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Pharma in Belgium and Europe, Quo Vadis?

THE PHARMA URGENCY FOR BELGIUM AND EUROPE

Frontrunner or Decline?

EXPERT ROUNDTABLE REPORT

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About this report

This report builds on Itinera's closed expert roundtable "Pharma in Belgium and Europe, Quo Vadis?", held in Brussels on 2 March 2026 under the Chatham House Rule. The roundtable invited a wide variety of business leaders, stakeholders and decision makers. After the stimulating keynote by Alicia Garcia-Herrero on global industrial challenges, parallel sessions were devoted to 'Global Shifts & Supply Chains', 'Innovation & Competitiveness' and 'Belgium & Europe's Industrial Biopharma Strategy'. The roundtable provided a wealth of information as it tested assumptions, brought operational evidence into the room and clarified where the strategic pressure points are. A varied audience of stakeholders, market watchers and industry experts voiced deep concerns and offered stark warnings about the current trends, but also voiced strong beliefs about Belgium's and Europe's remaining potential.

This document is a structured roundtable report, based on the plenary and parallel session discussions. The report is not a complete transcript, nor a negotiated consensus. A comprehensive reflection on the multiple strategic and geopolitical challenges requires much more than a concise roundtable report. Hence, this report captures the main storylines from the roundtable discussions and translates these into strategic recommendations.

When participants referred to recent figures or existing publications, Itinera did check available resources and integrated relevant data of cases into this roundtable report. A list with relevant sources is available in the appendix.

Itinera hosted the roundtable and produced this report. For Itinera, this roundtable report contributes to the broader debate on industrial policy challenges. This report is not a formal Itinera Analysis reflecting comprehensive policy exploration and Itinera's own position. It serves as a collective sign of urgency for policy action, an urgency Itinera will seek to contribute to in the near future

Disclaimer

This report is based on Itinera's closed expert roundtable "Pharma in Belgium and Europe, Quo Vadis?", held in Brussels on 2 March 2026, which was made possible with the support of AstraZeneca and Novartis. The analysis, storylines and recommendations were developed in full intellectual autonomy by the authors and reflect exclusively the views and conclusions of Itinera Institute. This report is not a formal Itinera Analysis reflecting comprehensive policy exploration, nor a negotiated consensus among roundtable participants. It does not bind AstraZeneca, Novartis, or any other institution or participant in any way.

Executive summary

Belgium should actively pursue frontrunner status in European biopharma. That will not happen through slogans, nostalgia or generic innovation language. It will require our governments to treat access, clinical trials, resilience, capital, IP anchoring and European scale as one strategic competitiveness agenda.

Belgium and Europe are not losing ground because the science is weak. They are losing ground because their pharma ecosystem underperforms in the conversion of science into patient access, clinical activity, manufacturing depth, decision centres and anchored investment. Increasingly, this decline is also the result fo deliberate geoeconomic strategies in key competing nations like China and the United States.

A country can have the best laboratories in the world and still lose the strategic game if patients wait too long, trials move elsewhere, companies scale abroad and procurement rewards cost optimisation that creates fragility.

For our governments, the call to action is straightforward: decide that Belgium will be one of Europe's fastest and most reliable biopharma ecosystems, organise and benchmark public systems accordingly, and make the trade-offs explicit. It is time to treat the bioharma sector as the key strategic industrial sector it is – for reasons of high-quality investment, innovation, growth and job creation, as well as for reasons of sovereignty, autonomy and security in the new world disorder.

Belgium still starts from strength, even after recent weakening:

- pharmaceutical exports reached roughly €79 billion and 15.5% of Belgian exports in 2024, then weakened by 6.8% to €73.1 billion in 2025;
- ± 45,000 direct jobs and ± 141,000 total jobs (direct, indirect and induced);
- more than €6 billion in annual R&D;
- world-class activity in vaccines, oncology, biologics, cell therapy, logistics and early-phase clinical work.

The strategic warning signs are just as material:

- the average rate of availability for new medicines across the EU is still below half, while US availability remains materially higher (roughly 80%);
- Europe has a legal 180-day upper limit for national pricing and reimbursement decisions under the Transparency Directive: 90 days for pricing, 90 days for reimbursement, or up to 180 days where both are handled together or sequentially. That is not a median target; it is the ceiling once the complete application is in. Clock-stops can extend the practical timeline when authorities request additional information. Even so, real-world access takes far longer: the EU average time to availability was 578 days in 2024, up from 531 days two years earlier, while Belgium's median was 476 days.
- according to industry experts around 1 in 7 new medicines are already considered economically non-viable to launch in Europe;
- Europe's share of global commercial clinical trials has fallen sharply over the past decade, while China has become a major clinical-trial location;
- the US most-favoured-nation pricing logic has turned low European prices from a domestic budget instrument into a global launch and revenue risk.

