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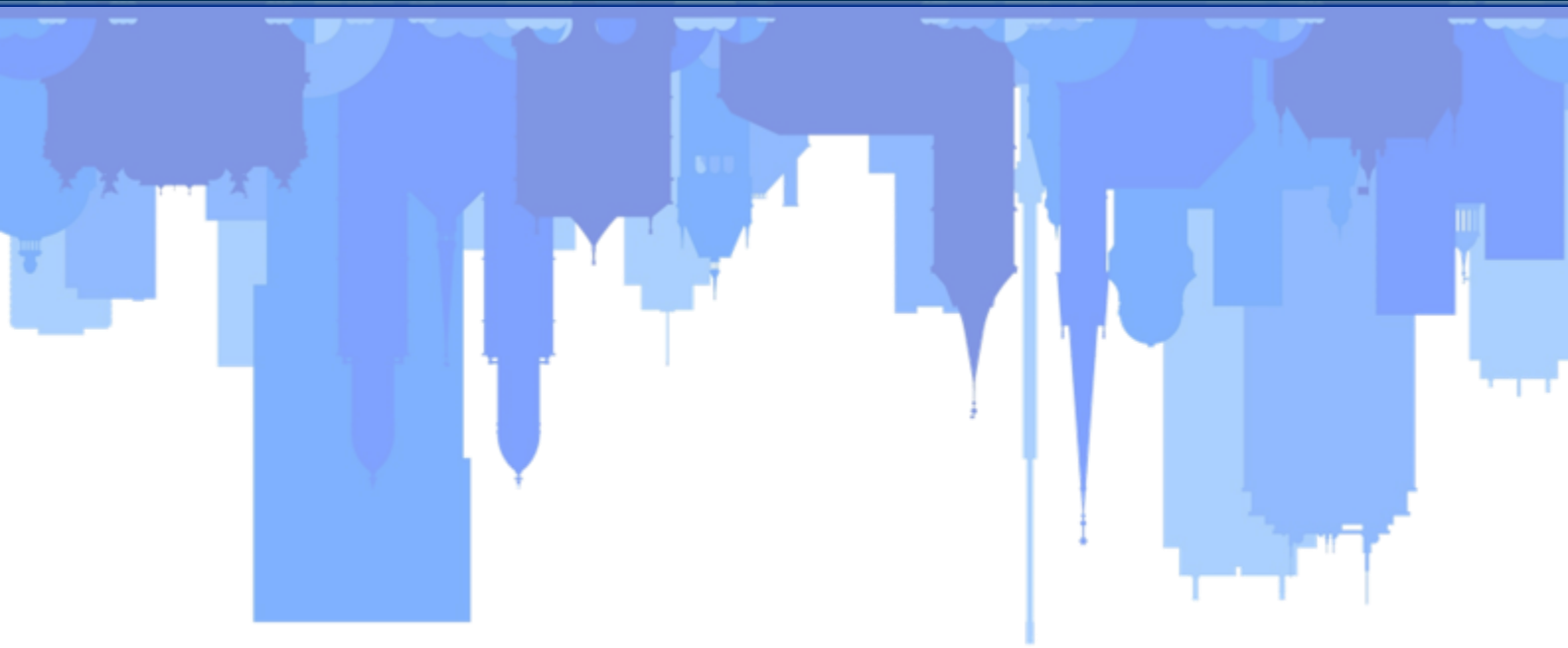
Life sciences excellence in Belgium and Switzerland: A comparative analysis to support forward-looking policies across key innovation dimensions

Ecosystem profiles, structural strengths, strategic challenges, best practices and learnings for mutual reinforcement



September 2025

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Executive summary

By pursuing the below priorities, Belgium and Switzerland can continue to position themselves as global leaders in the life sciences sector, not only as hubs of scientific innovation but as champions of patient-centred, evidence-based, and economically sustainable healthcare systems, while also strengthening Europe's competitiveness in life sciences on the global stage. Such cross-fertilisation of ideas and policies would help ensure end-to-end support for innovation – from initial research to patient access, bolstering the long-term sustainability and impact of both ecosystems.

Opportunities for cross-learning and mutual reinforcement on key strategic dimensions:

Belgium	Switzerland
CLINICAL DEVELOPMENT	
✓ **Phase I national procedure**: Dedicated framework for faster early-phase trial approval.	✓ **Fast-track procedures**: Accelerated approval timelines for high-need and early-phase trials.
✓ **Ethics committee reform**: Ongoing efforts to shorten approval timelines.	✓ **Scientific advice pathways**: Early regulatory guidance supports study design and alignment.
✓ **Sponsor budget tool**: Transparent, user-tested budgeting model for consistent and fair trial costing.	✓ **Regulatory flexibility**: Willingness to tailor frameworks to support innovation and complex designs.
✓ **NIHDI evidence platform:** Under development to improve study design, data collection & RWE generation.	
ACCESS TO MEDICINE	
✓ **BeNeLuxAIR**: Regional and collaborative HTA and horizon-scanning.	✓ **Project Orbis**: Accelerated oncology drug access mechanism.
✓ **Early & Fast access pathways** for pre- and post-EMA approved drugs.	✓ **Day 0 reimbursement**: Immediate access upon approval for high-need therapies.
✓ **NEED framework** for unmet medical needs prioritisation and for evidence-informed decision-making.	✓ **Reimbursement of next-gen sequencing** in oncology.
✓ **Aligned reimbursement for therapies and companion diagnostics in select areas.**	✓ **Strong integration of diagnostics and therapeutic approaches.**

Belgium	Switzerland

DATA & DIGITALISATION

Belgium	Switzerland
✓ **Health Data Agency**: Dedicated institution for data standardisation and secondary use.	✓ **DigiSanté**: Strategic coordination of national digital health transformation.
✓ **NEED framework**: Structured approach to define data requirements for burden of disease.	✓ **Secondary use legislation** under development.
✓ **Evidence platform**: Systematic approach to RWE in post-market authorisation under development.	✓ **Clinical Decision Support System (CDSS)** development via Swiss TPH.
✓ **Data pilots and network initiatives**: Enabling real-time data collection through integrated platforms.	✓ **Emphasis on clinical trial digitalisation** (EPRA reform, interoperability).

