prevention, expand personalised medicine to more cancer types, and promote care models that integrate physical, emotional, and social support. In addition, the collection and sharing of real-world evidence can help optimise clinical decision-making. Finally, aftercare and quality of life following treatment deserve greater attention and resources.

How can the biopharmaceutical sector help address these challenges and accelerate innovation?

The sector must continue to invest in R&D, but with greater attention to accessibility and affordability so that their innovations reach more patients. Close collaboration with healthcare professionals, regulators and patient organisations also remains crucial to align innovation more closely with clinical practice.

Further investment is needed in early detection, treatment resistance and personalised care, supported by data science and digital health tools. By embracing open innovation and patient-centred models, the sector can enhance not only survival rates but also the quality of life for cancer patients worldwide.



Which factors could contribute to a broader roll-out of promising therapeutic innovations in Belgium?

A first lever is faster approval and reimbursement. The Belgian Early and Fast Access procedure is an important step in this regard, as it makes promising treatments for serious or life-threatening conditions available even before full approval by the EMA. In addition, we must invest in care infrastructure and training. Many advanced therapies require specialised centres and equipment and highly trained healthcare professionals. It is important to eliminate geographical disparities to ensure equal access across the country.

A reworking of the reimbursement system is also needed, as it is not currently aligned with innovative therapies such as ATMPs. Pay-for-performance models, for example, can improve access and align reimbursement with achieved patient outcomes. In addition, close collaboration between biopharmaceutical companies, healthcare professionals, regulators and patient organisations remains essential. Belgium should also encourage greater participation in clinical trials, including international ones. Belgium could support patients more actively in this and remove financial barriers.

If we make progress on all these points, we can accelerate the roll-out of therapeutic innovations and further improve outcomes for cancer patients.

IN CONVERSATION WITH PROF. DR. GUY BRUSSELLE

Prof. dr. Guy Brusselle is a pulmonologist and head of the Laboratory for Translational Research into Obstructive Lung Diseases at Ghent University Hospital (UZ Gent). He specialises in asthma, allergy, severe asthma and pulmonary vasculitis.
He is currently Chair of the Global Initiative for Asthma (GINA), a global partnership of healthcare professionals, patients, and public authorities focused on improving asthma care and treatment access.

Is asthma common and what are the consequences for the patient?

Asthma is one of the most common chronic respiratory diseases and affects more than 260 million people worldwide. There are different forms of asthma. Asthma can occur in childhood, but it can also appear only in adulthood. The causes and the way the body responds also differ. Symptoms include coughing, wheezing, tightness in the chest and shortness of breath. Symptoms can worsen suddenly; these asthma attacks are not only frightening, they can also be fatal if not addressed immediately.

Are there currently effective treatments for asthma?

The fact that asthma is so heterogeneous makes it difficult to find effective solutions for all patients with asthma. Nevertheless, major progress has been made in various areas. For patients with severe, uncontrolled asthma who experience frequent attacks, the only option a decade ago was frequent oral corticosteroids. However, these brought complications such as diabetes, high blood pressure, osteoporosis and an increased susceptibility to infections such as pneumonia.

Thanks to outstanding fundamental, translational, and clinical research, the biopharmaceutical industry has developed several monoclonal antibodies for severe asthma. Since 2016, five such monoclonal antibodies have been approved by the European Medicines Agency (EMA). These are administered subcutaneously every two to eight weeks, as an add-on to inhalation therapy.

What do these new treatments mean for patients with asthma?

These new biological therapies have been a true breakthrough for patients with severe asthma. They not only reduce the number of asthma attacks and the associated need for care (use of oral corticosteroids, emergency admissions and hospitalisations), but also significantly reduce asthma symptoms and improve lung function and quality of life.

MOREOVER, ONE IN THREE PATIENTS WITH SEVERE ASTHMA ACHIEVES CLINICAL REMISSION – MEANING NO FURTHER ATTACKS AND NORMAL, SUSTAINED LUNG FUNCTION.

03

FOR WHOM WE CREATE ADDED VALUE

IN THIS CHAPTER, WE FIRST LOOK AT THE ADDED VALUE THE INNOVATIVE BIOPHARMACEUTICAL SECTOR CREATES FOR PATIENTS, THE HEALTHCARE SYSTEM, AND SOCIETY THROUGH THE NEW MEDICINES AND VACCINES IT DEVELOPS AND BRINGS TO MARKET. WE HAVE SELECTED FOUR STRIKING EXAMPLES AND ALSO EXAMINE THE IMPORTANCE OF VALUE-BASED PRICING FOR THESE INNOVATIONS.

OUR SECTOR IS ALSO A CORNERSTONE OF BELGIUM'S KNOWLEDGE ECONOMY, AS SHOWN BY THE STRONG FIGURES ON EMPLOYMENT, EXPORTS, PRODUCTION, ADDED VALUE, AND INVESTMENT IN 2024. THIS IS FURTHER ILLUSTRATED BY THE POSITIVE COST-BENEFIT ANALYSIS OF OUR SECTOR FOR THE BELGIAN GOVERNMENT.

DISCOVER THE PASSION OF GREGORY AND HIS COLLEAGUES IN THE BIOPHARMACEUTICAL SECTOR

GREGORY HAS A PASSION FOR PHARMA:

EVERY EFFECTIVE MEDICINE IS AN INVESTMENT IN HEALTH - AND IN SOCIETY!

Of course, a medicine relieves pain, treats a disease and sometimes saves lives, but its value goes much further.
Thanks to innovation and the most advanced treatments, some patients are not only helped; they also regain part of what the disease has taken from them.
That may mean they can return to work, resume their social life, or need to visit the hospital or doctor less often. In other words: the value of a medicine is not limited to the therapeutic effect. It also has social, human and even economic value.

GREGORY WILLOCQ,
External Affairs Director

3.1. A POSITIVE IMPACT FOR PATIENTS, THE HEALTHCARE SECTOR AND SOCIETY

3.1.1. GROUNDBREAKING TREATMENT PREVENTS AMPUTATIONS IN CHILDREN

A BELGIAN BIOPHARMACEUTICAL COMPANY HAS SHOWN HOW BIOTECHNOLOGICAL INNOVATION CAN BE USED NOT ONLY TO CURE BUT ALSO TO PREVENT DISEASE. THIS UNIVERSITY SPIN-OFF SUCCESSFULLY TESTED A GROUNDBREAKING TREATMENT TO PREVENT AMPUTATION IN CHILDREN WITH SEVERE BONE DEFECTS.

THE TREATMENT WAS TESTED IN FOUR CHILDREN – INCLUDING TWO BELGIAN CHILDREN – WHO SUFFER FROM CONGENITAL PSEUDARTHROSIS OF THE TIBIA. A RARE GENETIC CONDITION THAT LEADS TO BOWING AND EVENTUALLY A FRACTURE OF THE BONE, CAUSING SEVERE PAIN. YOUNG PATIENTS USUALLY HAVE TO UNDERGO MULTIPLE OPERATIONS; AMPUTATION IS OFTEN THE LAST RESORT.

From academic research to medical breakthrough

Thanks to this biotechnological innovation, treating physicians now have an effective option that prevents amputation. It involves a graft cultured from stem cells from the patient's adipose tissue. These cells are first reprogrammed to form bone tissue, then implanted at the fracture site.

The project originated at a Belgian university and its affiliated university hospital and has since grown into a spin-off company – once again demonstrating the importance of a thriving innovation ecosystem. Bringing together academic and industrial insights and know-how led to a groundbreaking treatment that spares children both physical and psychological suffering.

The entire value chain in Belgium

Although the treatment is being tested internationally by local surgeons, the entire value chain – from initial research to graft production – remains in Belgium. Innovations like this not only create highly specialised jobs but also strengthen Belgium's position as a biotechnology hub.

From medical need to broader application

The therapy is not yet on the market but has already been used under the medical need programme of the FAMHP. In the first phase, four children who otherwise faced amputation received the treatment. Four to seven years after implantation, their bones have completely healed, and no new fractures have occurred.

A pilot study involving four more children is now under way, and a larger clinical trial is being launched to bring the treatment to market. The company is also exploring applications for adults with severe bone diseases.

> By using personalised cell therapies, we offer an alternative to invasive surgery. This approach shows how innovation not only cures, but also prevents. Prevention through advanced biotechnology reduces both the physical and emotional impact on young patients. It is patient-centred innovation – vital for children who would otherwise live with lifelong consequences of amputation. Our treatment proves that investing in preventive innovation is equivalent to investing in quality of life.
>
> **DENIS DUFRANE,**
> CEO of Novadip

3.1.2. FROM HERD IMMUNITY TO ECONOMIC GAIN: WHY VACCINATION PAYS OFF

CHAPTER 2 HAS SHOWN THAT, VACCINATION IS ONE OF THE STRONGEST FORMS OF PREVENTION – PROTECTING NOT ONLY INDIVIDUALS BUT ENTIRE COMMUNITIES THROUGH HERD IMMUNITY. WHEN A LARGE SHARE OF THE POPULATION IS IMMUNE, DISEASE TRANSMISSION SLOWS OR EVEN STOPS.

IN THIS SECTION, WE TAKE A CLOSER LOOK AT THE TRUE VALUE OF VACCINATION AND THE SAVINGS GENERATED BY BELGIUM'S ROUTINE CHILDHOOD VACCINATION PROGRAMME.

Economic gains thanks to a healthier population

Scientific research has shown that vaccinations not only save lives, but also offer significant economic benefits. A simulation study examined 118 000 children born in 2018, comparing a no-vaccination scenario with Belgium's current childhood vaccination schedule over a 100-year period. The results speak for themselves. For every euro spent on child vaccination, 1.4 euros is saved in healthcare costs and a further 3.2 euros flows back to society[4].

According to this study, thanks to its basic immunisation schedule, Belgium saves 126 million euros in healthcare costs and 265 million euros in productivity losses – including 110 million euros due to illness and 155 million euros due to premature mortality. These savings far outweigh vaccination costs: fully vaccinating one person under the current schedule costs just 930 euros – or 2 010 euros if meningococcal B, varicella, influenza, pneumococcal, and herpes zoster (shingles) vaccines are included[5].

Vaccination also prevents 226 000 infections and 200 premature deaths among young children. These figures underline the importance of lifelong immunisation and the need for continued investment in vaccination programmes.

From less illness to greater productivity

Traditional cost-benefit analyses focus on direct healthcare costs, yet there are numerous indirect benefits that are harder to quantify but still have a real impact. Vaccination leads to fewer sick days at work, less strain on healthcare providers, less anxiety about infection, and fewer disruptions to family or workplace routines.

Even a short illness can generate extra childcare costs or missed work days for parents/carers. These hidden costs reveal just how broad vaccination's impact truly is and why a holistic approach is necessary[6].

> Vaccination is one of the most valuable investments we can make in ourselves and our society. The reimbursement of vaccines should reflect this societal value.
>
> **PROF. STEVEN SIMOENS,**
> Professor Health Economics, Faculty of Pharmaceutical Sciences, KU Leuven

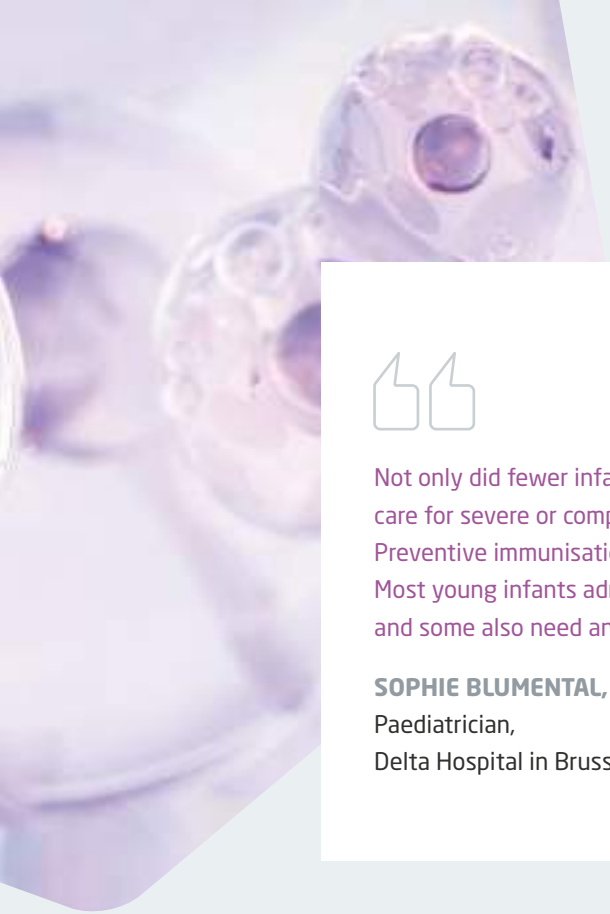
3.1.3. HOSPITALISATIONS FALL THANKS TO PREVENTIVE RSV IMMUNISATION IN INFANTS

THE GREATEST VALUE OF NEW MEDICINES LIES IN THEIR DIRECT IMPACT ON PATIENTS: THEY LIVE LONGER, HEALTHIER LIVES AND ENJOY A BETTER QUALITY OF LIFE. OFTEN, THERE ARE ADDITIONAL BENEFITS FOR THE HEALTHCARE SYSTEM, SUCH AS REDUCED HOSPITAL ADMISSIONS. THESE EFFECTS USUALLY TAKE YEARS TO SHOW UP IN STATISTICS – BUT PREVENTIVE RSV IMMUNISATION IN INFANTS IS AN EXCEPTION. FOLLOWING THE FIRST WINTER SEASON, HOSPITALISATION RATES HAD ALREADY DROPPED SHARPLY.
THIS ALSO BRINGS A WIDER SOCIETAL BENEFIT: FEWER HOSPITALISED BABIES MEANS FEWER PARENTS MISSING WORK.

WHAT IS RSV AND WHY IS IT DANGEROUS?

RSV (respiratory syncytial virus) is a common and highly contagious virus that affects the upper respiratory tract. By the age of two, approximately 95 % of young children have experienced an RSV infection. Symptoms can resemble a cold – a blocked or runny nose, dry cough, or mild fever – but RSV can spread to the lower airways and cause serious illness such as bronchiolitis or pneumonia, particularly in infants and young children.

RSV is particularly concerning in babies because it can cause severe breathing difficulties and dehydration, often requiring hospitalisation. The vast majority (75 % to 90 %) of babies admitted to hospital for a severe RSV infection were previously healthy, and most cases occur in infants under one year old[7].



> Not only did fewer infants fall ill, but the number of children needing intensive care for severe or complex bronchiolitis also dropped significantly. Preventive immunisation has greatly reduced pressure on the healthcare system. Most young infants admitted for RSV require respiratory or feeding support, and some also need antibiotics for secondary bacterial infections.
>
> **SOPHIE BLUMENTAL,**
> Paediatrician,
> Delta Hospital in Brussels

Belgium currently offers two options for protecting infants. In consultation with their treating physician, parents can choose between the maternal vaccine administered to the mother during pregnancy, or a long-acting monoclonal antibody administered directly to the child.

However, RSV does not only affect young children. Vulnerable older people are also susceptible to infection, with potentially serious consequences for their health. They too benefit from the immunisation of young children, as this reduces circulation of the virus. Since this summer, there has also been a reimbursed vaccine available specifically for older people at increased risk of severe RSV disease.

Dramatic decline in hospitalisations

In Belgium, a monoclonal antibody has been approved for reimbursement and has been administered since 1 October 2024. The positive effect of this preventive immunisation in infants was immediately visible during the 2024-2025 winter season. Data from Sciensano and a large Belgian study estimate that RSV immunisation prevented 35-45 % of hospitalisations in children under five – more than 4 000 admissions, including 2 000 during the epidemic peak[8].

The biggest reduction was seen among infants under six months, whose share of hospitalisations dropped from over 50 % in 2023-2024 to under 30 % in 2024-2025. The estimated effectiveness of immunisation in preventing RSV-related hospital admissions was 85.6 %. Similar results have been reported in neighbouring countries.

Fewer hospitalisations naturally also mean lower expenditure in the healthcare system. A KCE study estimated that before the possibility of preventive immunisation, RSV caused on average 8 638 standard hospital admissions and 428 intensive care admissions per year[9].

These admissions came at a cost of 30 million euros and 6.3 million euros respectively, or an average cost per admission of 3 473 euros for a standard admission and 14 719 euros for an intensive care admission[10].

If we link these figures to the 4 000 hospitalisations avoided and assume a proportional distribution between standard and intensive admissions, this means that preventive immunisation has led to savings of around 16 million euros in hospital expenditure.