The conclusion is not that Europe should imitate the United States or close itself off from China. The conclusion is that Europe must stop behaving as if strong science automatically translates into strategic strength and industrial leadership, and recognise it will either have both or none at all. Conversion is policy work. That policy work should be built around four pillars:

1. **Access and launch predictability:** make Belgium a credible early-access and launch country again, doing structurally better than the 180-day ceiling, especially for valuable innovations.
2. **Clinical trials, data and evidence speed:** make Belgium the country where trial feasibility, ethics review, permits, contracts, site start-up and real-world evidence systems work faster than in peer ecosystems, by raising administrative performance, not by lowering quality.
3. **Resilience and strategic depth:** secure critical older medicines and inputs, but do not confuse resilience with warehouses. You cannot stockpile innovation. Belgium and Europe also need the capacity to discover, test, produce, decide and scale.
4. **Capital, IP and European scale:** mobilise scale-up finance, keep intellectual property and decision centres anchored, and use EU scale or coalitions of the willing when national fragmentation blocks execution.

This is the policy message: Belgium should not ask whether it can preserve yesterday's strength. It should decide whether it wants to be a European frontrunner that helps define the next innovation model for European pharma. Embrace biopharma as a priority in the new age of industrial policy, or risk losing its legacy as other and bigger countries do it instead. ■

Introduction

The core strategic issue of this paper is the competitiveness of the Belgian and EU biopharma ecosystems. The question is not whether Belgium and Europe have important scientific assets. They do. The question is whether those assets are converted quickly enough into:

- patient access,
- clinical evidence,
- production depth,
- strategic autonomy and
- future investment.

Increasingly, this question sits at the intersection of health policy, industrial policy, economic security, fiscal sustainability, data governance and geopolitics. Medicines, clinical data, active ingredients, advanced therapies, manufacturing capacity, reimbursement speed and IP anchoring have all become strategic variables.

The answer cannot be another cautious statement that all stakeholders should work together. That is true, but insufficient. Belgium and Europe need sharper choices. Some will cost money; some will save money. Some will require administrative concentration. Some will require saying no to lowest-price reflexes. Above all, most solutions will require admitting that a fragmented European market throws away the biggest potential leverage Europe has: the scale of the EU Single Market.

Biopharma is not just a health-cost file. It is one of the few domains where Belgium has a world-class, dense ecosystem and where Europe still has the underlying assets to compete. Losing ground in this sector would weaken patient access, valuable exports, fiscal capacity, technological sovereignty and strategic relevance.

The strategic picture

The US is the launch market

The United States is by far the biggest pharmaceutical market in the world, accounting for nearly half of global prescription drug sales. It is also the de facto launch market. It combines scale, pricing power, faster launch incentives and management attention in a way Europe does not. Companies allocate trials, manufacturing, launch sequencing and leadership focus according to expected return, speed and strategic certainty, and these are high in the US.

Europe should not copy US pricing. That would be politically unrealistic and, in many areas, undesirable. Europe, however, does need to understand the strategic consequences of being slower, less predictable and more fragmented. If the first launch and highest-return decisions are elsewhere, surrounding decisions follow: clinical development priorities, manufacturing allocation, IP anchoring, headquarters attention and capital deployment.

Recent investment behaviour reinforces this point. Major pharmaceutical companies have announced large US manufacturing and R&D commitments as US policy pressure on pricing, supply chains and domestic production has intensified. The point is not one announcement. The point is the feedback loop: the market that offers the clearest launch and revenue signal also attracts more industrial commitment.

This matters directly for Belgium. The US is Belgium's largest biopharma trading partner, and Belgian sites are deeply integrated in global company portfolios. If Europe increasingly becomes the delayed-access market, Belgium-based activities become more vulnerable even when local assets are excellent. If the Trump administration continues down the path of strategic reshoring in biopharma – whether through pricing, tariffs, or industrial policy – Europe and Belgium risk becoming trapped in a negative spiral.