SOCIETAL & POLITICAL SUPPORT FOR THE LIFE SCIENCES AND PHARMA SECTOR

Belgium	Switzerland
✓ **Strong industrial base and structured stakeholder platforms.**	✓ **Strong industrial base and political stability.**
✓ **Biopharma platform:** Active government–industry collaboration (to be strengthened, regularised, and upscaled).	✓ **Transparent regulatory environment.**
✓ **Systematic planning through R&D Bioplatform and real-world evidence frameworks.**	✓ **Excellence in commercialising innovative medicines and diagnostics.**
❗ **Need for more cohesive end-to-end life sciences policy.**	❗ **Need for more integrated access and affordability strategy.**

This report is intended **as a catalyst for continued dialogue and concrete next steps**. It highlights insights and actionable practices that can serve as a foundation for further joint discussion and action.

Call to action: Via this report, we call for a structured and ongoing dialogue between governments, industry, academia, and patients, both nationally and across Europe. Only through open collaboration can Belgium and Switzerland sustain their leadership and help shape the future of life sciences.

Life sciences excellence in Belgium and Switzerland amid global shifts

The case for cross-border learning in life science policy

Belgium and Switzerland both feature strong, innovative, and highly attractive life sciences ecosystems (Tables 1 and 2). Each country brings together all the essential components: world-class hospitals, leading academic institutions and universities, a dynamic mix of small and large enterprises, a vibrant venture capital landscape, and a highly skilled clinical and research community. As a result, both have emerged as global hotspots and powerhouses in the life science and pharmaceutical sector, punching well above their weight given their relatively small size and populations. Beyond their scientific and industrial strengths, Switzerland and Belgium share a similar foundation. Both are multilingual nations, divided into regions and cantons, and operate across regional and national levels of governance. These structural and cultural parallels and similarities between the two countries provide an ideal basis for mutual learning and the sharing of best practices in areas where either country demonstrates a competitive edge or strengths.

This report aims to provide a **non-exhaustive comparative analysis of the life sciences ecosystems in Belgium and Switzerland, focussing on key strategic dimension such as clinical trials, access to medicines, data and digitalisation, societal and political support for the life science and pharmaceutical and diagnostics sectors**, as well as future prospects and lessons learned within the broader life sciences landscape.

The objective is to **encourage mutual learning and the exchange of best practices** by shedding light on the structural strengths and challenges each country faces. This comparative perspective enables both countries to deepen their understanding, enhance their ecosystems, and differentiate themselves in an increasingly competitive global environment.

The profiles of Belgium and Switzerland's life science ecosystems and their structural strengths

Belgium's life science ecosystem

Belgium is home to over 140 biotechnology companies, accounting for 7% of all biotech companies in Europe. Belgian biotech companies are responsible for 16% of total European biotech sales and contribute to nearly 10% of R&D spending in the sector across Europe. The country ranks second worldwide in biopharmaceutical export value per capita, benefiting from a strategic central location and highly specialised logistics infrastructure. Key hubs such as the Port of Antwerp, the world's first GDP-compliant maritime port, and Brussels Airport facilitate efficient global distribution. Together, they handle the export of over €230 million worth of biopharmaceuticals every day to destinations across the EU, China, North America, and beyond.[1,2] In addition to logistics excellence, Belgium is also a global hub for (next-gen) vaccine and ATMP (advanced therapy medicinal products) research & development, production, and distribution. This unique combination of strengths has earned it a well-deserved reputation as a "biotech and pharma valley" within Europe.[3, 4]

Swiss life science ecosystem

Switzerland, and particularly the Basel region, boasts a dense, agile, and innovation-driven life sciences and MedTech-ecosystem that spans the entire value chain. The area is home to more than 700 life sciences companies, over 1,000 research groups, and around 33,000 highly skilled life-science professionals in the sector. The presence of several global headquarters, combined with state-of-the-art research facilities, technology parks, and renowned academic institutions, has solidified Switzerland's position as a leading global hub for life sciences. The region's vibrant ecosystem supports both established players and innovative startups.[5,6,7] Switzerland also offers excellent infrastructure to support life sciences exports, with a highly connected multimodal transport network (road, rail, and air) and a strategic location at the crossroads of France and Germany. The Basel region plays a particularly critical role in facilitating international pharmaceutical shipping and distribution.

Table 1. Comparison of key demographic, economic, and health expenditure indicators between Belgium and Switzerland. Data includes population size[8,9], life expectancy[10], gross domestic product (GDP) and GDP per capita[11], health spending expressed as both a percentage of GDP and per capita expenditure[12,13], pharmaceutical spending expressed as both a percentage of GDP and per capita expenditure[14,15], and prevention budget as share of healthcare budget[16].