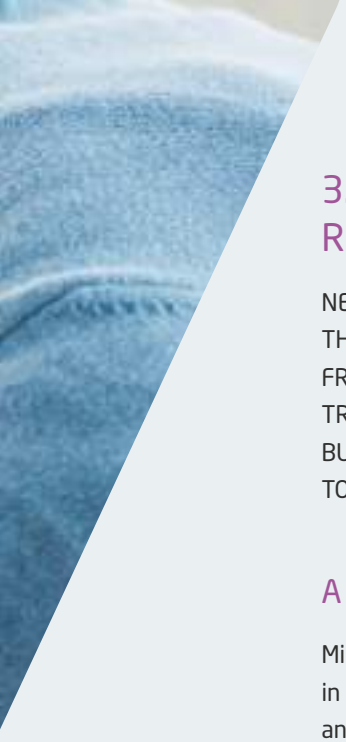
Significant economic impact

An additional advantage is that parents experience less emotional and organisational strain, as well as a significant economic benefit[11,12] due to reduced parental absenteeism. Despite the excellent care in hospitals, parents understandably want to stay with their child during a hospital admission. For working parents, this means taking leave, which entails an economic cost. A child's hospitalisation due to an RSV infection leads to an average of four days' parental absenteeism[13]. This corresponds to an average economic cost of 1 162 euros per hospitalised child[14].
If we link this back to the 4 000 hospitalisations avoided, we arrive at an avoided economic cost of around 4.7 million euros, a considerable societal benefit.

But there is room for further improvement

Immunisation coverage in 2024–2025 was estimated at 62–74 %. Raising this to 90 % could reduce the number of hospitalisations by a further 10 % to 15 %, which amounts to an additional 1 500 hospitalisations avoided[15]. International results show what is possible: in Spain, RSV-related hospitalisations dropped by as much as 89 % last winter.

Hopefully, we can move towards a situation in which hospitalisations of infants due to RSV infection can be almost completely avoided. This would spare young children and their families a great deal of suffering in the first place. It would also relieve the burden on outpatient care and especially on paediatric hospital departments, freeing up space for other essential care.



3.1.4. NEW MIGRAINE TREATMENTS REDUCE ABSENCE FROM WORK

NEW INNOVATIVE MEDICINES NOT ONLY DELIVER DIRECT CLINICAL BENEFITS FOR PATIENTS, THEY OFTEN ALSO GENERATE BROADER SOCIETAL ADDED VALUE. FOR INSTANCE, PATIENTS ARE ABSENT FROM WORK LESS OFTEN OR REMAIN MORE PRODUCTIVE. A GOOD EXAMPLE OF THIS IS THE NEW TREATMENTS FOR MIGRAINE, WHICH PROVIDE SUBSTANTIAL ADDED VALUE NOT ONLY FOR PATIENTS BUT FOR SOCIETY AS A WHOLE. TO ILLUSTRATE THIS, RESULTS FROM A SPANISH STUDY WERE ADAPTED TO THE BELGIAN CONTEXT.

A condition with major impact

Migraine is the most common neurological disorder in Belgium. Around one in five Belgians experience it, and roughly one-third of them have several migraine days each month.

The disease has a substantial negative impact on patients' social and professional lives. Almost half experience tensions in their relationship with their partner, and 13 % of young people report that their school performance suffers due to a parent's migraine. In some cases, migraine even influences choices around family planning[16]. One in three patients say migraine holds back their career, and more than 20 % fear losing their job because of it.

Because migraine mainly affects people between 30 and 50 years old – the core of the active workforce – the impact on businesses is also substantial. Migraine leads to both absenteeism (time off work) and presenteeism (reduced productivity while at work). According to Prof. Jean Schoenen, migraine results in around 65 million lost working days per year in Belgium, a burden borne mainly by employers[17].

A breakthrough in preventive care

The advent of a new generation of preventive treatments, the so-called anti-CGRP monoclonal antibodies, mark an important step forward in the treatment of migraine. These medicines act more precisely, are more effective, and are better tolerated by patients.

A large-scale Spanish study tracking migraine patients after treatment with these new medicines showed that after only three months, patients experienced a significant reduction in both headache days and migraine days. At the same time, their quality of life improved: they functioned much better and were able to participate more actively in their social and family life[18].

Economic value through reduced absenteeism and increased productivity

The benefits of anti-CGRP therapies extend far beyond clinical results. The Spanish study demonstrated that fewer headache and migraine days lead to a clear reduction in both absenteeism and presenteeism. These findings are striking: anti-CGRP therapies not only improve patients' quality of life but also generate tangible economic value, making them both medically and socially valuable.

The study focused on patients eligible for these new preventive therapies under Spanish national guidelines and the European Headache Federation's recommendations. In Spain, patients are eligible for reimbursement if they experience at least eight migraine days per month and have already tried three or more preventive treatments without success, criteria that are similar to those applicable in Belgium.

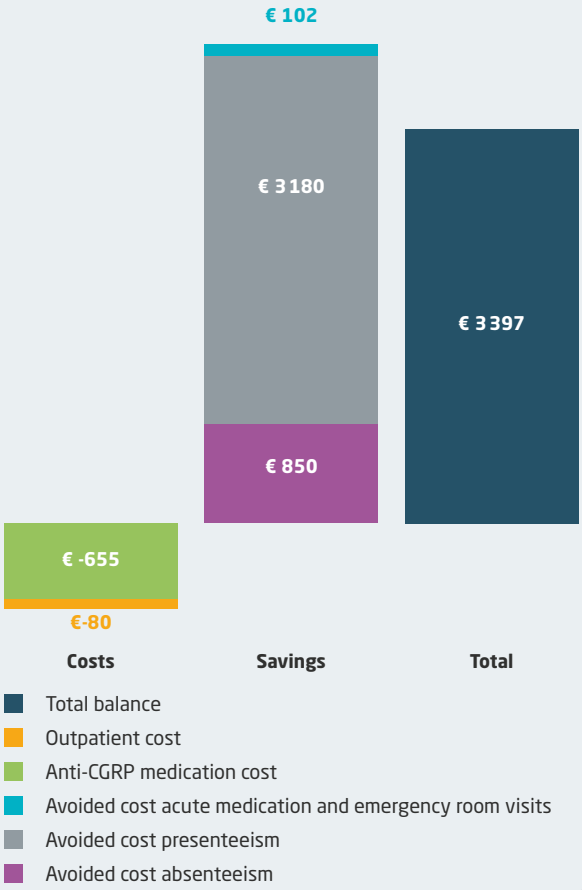
At the start of the study, patients reported an average of eighteen headache days and thirteen migraine days per month, despite the use of existing medication. After three months of anti-CGRP therapy, headache days were reduced by nearly a week, along with decreased use of acute medication. Patients who continued treatment for six months maintained these improvements.
These results are consistent with other studies evaluating the impact of this new medication, including in the Belgian context.

Cost savings and economic value

The Spanish study also examined the effect after three months of anti-CGRP treatment on the number of missed workdays and reduced productivity at work. The figures were equally impressive: absenteeism fell from 13.4 % to 8.4 %, while presenteeism improved from 42.7 % to 24.3 % – a substantial productivity gain.

Translating these findings to the Belgian context, with an adjustment for local economic parameters, and assuming a comparable impact of anti-CGRP treatment on absenteeism and presenteeism, these treatments yield an estimated saving of 850 euros (less absence) and 3 180 euros (higher productivity) per patient over three months, or a total of 4 030 euros in lower indirect costs. On top of that, there are a further 102 euros in direct savings due to reduced use of acute medication and fewer emergency admissions.

The estimated savings thus amount to 4 132 euros per patient over three months. Subtracting treatment costs (655 euros) and consultation costs (80 euros) yields a net saving of 3 397 euros per patient in the first three months.
These savings were maintained in patients who continued treatment, indicating sustained economic benefits over the longer term.



Source: pharma.be

Societal investment

While most of the costs of these treatments lie in the medicine itself, 97.5 % of the resulting savings are indirect – through greater productivity and less work loss. Although these benefits are not always visible within traditional healthcare budgets, this example of anti-CGRP treatments clearly demonstrates the substantial societal return on investment that innovative medicines can bring.

METHODOLOGY

Indirect costs

To calculate indirect costs, the Spanish study used the most recently published hourly wage in Catalonia, namely 17.93 euros. According to the Belgian KCE guidelines for economic evaluations and budget impact analyses, productivity costs must be calculated on the basis of the national average labour cost per hour. In 2024, according to Eurostat data, this cost amounted to 48.20 euros per hour. This ratio was applied to translate the Spanish study's findings to the Belgian context.

Direct costs

It was assumed that direct cost savings from reduced acute medication use and emergency admissions were comparable in both countries.

Medicine prices

Average gross prices in Belgium for anti-CGRP treatments (https://www.cbip.be/fr/chapters/11?frag=8901811) were adjusted for reimbursements under ongoing Managed Entry Agreements (MEAs). This adjustment is based on the most recent average reimbursement rate published by the NIHDI.

Outpatient consultations

It was assumed that outpatient consultation costs are comparable in both countries.

VALUE-BASED PRICING OF INNOVATIVE MEDICINES AND VACCINES

FOR THE INNOVATIONS DESCRIBED IN THE EXAMPLES ABOVE, SOCIETY PAYS A PRICE. SOMETIMES THE PATIENT ALSO PAYS A SHARE. THE PRICE OF INNOVATIVE MEDICINES HAS OFTEN BEEN A TOPIC OF PUBLIC DEBATE, REFLECTING GROWING CONCERNS ABOUT THE FUNDING AND AFFORDABILITY OF OUR HEALTHCARE SYSTEM. THESE CONCERNS ARE JUSTIFIED. PHARMA.BE THEREFORE AIMS TO SHED LIGHT ON HOW BIOPHARMACEUTICAL COMPANIES DETERMINE THESE PRICES.

Innovation as part of the solution

Population ageing is putting increasing pressure on our healthcare system. With an ageing population we are seeing not only the number of chronic diseases increase but also, for example, an increase the number of cancer cases, as cancer is increasingly age-related. The need for adequate treatments and more complex care is rising accordingly. For the healthcare system to be able to respond, biopharmaceutical innovation is crucial.

According to some, however, innovative medicines are part of the problem, not the solution. That view is incorrect. The notion that biopharmaceutical companies can simply charge whatever they like when setting prices or negotiating reimbursement is a misconception. In reality, the launch price and reimbursement are always based on the added value the medicine offers.

Value as the starting point

That added value plays out at three levels:

- For the patient: does the medicine improve health and/or quality of life?
- For the healthcare system: does the medicine replace more expensive or less effective treatments, or help prevent complications?
- For society: does the medicine contribute to herd immunity, reduce the mental and physical burden on caregivers, or lower absenteeism among patients and caregivers?

These three dimensions together form the basis on which biopharmaceutical companies propose a price for an innovative medicine. Thanks to this value-driven approach, patients gain access to innovative treatments in a way that remains affordable in the long term.

A continuous stream of better treatments

At the same time, this approach enables companies to keep investing in innovation and ensures healthcare professionals can continue relying on ever-improving treatments. The proceeds from the sale of a new medicine or vaccine enable fresh investment in research and development.

In this way, companies can continue to innovate and remain relevant in a rapidly changing world. This is crucial for the growth of biopharmaceutical companies but also for society, as their innovations offer many benefits for both health and well-being and for prosperity.

As the Office of Health Economics puts it, value-based pricing delivers a triple win:

1. Patients gain access to the latest innovations;
2. The healthcare system maintains affordability;
3. Companies receive the right incentives to keep reinvesting in R&D for new treatments.

Innovations that truly make a difference

The added value of a new medicine is the most important criterion in reimbursement discussions. However, such an assessment cannot be captured in a fixed formula or based on costs incurred. Many elements influence the assessment, and existing therapeutic options also play a role, which may vary between countries or regions. Price is therefore always the result of negotiation.

The price-setting process starts years before the launch of a new medicine or vaccine. Development often starts with a molecule that shows promise for multiple – and often very different – indications. As the R&D process progresses, the potential uses are gradually narrowed down, taking into account existing treatments and competitors' pipelines. This also involves examining existing treatments and potential solutions being developed by competitors. If the new medicine or vaccine cannot outperform what is or will soon be on the market, the project is halted. This naturally entails considerable risks for the company, but at the same time, it ensures that only innovations that truly make a difference ultimately reach the patient.

A sustainable model

A value-based approach to pricing means prioritising access to the most valuable innovations. Innovative companies receive a clear signal that they must continue to focus their R&D investments on what matters to patients and society.

This approach is not a magic solution that addresses all unmet medical needs. Sometimes, for example, scientific knowledge is still insufficient or a concept may prove unworkable in practice.

BUT WHEN A COMPANY SUCCEEDS, AFTER A LONG AND COSTLY R&D JOURNEY, IN OVERCOMING THESE CHALLENGES, A PRICE THAT REFLECTS THE VALUE DELIVERED IS THE RIGHT RECOGNITION – AND THE BEST WAY TO ENSURE PATIENTS CONTINUE TO BENEFIT FROM A STEADY FLOW OF NEW AND BETTER TREATMENTS.

3.2 A POSITIVE IMPACT ON THE ECONOMY

3.2.1. THE ECONOMIC VALUE OF THE BIOPHARMACEUTICAL SECTOR

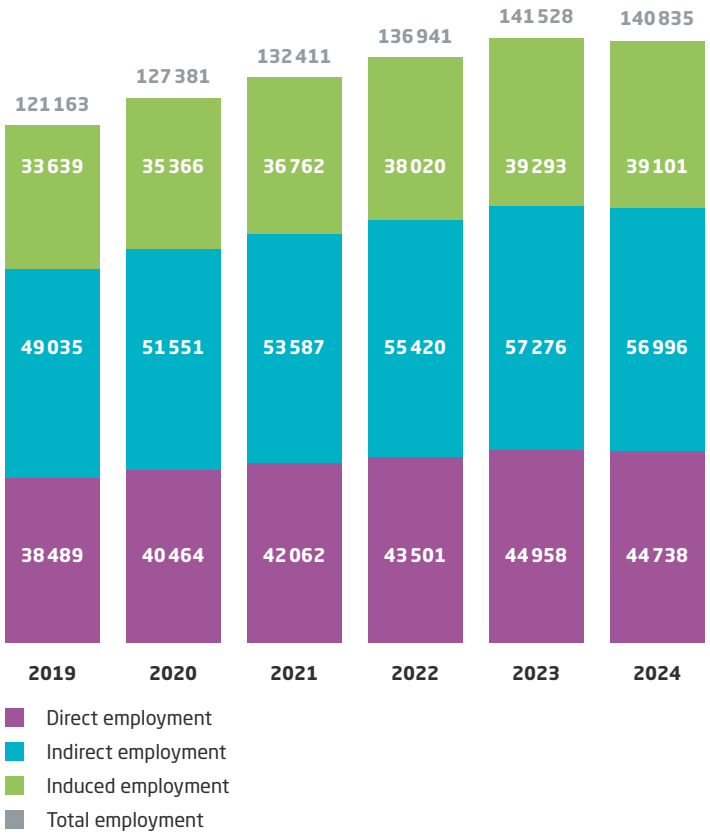
Employment

In Belgium

Year after year, the biopharmaceutical sector has shown strong positive employment growth. However, in 2024 this trend was interrupted for the first time: total employment fell by half a percent to 44 738 jobs. Over a five-year period, the sector still recorded growth of 16.2 %, and it continues to outperform the broader manufacturing industry, where employment fell by 2.1 % in 2024 and by 0.8 % over the past five years. Nevertheless, the decline in employment within the biopharmaceutical sector should be seen as an important signal that the sector's position is under pressure and that continued efforts are needed to protect and strengthen the sector.

This turning point also affects the wider ecosystem in which these companies operate, since every direct job in the sector creates more than one additional job among suppliers, such as in logistics. As a result, total indirect employment also declined. Nevertheless, the biopharmaceutical sector remains an important source of employment in Belgium. If we look beyond direct and indirect employment to include the jobs created by the spending of all these employees (both direct and indirect), the biopharmaceutical sector in Belgium generates nearly 141 000 jobs. That is almost 20 000 more than five years ago.

Evolution of direct, indirect, and induced employment in the Belgian biopharmaceutical sector



Source: pharma.be, PwC, 'Economic Footprint of the Pharmaceutical Industry in Europe', November 2024

In Europe

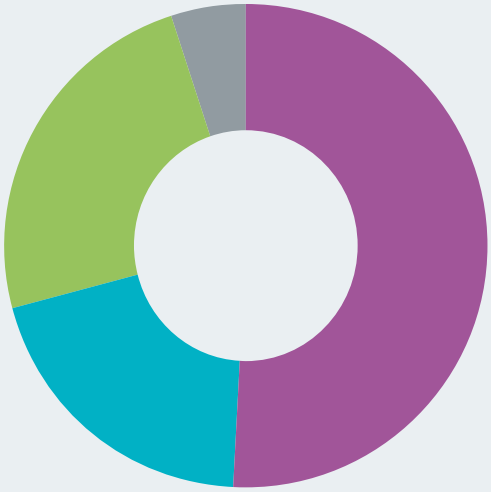
The importance of the sector becomes even clearer from a European perspective. In 2023 Belgium ranked fourth in terms of total biopharmaceutical employment (direct, indirect and induced) as a share of total national employment. It remains a strong position, though Belgium has lost some ground as other countries have grown more rapidly.