"Most Favoured Nation" is the catalyst, not the original cause

The US policy shift towards most-favoured-nation (MFN) pricing did not create Europe's weaknesses, but it did expose them. Slow access, fragmented reimbursement, tight budgets, differential pricing and uneven launch incentives were already there. MFN made those weaknesses strategically sharper.

Under MFN logic, low prices in European countries can become reference points for US pricing. That changes the calculation. A low European price is no longer only a European budget issue. It can easily become a global revenue risk. For companies, the rational response is to become more selective about where, when and under which conditions they launch in Europe.

This is why MFN should be treated as a catalyst. It accelerates a trend that was already visible: Europe is moving from a slow launch market to a strategically and even geopolitically risky launch market. If Belgium wants to avoid being pulled into that category, it needs faster and more predictable access, clearer value assessment and a more coherent European position on pricing spillovers.

The policy implication is uncomfortable but unavoidable. Europe cannot assume that it can remain a low-price reference region, demand first-wave access, preserve investment and avoid global pricing consequences all at the same time. Those objectives now collide. Governments have to decide which realistic combination of elements they actually want. Something has to give.

China is a market, a trial engine and an innovation challenger

China should no longer be treated as just a low-cost manufacturing base. That view is outdated. China has become a large market, a strategic growth opportunity, a price competitor, a fast clinical-trial system and an increasingly serious source of innovative medicines. Global leadership in biopharma is one of China's key industrial policy aims, embedded in its 15th Five-Year Plan (2026–2030), implying an assertive, coordinated push to develop China as a fully integrated ecosystem — and increasingly a commercialisation platform — for industry players worldwide.The key competitive edge in the Chinese approach is speed at scale. China has large patient pools, strong industrial policy, in-

tense price discipline, growing scientific capacity and a more capable regulatory system than in the past. In mature medicines, this puts pressure on European prices and margins. In innovative medicines, it helps Chinese companies move up the value chain. In clinical development, it changes how quickly evidence can be generated.

China's market-access environment also matters. It is a large opportunity, but not an easy high-price market. Reimbursement and procurement mechanisms can create rapid inclusion for selected medicines, while also imposing sharp price pressure. That makes China both attractive and demanding: companies can learn quickly, scale quickly and face strong pressure to prove value.

This matters directly for Europe because a new trend has emerged very quickly. European approval no longer always depends on evidence generated in European hospitals or European patients. Increasingly, high-quality clinical evidence generated in China, without any European patients in the pivotal trial, can support European market access as long as the European Medicines Agency (EMA) considers the evidence reliable and applicable to European patients.

The timeline of this new trend is compressed:

- **Early 2024:** the first signals. EU dossiers such as Ryzneuta and Fruzaqla already included China-only or all-Asian Phase III evidence. In those cases, the Chinese evidence was part of a broader package or played a supporting role.
- **April 2024:** the signal became clearer. Tizveni/tislelizumab received EU marketing authorisation for non-small-cell lung cancer. The evidence included Phase III studies conducted in China, with patients who were 100% Asian and all enrolled in China. This showed that China-only clinical evidence could play a central role in a European oncology decision.
- **July 2024:** Cejemly made the shift emblematic. Cejemly/sugemalimab was authorised in the EU on the basis of a pivotal Phase III study for metastatic non-small-cell lung cancer conducted exclusively in China, with exclusively Asian patients. This was strategically important because a Chinese-origin oncology medicine could reach the European market on the basis of decisive clinical evidence generated exclusively in China, without any European patients in the pivotal trial.
- **2025:** the pattern continued. Further oncology label extensions again relied on China-only or Asia-only evidence packages. In Cejemly's later stage III lung-cancer assessment, EMA itself referred to several previous applications based on studies conducted exclusively in China. By then, this was no longer an isolated signal. It had become a recognisable pattern.
- **2026:** the trend broadens. Aumseqa/aumolertinib shows that the trend is not limited to PD-1 or PD-L1 cancer antibodies. It is an EGFR tyrosine kinase inhibitor with a development programme that was overwhelmingly China-based and included no EU patients.

This evolution is rapid and strategically important. In roughly two years, China-only or Asia-only clinical evidence moved from a supporting role in some European dossiers to a recurring feature in selected innovative medicine approvals and extensions. China is no longer

only a market, a manufacturing base or a price competitor. It is becoming a clinical-evidence platform for medicines that can enter Europe.

This does not mean Europe should close itself off from Chinese science. Good evidence should be accepted when it is reliable, relevant and properly assessed. The problem is not that Chinese evidence can be good. The problem is that Europe can no longer assume that European patients, hospitals and trial sites will automatically remain central to medicines approved for European use.