	Belgium	Switzerland
Population	11.8 M (2025)	9 M (2025)
Average life expectancy	82.43 years	84.23 years
GDP (in billion US$)	644.6 (2024)	936.6 (2024)
GDP per capita (US$)	≈ 54,627	≈ 104,067
Health spending (% of GDP)	8.4% (2022)	11.3% (2023)
Health spending per capita (US$)	≈ 4,589	≈ 11,760
Pharmaceutical spending (% of GDP)	16.6% (2022)	11.7% (2022)
Pharmaceutical spending (% total healthcare budget)	2.5% (2022)	4.1% (2022)
Preventive healthcare spending (% total healthcare budget)	11.8 M (2025)	9 M (2025)

Table 2. Comparison of the size of the pharma sector between Belgium and Switzerland. Data includes money invested in biopharma R&D[17,18], number of jobs in pharma and life sciences sectors[17,19], pharma export[17,20], number of clinical trials authorised[17,21], value contribution per employee[22,23], amount of biomedical public & filed patents[17,24] amount of venture capital funding attracted[25,26], amount of MedTech jobs[27,28], and MedTech revenue[29,30].

	Belgium	Switzerland
Invested in biopharma R&D	€6 B (2024)	6.5 B CHF (2024)
# of jobs in pharma and life sciences	44,738 (2024)	50,600 (2024)
Pharma exports	$79.0 B (2024)	$80.70 B (2023)
# of clinical trials authorised	574 (2021)	156 (2023)
Value contribution per employee	€403 K (2023)	922 K CHF (2024)
Biomedical public & filed patents	417 (2024)	±10,000 (2024)
Venture capital funding attracted	€500 M (2022)	739.2 M CHF (2024)
MedTech jobs	17,000 (2023)	71,700 (2022)
MedTech revenue	€3.4 B (2022)	23.4 B CHF (2023)

Innovation at risk: The growing investment divide

While both Belgium and Switzerland offer robust, world-class life sciences ecosystems, they also face significant challenges that impact the overall attractiveness of their markets, particularly in the broader European context. This declining competitiveness is most starkly illustrated when compared to China, with its large population and strong commitment to investing in innovation, is rapidly emerging as a key player in the global life science landscape. Meanwhile, the United States accounts for nearly half of the global pharmaceutical market, underpinned by a regulatory environment that rewards innovation and facilitates rapid market access. United States' biopharmaceutical companies have recently announced investment plans exceeding USD 150 billion. By contrast, no comparable investment commitments have been made within Europe, despite its larger population base. Europe's pharmaceutical market, in fact, remains only half the size of the U.S. market. Key deterrents include the systematic use of price controls, austerity measures, and ongoing regulatory uncertainty, particularly around tariffs. These policies are increasingly seen as barriers to innovation and long-term investment.

The consequences are clear:

- More than 30% of medicines approved in the U.S. remain unavailable in Europe two years later.

- Clinical trials, R&D activities, and life sciences jobs are steadily shifting to the U.S. and, increasingly, China, where pro-innovation policies and strong investment incentives are driving rapid growth.

Europe, and Belgium in particular, are increasingly positioned as net receivers within the pharmaceutical industry, benefiting from but not always driving innovation. To ensure continued access to cutting-edge therapies and maintain a leadership role in the global life sciences ecosystem, it is essential that Europe strengthens its ability to reward and incentivise innovation. Without strategic policy shifts and renewed investment in competitiveness, Europe risks falling behind, even in its traditionally strong life science hubs like Belgium and Switzerland. Maintaining global leadership in biotech and pharma will require proactive efforts to address these systemic issues and strengthen the continent's position as an innovation-driven life sciences region.[31,32]

Learnings and best practices focussing on key strategic dimensions

To strengthen Belgium's and Switzerland's positions, we conducted a targeted comparative analysis of the life sciences ecosystems in both countries, focusing on key strategic dimensions that shape national and international competitiveness, with the aim of identifying strengths and opportunities for mutual learning and reinforcement.

These include:

- Clinical trials
- Access to innovative medicines
- Data and digitisation
- Societal and political support

Each chapter provides a structured comparison of both countries, highlights key reforms, and outlines opportunities for mutual learning and strategic improvement.

Rather than being exhaustive, the analysis highlights actionable insights and best practices from each country. It aims to inform policy decisions and identify opportunities for mutual learning and collaboration. The findings underscore the importance of aligning innovation policies with structural strengths to maintain and enhance global leadership in life sciences.

Clinical trials in a changing global landscape

Europe's declining share in global clinical research

The global clinical trial landscape is undergoing major shifts. Europe's relative share in clinical research has dropped significantly, falling from 15% of all global clinical trials in 2018 to just 9% in 2023 (Figure 1). This trend is shaped by several factors:

- A plateau or decline in the absolute number of trials initiated in Europe.
- Rapid growth of clinical trial activity in non-Western markets, especially China, Japan, and other parts of Asia.[33]

Figure 1. *Overview of the number of global clinical trials started by regions (2013, 2018-2023; Phase 1-4).*[33]

Switzerland's position: Challenges and strategic shifts

Switzerland mirrors the broader European trend, with a modest decline in Phase I clinical trials.[33] However, this is not solely a negative indicator – rather, it reflects a strategic national focus on later-stage trials with higher commercial relevance and proximity to market authorisation. Despite this strategic intent, Switzerland faces structural challenges that limit its competitiveness in clinical research:

- Small population size restricts patient recruitment.
- High operational costs of conducting trials.
- A fragmented healthcare system.
- Limited digitalisation, with poor adoption of electronic health records (EHRs).[34,35]

A notable structural weakness lies in clinical trial budgeting:

- Overoptimistic budget estimations and under-funding frequently lead to trial discontinuation and research waste.
- Budget calculation tools used by Swiss Clinical Trial Units (CTUs) are often inconsistent across institutions, none of the available tools had undergone user-testing for reliable cost estimates and only one CTU had made a tool publicly accessible.[36]

These inefficiencies undermine Switzerland's ability to attract and sustain high-quality clinical trials.