A diverse sector – a role model for our economy

The Belgian biopharmaceutical landscape is very diverse, ranging from small start-ups and highly innovative biotech companies to medium-sized family businesses, local subsidiaries of multinationals and large multinational manufacturing companies. This diversity is also reflected in employment. SMEs represent almost 90 % of the market in numbers, accounting for around a quarter of employment within the sector.

Not only are the companies within the sector diverse, the profiles the sector needs also vary widely: from roles with modest qualifications to highly skilled employees. In this knowledge-intensive sector, the number of highly educated employees is considerably higher than in other sectors: around 71 % of employees have a higher education degree. For the manufacturing industry as a whole, this is only 41 %.

Distribution of profiles in the biopharmaceutical sector in 2024



51 %	Non-university higher education (longer duration) University education Academic bachelor Academic master's degree
20 %	Non-university higher education (shorter duration) Vocational education
24 %	Higher secondary education
5 %	Lower secondary education Primary education No degree

Source: Statbel labour force survey, 2024

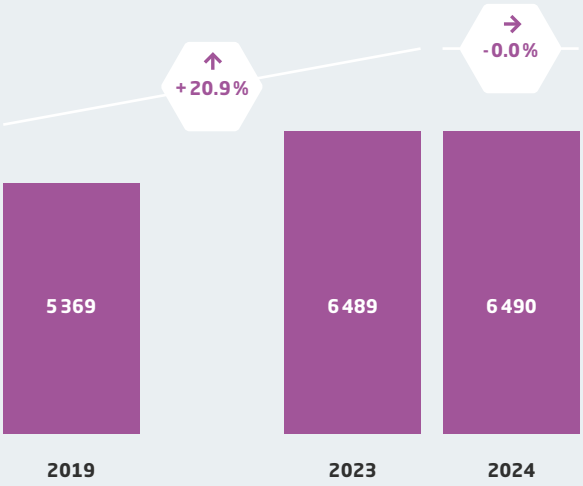
A strong foundation

The sector has an extensive pool of skilled employees to draw from in Belgium This is made possible in part by the presence of 12 universities that provide a strong educational foundation and a steady supply of highly qualified and highly productive workers. Some of these highly skilled employees are employed as researchers in R&D.

In contrast to overall employment within the sector, the number of researchers has remained stable, with 6 490 employed in the sector in 2024 – a 20 % increase over the past five years. This growth highlights the strongly innovative nature of the industry.

RESEARCHERS ARE THE CORNERSTONE OF THE BIOPHARMACEUTICAL ECOSYSTEM AND PLAY A CRUCIAL ROLE IN ITS SUCCESS.

Increase in the number of researchers in 5 years



Source: pharma.be, companies that are members and conduct fundamental research in Belgium

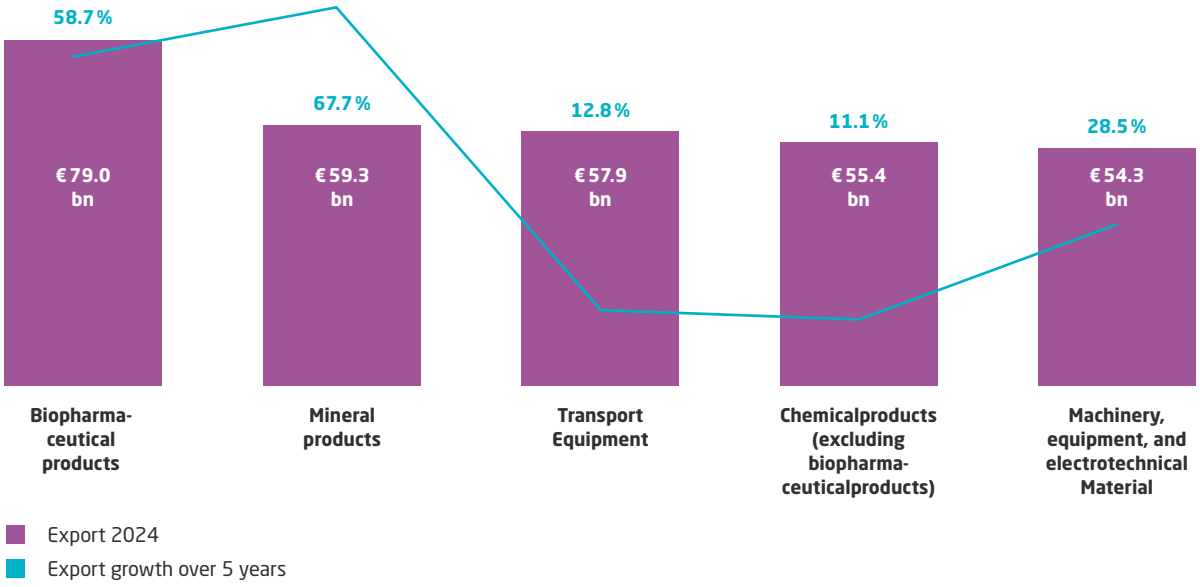
Global export

In Belgium

Thanks to a combination of strategic advantages – such as its favourable location, high-quality infrastructure, and strong biopharmaceutical industry – Belgium has become an international hub for the distribution of medicines and vaccines.

Even so, export figures declined in 2024 for the first time in years, largely due to reduced exports of COVID-19 vaccines. This drop is partly due to declining exports of COVID-19 vaccines. Excluding these, however, the sector still recorded export growth of 4.1 % in 2024. With 79 billion euros in exports, representing 15.5 % of Belgium's total exports, the biopharmaceutical sector remains Belgium's undisputed export champion.

Top 5 Belgian export sectors



Source: NBB

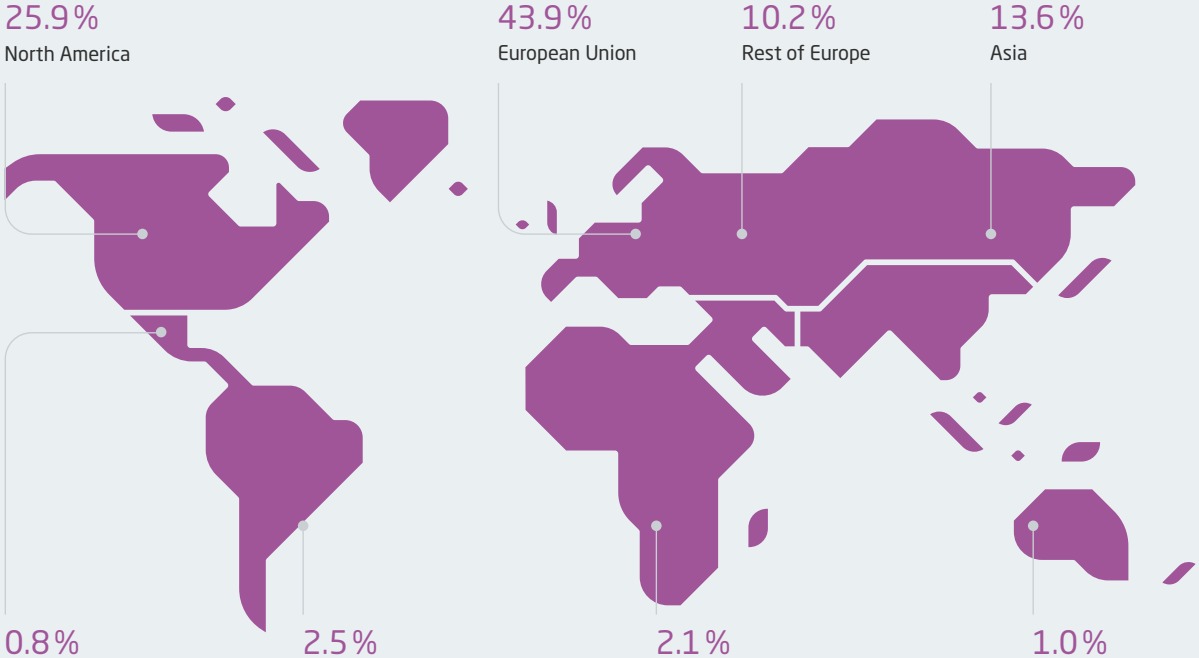
OVER FIVE YEARS, ITS EXPORT GROWTH HAS ALSO OUTPACED MOST OTHER INDUSTRIES, FURTHER REINFORCING ITS ROLE WITHIN BELGIUM'S EXPORT-DRIVEN ECONOMY.

In Europe and globally

Belgium is also performing very well from a global perspective. Within the EU, it ranks third in total biopharmaceutical exports, behind only Germany and Ireland. Adjusted for population size, it ranks third after Ireland and Slovenia. Nearly 13% of all EU biopharmaceutical exports originate from Belgium.

While less than one-third of Belgium's total exports leave the EU, more than half of its biopharmaceutical exports do. Within the EU, Germany and Italy are the main trading partners, accounting for 10.6% and 8.5% respectively. In 2024, the United States remains Belgium's leading trade partner by far, representing almost 23.9% of all Belgian biopharmaceutical exports. Together, they represent almost 23.9% of Belgium's biopharmaceutical exports. This also means the sector is heavily dependent on the US market and particularly vulnerable to trade disruptions such as new import tariffs.

EXPORT 2024



LIEGE AIRPORT, A KEY PARTNER FOR THE EXPORT OF BIOPHARMACEUTICAL PRODUCTS FROM BELGIUM

Alongside Brussels Airport and the Port of Antwerp-Bruges, which were already featured in a previous edition of the Report to Society, Liege Airport has established itself as a strategic hub for biopharmaceutical logistics in Belgium, thanks to the expertise and infrastructure of several leading operators.

Aviapartner provides modern facilities including refrigerators, freezers and a large temperature-controlled warehouse. The company is actively pursuing its CEIV recertification and is training nearly half of its staff in the specific management of pharmaceutical products.

CEIV (Centre of Excellence for Independent Validators in Pharmaceutical Logistics) certification is an international certification issued by IATA (International Air Transport Association) to ensure that players in the air logistics chain (airports, airlines, freight forwarders, warehouses, etc.) comply with the strictest standards for the transport and handling of biopharmaceutical products.

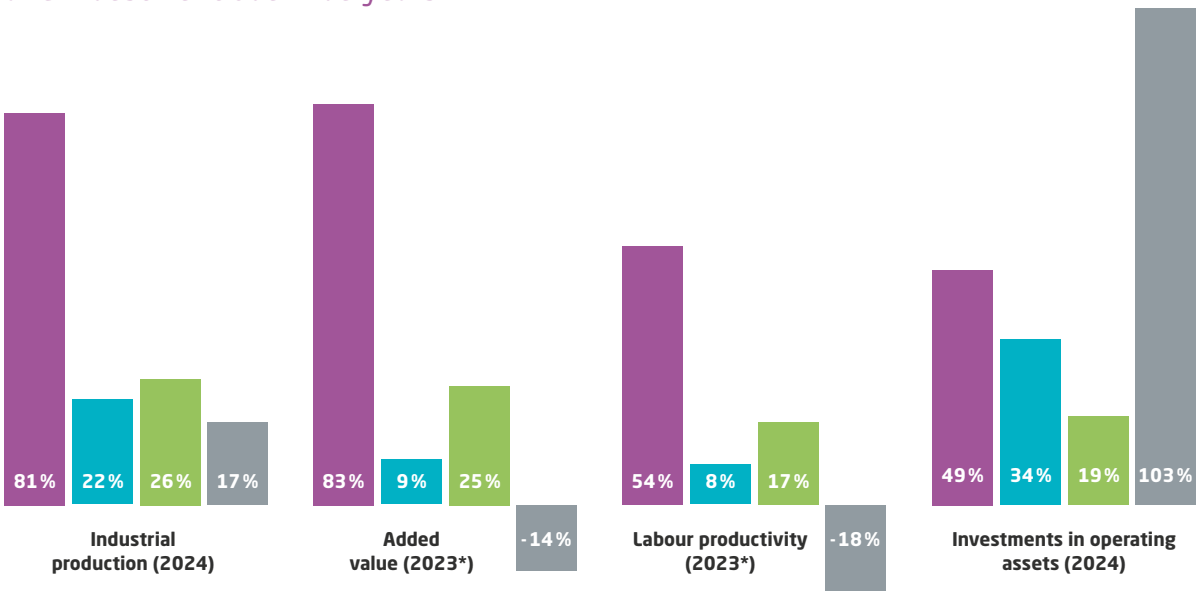
Challenge Handling, certified since 2015, has storage capacity covering all types of healthcare products, tailored packaging solutions and real-time visibility of exports, guaranteeing the traceability and security of goods. Swissport Cargo, a partner to numerous airlines, operates a 12 000 m^2 warehouse equipped with temperature-controlled rooms and a thermally controlled ULD (Unit Load Device) centre for receiving goods, placing them in suitable containers and transporting them quickly to aircraft, while ensuring that the cold chain is maintained.

Liege Airport is strengthening this offering with several hangars equipped with switchable temperature rooms, direct warehouse-runway access and the upcoming extension of its GDP (Good Distribution Practice) certification, consolidating its position as an integrated logistics platform for healthcare products. GDP certification guarantees that biopharmaceutical products are stored, handled and transported under conditions that preserve their quality, safety and efficacy throughout the supply chain.

Thanks to this combination of expertise, innovation and adapted infrastructure, Liege Airport is establishing itself as an essential link in the Belgian ecosystem and actively contributing to the rapid and efficient distribution of innovative treatments on an international scale.

Production, added value and investment

Evolution of added value, labour productivity and investment over five years



* The figures on value added and labour productivity are not yet available for 2024.

Source: NBB, Added value (at basic prices), Statbel, Industrial production index, working day adjusted index, Statbel, Turnover and investments according to VAT returns

Production

In 2024, industrial production in Belgium's overall manufacturing sector remains largely unchanged. Only four sectors show any growth, and the biopharmaceutical sector is one of them, with a notable increase of 10%. Without this growth rate, total Belgian manufacturing would have faced a production decline for the second consecutive year.

Looking at the five-year trend, industrial production in the biopharmaceutical sector has risen by more than 80%, almost three times the increase seen in the manufacturing industry as a whole. No other industry can boast such growth rates.

Added value

While total added value in Belgium's manufacturing sector declined by 4% in 2023 (figures for 2024 are not yet available), the biopharmaceutical sector achieved a 12% increase – accounting for nearly one-quarter of the total added value in manufacturing. Looking at the five-year trend, the value added by the biopharmaceutical sector has increased by more than 80%. And over the past 25 years, it has more than quadrupled.

This strong performance is largely due to the high productivity of employees in the sector. Gross value added per employee exceeds 420 000 euros, more than three times higher than that of the other sectors within manufacturing. Compared to five years ago, this represents a 50% increase, while manufacturing overall grew by only 18%.

Even in an international context, this is a very good result: employees in the Belgian biopharmaceutical sector thus rank second within the EU-7 countries. Compared with the EU-27 as a whole, Belgium's result is more than twice as high.

GROSS ADDED VALUE PER EMPLOYEE (2023)

420 802 euros
Biopharmaceutical sector

184 567 euros
Chemical industry

116 642 euros
Manufacturing industry excluding the biopharmaceutical sector

106 255 euros
Food industry

Source: NBB, Value added (at basic prices), NSSS, Employment

Investments in fixed assets

These performances are thanks in part to the enormous efforts in R&D and the ongoing investments in fixed assets. These are investments in land, buildings, installations, machinery, and equipment – for example, to expand production capacity or to implement more sustainable and environmentally friendly production methods.

In 2024, the biopharmaceutical sector accounted for nearly 9 % of all capital investments made by the manufacturing industry in Belgium. Over a five-year period, investment in fixed assets within the biopharmaceutical sector has increased by roughly half. By comparison, growth in the manufacturing industry as a whole has been just 35 %.

A striking example of this commitment is the investment in Europe's first CAR-T cell therapy production site, located in Belgium – a clear demonstration of the sector's dual role as a driver of both public health and economic growth.

JULIE HAS A PASSION FOR PHARMA

WHAT DOES 'MADE IN BELGIUM' MEAN TO ME? IT MEANS EXCELLENCE – WORLD-CLASS QUALITY!

With over 30 state-of-the-art sites across Belgium, we produce innovative medicines every day for patients around the world. Our expertise is valued and recognised worldwide. Pharmaceutical manufacturing is not just about making medicines. It is about cutting-edge technology, innovation, reliability, etc. – and above all, the dedication of thousands of colleagues who give their best every single day. You can feel that quality in the end product, but also in every step of the manufacturing process. That is what makes the Belgian pharmaceutical industry one of the best – if not the best – in the world.