Europe should not just copy every element of the Chinese model. Its comparative advantages are very different from those of China, so it should optimise its strategy to its own strengths. Europe should learn from China's speed, scale and operational discipline, not from weaker IP safeguards or weaker legal protection. The European answer should be faster execution inside a high-trust, high-standard system.

Clinical trials are more than just a regulatory step, they are a strategic anchor. They give patients earlier access to promising treatments. They build expertise in local hospitals. They generate data in European health systems. They connect companies to European clinical centres. They influence where companies place future research teams, manufacturing capacity and decision-making functions. If high-value trials move elsewhere, Europe loses more than trial activity. It loses proximity to innovation.

The risk is straightforward. If trials can be run faster in China, if patients can be enrolled more easily there, and if data generated exclusively in China can support European approval, companies have fewer reasons to place high-value trials in Europe. Over time, that means fewer early-access opportunities for European patients, less trial experience in European hospitals, less European data, and fewer reasons to anchor future R&D, manufacturing and strategic decisions in Europe. And this is merely the innovation-led dimension of looming industrial decline.

Europe should stay open, but it should stop being passive. It needs to:

- **Manage dependency.** Europe should remain open to high-quality Chinese science, partnerships and market opportunities. But strategic dependencies in active ingredients, intermediates, data, critical production steps and sensitive research collaboration must be screened and managed. Openness should not mean losing control over critical capabilities.
- **Compete for trials.** Europe must make it easier and faster to run valuable clinical research here. That means faster trial approvals, simpler contracting, better patient recruitment, better use and integration of health data, one ethics opinion per trial wherever legally possible and one clear point of contact for companies and researchers.

For Belgium, its strong clinical-research legacy is not enough to guarantee future success. Belgium has a vested interest in becoming one of the fastest and most reliable places in Europe to run high-value clinical trials. That is not only good for patients. It is also a way to keep existing expertise in Belgian hospitals, keep companies engaged with Belgian sites, generate Belgian and European data, and anchor future investment.

The strategic choice is therefore not between openness and protectionism. The real choice is between openness with competitiveness, or openness with gradual dependence. We believe Belgium and Europe should choose the first.

Europe's problem is conversion, not capability

Europe still has top universities, hospitals, scientists, industrial assets and a population market larger than the United States. The EU problem is not an absence of capability. It is the poor conversion of that capability into patient-ready products, scaled companies, strategic supply and anchored decision-making.

The pattern is familiar and has been repeating for decades: Europe hosts strong researchers but scales too few companies because late-stage capital is thinner, access is slower, procurement is fragmented, data systems are harder to use and companies often find larger commercial upside elsewhere.

Europe has capable regulators but too many duplicated procedures. It has a half-billion-patient market but behaves like a fragmented archipelago on access, procurement, data and implementation.

The scale-up problem and the IP problem are linked. When Europe cannot turn research into large companies, commercial launches and predictable access, the knowledge generated here is more easily bought, financed, scaled and controlled by non-EU companies.

That is why the strategic question is not whether Europe has assets. It does. The question is whether Europe can use its scale more effectively, and whether Belgium can become a pioneering national ecosystem that helps Europe move towards better policy choices.

The well-known Draghi report acknowledged these concerns and developed the following overall recommendations:

- **Close the investment gap:** EU private investment in pharma stands at roughly a quarter of US levels; public R&D spending is less than half. Focus EU funding on a limited number of world-class innovation hubs in life sciences, particularly in advanced therapy medicinal products (ATMPs) — cell and gene therapies.
- **Fix regulatory fragmentation:** Overburdensome regulation and fragmentation across national borders has driven investment away from the continent. Drug approval in the EU takes on average 430 days, versus 334 in the US and 322 in Japan.
- **Strengthen IP predictability:** The report singles out intellectual property rights as a key driver of medical innovation and advocates for predictability in Regulatory Data Protection and incentives.
- **Integrate the value chain:** Greater integration or coordination is required among national agencies across clinical trials, use of real-world evidence, and pricing and reimbursement, with the ultimate goal of integrating the entire value chain.
- **Reform pricing and reimbursement:** Member States should adhere more closely to pricing principles established under the EURIPID collaboration and step up cross-country initiatives for joint pricing and reimbursement negotiations for specific medicines.