Switzerland has recognised these issues and is implementing several initiatives to strengthen its position and regain competitiveness in clinical research:

- Regulatory streamlining:
  Swissmedic introduced fast-track procedures for trials addressing high medical needs with application processing time reduced from 30 to 20 days, review periods for first-in-human studies reduced from 60 to 40 days.[37]
- Innovation in study design:
  Interpharma is advocating for a regulatory framework that supports more efficient and complex trial designs, enabling accelerated progression through clinical studies.
- Digital consent and decentralised trials:
  A proposed revision of the Human Research Act aims to enable digital consent, paving the way for decentralised clinical trials. This would enhance patient access and recruitment, aligning Switzerland with global innovation trends.[38]

Switzerland also stands out in offering early scientific guidance for trial sponsors.

- Swissmedic's Scientific Advice Program allows sponsors to assess whether a planned study setup meets scientific and regulatory requirements, reducing uncertainty before submission.[39]

Belgium's position: A strong foundation under pressure

Belgium has long held a leading position in clinical research, underpinned by efficient approval processes, high-quality infrastructure, and a deep pool of expertise. Historically, Belgium distinguished itself with fast clinical trial start-up times, securing approvals in as little as 20 days, far below the previous EU average of 66 days.[33] However, with the introduction of the EU Clinical Trial Regulation (CTR) and the harmonisation of timelines across member states, Belgium's competitive edge has diminished and lags some of its European peers. Several factors have contributed to this shift:

- Longer regulatory and ethics approval timelines.[33]
- Less/limited interaction and consultation between principal/coordinating investigator and ethics committees.[33]
- Increased uncertainty around future reimbursement decisions.[2]

These developments have made Belgium less attractive for certain types of clinical trials, particularly in a globally competitive environment. In response, Belgium has launched a series of targeted reforms and initiatives to regain competitiveness and restore its position as a premier destination for clinical research:

- Phase I fast-tack procedure:
  To retain its advantage in early-phase research, Belgium introduced a national fast-track procedure specifically for Phase I clinical trials. This regulation only applies to clinical trials conducted within Belgian borders and is overseen by the FAMHP and a single designated ethics committee. It enables faster approval timelines and reinforces Belgium's attractiveness as a location for early-stage clinical development.[40]
- Ethics committee reform:
  To further accelerate clinical trial start-up time, the government is reviewing the functioning of ethics committees, with the goal of streamlining approvals and reducing administrative delays.[41]
- Renewed focus on disease registry legislation & Real-World Data (RWD) infrastructure:
  Developed by NIHDI, Belgium's new disease registry legislation establishes a federated, GDPR-compliant infrastructure aligned with the European Health Data Space (EHDS). It facilitates secure access to high-quality real-world data, supporting both general and study-specific needs, ultimately improving the efficiency, compliance and feasibility of clinical trials.[42]
- Scientific and Technical Advice (STA)
  The FAMHP offers a Scientific and Technical Advice (STA) service to help sponsors navigate complex regulatory pathways. It provides early-stage guidance on study design, endpoint selection, regulatory compliance. This service aims to improve trial design quality and reduce risks of rejection or costly amendments later in the process.[43]
- Clinical trial budgeting – the KCE (Belgian's Knowledge Institute) model:
  Belgium's KCE Sponsor Budget Tool represents a best practice in clinical trial budgeting. It is publicly accessible and user-tested, provides detailed cost lists with ranges and includes a user manual and dedicated support services. The KCE Sponsor Budget Tool makes sure that the applicant considers all necessary trial activities for budgeting, as well as ensures fair, and consistent compensation for all trial activities.[44]
- Evidence platform for reimbursement and study design:
  As part of its roadmap to modernise drug reimbursement, NIHDI is developing an evidence platform that will serve as an advisory body on study design, data collection, and methodology, and support researchers to optimise protocols for both trials and real-world studies to increase the likelihood of generating high-quality, actionable evidence.[45]

If these initiatives are implemented effectively, Belgium can not only reclaim its former advantage but also emerge as a model for clinical trial innovation and efficiency in Europe.

Table 3. Number of active trials in BE[46] and CH[47] as per September 2025

	Belgium	Switzerland
Phase I	146	86
Phase II	279	159
Phase III	436	202
Phase IV	65	54

Table 4. Number of active trials in BE[48] and CH[49] corrected per million inhabitants as per September 2025

	Belgium	Switzerland
Phase I	12	9
Phase II	23	17
Phase III	36	22
Phase IV	5	6

Clinical trials - Opportunities for cross-learning and mutual reinforcement

Belgium and Switzerland both possess strong clinical research ecosystems but face shared challenges amid increasing global competition. A comparative analysis reveals a range of complementary strengths and best practices that, if adopted across borders, can enhance performance and international competitiveness.

Belgium	Switzerland
✓ Phase I national procedure: Dedicated framework for faster early-phase trial approval.	✓ Fast-track procedures: Accelerated approval timelines for high-need and early-phase trials.
✓ Ethics committee reform: Ongoing efforts to shorten approval timelines.	✓ Scientific advice pathways: Early regulatory guidance supports study design and alignment.
✓ Sponsor budget tool: Transparent, user-tested budgeting model for consistent and fair trial costing.	✓ Regulatory flexibility: Willingness to tailor frameworks to support innovation and complex designs.
✓ NIHDI evidence platform: Under development to improve study design, data collection & RWE generation.	