JULIE RIVIÈRE-LORPHÈVRE,
Head of Manufacturing Sciences

DISCOVER THE PASSION OF JULIE AND HER COLLEAGUES IN THE BIOPHARMACEUTICAL SECTOR

EUROPE'S FIRST CAR-T CELL THERAPY PRODUCTION SITE OPENS IN BELGIUM

A LANDMARK INVESTMENT HAS BEEN MADE IN BELGIUM WITH THE ESTABLISHMENT OF EUROPE'S FIRST CAR-T CELL THERAPY PRODUCTION SITE BY JOHNSON & JOHNSON (J&J) AND LEGEND BIOTECH. CAR-T CELL THERAPIES ARE INNOVATIVE, PERSONALISED TREATMENTS IN WHICH A PATIENT'S OWN T-CELLS ARE REPROGRAMMED TO ACTIVELY AND SPECIFICALLY TARGET CANCER CELLS.

This breakthrough not only offers new treatment options for patients but also confirms the innovative strength of Belgium's biopharmaceutical sector and its ability to attract major investment.

Belgian roots

To start production as quickly as possible, investments were made both in an existing brownfield site in Ghent and in a completely new 22 000 m^2 greenfield site. These investments in Ghent have not only expanded production capacity, they have also laid the foundation for a strong engagement with the East Flanders biotech cluster.

In addition, a quality control centre and cryopreservation laboratory were built in Beerse. The latter handles the first stage of the production process – freezing the patient's unprocessed T-cells – thereby fully anchoring the entire cell therapy production chain in Belgium.

Through these strategic investments, Belgium is positioning itself as a key centre for CAR-T therapy production and distribution, serving not only Europe but also the Middle East and Africa.

Strong foundations for economic growth

The decision to locate this facility in Belgium underscores the country's strengths for the biopharmaceutical sector: its central position, highly skilled workforce and healthcare professionals, and its network of renowned universities and research institutions. Together, these provide a solid foundation for both R&D and production, essential for the industry's sustainable growth.

The investments help strengthen the local biotech cluster and make an important contribution to the Belgian economy. In this case, setting up the CAR-T cell production chain has also gone hand in hand with a significant increase in employment. Since 2022, more than 1 000 new jobs have already been created, with further growth ahead. Moreover, each direct job in the sector generates almost three additional indirect and induced jobs, underlining the broader economic and social impact.

THESE EFFORTS DEMONSTRATE THE SECTOR'S COMMITMENT TO SUSTAINABLE INNOVATION AND BETTER PATIENT CARE – IMPROVING LIFE EXPECTANCY AND QUALITY OF LIFE WHILE CONTRIBUTING TO THE NATION'S SOCIAL AND ECONOMIC PROSPERITY.

3.2.2. COST-BENEFIT ANALYSIS FOR THE BELGIAN GOVERNMENT

The direct economic impact of a strong biopharmaceutical sector in Belgium is clear. **The presence of the sector** also has a **positive impact on public finances**, as shown in the following calculation based on 2024 statistics.

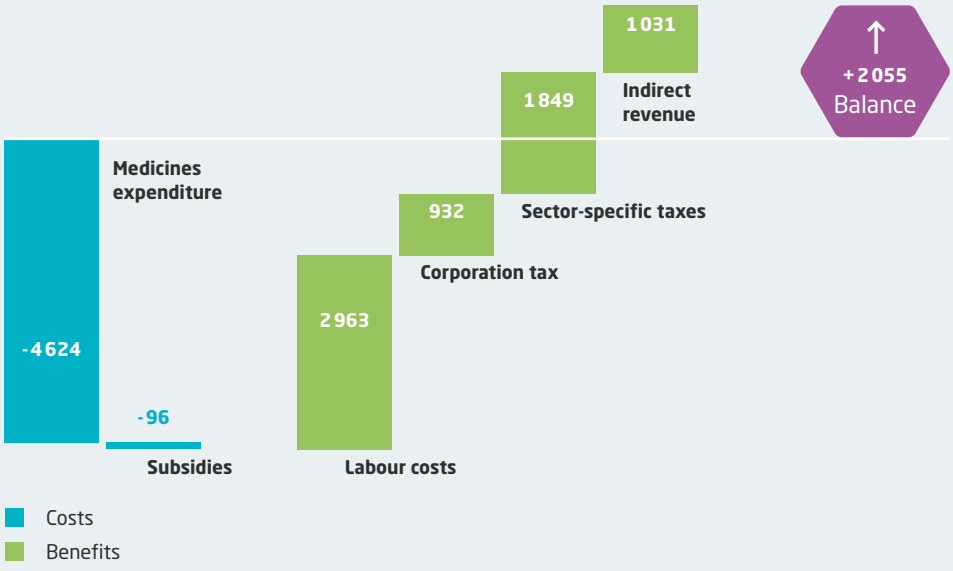
To conduct this cost-benefit analysis (see also Appendix 1), the first step is to take into account the government's expenditure on medicines. These costs are reimbursed by the NIHDI and include expenditures on all reimbursed medicines. Government expenditure in the form of subsidies to the biopharmaceutical sector is also included here. In total, these expenditures amount to 4.7 billion euros.

However, the biopharmaceutical sector also generates substantial revenues for the government through:

1. Labour taxes, amounting to almost 3.0 billion euros;
2. Sector-specific levies (such as turnover taxes);
3. Corporate income tax;
4. Revenues linked to the wider economic chain created by the biopharmaceutical sector.

IN TOTAL, REVENUES FOR THE GOVERNMENT AMOUNT TO 6.8 BILLION EUROS

Costs and benefits of the biopharmaceutical sector for Government Finances



Source: pharma.be

This comparison between government expenditure and revenue shows that the biopharmaceutical sector's contribution to national revenue is substantially higher than the amount Belgium spends on the sector. The surplus amounts to more than two billion euros. A comparison with other countries shows that this position is unique, and one that many nations envy.

04 HOW WE OPERATE

4.1. TAKING RESPONSIBILITY

4.1.1. A STRICT ETHICAL FRAMEWORK

Ethical principles have been at the heart of pharma.be's mission for half a century, particularly in its interactions with others.

Essential cooperation with healthcare professionals

From research and development to long after a medicine has reached the market, biopharmaceutical companies work closely with physicians and other healthcare professionals. This collaboration is not only legitimate, but also essential. As the first point of contact for the patient, healthcare professionals have invaluable practical experience. Their insights are crucial for developing treatments that respond ever more effectively to patients' needs. Conversely, companies have a duty to inform healthcare professionals about new therapies. This ensures that every patient receives the best possible treatment.

Strictly regulated and transparent collaboration

In Belgium, interactions between healthcare professionals and the biopharmaceutical sector are strictly regulated. This safeguards the independence of both parties and ensures that collaboration always focuses on what truly matters: sharing knowledge, stimulating scientific research and improving patient care.

The sector bears great responsibility for the nation's health and quality of life, operating within a robust legal framework covering everything from medicines legislation to competition law, intellectual property, data protection, and anti-bribery rules. Transparency, integrity and quality are central to this.

Half a century of ethical commitment

At pharma.be, we take that responsibility to heart. For half a century, our members have adhered to ethical principles that go well beyond the legal minimum standards. Care, justice, respect and honesty are the guiding principles in everything we do, shaping our interactions with academia, government, healthcare professionals, patients, and patient organisations. Only through strong, principled collaboration can we develop effective and innovative treatments that always put patients first.

Our Ethos.
Build a culture of trust

Source: www.ifpma.org

The Code of Ethics: a living commitment

A pioneer in ethical standards

These core values have been formally upheld since pharma.be's inception. Nearly 50 years ago, pharma.be became Belgium's first business federation to adopt its own Code of Ethics. In 1976, we became the first association within an industrial sector to require our members to comply with a strict ethical code. Indeed, pharma.be's code is a condition of membership.

And although the core values have remained the same, the way they are expressed in the Code of Ethics has evolved over time. The rapid pace of scientific, technological, and social change continually introduces new ethical challenges that require new solutions.

Industry responsibility through self-regulation

In addition to the legal framework, pharma.be deliberately embraces self-regulation. By developing, enforcing, and continually reviewing its own standards, the sector can respond faster to emerging challenges and societal expectations – demonstrating that it takes these expectations seriously. Self-regulation remains a cornerstone of ethical conduct in our sector and enables a faster response to new developments, such as the growing role of patient participation, digitalisation and sustainability. It is a privilege that requires transparency, accountability and continuous improvement, and one that retains legitimacy only through shared commitment across the sector.

A continually renewed commitment

The code is not static: it evolves alongside a rapidly changing scientific, technological and societal landscape. In 2024, it underwent a major revision, followed by additional updates in 2025, with special emphasis on enhanced collaboration with patients and patient organisations.

WRITING ETHICAL GUIDELINES IS ONE THING; APPLYING THEM ROBUSTLY IN PRACTICE IS ANOTHER. AS PART OF QUALITY CONTROL, WE HAVE ESTABLISHED SEVERAL MECHANISMS TO SUPPORT MEMBERS IN THEIR INTERACTIONS WITH HEALTHCARE STAKEHOLDERS – INCLUDING THE BUREAU FOR CONTROL ON WRITTEN COMMUNICATION (BCWC) AND A DEDICATED COMPLAINTS PROCEDURE.

pharma.be's Code of Deontology

BCWC – Ensuring accuracy in written communication

THE BUREAU FOR CONTROL ON WRITTEN COMMUNICATION (BCWC) IS AN INDEPENDENT BODY THAT ENSURES THAT WRITTEN COMMUNICATION FROM OUR MEMBER COMPANIES TO HEALTHCARE PROFESSIONALS ABOUT THEIR MEDICINES IS CORRECT, COMPLETE AND IN LINE WITH APPLICABLE LEGISLATION AND OUR CODE OF ETHICS.

Purpose and origin

In Belgium, advertising for medicines for human use is strictly regulated. The legislation aims to promote rational use of medicines based on objective, correct and complete information. To support our members in this, the BCWC was established fifteen years ago. Comprising a lawyer, a doctor, and a pharmacist, the bureau reviews and guides companies to ensure fair, high-quality communication. This form of self-regulation is unique in the world.

Why communication with healthcare professionals?

Biopharmaceutical companies invest an average of ten to twelve years in developing a new medicine. During this process, they gather extensive scientific knowledge, which they share with healthcare professionals to support them in guiding patients and promoting appropriate medicine use. It is important to note that the BCWC focuses exclusively on communication intended for professional healthcare providers, not on patient information.

The process

Each year, fifty medicines are selected at random, each from a different pharma.be member company. The companies concerned provide all written communication relating to the selected medicine. The BCWC assesses these materials for compliance with legal requirements and the Code of Ethics, verifying that essential information is present, clear, balanced, and not misleading.
Companies first receive a preliminary report and, following feedback and adjustments, a final report to guide further improvement. This enables companies to improve their communication in a targeted way.

Beyond supervision

In addition to its supervisory role, the BCWC serves as an adviser and sounding board. It closely follows legislation and communication trends, including online and cross-media communication, and formulates recommendations to further improve quality. Each year, the BCWC publishes a report with summaries of evaluations, recommendations and best practices, helping member companies develop effective and responsible promotional material.

Ethical principles

Through this supervisory process, pharma.be members take responsibility for sharing scientific information and ensuring its quality. The BCWC thus helps uphold one of the three core ethical principles outlined in pharma.be's Code: "Member companies strive to ensure that the information in promotional materials presents a balanced view of the risks and benefits of their medicines and supports their appropriate use. Advertising must be ethical, accurate, balanced and not misleading."

THE BCWC ANNUAL REPORT 2024: FIGURES, CONCLUSIONS AND TIPS

Figures

- The BCWC analysed fifty medicines from fifty different members;
- In 64 % of cases, audited members provided comments and/or additions to the draft report;
- Fifty final reports were prepared.

General Conclusion

In 2024, pharma.be members generally adhered well to ethical and regulatory requirements for written communication.

The fact that 64 % of members responded to the preliminary reports demonstrates that companies prioritise clear and high-quality communication. Most responses either confirmed the implementation of necessary adjustments or offered further clarification.

We have seen a high level of willingness among companies to be transparent about the evaluation of their written communications by the BCWC.
The BCWC, in turn, strives for that same transparency by sharing its comments and observations openly and directly through its conclusions.
In 2024, more than 60 % of the companies that received these conclusions responded and shared their comments with the Bureau.
These responses underline how strongly pharma.be members value the dissemination of high-quality information and advertising that meet both legal and ethical standards.

MARC VAN GRIMBERGEN,
Chair, BCWC

Tips

Multiple communication channels are now used more frequently. This requires extra care to ensure that information remains accurate and easily accessible everywhere. For example, companies do not always repeat the price or other essential elements in online communications but instead include a link to that information. This makes it easier to keep the information up to date, but it should not require readers to go searching for it. The BCWC therefore requests that the link lead directly to the relevant data, without the need for multiple clicks.

Graphic representations are frequently used as well. These can convey information more quickly but, like the written text, must be clear and complete. The BCWC recommends providing additional explanations for graphs and similar visuals where necessary, to avoid confusion or misinformation.

The use of technical terms or specific abbreviations also poses a risk of confusion or misinformation. While such terms may be well established within biopharmaceutical companies, readers are not always familiar with them, or they may interpret them differently. The BCWC recommends clarifying specific terms and abbreviations.

A DIGITAL VERSION OF THE 2024 REPORT CAN BE REQUESTED VIA **DEONTO@PHARMA.BE**.

The complaints procedure: accessible and solution-oriented

DEP and appeals procedure

Any individual or legal entity that identifies a breach of our Code of Ethics may submit a written complaint to the Secretariat of the Code of Ethics. The Committee for Deontology and Ethics in the Pharmaceutical Industry (hereinafter referred to as the 'DEP Committee') handles these complaints. If the DEP Committee's decision is appealed, the matter is reviewed by the Appeals Chamber. These ethical bodies are independent of pharma.be. They are comprised of:

- A chairperson with legal expertise who is not active in the pharmaceutical industry;
- A member representing the pharmaceutical industry (products for human or veterinary medicine), depending on the product/issue;
- A non-industry member representing either the medical/pharmaceutical sector, or the scientific/academic community.

This composition reflects a strong trend towards the externalisation of self-regulatory procedures within the pharmaceutical sector. The involvement of representatives from all healthcare stakeholders, together with impartial legal experts (including former judges from the highest courts), offers a clear advantage in terms of independence and aims to further professionalise such procedures.

If the DEP Committee or Chamber of Appeal finds a breach of the code, they can impose appropriate sanctions, such as the immediate cessation of the practice, corrective or additional measures, a payment to the King Baudouin Foundation, or publication of the decision.

Additional role for the BCWC: informal complaints procedure

In 2024, this procedure was updated following consultations with patients and patient organisations. Given the increasing collaboration between patient organisations and innovative biopharmaceutical companies, it was important to create a level playing field in the event of disputes. The complaints procedure was therefore made more accessible at their request: it now allows for informal exchanges and mediation, led by the BCWC chair, when doubts arise about whether a pharma.be member is properly complying with the code. This low-threshold procedure makes it possible to reach a constructive resolution in an open manner, without legal barriers.

The DEP procedure also provides a more accessible option when no agreement is reached

If the mediation meeting still does not lead to an agreement, the parties can always initiate a formal procedure before the DEP Committee (as described above). The revised Code of Ethics provides that this DEP procedure, like the mediation process, remains free of charge for the patient or patient organisation and can be conducted in the language of their choice. Unlike before, they are no longer bound by the language of the pharma.be member's registered office.

Through this update to its Code of Ethics, pharma.be reaffirms its commitment to an ethical, transparent and sustainable collaboration with patients and patient organisations. Interested parties can request extracts of decisions via **deonto@pharma.be**. However, communication of such extracts always requires the prior consent of the parties involved.

4.1.2. RESPONDING TO URGENT PATIENT NEEDS

COMPASSIONATE USE AND MEDICAL NEED PROGRAMMES MAKE IT POSSIBLE, IN EXCEPTIONAL CASES, TO ADMINISTER A MEDICINE THAT HAS NOT YET BEEN APPROVED BY THE EMA BECAUSE THE AUTHORISATION PROCEDURE IS STILL ONGOING. THESE PROGRAMMES ARE INTENDED FOR PATIENTS SUFFERING FROM CHRONIC OR SERIOUS DISEASES WHO CANNOT BE TREATED WITH A MEDICINE THAT IS ALREADY AVAILABLE ON THE MARKET.

Belgium implemented European Regulation 726/2004 (Article 83) in 2014 through new legislation introducing the concept of compassionate use. At the same time, the country took the opportunity to broaden the legal framework to include medical need programmes.

The main difference between these two programmes has to do with marketing authorisation:

- **Compassionate use programmes (CUPs)** concern medicines for which no marketing authorisation has yet been granted;
- **Medical need programmes (MNPs)** concern medicines that already have a marketing authorisation for a specific indication but are used for a second or third indication that has not yet been approved.