- **Leverage health data:** The report praises the European Health Data Space as a positive step, noting its potential to anchor pharmaceutical research and innovation within the EU by enabling secondary use of health data, while flagging that fragmentation remains a significant barrier.
- **Integrate AI and digital health:** The report underscores the importance of integrating AI and digital health solutions to enhance drug discovery, optimise clinical trials, and improve patient outcomes, while noting that European pharmaceutical companies lag behind non-EU jurisdictions in incorporating AI into core operations.
- **Build supply-chain resilience:** The report calls for diversifying supply chains and forging strategic international partnerships to bolster pharmaceutical trade, establish strategic production capacity, and guarantee resilience for critical medicines

Belgium should not wait for the perfect EU answer. It should align nationally where it can, build coalitions of the willing where it must, and use European instruments where they help. Waiting for full EU27 alignment is not a fruitful strategy. It is a recipe for delay in a rapidly evolving, highly competitive global landscape. ■

Operational diagnosis

The competitiveness of Belgium and Europe hinges on four operational bottlenecks: access, clinical trials, resilience and scale. Together, they determine whether scientific strength can be turned into patient access, anchored investment and strategic control.

1. Access is now a competitiveness signal

Market access is no longer only a reimbursement issue, it is an investment signal. Slow or uncertain access tells companies where not to launch first, where not to place the next trial, where not to anchor manufacturing and where senior management attention can safely decline.

EU policy is moving toward more disciplined timelines. The 2025 political agreement on the EU pharmaceutical package aims to improve patient access, reduce administrative burden and shorten parts of the upstream regulatory pathway. This should not be confused with the national pricing and reimbursement clock of the Transparency Directive. But the direction is clear: **future policy will reward systems that can move faster without lowering quality.** Earlier attempts to revise the Transparency Directive already explored shorter pricing and reimbursement limits, including 120-day models.

Two clocks are often confused in the access debate. The first is the formal legal decision clock. **Under the EU Transparency Directive, national pricing and reim-**

bursement decisions should be taken within defined limits: 90 days for pricing, 90 days for reimbursement, or up to 180 days where both decisions are handled together or sequentially. That 180-day period is not a median target or an aspiration. It is the legal ceiling once a complete application is in, although the clock can be stopped when authorities request additional information.

The second is the real-world patient-access clock. WAIT data measure the time from central EU marketing authorisation to actual patient availability, usually the point at which a medicine enters the reimbursement list. That wider timeline includes more than the formal public decision period. **Company filing choices, launch sequencing, dossier quality, evidence requests, negotiation, clock-stops, budget procedures and national implementation all shape the final delay.**

This distinction matters, but it does not soften the conclusion. If the legal ceiling for pricing and reimbursement decisions is 180 days, while **the EU average time to availability is 578 days and Belgium's median remains 476 days**, the system is not converting authorisation into patient access at competitive speed. **This delay is detrimental not only to patients, but also to our biopharma ecosystem.**

Belgium should therefore treat 180 days as the maximum acceptable decision time, not as the ambition. A frontrunner country should benchmark itself against the fastest systems, not against a weak EU average. That means fewer avoidable clock-stops, earlier scientific and budget dialogue, better prepared dossiers, faster value assessment, clearer negotiation discipline and credible early-access routes.

Belgian policymakers should lead this correction. That does not mean ignoring budget discipline or company responsibilities. Companies also influence launch timing through filing choices, data responses, sequencing and pricing strategy. But public authorities own the architecture: assessment capacity, process clarity, negotiation discipline, early-access pathways, coordination between regulatory and reimbursement steps, and accountability for avoidable delay.

The payer-versus-industry framing is too narrow. **Faster, predictable access is simultaneously a patient issue, a competitiveness issue, an industrial policy issue and a credibility test for Belgium as a launch country.** If a medicine offers real value, the system should recognise it, negotiate fairly and bring it to patients without avoidable delay.

Access policy should also be linked to evidence policy. Early access, real-world evidence, post-launch monitoring and value assessment should not be separate files. They are parts of the same end-to-end system: bring valuable medicines to patients faster, learn from use, update decisions when evidence changes, and keep companies engaged with Belgian and European clinical sites.

2. Clinical-trial competitiveness determines where innovation is created.

Clinical trials are a core element of our innovation system. They are where patients gain early access, where hospitals build expertise, where data are generated, where companies learn and where future investment

decisions are influenced. A country that loses clinical trials loses more than research activity. It loses proximity to innovation itself.