By sharing and adopting each other's strengths, Switzerland's regulatory foresight and Belgium's structural and methodological frameworks, both countries can enhance their global competitiveness, support more efficient, patient-centred clinical research and consecutively strengthen Europe's clinical research ecosystem.

Europe's overall decline in clinical trial activity should act as a wake-up call, even for countries like Switzerland and Belgium. Without bold policy shifts, both countries risks falling behind in the global innovation race.

Access to innovative therapies: Performance, reforms, and opportunities

Ensuring timely and equitable access to innovative medicines remains a key challenge across Europe. While both Belgium and Switzerland have implemented meaningful reforms in recent years, they continue to face systemic obstacles that hinder fast patient access.

Switzerland: Moving towards faster and more flexible access

Switzerland performs relatively well on the W.A.I.T. (Waiting to Access Innovative Therapies) indicator, with an average of 451 days between marketing authorisation and patient access. While this is an improvement over many EU countries, it still falls significantly behind access leaders such as Germany (128 days) and Denmark (339 days) (Figure 2). In terms of availability, approximately 73% of authorised innovative medicines are accessible to Swiss patients, placing the country among the stronger performers in Europe, but still leaving room for improvement.[50]

Switzerland has recently introduced several targeted measures to accelerate access without compromising safety or efficacy:

- Project Orbis participation:
  Swissmedic's involvement in Project Orbis marks a significant step forward. Led by the U.S. FDA, this global initiative enables simultaneous submission and parallel review of oncology therapies in multiple countries. For Switzerland, this means accelerated timelines for approval of high-impact oncology treatments, without compromising on safety or quality.[51]
- 'Day 0' reimbursement for high-need medicines (Art. 52d KVG):
  Introduced as part of the second cost-containment package adopted in March 2025, this mechanism

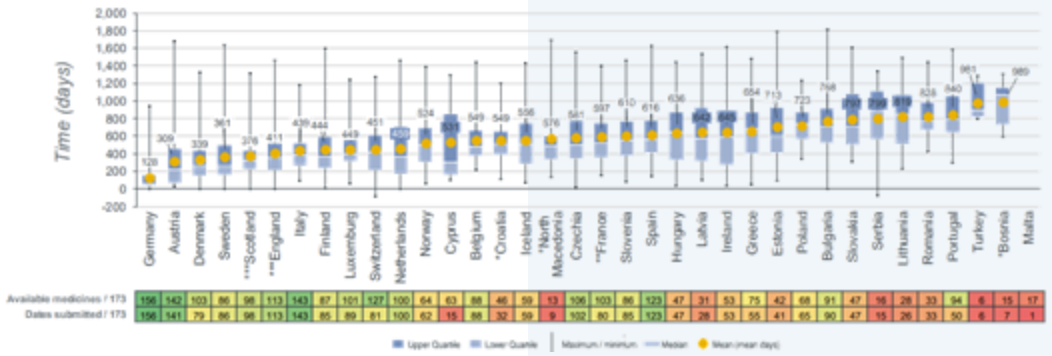

Figure 2. *The EPPIA WAIT indicator demonstrating the total availability by approval year is the number of medicines available to patients in EU countries as 5th of January 2025 (for most countries this is the point at which the product gains access to the reimbursement list), split by the year the product received marketing authorisation.*[50]

allows certain medicines addressing high medical need to be reimbursed provisionally as soon as they are approved by Swissmedic, prior to the finalisation of price negotiations. While the measure has strong potential to improve patient access, its long-term impact will depend on how implementation challenges are addressed.[52]

- Support for precision medicine:
  Switzerland also leads in the reimbursement of next-generation sequencing (NGS), particularly for oncological diagnosis and treatment. This integration ensures that patients have access not only to innovative therapies but also to the necessary diagnostic tools to target treatments effectively.[53]

These reforms are promising, but the broader implications of the second cost-containment package raise questions about future access and long-term sustainability.

Belgium: Strategic reforms to regain competitive ground

Belgium currently faces longer access delays, with an average W.A.I.T. time of 549 days. Only 51% of centrally approved medicines are available to Belgian patients, significantly lower than in Switzerland, Germany, or Italy. This lag can be attributed to multiple factors: longer regulatory timelines, layers of decision-making, misalignment on value assessment (volarisation), and uncertainty in reimbursement decision-making. However, Belgium is actively pursuing multiple strategic reforms to address these issues.

Key Reforms and Initiatives:

- BeNeLuxA(IR) cooperation:
  Belgium plays a leading role in the BeNeLuxAIR initiative, a payer collaboration with the Netherlands, Luxembourg, Austria, and – at times – Ireland. This cross-border approach facilitates joint health technology assessments (HTA), and horizon scanning. It can help reduce duplication, accelerate access decisions, and sharing of best practices.[54]
- Early and Fast Access Reform (Effective January 2026):
  To improve access timelines, Belgium has introduced two distinct pathways: (1) Early Access: Allows access prior to formal EMA approval, after a positive CHMP opinion and inclusion on the unmet medical needs list. (2) Fast Access: Enables patient access immediately after EMA approval, even before the final reimbursement decision has been made. These new pathways are intended to provide patients with quicker access to promising treatments, particularly in high-need therapeutic areas.[55] Although the measure holds significant promise for enhancing patient access, the impact will be based on the implementation and financial mechanism behind it (still to be determined) and eventual utilisation.
- NEED framework (KCE):
  To ensure transparent prioritisation of healthcare spending, Belgium has developed the NEED framework, a structured tool for evaluating the full burden of disease across medical, therapeutic, and societal dimensions. This framework supports more strategic, evidence-based allocation of limited healthcare resources and strengthens alignment between regulatory priorities and societal needs.[56]
- Aligned reimbursement for companion diagnostics: Since 2019, Belgium has streamlined reimbursement for targeted therapies and their companion diagnostics. This has helped contribute to better alignment so that both the treatment and the diagnostic test are reimbursed simultaneously, reducing delays in personalised medicine access.[57]

Despite these forward-thinking initiatives, Belgium continues to grapple with long approval timelines, increasing healthcare costs, and systemic pressures that threaten the sustainability of universal access.