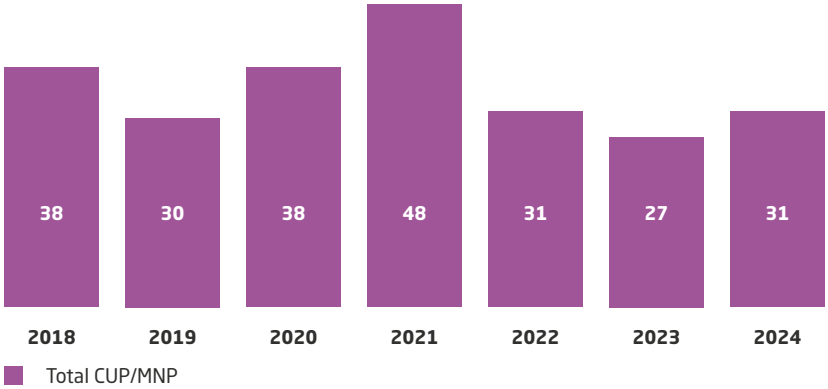
To give patients early and free access to the latest treatments before the European registration procedure has been completed, the FAMHP must grant a temporary permit, or Early Temporary Authorisation (ETA).

Because the EMA has not yet approved the medicine for the market, the FAMHP must carefully weigh its potential benefits against the risks, as well as any available alternatives. If the application is approved, the company provides the new medicine free of charge to patients enrolled in the programme at the request of their doctor. The programmes continue until the medicine becomes available on the market for the indication concerned.

This exceptional availability is fully transparent: all approved programmes are published on the FAMHP website, where patients and healthcare professionals can consult them.

BY THE END OF JULY 2025, ALMOST 47 PROGRAMMES WERE ONGOING

Number of CUP and MNP applications submitted to the FAMHP over the past seven years



Source: FAMHP

This CUP and MNP system will soon be strengthened by new legislation regulating early and free access to medicines for patients (see next section).

4.1.3. THROUGH EDUCATION AND DIALOGUE

pharma.be closely involved in initiatives for faster access to innovative medicines

IN 2022, THE NIHDI LAUNCHED AN EXTENSIVE CONSULTATION TO TRANSFORM THE BELGIAN REIMBURSEMENT PROCESS FOR MEDICINES INTO AN INNOVATIVE, FAST AND FUTURE-PROOF SYSTEM WITH TRANSPARENT AND INCLUSIVE DECISION-MAKING. PHARMA.BE TOOK PART IN THESE DISCUSSIONS, WHICH LED TO A ROADMAP FOR REFORM THAT ENTERED INTO FORCE GRADUALLY ON 1 JANUARY 2025 AND IS DUE TO BE FULLY IMPLEMENTED WITHIN TWO YEARS.

One of the next major steps is **a new system for accelerated temporary access to groundbreaking medicines from 1 January 2026,** pending final reimbursement. Given the rapid evolution of medical science and biopharmaceutical innovation, this could have a substantial impact on patients with serious or rare diseases who have few or no treatment options.

The revised process includes:

- An 'early' access route through improvement of the Unmet Medical Need procedure (before European marketing authorisation), enabling patients to be treated up to 17 months earlier;
- A 'faster' access route through the integration of a new procedure (after European marketing authorisation) enabling breakthrough medicines to reach patients up to 10 months earlier.

Key building blocks of the reform:

1. **An active role for the patient**
   For the first time, patients and patient organisations are directly involved in evaluating access to medicines and can propose new indications to be added to the list of unmet medical needs, just like companies and other stakeholders;

2. **An active role for the physician**
   In addition to submitting an application to the NIHDI advisory committee (CATT) to include a patient in this new program, the treating physician will also be asked to enter data in accordance with the protocol for use and therapeutic follow-up. Moreover, physicians can, through their professional associations, be consulted as ad hoc experts during the procedure and can submit proposals to add indications to the list of unmet medical needs;

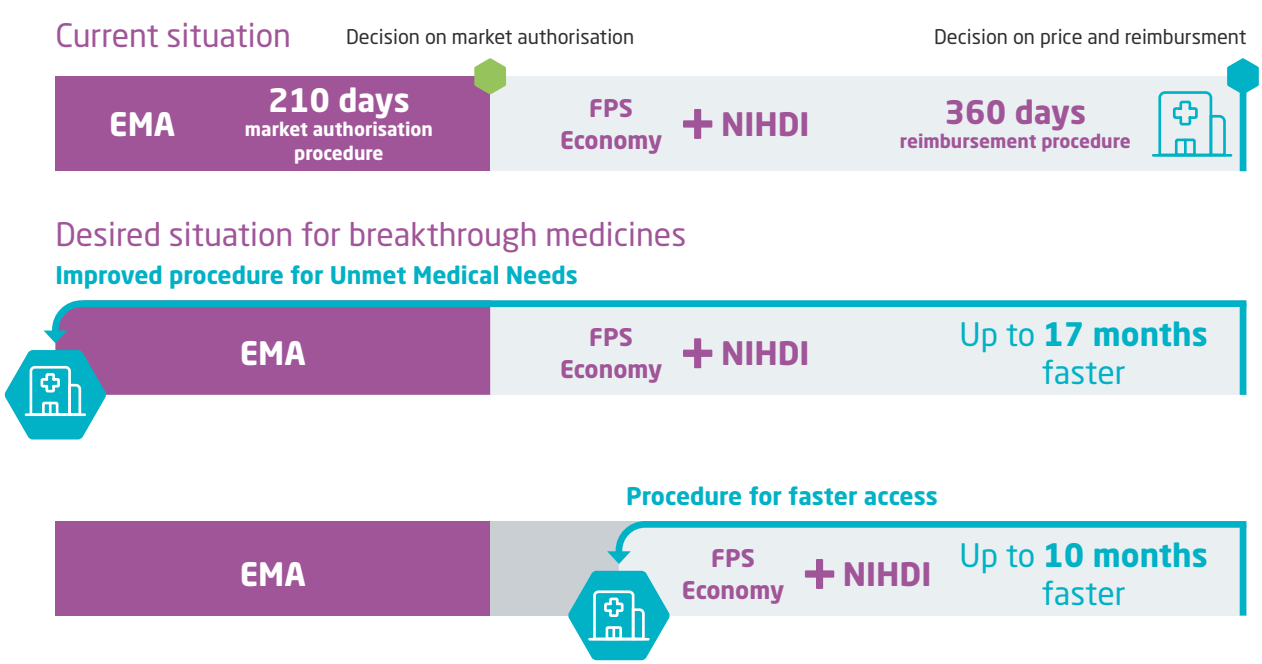
3. **Strengthening early dialogue**
   It is crucial to start an early dialogue between the authorities and the biopharmaceutical industry in order to better align expectations and intentions;

4. **Voluntary participation in this process**
   Participation is voluntary, which can be important, for example, to avoid jeopardising a randomised clinical trial;

5. **A clear exit strategy**
   Fair compensation and a clear exit strategy with shared responsibility if a negative reimbursement decision should later follow;

6. **A high-quality and representative data collection**
   A **high-quality and representative data collection** is set up in co-creation between the government and industry, in collaboration with representatives of physicians, pharmacists and patients. The key words are feasibility and shared responsibility in both the design and financing of the project.

PHARMA.BE IS ALREADY SUPPORTING THE ROLL-OUT OF THIS IMPORTANT REFORM SO THAT TOMORROW'S INNOVATIONS REACH THE PATIENT QUICKLY AND AFFORDABLY.



Source: NIHDI

pharma.be provides input for the new KCE guidelines for economic evaluations and budget impact analyses

On 8 May 2025, the Federal Knowledge Centre for Healthcare (KCE) published the third edition of the Belgian guidelines for economic evaluations and budget impact analyses[19]. pharma.be and its members were involved in their preparation. These guidelines form the foundation for evaluating the reimbursement of new medicines and other healthcare interventions.

However, the impact goes far beyond purely technical assessments:

- The guidelines also support policymakers in making informed choices that enable the sustainable use of public funds;
- At the same time, they offer the biopharmaceutical industry a predictable framework, which can stimulate collaboration and innovation within clear boundaries;
- For healthcare professionals, the guidelines provide important information on assessing the added value of new treatments, helping them make therapeutic choices in the patient's interest;
- For patients, the guidelines provide access to effective and cost-efficient treatments.

The intensive preparation for the revision of the guidelines started in March 2024, and pharma.be and its members were invited to provide input. We shared our experiences with the application of the current guidelines, identified uncertainties and shortcomings, and made recommendations on which aspects should be explicitly clarified.

> With these guidelines we want to provide as much support as possible to anyone who draws up study protocols, carries out economic evaluations and budget impact analyses, or assesses these analyses.

MATTIAS NEYT,
Senior Expert in Economic Analysis,
Federal Knowledge Centre
for Healthcare (KCE)

pharma.be actively involved in the development of a new national cancer plan for Belgium

At the beginning of 2021, the European Commission launched Europe's Beating Cancer Plan (EBCP), an ambitious action plan against cancer. To seize this European momentum, pharma.be set up a focus group to advocate in Belgium for a new national cancer plan with clear, measurable goals and the associated resources.

We are convinced that such a plan is needed to join patients in the fight against cancer. A strong national cancer plan helps improve care for cancer patients in Belgium, ensures rapid and fair access to innovative treatments, and stimulates collaboration across the various policy levels.

That is why pharma.be and several member companies are actively participating in BE EBCP, the Belgian mirror group of the European cancer plan. We also support initiatives by Sciensano's Cancer Centre, such as the benchmarking survey launched in early 2025. The aim of this survey was to map current needs and gaps in cancer policy and to identify relevant objectives to improve outcomes for cancer patients in Belgium.

HOWEVER, OUR WORK DOES NOT STOP WITH THE LAUNCH OF A NEW BELGIAN CANCER PLAN. TOGETHER WITH THE FOCUS GROUP AND MEMBER COMPANIES, PHARMA.BE WILL ENSURE THAT THE PLAN DOES NOT STOP AT FINE – AND HOPEFULLY AMBITIOUS – WORDS, BUT IS ACTUALLY IMPLEMENTED. THE IMPACT OF SUCH A PLAN STANDS OR FALLS WITH ITS EXECUTION. IN ADDITION, AS A KEY FIGURE IN THE BELGIAN ECOSYSTEM, PHARMA.BE WANTS TO CONTINUE ENCOURAGING POLICYMAKERS TO TAKE THE NECESSARY STEPS SO THAT PATIENTS IN OUR COUNTRY CAN FACE CANCER WITH EVEN BETTER PROSPECTS.

pharma.be is meanwhile recognised within the Belgian ecosystem as an expert in the fight against cancer:

- The Health and Equal Opportunities Committee of the Chamber of Representatives asked pharma.be in early 2025 for a written opinion on a draft resolution concerning the systematic fight against cancer (56K0350). In that opinion, pharma.be supports the proposal; at the same time, we ask for additional attention to:
  - Prevention strategies tailored to different target groups;
  - High-quality data recording;
  - An innovative framework for diagnosis;
  - Measures to further improve access to innovative treatments;
  - Maintaining and strengthening our country's leading role in clinical trials;
- Sciensano's Cancer Centre developed a framework for monitoring the implementation of the EBCP in EU Member States and therefore interviewed pharma.be at the end of February 2025 about Belgium's experience participating in the EBCP.

With the inclusion in the 2025-2029 federal coalition agreement of a commitment to develop a new national cancer plan, and with the Minister of Health, Frank Vandenbroucke, setting a deadline of the end of 2025 for a first version, pharma.be and the focus group have further intensified their efforts.

In September, pharma.be took part in stakeholder workshops, where the Belgian ecosystem could provide input for the new national cancer plan. In this way, pharma.be actively contributed on the topics of prevention and health promotion, early detection and screening, diagnosis and treatment, quality of life and survival, data innovation and CAYA (Children, Adolescents and Young Adults).

4.1.4. PROMOTING THE GOOD USE OF MEDICINES

MEDICINES PLAY AN IMPORTANT ROLE IN IMPROVING AND PROTECTING OUR HEALTH. BUT THEY CAN ONLY WORK EFFECTIVELY WHEN USED APPROPRIATELY. THAT MAY SOUND OBVIOUS, YET IN PRACTICE IT OFTEN GOES WRONG – PEOPLE TAKE THEIR MEDICINES INCORRECTLY, TOO INFREQUENTLY, OR TOO OFTEN.

Why appropriate use matters

There are few concrete figures on treatment adherence in Belgium, but the World Health Organisation (WHO) has estimated that worldwide, more than half of patients do not take their prescribed medicines properly.

This worrying number could rise further in the coming years, as we face growing challenges such as patients who consciously refuse treatment, the spread of misinformation, and increasing pressure on healthcare budgets.

Yet appropriate use of medicines brings many direct and indirect benefits:

- Better health: appropriate use of medicines increases the chance of curing or preventing diseases;
- Fewer treatment failures: appropriate use keeps therapies effective and prevents issues with drug effectiveness such as antibiotic resistance;
- General confidence: when medicines prove their effectiveness, public trust in treatments grows;
- Less waste: appropriate use avoids unused or expired medicines and the need for additional treatments;
- A sustainable healthcare system: patients who follow their therapy properly require less care overall, which benefits the healthcare system as a whole.

The role of the biopharmaceutical sector

It is clearly in everyone's interest to encourage the appropriate use of medicines. The biopharmaceutical sector has long recognised this. Alongside providing safe, high-quality medicines, our member companies systematically promote correct usage.

They do this in various ways:

- Research: Even before a medicine reaches the market, our companies determine the optimal dosage with the fewest side effects;
- Support: After a medicine is launched, our companies continue to support patients in the appropriate use of medicines, for example, by improving ease of administration;
- Information: Our companies provide clear and accessible information on the importance of appropriate use, for both patients and healthcare professionals. This is done not only via the package leaflet, but also through brochures, websites, apps or tutorials.

Shared responsibility

At pharma.be, we will continue to actively promote the appropriate use of medicines in the future, but we cannot do this alone. If we want to give appropriate use a real boost, joint efforts are needed: not only from the biopharmaceutical sector, but also from policy makers, healthcare professionals, patients and their support network. Only through collaboration can we maximise the positive effects of appropriate use.

CAMILLE HAS A PASSION FOR PHARMA

We consider it extremely important that medicines are used appropriately: at the right time, in the right dose and in the right way. To support treatment adherence, the sector works with physicians, pharmacists, health insurance funds, patient organisations and other stakeholders, because clear and understandable information is essential. Think, for example, of clear patient leaflets, instructional videos and awarenessraising campaigns to support people in the appropriate use of their medicines.

IN THIS WAY, WE ENSURE SAFE AND APPROPRIATE USE OF MEDICINES AND AVOID UNNECESSARY COSTS FOR OUR HEALTHCARE SYSTEM.

CAMILLE ROELENS,
Patient Engagement Manager

DISCOVER THE PASSION OF CAMILLE AND HER COLLEAGUES IN THE BIOPHARMACEUTICAL SECTOR

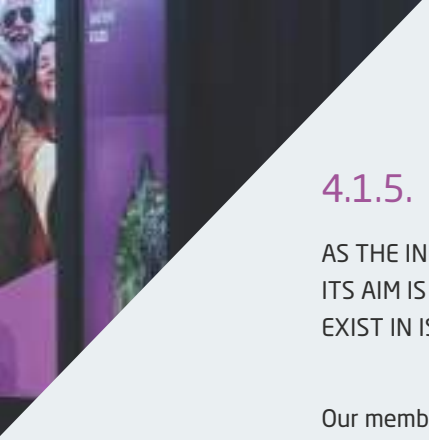
GOOD USE OF MEDICINES: UNLOCK POTENTIAL FOR BETTER HEALTH

ON 7 OCTOBER 2025, PHARMA.BE BROUGHT TOGETHER A BROAD GROUP OF STAKEHOLDERS AT THE EVENT *'GOOD USE OF MEDICINES: UNLOCK POTENTIAL FOR BETTER HEALTH'.* THE DAY FOCUSED ENTIRELY ON HOW WE CAN JOINTLY IMPROVE MEDICINE USE, FOR THE BENEFIT OF PATIENTS, HEALTHCARE PROFESSIONALS AND SOCIETY AS A WHOLE.

Key lessons from the event:

- **Treatment adherence is the key to public health**
  Effective interventions that improve adherence have a greater impact on public health than individual treatment improvements alone. The appropriate and consistent use of medicines must therefore remain a social, economic and political priority;
- **Collaboration and data are the driving force behind progress**
  An integrated, data-driven approach and close collaboration between healthcare professionals, policy makers and industry are crucial to achieve better health outcomes;
- **Education, innovation and patient centred care are central**
  Future strategies must focus on education, innovative solutions and care that starts from patients' needs. Only in this way can we ensure sustainable and inclusive healthcare.