Additionally, to remain at the forefront of personalised medicine, building on, and expanding the system of parallel reimbursement of companion diagnostics and therapies will be essential.

Access to innovative medicines - Opportunities for cross-learning and mutual reinforcement

Belgium and Switzerland differ in policy approaches; they face many of the same structural pressures – ranging from delayed access and rising healthcare costs to increased global competition. Each country's distinct strengths offer valuable lessons for the other. While Switzerland currently outperforms Belgium on speed and availability, both countries are actively working to address structural barriers. Their complementary approaches offer valuable lessons and models:

Belgium	Switzerland
✓ Collaborative HTA and horizon-scanning via BeNeLuxA(IR).	✓ Fast-track access mechanisms for oncology through Project Orbis.
✓ Early and fast access pathways pre- and post-EMA approval.	✓ 'Day 0' reimbursement for high-need therapies.
✓ Structured frameworks (e.g. NEED) for evidence-informed decision-making.	✓ Early adoption of reimbursement of NGS in oncology.
✓ Aligned reimbursement for therapies and companion diagnostics.	✓ Strong integration of diagnostics and therapeutic approaches.

Shared Priorities Moving Forward

- Enhance early access to innovation while safeguarding sustainability.
- Build national RWE ecosystems to inform real-world value and reimbursement.
- Expand regulatory agility through early advice and adaptive pathways.
- Ensure greater alignment between innovation, pricing (valorisation of innovative solutions), and patient access, for both diagnostics and therapies.
- Promote structured government–industry collaboration on long-term strategy (collaboration to create 'win-win' situations).

Both countries have made significant progress in aligning regulatory and reimbursement strategies with innovation. If effectively implemented, their initiatives could serve as European models for timely, equitable, and sustainable access to breakthrough therapies and, where applicable, their accompanying diagnostics tests (companion diagnostics).

Data & Digitalisation: Building the foundations for Real-World Evidence

Digital health data and real-world evidence (RWE) are becoming central pillars in the transformation of healthcare systems across Europe. Both Switzerland and Belgium have recognised the growing strategic importance of data – not only for healthcare delivery but also as a critical enabler of innovation, clinical research, regulatory decision-making, and reimbursement. There is a clear shift underway in both countries: from relying solely on traditional clinical trial data to actively incorporating real-world data (RWD) throughout the lifecycle of medicines and medical devices. When properly structured and analysed, RWD can generate robust RWE that supports everything from early development and market access to post-market evaluation and value-based reimbursement. However, despite the clear policy intent, both Switzerland and Belgium still face persistent obstacles. Health data remains fragmented, data standards vary, and electronic health record systems are not yet fully interoperable or widely adopted. Overcoming these challenges requires coordinated national strategies that prioritise data quality, accessibility, security, and real-time exchange across systems and care providers.

Switzerland: Addressing fragmentation and enabling digital transformation

Switzerland has traditionally faced significant challenges in the digital health landscape. Its decentralised healthcare system and hospital autonomy have led to a fragmented digital infrastructure, complicating efforts to conduct large-scale research, generate real-world data, or scale innovation. For example, the lack of integration across electronic patient record (EPR) systems makes it difficult to identify and enrol eligible patients in clinical trials efficiently, slowing down research and increasing operational costs. In parallel, Switzerland is advancing a Real-World Evidence (RWE) framework; Swissmedic recently published an annex to its RWE position paper, aligning with international standards. The framework allows RWE to be used as supportive evidence in regulatory assessments, enhancing decision-making and optimising resource use.58

Key National Initiatives:

- Revision of the Act on the Electronic Patient Record (EPRA):
  Switzerland is revising its foundational EPR legislation to improve uptake, ensure long-term scalability, and address critical interoperability issues. The updated law aims to enhance access, trust, and participation from both healthcare professionals and patients.[59]
- Secondary use framework for health data:
  A new legislative framework is being introduced to enable the secondary use of health data for research, innovation, and policy. This marks a pivotal shift towards making health data available for broader public health purposes, while ensuring strict privacy and governance controls.[59]
- DigiSanté programme (Launched January 2025):
  This federal multi-year initiative represents a strategic step toward the digital transformation of Swiss healthcare. DigiSanté is structured around four pillars:
  - Digitalise key healthcare workflows
  - Standardise data collection and exchange
  - Anchor governance and legal frameworks
  - Orchestrate stakeholder collaboration

  The programme's overarching aim is to create a secure, interoperable infrastructure that can support evidence-based policymaking and innovation at scale.[60]
- Digital Tools for Decision Support:
  The Swiss Tropical and Public Health Institute (Swiss TPH) is developing a Clinical Decision Support System (CDSS) that integrates diagnostic algorithms with accessible data tools. This will help healthcare professionals make informed decisions, optimise diagnostic testing, and reduce unnecessary treatments, ultimately improving quality of care and resource efficiency.[61]

Switzerland is taking significant steps to lay the digital foundation for a learning healthcare system. However, success will depend on the full implementation of legal reforms, improved stakeholder adoption, and better data interoperability across cantons and institutions.

Belgium: Building a purpose-driven real-world evidence ecosystem

Belgium has also placed digitalisation and data reuse high on its healthcare agenda. National strategies focus on enabling secure, standardised, and interoperable health data systems that support RWD collection and broader evidence generation across the care continuum.