Event recap



4.1.5. CARING FOR THE ENVIRONMENT AND THE CLIMATE

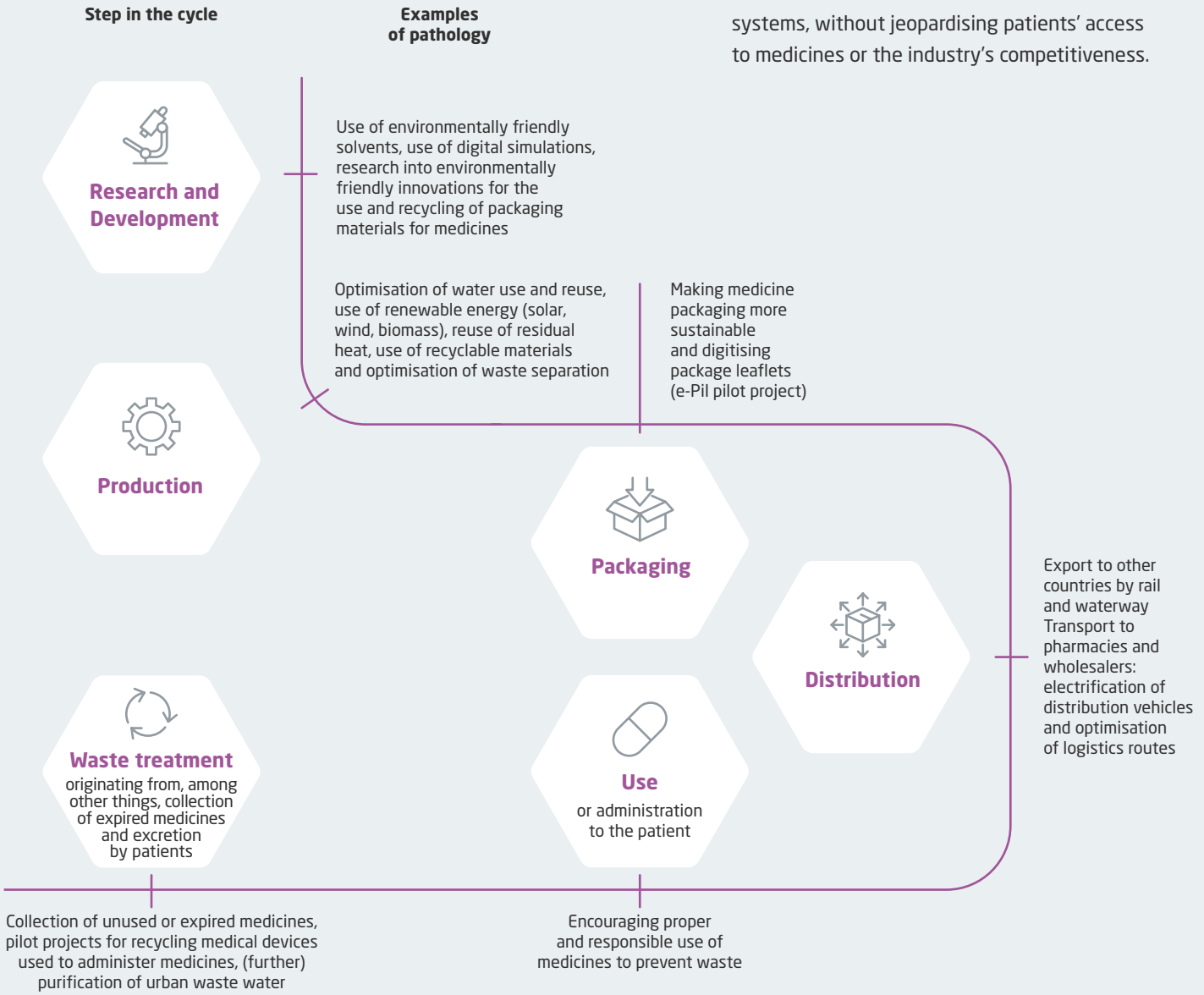
AS THE INNOVATIVE BIOPHARMACEUTICAL INDUSTRY STATES IN ITS MANIFESTO, ITS AIM IS TO MAKE BELGIUM THE HEALTHIEST PLACE TO LIVE. HOWEVER, HEALTH DOES NOT EXIST IN ISOLATION – IT IS INSEPARABLE FROM THE ENVIRONMENT IN WHICH WE LIVE.

Our member companies are therefore actively working to reduce their ecological footprint. Sustainability is approached from a full life-cycle perspective: from research and development to production, distribution, use, and the post-use phase, including excretion and the collection of unused or expired medicines. At every stage, companies take measures to minimise their environmental impact, working in collaboration with all stakeholders – from suppliers to healthcare providers.

A key priority within this approach is the fight against climate change. The sector recognises the need to drastically reduce greenhouse gas emissions and aims to achieve full climate neutrality by 2050 at the latest[20]. According to a 2022 survey by EFPIA, our European sister association, all participating biopharmaceutical companies have set long-term CO_2 reduction and neutrality targets, and more than 60% have also defined concrete short-term goals. In two years, EFPIA members have succeeded in reducing their CO_2 emissions by 10%[21].

These efforts are part of a broader transition towards a circular economy, with the conservation of natural resources at its core. The pharmaceutical sector aims to contribute to sustainable and resilient health systems, without jeopardising patients' access to medicines or the industry's competitiveness.

Sustainable developments in the medicine's life cyle



Four central themes

THE BIOPHARMACEUTICAL INDUSTRY ENDORSES THE EUROPEAN SUSTAINABILITY AGENDA. AT THE SAME TIME, IN A CONTEXT OF FAR-REACHING REGULATORY CHANGES, IT FACES THE CHALLENGE OF BALANCING ECOLOGICAL AMBITIONS WITH THE AVAILABILITY OF SAFE, INNOVATIVE MEDICINES AND THE SECTOR'S CAPACITY FOR INNOVATION AND COMPETITIVENESS.

To help maintain this balance, pharma.be works with multidisciplinary groups of experts from member companies. They focus on four central themes within ecological sustainability:

- **General pharmaceutical policy**
  e.g. Environmental Risk Assessment;
- **Water**
  e.g. the implementation of the European Urban Wastewater Directive in Belgium;
- **Chemical substances**
  e.g. PFAS and F-gases;
- **Climate & circularity**
  e.g. sustainable packaging.

In addition, pharma.be participates in consultation platforms and policy forums such as the Green Deal Sustainable Care Flanders, the platform for expired and unused medicines and the OVAM working group on waste in healthcare. pharma.be is also a member of organisations such as Fost Plus and Valipac.

THROUGH THIS APPROACH, THE SECTOR AIMS TO CONTRIBUTE TO A SUSTAINABLE FUTURE. IN PARALLEL, MEMBER COMPANIES ARE IMPLEMENTING CONCRETE ACTIONS TO REALISE THE TRANSITION TO A SUSTAINABLE INDUSTRY ON THE GROUND. THE FOCUS IS ON TWO AREAS: SUSTAINABLE PRODUCTION AND LOGISTICS, AND SUSTAINABLE PACKAGING.

Sustainable production processes and logistics

PRODUCING MEDICINES IS A TECHNOLOGICALLY DEMANDING PROCESS INVOLVING VARIOUS RAW MATERIALS, ENERGY-INTENSIVE STEPS, AND STRICT QUALITY AND SAFETY REQUIREMENTS. WITHIN THIS CONTEXT, OUR MEMBERS ARE ACTIVELY SEEKING WAYS TO MAKE THEIR PROCESSES MORE SUSTAINABLE WITHOUT COMPROMISING ON QUALITY, SAFETY, OR EFFICACY.

- **Water use**
  Manufacturing sites are investing in advanced purification technologies that allow process water to be treated to a high standard and reused.

  Rainwater capture and the reuse of water that does not require high purity are also being promoted. Techniques such as reverse osmosis make it possible to use purified water as cooling water, significantly reducing the water consumed by cooling towers. In this way, production sites aim for the principle of *zero liquid discharge*: no wastewater is discharged into the environment and all water flows are captured, treated and reused locally;

- **Energy consumption**
  Biopharmaceutical companies are increasingly integrating renewable energy sources such as solar, biomass and wind energy into the energy supply of their production sites. Heat pumps and district heating networks make it possible to reuse residual heat in the production process;

- **Use of materials and raw materials**
  Efforts are being made to use materials and resources more sustainably, for example by replacing solvents with more environmentally friendly alternatives and using recyclable or reusable materials in production environments. Optimising waste separation also contributes to a circular approach.

  Another important focus is the packaging of medicines, where innovative solutions help to reduce material use and increase recyclability;

- **Logistics chain**
  Finally, the biopharmaceutical industry is also reviewing the logistics chain. Where possible, transport by rail or inland waterways is chosen as an alternative to air transport.

Sustainable packaging

Pharmaceutical packaging plays a crucial role: it not only protects the medicine from light, moisture and contamination, but also supports correct administration, dosing and safe use by patients. It is also essential for communicating key product information to both patients and healthcare providers.

At the same time, packaging represents a significant ecological footprint within the pharmaceutical value chain. The call for more circular, sustainable packaging solutions is therefore growing louder, from policy makers, society and the sector itself. But how can sustainability be reconciled with strict regulatory requirements and the absolute need for product safety?

Sustainable packaging in a regulated landscape

At both European and national levels, packaging requirements are strictly defined as part of the marketing authorisation process. These requirements ensure that a medicine maintains its quality, safety, and efficacy throughout its shelf life. Any change – even a minor one – to the packaging material, format, or leaflet can trigger a new assessment or registration. The implementation of circular solutions such as recycled materials, reusable packaging or alternative formats therefore cannot happen overnight.

Strict quality standards also apply to packaging materials. For instance, recycled cardboard cannot be used as outer packaging if it risks compromising strength or introducing impurities.
Blister packs – widely used for tablets, syringes and vials – are often made of complex layers of materials such as aluminium and PVC to provide an effective barrier against oxygen and moisture. These layers are difficult to separate and therefore cannot be recycled through conventional waste streams.

Technological innovation and collaboration

Despite these challenges, the biopharmaceutical industry is taking important steps towards more sustainable packaging. Technological innovations play a key role here, as does collaboration between industry, regulators, academic institutions, patients and packaging manufacturers.
Only in this way can sustainable innovations be introduced without compromising public health.

A few examples:

– **Smaller and lighter packaging**
  Biopharmaceutical companies are adapting packaging design to reduce material use and improve recyclability.
  For example, think of more compact package leaflets or replacing plastic trays – packaging holders that keep products such as injection pens in place in the box – with fibre-based alternatives (cardboard). These fibre-based trays can be disposed of via regular cardboard recycling;

Alternative to plastic trays

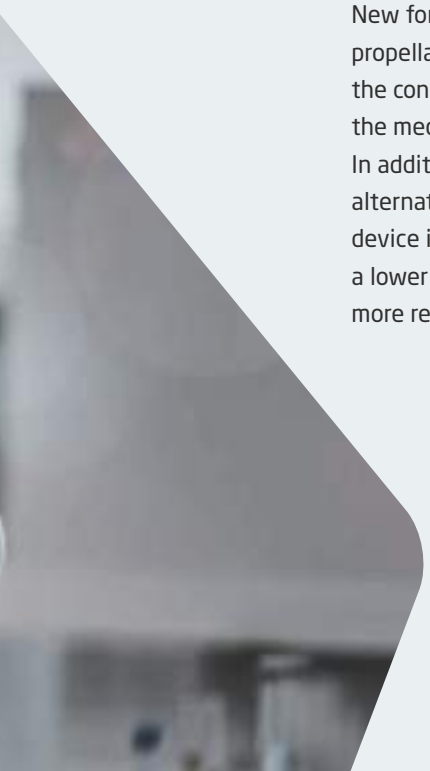
- **Mono material blister packs**
  The sector is working intensively on blisters made from a single recyclable material, such as polypropylene or PET, as an alternative to multilayer combinations with PVC. There are already several examples showing that it is possible to increase recyclability without compromising barrier performance. Nevertheless, thorough testing and regulatory approval remain crucial;

- **More sustainable inhalers**
  New formulations for medical aerosols use propellants with a lower climate impact; the condition is that they continue to guarantee the medicine's effectiveness and dosing accuracy. In addition, more environmentally friendly alternatives are being explored for the inhaler device itself, such as using materials with a lower ecological footprint or designs that are more recyclable;

- **Multistakeholder collection of expired and unused medicines**
  In this initiative, the biopharmaceutical sector joins forces with pharmacists, wholesalers and other parties to collect and dispose of expired and unused medicines in a safe and sustainable way;

- **Recycling and reuse**
  For devices such as injection pens, feasible recycling programmes are being explored, with attention to safety, traceability and patient-friendliness. An example is reusable insulin pens with replaceable cartridges; the used components are collected via a recycling programme;

- **Digitalisation of package leaflets**
  Since 2018, the Belgian biopharmaceutical industry has been piloting electronic package leaflets: *the Electronic Patient Information Leaflet*, or e-PIl. The positive results are now being recognised across Europe.



FROM PAPER TO ELECTRONIC MEDICINE INFORMATION

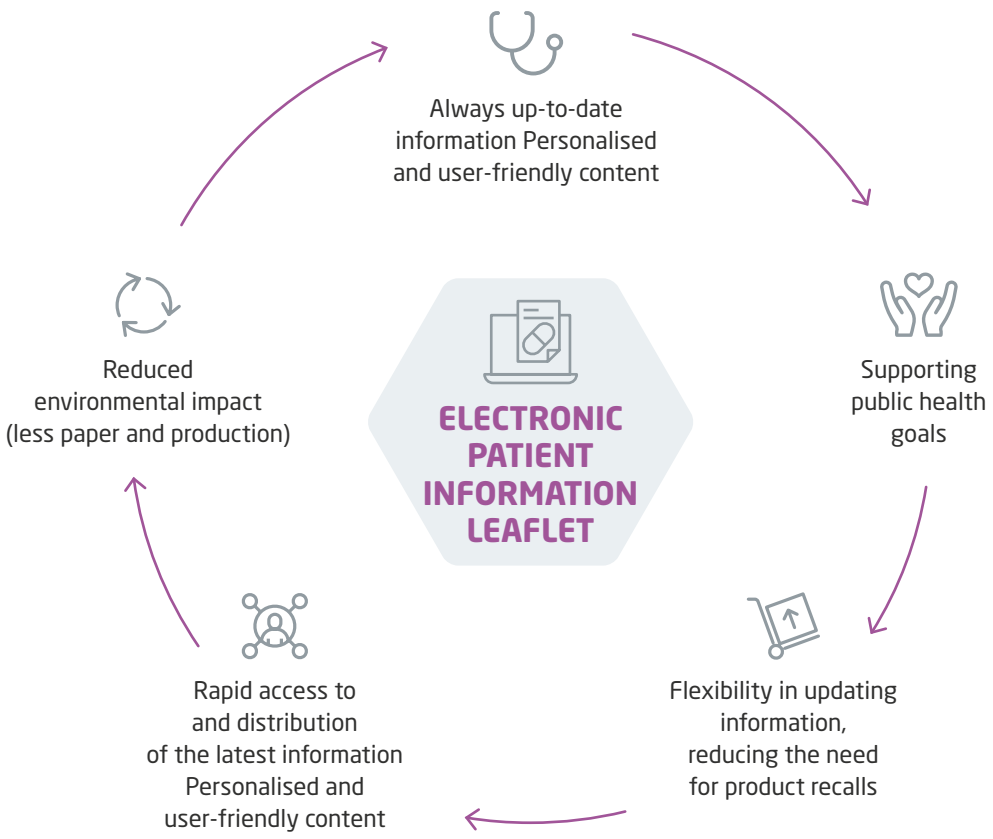
EVERY MEDICINE PACK CONTAINS A PAPER LEAFLET WITH INSTRUCTIONS AND INFORMATION FOR THE APPROPRIATE USE OF THE MEDICINE. UNDER EUROPEAN LEGISLATION, SUCH A LEAFLET MUST BE PRESENT IN EVERY PACK OF ALL MEDICINES. IN BELGIUM ALONE, MORE THAN 100 MILLION PACKAGES OF REIMBURSED MEDICINES ARE DISPENSED EACH YEAR. PAPER LEAFLETS THEREFORE HAVE A HUGE ENVIRONMENTAL IMPACT.

e-Pil: a European first

The Belgian biopharmaceutical industry therefore launched a pilot project in 2018 to test *electronic patient leaflets* (e-Pils) – a European first. Testing took place within a controlled hospital environment, and the leaflet was made available through trusted sources such as the FAMHP database, the website of the BCFI (Belgian Centre for Pharmacotherapeutic Information) and pharma.be's e-compendium website.