Key national strategies and tools:

- Belgian Health Data Agency (HDA):
  Belgium established the HDA as a national body tasked with unlocking the value of health data. Its mandate includes supporting data standardisation, enabling secondary data use, and ensuring alignment with the European Health Data Space (EHDS).[62]
- NEED framework – Defining Data Requirements:
  Developed by the Belgian Health Care Knowledge Centre (KCE), the NEED framework identifies the key types of data required to assess the burden of disease. It sets clear expectations for data collection across the patient journey and links this to regulatory, clinical, and reimbursement decision-making (see also the chapter on Access to Medicines).[56]
- The Evidence Platform – Post-Market Data Governance:
  The Evidence Platform is an independent, science-based advisory body that evaluates evidence requirements throughout a product's lifecycle. Initially focused on post-market authorisation and managed entry agreements (MEAs), the platform

helps determine when RWD collection is necessary, feasible, and meaningful. In later phases, its mandate will expand to include pre-market evaluations and medical devices, supporting a broader transition to a learning health system.[45]

- Data pilots and network initiatives:
  Government-funded pilot projects are enhancing real-world data collection. Thess projects involve collaboration between hospitals, pharma, and government under formal agreements: hospitals collect data in a standardised format, send it to a shared platform for processing, and pharma companies can then pay to access the data through reports.

Belgium is laying the foundations for a robust, purpose-driven RWE infrastructure. Through tools like the NEED framework and Evidence Platform, combined with digital enablers like data capability projects, Belgium is positioning itself to become a leader in data-driven health innovation and evidence-based reimbursement. Overcoming the data fragmentation, ensuring widespread adoption after successful pilot programmes, and driving acceptance of RWD/RWE in decision-making processes will be key hurdles to tackle from Belgium to realise this leadership position

Data pilot example - BELHINDA

The Belgian Hospital-Industry Data Alliance (BELHINDA) brings together eight Federate Health Innovation network (FHIN) hospitals, eight pharmaceutical companies, and specialist partners. In the NSCLC pilot, Levilo provides data engineering and harmonisation services, converting raw hospital data into standardised formats. INAH contributes expertise in data governance and ethics, helping to design the legal and privacy framework that enables compliant data sharing. Hospitals retain control of their data, and the model is jointly shaped with industry, this makes BELHINDA a genuine multi-stakeholder initiative for the collection of real-world data.[63]

Data & digitalisation - Opportunities for cross-learning and mutual reinforcement

While both Switzerland and Belgium are investing heavily in digital health infrastructure, each country's approach reflects its unique system structure, priorities, and policy challenges. However, a number of complementary strengths emerge that offer concrete opportunities for shared learning:

Belgium	Switzerland
✓ Health Data Agency: Dedicated institution for data standardisation and secondary use.	✓ DigiSanté: Strategic coordination of national digital health transformation.
✓ NEED framework: Structured approach to define data requirements for burden of disease.	✓ Secondary use legislation under development.
✓ Evidence Platform: Systematic approach to RWE in post-market authorisation.	✓ CDSS development via Swiss TPH.
✓ Data pilots and network initiatives	✓ Emphasis on clinical trial digitalisation (EPRA reform, interoperability).

Strategic Takeaway:
To enable a truly data-driven healthcare ecosystem, both countries must continue to:

- Break down institutional and regional silos.
- Align data governance with European frameworks (e.g., EHDS).
- Promote interoperability and standardisation of digital tools.
- Build digital infrastructure that supports continuous learning, from R&D to reimbursement.

By learning from Belgium's policy-led data frameworks and Switzerland's efforts to modernise digital health governance, both countries can accelerate their progress toward becoming model ecosystems for RWE generation and data-driven healthcare innovation.

Societal and political support for the life science sector

A strong life sciences ecosystem does not rely solely on scientific excellence or industrial capacity; it also requires long-term societal and political commitment. In both Switzerland and Belgium, pharmaceutical and diagnostics companies benefit from a supportive foundation that includes high-quality academic institutions, specialised talent pipelines, and access to advanced research infrastructure. However, in today's rapidly evolving healthcare and innovation landscape, this foundational support must be matched by strategic, forward-looking policy engagement.

Growing pressures, such as population ageing[64], rising healthcare costs, intensified global competition, and the increasing complexity of personalised medicine require a more structured, holistic dialogue between governments and the life sciences industry. As the US and China continue to redefine standards for incentivising innovation[65], and international pricing dynamics evolve (e.g. the U.S. Most-Favoured-Nation pricing rule)[66], domestic policy decisions in Europe now carry global repercussions. Against this backdrop, both Switzerland and Belgium are seeking ways to align policy, regulation, and innovation to maintain their competitiveness while ensuring sustainable access to healthcare for their populations.

Switzerland: Stability as a foundation, strategy as a necessity

Switzerland enjoys a globally recognised reputation for its stable political climate, transparent regulatory environment, and advanced research capabilities – all of which contribute to its strength as a life sciences hub. The country's pharmaceutical sector is deeply integrated into a knowledge-based ecosystem, supported by proximity to leading universities and a highly skilled workforce.[34]

However, Swiss stakeholders are increasingly calling for a coordinated national strategy that proactively addresses:

- Global competitive pressures (particularly from U.S. and Asian markets)[67],
- Fragmented healthcare and innovation policies, and
- Structural access barriers that disconnect innovation from patient benefit, as well as the wider benefit to society arising out of innovative therapies (societal impact).

Although Switzerland excels in developing and commercialising innovative medicines, it has yet to fully integrate access to medicines into its national innovation agenda. The resulting gap can diminish the impact of innovation on population health and patient outcomes. Creating a more cohesive national vision that includes access and affordability considerations alongside innovation, talent, and industrial policy will be essential. Such a strategy would not only strengthen competitiveness but also ensure the societal value of innovation is fully realised.

Belgium: A renewed focus on dialogue and system coherence

Belgium, with its long-standing pharmaceutical tradition, also benefits from a strong talent base and an established industrial footprint.[68] Yet maintaining this position in the face of global competition demands continuous evolution of its policy frameworks and more integrated decision-making. A major recent step in this direction is the revival of the R&D Bioplatform, an initiative launched under former Prime Minister De Croo and now re-emphasised by the Arizona Coalition.[69] Envisioned as a structured forum for stakeholder–government dialogue, this platform aims to:

- Link all phases of the pharmaceutical value chain – from R&D and innovation to access, reimbursement, and post-market evaluation.
- Address fragmentation between regional and federal decision-making.
- Align incentives across the life cycle of medicines – from R&D incentives to valorisation of innovation in reimbursement – to ensure innovation is translated into patient benefit in a timely and sustainable manner.

Currently, these phases are often addressed in isolation, leading to mismatches – for example, public funding for early-stage R&D may not be matched by mechanisms that ensure timely or equitable access to the resulting therapies.

If implemented effectively, the R&D Bioplatform could serve as a model for end-to-end pharmaceutical policy, ensuring that each stage of the value chain is coherent, coordinated, and purpose driven.

In parallel, Belgium is also exploring new policy mechanisms to support system sustainability. One such approach involves generating efficiency savings from off-patent or low-value treatments and reallocating these savings to reward high-impact innovations. Real-world evidence (RWE) will be instrumental here, allowing policymakers to distinguish between treatments with high versus limited real-world value and to direct resources accordingly.

Societal & political support - Opportunities for cross-learning and mutual reinforcement

Despite their differences, both Belgium and Switzerland are grappling with similar structural challenges, and both stand to benefit from each other's best practices.

Belgium	Switzerland
✓ Strong industrial base and structured stakeholder platforms.	✓ Strong industrial base and political stability.
✓ Active government–industry collaboration via Arizona Coalition.	✓ Transparent regulatory environment.
✓ Systematic planning through R&D Bioplatform and real-world evidence frameworks.	✓ Excellence in commercialising innovative medicines and diagnostics.
✓ Need for more cohesive end-to-end life sciences policy.	✓ Need for more integrated access and affordability strategy.

Shared priorities moving forward:

- Adopt a holistic, end-to-end policy framework that integrates innovation, access, and sustainability.
- Strengthen structured dialogue between governments and the life sciences sector.
- Improve alignment between R&D investments and patient access outcomes.
- Harness RWE to assess real-world value and inform pricing and reimbursement policies.
- Respond proactively to international pricing pressures by reinforcing local competitiveness and value demonstration.

By pursuing these priorities, Belgium and Switzerland can continue to position themselves as global leaders in the life sciences sector, not only as hubs of scientific innovation but as champions of patient-centred, evidence-based, and economically sustainable healthcare systems.

Conclusion

Belgium and Switzerland both stand as global leaders in life sciences, offering robust ecosystems built on innovation, world-class infrastructure, academic excellence, and a skilled workforce. Despite their relatively small size, both countries consistently punch above their weight, not only in R&D investment and pharmaceutical exports but also in their capacity to drive scientific and clinical advancement.

Yet, as the global life sciences landscape undergoes significant transformation, shaped by accelerating innovation cycles, increasing global competition, rising access demands, and complex regulatory environments, structural strengths alone are no longer sufficient to ensure long-term competitiveness. The comparative analysis presented in this report reveals that while both countries have made commendable progress, they also face shared challenges and emerging pressures that require more strategic coordination and forward-thinking policy responses to ensure that health innovation keeps thriving and remains accessible.

Crucially, the report identifies complementary best practices that Belgium and Switzerland can learn from one another:

- Belgium's strengths lie in accelerated clinical trial approval, and its structured and transparent clinical trial budgeting (e.g., the KCE tool), growing investments in real-world data governance (HDA) and infrastructures (through eHealth, Levilo/FHIN/INAH), and collaborative initiatives like BeNeLuxA(IR) and the Early and Fast Access framework.
- Switzerland demonstrates excellence in regulatory agility (e.g. Project Orbis and fast-track clinical trials), scientific advice integration, proactive digital health reforms (e.g. DigiSanté), and promising steps toward broader use of real-world evidence and decentralised trials.

By exchanging insights and adopting an end-to-end, patient-centric approach to the innovation lifecycle, both countries can reinforce their ecosystems, from clinical research to access and post-market evaluation. Accelerating digitalisation, integrating access considerations earlier in the development process, and creating predictable and transparent policy environments will be critical levers for the future.

Ultimately, the future competitiveness of both ecosystems will not only depend o<n national policy strength, but also on cross-border collaboration, strategic foresight, and willingness to adapt. Belgium and Switzerland are well-positioned to lead in shaping a more resilient, agile, and innovation-driven European life sciences model, but seizing this opportunity will require translating these insights into concrete, collaborative next steps.

To that end, we call for an open and ongoing dialogue between governments, industry stakeholders, academia, and patients in both countries, and across Europe more broadly. A regular, structured exchange of ideas, challenges, and best practices can help ensure that the policies and systems put in place today will remain fit for purpose tomorrow. Only through such collaboration can Belgium and Switzerland not only preserve their leadership – but define the future of life science in Europe and beyond.

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