Initially limited to a small number of medicines, the e-Pil pilot expanded after consistently positive interim results.
By June 2023, 129 medicines from 27 pharmaceutical companies were included. The project concluded in 2024 with excellent results:

- 100 % of the hospital pharmacists interviewed reported that the absence of the paper leaflet caused no inconvenience in their daily practice;
- According to the hospital pharmacists, this was also true for 100 % of physicians and 97 % of nurses;
- 97 % of the hospital pharmacists interviewed agree that paper leaflets should be removed from medicines intended exclusively for hospital use.



The project demonstrated that electronic leaflets can fully replace paper versions in hospitals.
In addition to environmental benefits, the e-Pil offers other advantages: always-up-to-date information, adjustable font size, and easy searchability.

e-Pil, the new European standard?

European pharmaceutical legislation is currently being revised. One topic under discussion is the transition from paper to electronic patient leaflets, with Member States allowed to determine a phased rollout themselves. While discussions are still ongoing, pharma.be supports this transition – provided that patients always retain the right to request a paper leaflet, even if the default version is digital.

Multistakeholder collection of expired and unused medicines

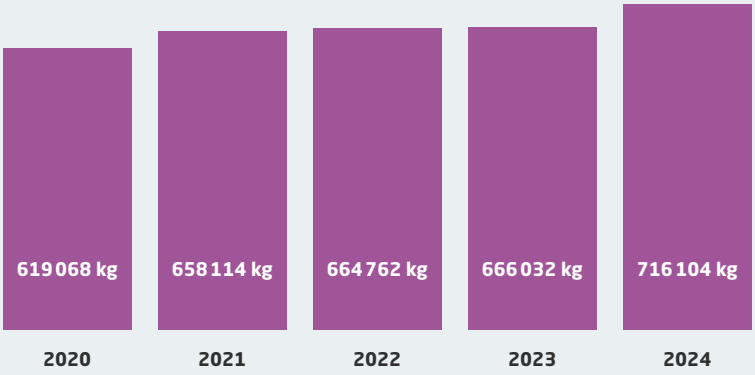
Another example of pharma.be members' efforts to reduce their impact on the environment concerns the collection of expired and unused medicines. These must not be flushed down the toilet or thrown in the bin. They must be sorted and collected separately, as they can be harmful not only to the environment but also to public health. A discarded medicine remains a medicine and must not be misused (for example, by children playing with it or animals searching for food).

To encourage sorting and ensure proper collection, the biopharmaceutical sector has collaborated with various stakeholders to develop a convenient zero-cost solution to the patient. Thanks to this multistakeholder initiative, you can simply drop off unused and expired medicines at your pharmacy. The pharmacist collects the medicines in a special container. The containers are then collected by wholesale distributors and destroyed in incinerators, with the energy released being recovered and reused.

The biopharmaceutical industry bears the costs of the containers and incineration, including transport costs from the wholesaler's distribution centre to the incinerator. These costs are allocated based on the number of medicines sold on the outpatient market in the previous year.

Thanks to this collaboration, an estimated 716 104 kg of unused and expired medicines were collected in Belgium in 2024.

Total quantity of expired and unused medicines collected



Source: pharma.be

4.1.6. CARING FOR PEOPLE AND ANIMALS

ANIMALS ARE AN INTEGRAL PART OF OUR LIVES. PETS PROVIDE COMPANIONSHIP, THERAPY ANIMALS OFFER COMFORT, ASSISTANCE ANIMALS HELP US LIVE MORE INDEPENDENTLY, AND ANIMALS EVEN PLAY A ROLE IN PUBLIC SAFETY. ANIMALS ARE ALSO INDISPENSABLE IN AGRICULTURE, AS A SOURCE OF FOOD AND INCOME. THEIR HEALTH THEREFORE AFFECTS NOT ONLY THE ANIMALS THEMSELVES, BUT ALSO PEOPLE AND OUR ENTIRE ECOSYSTEM.

The Animal Health Group, part of pharma.be, represents thirteen pharmaceutical companies committed to animal health and welfare in Belgium. Together, they bring more than 1 500 products to the market, from vaccines to innovative treatments.

Animal health is our responsibility

Whether the patient is a dog with osteoarthritis or a cow that needs protection against the bluetongue virus, there is a whole team behind every treatment. In Belgium, around 1 500 people work in the research, production and distribution of veterinary medicines. Every day they devote themselves to treating and curing animals, in both social and economic contexts:

- **Innovation for companion animals**
  For many people, animals are truly part of the family. Owners therefore want only the best for their companion. Our sector responds with advanced treatments such as monoclonal antibodies and mRNA vaccines – technologies that were previously available only for humans. Thanks to these innovations, animals are living longer and healthier lives, which also benefits their owners' well-being;
- **Protecting the food chain**
  Standards in agriculture are equally high. A healthy herd is essential for safe food. Through vaccinations, rapid diagnostics and digital monitoring, our sector helps prevent animal diseases that can disrupt the food chain. Consider the recent bluetongue outbreak. Thanks to the government's comprehensive approach, in consultation with our sector and veterinarians, vaccines came to market in record time and additional measures were taken to minimise the impact on food supply.

One Health: one world, one health

Human, animal and environmental health are inextricably linked. That is the essence of the One Health concept – a concept made painfully tangible by the COVID-19 crisis.

We must break down silos and collaborate across disciplines to protect food safety and biodiversity, prevent future outbreaks, and tackle chronic and infectious diseases effectively. In this way we help to build a healthy, sustainable and resilient society.

ONE HEALTH: THE SHARED FIGHT AGAINST ANTIMICROBIAL RESISTANCE

ANTIBIOTICS ARE INDISPENSABLE FOR TREATING BACTERIAL INFECTIONS IN HUMANS AND ANIMALS. BUT INAPPROPRIATE OR EXCESSIVE USE ENABLES BACTERIA TO BECOME RESISTANT AND MEDICINES TO LOSE EFFECTIVENESS. ANTIMICROBIAL RESISTANCE, OR AMR, IS NOW SEEN WORLDWIDE AS ONE OF THE GREATEST THREATS TO HUMAN, ANIMAL AND ENVIRONMENTAL HEALTH.

National action plan

To counter this threat, a national AMR action plan has been drawn up in Belgium.
This plan includes, among other things, the following actions:

- Strict monitoring of antibiotic use, both in animals and in humans. The former is carried out by AMCRA, the latter by BAPCOC. pharma.be actively supports both organisations in this;
- Developing measures to reduce the environmental impact of antibiotics (wastewater, manure, sludge). This is taking place within the framework of the European JAMRAI project, in which Belgium plays an active role;
- The development of new antibiotics, alternative treatments such as bacteriophage therapy, and preventive solutions (vaccines).

Stronger together

Our sector aims to be a reliable partner for everyone concerned with animal health. We therefore work closely with veterinarians, livestock farmers, scientists and policy makers.

Our goal is to sustainably develop and make available effective solutions at an affordable price, for both pet owners and livestock farmers. pharma.be therefore advocates for a widely supported policy that combines strict control with flexibility.

IN THIS WAY WE CAN RESPOND ADEQUATELY IN CRISES WHILE BUILDING A FUTURE IN WHICH ANIMALS ARE HEALTHY, PEOPLE ARE PROTECTED AND OUR PLANET REMAINS LIVEABLE.

WHO OR WHAT IS AMCRA?

AMCRA STANDS FOR ANTIMICROBIAL CONSUMPTION & RESISTANCE IN ANIMALS.
AMCRA IS A FEDERAL KNOWLEDGE CENTRE DEDICATED TO REDUCING ANTIBIOTIC RESISTANCE AND THE USE OF ANTIBIOTICS IN ANIMALS IN BELGIUM. THE ORGANISATION COLLECTS AND ANALYSES RELEVANT DATA AND USES THIS DATA TO RAISE AWARENESS WITH VETERINARIANS AND ANIMAL OWNERS AND PROVIDE TARGETED ADVICE.

It is no coincidence that the Animal Health Group of pharma.be was one of the co-founders of AMCRA in 2012. AMCRA's objectives largely reflect the vision of our own organisation.

pharma.be aims to ensure that sick animals in Belgium are treated with high-quality veterinary medicines. The 'One Health' concept is key in this respect: animal health, human health and environmental health are all closely connected and affect one another. Sustainable use of antibiotics in veterinary medicine is therefore important to help safeguard public health.

Limiting animal testing

One of the cornerstones of animal testing is the '3 Rs' principle, which requires researchers to **reduce** the number of test animals, **refine** experiments to minimise animal suffering, and **replace** animal testing with alternative methods wherever possible. The biopharmaceutical industry is firmly committed to these principles.

In 2022 (the latest year for which data is available), 430 671 animals were used in research, a reduction of 1.5 % compared to 2020. Of the animals used, 56.1 % were mice and 14.6 % were rabbits. Dogs and cats were used to a much lesser extent (0.08 % and 0.05 %, respectively).

The majority of laboratory animals used in 2022 were involved in fundamental and applied research (77 %). In 2020, this share was 66.2 %. For legally required research and routine production (such as testing product quality and efficacy or determining toxicity), just under 100 000 laboratory animals were used, representing 23 % of the total number. This represents a reduction of nearly 30 000 animals compared with 2020.

4.2. WE WORK TOGETHER IN THE PATIENT'S INTEREST

4.2.1. COLLABORATION WITH PATIENT ORGANISATIONS

We also worked intensively with patient organisations in 2025. The input from our Patient Roundtables and the Patient Advisory Board served as a starting point. Innovative biopharmaceutical companies and patient organisations are increasingly converging, and this is delivering tangible results. Thanks in part to our code of ethics on interaction with patient organisations and the 10-point checklist we developed together, we remain close to the patient's lived reality. We thereby also underline our request in the 'Memorandum for a Healthy Belgium', *"to strengthen the patient's voice in health policy by supporting disease-specific patient organisations in their professionalisation, self-sufficiency, and independence."*

Discover the 10-point checklist

Our objectives

In 2025 we worked on:

– **Collaboration**
Launch of a guide to stimulate cross-healthcare collaborations with patient organisations;

– **Integration**

- Including the patient's voice in our guide for Patient Support Programmes;
- Projects on prevention and responsible use of medicines;
- Update on our survey to gain additional insight into the needs of patient organisations;

– **Education**

- Project on literacy in health data and the surrounding policy framework;
- Patient forum on current topics such as the patient's voice in the Belgian pricing and reimbursement system.

> There is still a long way to go. Hospitals, public services, insurance companies and other sectors could learn more from the example set today by the pharmaceutical industry.
>
> **STEFAN GIJSSELS,**
> Patient Expert Centre

A new guide: Cross-Healtcare Collaboration with Patient Organisations

The aim of this guide is to support and inspire patient organisations to collaborate with a broader set of stakeholders in healthcare. By seeking synergies, they can make their projects or initiatives even higher quality and more sustainable.

This guide includes model contracts and numerous examples of broader collaborations: setting up awareness campaigns, developing educational materials, organising registries, designing patient journeys, etc. By sharing good practices and do's and don'ts, we can all continue to learn and grow.

This guide is regularly supplemented with inspiring new projects and initiatives. It is a warm call to share experiences, so that we all benefit.

New process: the patient's voice in the Belgian pricing and reimbursement system

Since 1 April 2025, the NIHDI has given patient organisations a larger role in the roadmap for reforming Belgium's medicines reimbursement procedures. As a result, the entire decision-making process is much more patient-centred.
Newly available treatments are also better aligned with patients' real needs. The umbrella organisations Flemish Patients' Platform (VPP) and League of Users of Health Services (LUSS) represent patients. They sit, without voting rights, on the Medicines Reimbursement Committee (CRM). Together they provide input during CRM meetings via standard questionnaires available on the NIHDI website. These focus on three perspectives:

1. The impact of the condition on the patient's quality of life;
2. Patients' experience with existing treatments;
3. Patients' experience with the new medicine under evaluation (if applicable).

Answers should preferably be based on the collective experiences of patients with the same condition.

> The value of this guide lies in its ability to promote constructive partnerships that go beyond our individual agendas.
>
> **GITTE BORGERS,**
> Patient Relations Manager, AbbVie

WHAT DOES PATIENT INVOLVEMENT MEAN FOR THE CRM PROCEDURE?

- The approach applies to CRM files submitted from 1 April 2025 for:
  - Class 1 medicines;
  - Orphan medicines;
  - New indications for which there is a therapeutic or social need;
- Within 20 days of submitting the file to the CRM (the sooner, the better), the patient organisation is designated;
- The patient organisation has 20 calendar days to return the completed questionnaire to the CRM secretariat via the umbrella organisations VPP or LUSS;
- The completed questionnaire is added to the D60/D90 report;
- In 2025, several patient organisations submitted questionnaires. Initial insights are now being gathered to further improve the quality and impact of this new process.

Supporting materials

We are continuing our journey with and for patient organisations.
All the supporting materials we develop can be found on our website:

- A contact list: to quickly find the right contact person at the pharmaceutical companies;
- 10-point checklist: our standard for proper collaboration with patient organisations;
- Q&A on our code of ethics: to guarantee the independence of patient organisations;
- Consultancy agreement: a simple contract for setting up collaborations;
- Webinar: The ABC of Cell and Gene Therapy;
- Brochure: Clinical research in Belgium, explained in clear language;
- Guide 'Cross-Healthcare Collaboration with Patient Organisations': a roadmap for broad collaboration to achieve greater quality and impact;
- Health data literacy: what it is and where to find information.

Discover our available materials

INA HAS A PASSION FOR PHARMA

Every patient has a unique story and, based on their experience, knows exactly from their patient perspective what is needed to provide good care.

That is why we work closely with patient organisations from the start of innovation development to bringing treatments to market – because patients know best what it is like to live with a disease and what the challenges are for treatments.

BY SYSTEMATICALLY INTEGRATING THE PATIENT'S VOICE INTO THE INNOVATION PROCESS, WE BUILD SOLUTIONS TOGETHER WITH AND FOR THE PEOPLE THEY ARE ULTIMATELY INTENDED FOR.

INA GESQUIERE,
Patient Engagement Manager

DISCOVER THE PASSION OF INA AND HER COLLEAGUES IN THE BIOPHARMACEUTICAL SECTOR

4.2.2. COLLABORATION FOR RELEVANT HEALTH DATA

REAL WORLD DATA (RWD) REFERS TO PERSONAL DATA ABOUT AN INDIVIDUAL'S HEALTH. THIS MAY INCLUDE MEDICAL INFORMATION SUCH AS DIAGNOSES, REFERRALS, PRESCRIPTIONS, LABORATORY TESTS AND RADIOGRAPHS. IT ALSO INCLUDES ADMINISTRATIVE AND FINANCIAL DATA SUCH AS HEALTHCARE INVOICES AND SICK LEAVE CERTIFICATES, AS WELL AS BROADER HEALTH DETERMINANTS SUCH AS SOCIAL, BEHAVIOURAL AND ENVIRONMENTAL FACTORS.

Because health data is particularly sensitive, it is crucial to handle it with care. As an industry, we therefore place great importance on the responsible use of data, especially when it is used for purposes beyond direct patient care (secondary use). 'Responsible' means using the data to obtain valuable insights for healthcare without compromising individuals' privacy.

pharma.be also supported member companies in this in 2025. For example, we developed a harmonised decision tree for the application of the GDPR (General Data Protection Regulation) and accompanying contracts.

pharma.be and the health data ecosystem

Our member companies are not the only ones using data. To build a robust and reliable data system that various parties can draw on to improve healthcare, a health data ecosystem is needed.

The basis of such an ecosystem is FAIR data, where FAIR stands for:

- **Findable**
  To be usable, data must of course be easy to find, for example through a metadata catalogue available in one central location;
- **Accessible**
  Data must be accessible (within a predefined and transparent framework);
- **Interoperable**
  Databases and collections must be compatible with our Belgian e-health infrastructure so that they can be linked to each other;
- **Reusable**
  Data must be reusable for research, healthcare, and policy-making.

From pharma.be, we set up and supported various partnerships in 2025 to strengthen this ecosystem.

Health Data Talk Series

In this series of opinion articles by the Health Data Agency, authors from pharma.be and other stakeholders from across the ecosystem delve deeper into health data and their secondary use.
We focus on aspects where general knowledge is still limited. In this way, we help build a strong health data ecosystem.
Each article is co-signed by multiple stakeholders, demonstrating mutual recognition and respect.

Hendrik De Rocker (APB)

Inge Van de Velde **Stefan Gijssels** (Patient Expert Center)

Isabelle Huys (KULeuven)

Katleen Janssens (Health Data Agency)

Karen Crabbé (pharma.be)

Nick Marly (Cabinet public health)

Stefanie Devos (beMedTech)

Sotie Bekaert (King Baudouin Foundation)

Sotie De Broe **Wannes Van Hoof** (Sciensano)

Teodora Lalova-Spinks (Ghent University, KULeuven)

An innovative alliance for RWD

The Federated Health Innovation Network (FHIN) is a collaborative initiative of eight academic and non-academic hospitals in Belgium.
Its aim is to stimulate data-driven care by harmonising data, with a focus on predictive models for lung and prostate cancer. Through pharma.be, FHIN sought collaboration with pharmaceutical companies to conduct joint RWD research in lung cancer.

Together with representatives of the hospitals and pharmaceutical companies, pharma.be agreed principles for a product-agnostic, non-competitive collaboration on non-small cell lung cancer (NSCLC). In a traditional set-up, this collaboration would result in five times nine contracts.

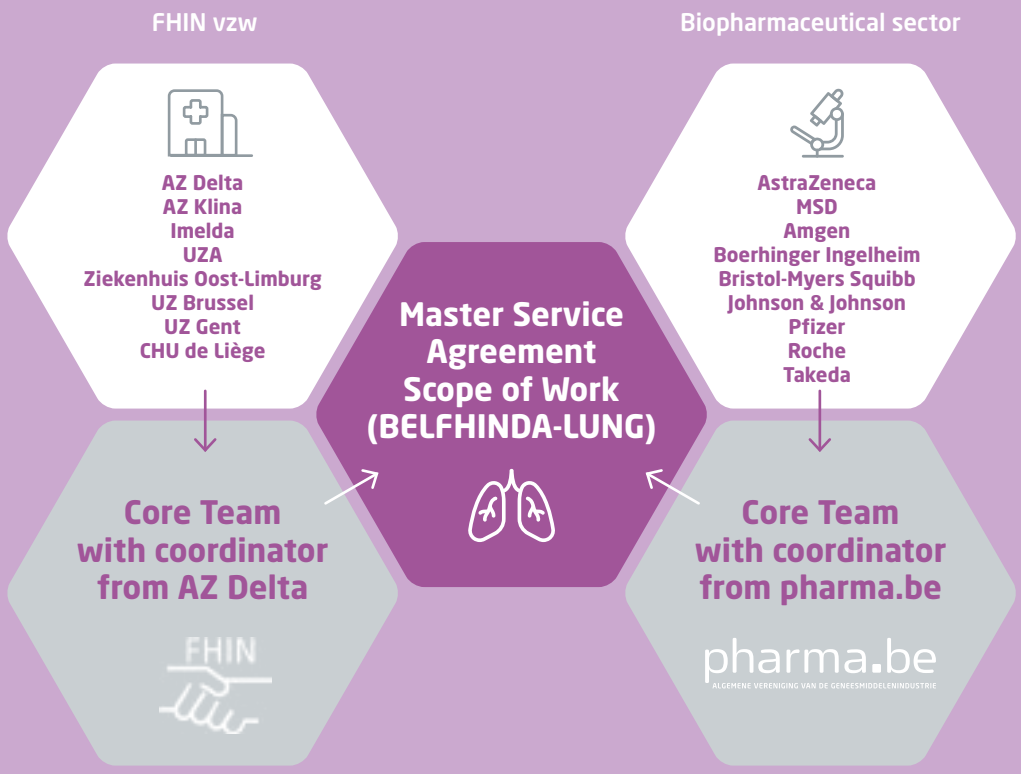
Thanks to this innovative partnership, named BELFHINDA (Belgian FHIN-hospitals Industry Data Alliance), this was reduced to three contracts:

- A multilateral teaming agreement between eight industry partners;
- A master service agreement between FHIN and pharma.be to enable collaboration on RWD research;
- A scope of work agreement between five FHIN hospitals and pharma.be, representing eight pharmaceutical companies.

The partnership also jointly developed the requirements for a feasibility study with a use case in NSCLC.

These efforts lay the foundation for a leading, sustainable framework for joint RWD research in Belgium. This innovative data alliance was presented in July 2025 at the Observational Health Data Sciences and Informatics Europe conference. The partnership model was also presented to the Luxembourg Ministry of the Economy, the Dutch Association for Innovative Medicines (VIG) and the Joint Research Centre (JRC) of the European Commission and the EMA.

BELFHINDA



Trust is extremely crucial. The unique fact that we have come together is thanks to pharma.be.

KATOO MUYLLE,
Real World Evidence Manager,
AstraZeneca

KIM DENTURCK,
Innovation coördinator RADar,
AZ Delta

Support for the Health Data Agency

The pharmaceutical industry is a user of health data in research questions on patient treatment. It is extremely important to factor in the user perspective from the outset when setting up a new legal basis or procedures for the secondary use of data.

pharma.be therefore again supported the Health Data Agency (HDA) in 2025 in rolling out the European Health Data Space (EHDS) in Belgium. Our Health Data & Digitalisation taskforce and our RWE focus group shared their experience in health data projects and their technical insights with the entire ecosystem.

Dialogue with stakeholders

Finally, pharma.be and the member companies of our Health Data & Digitalisation taskforce and the RWE focus group also engaged with various partners within the health data ecosystem.

The goal? To make more structured, higher-quality health data available in the short term, with minimal burden for healthcare professionals and maximum benefits for patients.

The pharmaceutical industry's expertise—built up over many years of RWD projects—can be a lever here. Our member companies are well versed in the use of various technical platforms, data languages, digital tools and in setting up complex contracts.

AN INSPIRING ROUND-UP: FORUM HEALTH DATA & DIGITALISATION

EACH YEAR WE ORGANISE THE FORUM HEALTH DATA & DIGITALISATION TO SHARE THE LATEST INSIGHTS ON THE SECONDARY USE OF RWD WIDELY. IN 2025, THIS INSPIRING EVENT TOOK PLACE ON 26 SEPTEMBER IN BRUSSELS, WITH OVER A HUNDRED STAKEHOLDERS FROM THE HEALTH DATA ECOSYSTEM TAKING A PART.

Key themes were:

- Real World Data and Evidence (RWD/RWE) are crucial for reliable scientific evidence; quality, interoperability and international standards such as OMOP are essential;
- Innovative projects:
  - MOOD project (Johnson & Johnson) uses RWD to improve treatment of treatment-resistant depression;
  - AZ Klina's 'Dr EPD' project shows how NLP technology unlocks hidden value from clinical notes;
- Belgian pilot projects: lessons from oncology and rare diseases led to a playbook and an evidence platform;
- International collaboration: the INVENTS project (Roche) with the French Health Data Hub shows that secure data exchange accelerates innovation;
- Telemedicine: solutions such as Byteflies connect patients and healthcare professionals continuously and enrich databases in real time.

Event recap

4.2.3. COLLABORATION FOR THE AVAILABILITY OF MEDICINES AND VACCINES

MEDICINES SHOULD ALWAYS BE AVAILABLE WHENEVER PATIENTS NEED THEM. IN REALITY, MEDICINES ARE SOMETIMES TEMPORARILY UNAVAILABLE. THIS CAN BE PROBLEMATIC FOR PATIENTS, BUT OF COURSE BIOPHARMACEUTICAL COMPANIES ALSO WANT THEIR MEDICINES TO BE CONTINUOUSLY AVAILABLE. TACKLING MEDICINE SHORTAGES, HOWEVER, REQUIRES MORE THAN JUST THE GOODWILL OF THOSE INVOLVED IN THE FIELD.

Situation in Belgium

In Belgium, many initiatives have already been taken, in consultation with the Federal Agency for Medicines and Health Products (FAMHP), to ensure that wholesale distributors and pharmacists are supplied in time so that patients can access their medicines. The FAMHP was the first in Europe to launch a reporting system, PharmaStatus providing in depth transparency about the causes and duration of shortages for healthcare professionals and patients. For their part, companies maintain precautionary stocks of medicines to enable them to supply pharmacists directly, ensuring continued availability for Belgian patients.

HOWEVER, UNAVAILABILITY IS A COMPLEX ISSUE WITH MANY CAUSES AT DIFFERENT LEVELS.

Complex production process

Firstly, pharmaceutical companies take no risks whatsoever when it comes to the safety and quality of their products. Controls are also particularly strict in Europe. Medicine and vaccine manufacturing processes are very time-consuming, extremely complex and delicate. Most vaccines, for example, have a manufacturing process that takes more than 18 months. The same applies to other biological medicines developed from living cells.
An unexpected event at any stage of the process cannot always be resolved immediately or easily, and may cause significant delays in the delivery of the next batch. This can lead to stock shortages, often affecting not only the Belgian market but also other European and even non-European countries. After all, medicines are rarely produced for a single country, but for an entire region or even the world. Scaling up in the face of increased demand cannot be done overnight. Raw materials are also often scarce and these need to be handled very carefully. Maintaining large reserve stocks is therefore not justified, as it could create significant upward pressure on prices or even cause shortages of other medicines that require the same raw materials.

Price pressure

Secondly, we find that maintaining local production in Europe is a major challenge for all industrial sectors. Higher labour and energy costs mean that low-cost production is no longer competitive, causing these activities to shift to other parts of the world.

The biopharmaceutical sector is not immune to this trend. Only high-value activities that require substantial specialised expertise have escaped this so far.

Moreover, frequent price reductions for off-patent medicines imposed by the Belgian government sometimes make it impossible for companies to keep a medicine on the market, leading to its permanent withdrawal from Belgium – a development that can be very detrimental to patients.

Free movement of goods

Finally, medicines in Belgium must be able to circulate in accordance with the free movement of goods within the European Union. Because medicine prices are set by national authorities, flows emerge from countries where prices are lower to those where they are higher. We call this parallel export. The quota system seeks to mitigate this, but it is often impossible for biopharmaceutical companies to replenish stock quickly enough when parallel exports occur. Scaling up production is no easy matter.

Protecting patients from additional costs

In collaboration with all stakeholders, a system was developed in 2024 to protect patients from additional costs if their medicine is unavailable and the alternative needs to be imported by the pharmacist from abroad.

In many cases, these medicines are more expensive and not reimbursed, which can lead to high out-of-pocket costs. Through a new system, to which all biopharmaceutical companies contribute, patients will no longer have to pay extra for a medicine imported from abroad to replace an unavailable product.

Our commitment

The issue of unavailability is being discussed with the Minister of Health as part of the reform plans. To ensure that medicines remain available to Belgian patients in the future, long-term adjustments will be needed to make our distribution system less vulnerable to external factors. Encouraging a healthy, competitive economic environment that allows multiple players to operate in the Belgian market is one key measure for establishing a sustainable distribution framework.

That is our commitment to society, a role we take very seriously as an industry.

That is why pharma.be, together with all stakeholders in the distribution chain and the FAMHP, is seeking solutions to minimise the impact of medicine shortages on patients.

WHAT DOES PHARMASTATUS SHOW US?

TOGETHER WITH OTHER STAKEHOLDERS, THE BIOPHARMACEUTICAL SECTOR MUST BE TRANSPARENT AND PROVIDE CLEAR INFORMATION ABOUT MEDICINES THAT ARE UNAVAILABLE.

The FAMHP's online application PharmaStatus plays an important role in this. Thanks to PharmaStatus, physicians, pharmacists, and patients can easily find out why a medicine is unavailable and how long the shortage is expected to last. Through PharmaStatus, the FAMHP can also provide alternatives for unavailable medicines. Finally, wholesale distributors, pharmacists, and companies can use PharmaStatus to work together to find a solution when a medicine is unavailable at a pharmacy or with a distributor.

If we look at the concrete figures, we can see that as of 3 November 2025, 650 medicines were temporarily unavailable. Although this affects patients and healthcare professionals (for example, requiring a new prescription or an additional visit to the pharmacy), the impact on continuity of treatment is limited. In 455 cases, at least one alternative was available, and in 312 of those, there were three or more. In most of the remaining cases, patients could be helped by importing a medicine from abroad or by adjusting their treatment.

WHERE THESE SOLUTIONS ARE NOT POSSIBLE, THE FAMHP CONVENES A WORKING GROUP TO DRAW UP RECOMMENDATIONS TO ENSURE CONTINUITY OF CARE FOR THE PATIENTS CONCERNED.

APPENDIX 1 - METHODOLOGY OF COST-BENEFIT ANALYSIS

IN 3.2.2 WE PROVIDED A SUMMARY OF THE COST-BENEFIT ANALYSIS OF THE BIOPHARMACEUTICAL INDUSTRY FOR THE BELGIAN GOVERNMENT. ON THE NEXT PAGE ARE THE DETAILED BREAKDOWNS OF EXPENDITURE AND REVENUE ON WHICH OUR ANALYSIS IS BASED.

DETAILED BREAKDOWN OF EXPENDITURE (IN THOUSANDS OF EUROS)

Cost for the government (2024)	**4719113**
1.1. State expenditure on medicines (industry costs, excluding VAT) - NIHDI	4623508
1.2. Subsidies	95605

Government expenditure on medicines is based on NIHDI data on spending for pharmaceutical specialities. This expenditure consists of the ex-works price of medicines, distribution costs, and VAT. In this analysis, we only take into account the ex-works price, excluding distribution costs and VAT.

The amount of subsidies paid by the government to the biopharmaceutical industry is based on the annual accounts of companies operating in Belgium. These relate to items 740 (operating subsidies and compensatory amounts received from the government), 9125 (capital subsidies granted by the government), and 9126 (interest subsidies granted by the government).

DETAILED INCOME STATEMENT (IN THOUSANDS OF EUROS)

Government revenue (2024)	**6775065**
2.1. Labour costs	2963420
2.1.1. Employer's social security contributions	1027975
2.1.2. Employee's social security contributions	561674
2.1.3. Amounts withheld on behalf of third parties such as witholding tax	1373771
2.2. Corporate tax	931599
2.3. Taxes	1848973
2.3.1. VAT on turnover (6% of the ex-works price of non-reimbursed medicines)	223459
2.3.2. NIHDI levies on turnover	557874
2.3.3. Withholding tax on movable income withheld on behalf of third parties	47534
2.3.4. Corporate taxes and levies	1020106
2.4. Indirect revenue resulting from purchases from third parties and from investments	1031074
2.4.1. Purchase of raw materials and goods for resale, miscellaneous goods and services	955631
2.4.2. Investments	75443

The revenues from labour charges come from the annual accounts of companies active in Belgium.
These concern items 621 (employers' social security contributions), 620 (wages and direct social benefits, NSSO share) and 9147 (withholding tax). The same applies to corporate income tax.
This concerns item 670 (taxes).

Taxes are divided into four elements:

1. VAT on non-reimbursed medicines.
   For the calculation, we use the turnover figure for non-reimbursed medicines as reported by IQVIA. We do not take VAT on reimbursed medicines into account, as this is paid to the government by the NIHDI, meaning it has no effect on the comparison;
2. The taxes that companies pay to the NIHDI based on their turnover.
   This figure comes from the NIHDI;
3. Balance sheet item 9148 (withholding tax on movable income);
4. Balance sheet item 640 (business taxes and levies).

In addition to direct revenues, there are also indirect revenues for the government:

1. Revenues resulting from the domestic purchase of raw materials, goods for resale, and various goods and services by the biopharmaceutical industry.
   The calculation is based on information from the input-output tables (Federal Planning Bureau), which show the domestic demand of the biopharmaceutical sector for other sectors. For each sector, we apply the ratio between value added and turnover to this domestic demand (also available in the input-output tables). We then apply the average (para)fiscal rate (42.58%, OECD);
2. Receipts resulting from investments by the biopharmaceutical industry.
   We apply the ratio between value added and turnover in the manufacturing industry to the amount of investment, based on Statbel data. The average (para) fiscal rate is then applied (42.58%, OECD).

APPENDIX 2 – ABBREVIATIONS

- AMCRA: Antimicrobial Consumption & Resistance in Animals
- ATC: Anatomical Therapeutic Chemical
- ATMP: Advanced Therapy Medicinal Product
- BCFI: Belgian Centre for Pharmacotherapeutic Information
- BCWC: Bureau for Control on Written Communication
- CRM: Medicines Reimbursement Committee
- CUP: Compassionate Use Programme
- DALY: Disability Adjusted Life Years
- DEP Committee: Committee for Deontology and Ethics in the Pharmaceutical Industry
- EFPIA: European Federation of Pharmaceutical Industries and Associations
- EMA: European Medicines Agency
- E-PIL: Electronic Patient Information Leaflet
- ETA: Early Temporary Authorisation
- FAMHP: Federal Agency for Medicines and Health Products
- FAIR: Findability, Accessibility, Interoperability, and Reusability
- FDA: Food and Drug Administration
- HRQoL: Health Related Quality of Life
- IFPMA: International Federation of Pharmaceutical Manufacturers & Associations
- MIDAS: Migraine Disability Assessment
- MNP: Medical Need Programme
- NIHDI: National Institute for Health and Disability Insurance
- OECD: Organisation for Economic Co-operation and Development
- PEC: Patient Expert Centre
- PO: Patient organisation
- PRO: Patient-Reported Outcomes
- QALY: Quality-Adjusted Life Year
- RCT: Randomised Controlled Trial
- R&D: Research and Development
- RWD: Real World Data
- RWE: Real World Evidence
- SmPC: Summary of Product Characteristics
- Statbel: the Belgian statistical office
- STEM: Science, Technology, Engineering & Mathematics

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