Europe's and Belgium's clinical-trial erosion is measurable. Europe's share of global commercial trials has fallen sharply over the past decade, while China has become a major trial location. Trial activity is sticky: when teams, sites, patient pathways and data infrastructure move elsewhere, they are difficult to rebuild.

Belgium still has real strengths, especially in early-phase work and specialised domains. But decline often starts subtly through portfolio choices: one trial not placed, one team not rebuilt, one site activation judged too slow, one regional role moved elsewhere.

One confidential expert indicated that, between 2020 and 2025, clinical-trial staffing inside one large company in Belgium fell from around 50 to around 3. This captures what early erosion looks like in practice: no major announcement, no sweeping change, but incremental pruning in the background with cumulative effects.

The China-EMA evolution reinforces the urgency. It is not a reason for defensive regulation; it is a reason for operational competitiveness. If high-quality evidence can be generated at scale outside Europe and still support European decisions, Belgium cannot rely on tradition, reputation or proximity to EMA to keep clinical research here. It has to make participation in Belgium faster, cleaner and more valuable than the alternatives.

Belgium should set a concrete ambition: become the fastest practical clinical-trial ecosystem in Europe for selected priority domains. That means:

- one ethics opinion per trial wherever legally possible;
- standard contract templates that are actually used;
- site start-up in days or a few weeks, not months;
- a federated health-data layer that can return lawful feasibility counts in seconds rather than through e-mail chains;
- the same data infrastructure supporting trial feasibility, patient recruitment, real-world evidence, post-launch monitoring and value assessment;
- clear recruitment pathways, including cross-border pathways where relevant;
- one accountable front door for companies, hospitals and researchers.

The biggest gains are not only budgetary. They are operational. In clinical trials, Belgium can outperform larger countries if it chooses speed, coordination and accountability over institutional complexity.

3. Resilience means capability, not only stockpiles.

Resilience is often discussed through the lens of generics, critical older medicines, APIs and shortages. That is necessary. Europe has real vulnerabilities in antibiotics, intermediates, logistics, energy-intensive chemical production and low-margin products where lowest-price procurement has helped optimise redundancy out of the system.

But resilience should not stop there. You can stockpile masks, APIs and selected older medicines, but you cannot stockpile innovation. **A resilient biopharma system must also be able to discover, test, manufacture, regulate, reimburse, scale and decide.** Otherwise Europe becomes a purchasing office for innovation created elsewhere and a sales office for supply chains controlled elsewhere.

The lowest-price procurement reflex is therefore strategically dangerous for critical medicines and vulnerable supply chains. Price still matters, but it cannot be the only public value. Reliability, quality, dual sourcing, strategic redundancy, European or allied production capacity, and possibly carbon intensity must count when security of supply is at stake.

A serious resilience strategy should distinguish between at least three layers:

1. **Critical older medicines and inputs:** identify products where shortages create unacceptable health risk, then pay explicitly for reliability, diversified supply and strategic stock where stockpiling makes sense.
2. **Industrial capability:** retain or rebuild production, quality, logistics and process know-how for strategically relevant products and technologies.
3. **Innovation capability:** keep the ability to generate evidence, make quick and high-quality reimbursement decisions, protect IP, scale companies and anchor management decisions in Europe.

The third layer is often missing, to the detriment of European resilience. **Strategic autonomy** in biopharma is not only about having enough of the right boxes in a warehouse. It is **also** about having the **capability to act when the next innovation wave arrives.**

4. Europe has scale on paper and fragmentation in practice.

Europe is large enough to matter, but it often acts too small to win. An affluent half-billion-patient market should be a decisive asset for launches, trials, real-world evidence, manufacturing attractiveness and negotiations. In practice, too much of that scale is trapped behind national access systems, duplicated procedures, inconsistent data infrastructure and fragmented implementation.

This is why coalitions of the willing should become a normal policy instrument. EU-wide action is preferable where it is feasible and timely. Where it is not, serious countries should move first, prove the model and allow others to join later. Belgium is well placed to lead pharma-centric coalitions in access coordination, clinical-trial facilitation, data feasibility, critical-medicine resilience and scale-up finance. This requires a policy mindset to embrace the biopharma ecosystem as a strategic asset within the overall European market development.

The alternative for Europe is familiar but damaging: waffle-iron politics. The EU should avoid spreading money and ambition thinly across countries or regions so that nobody is offended and little is transformed. The political logic behind that approach is understandable, but it does not work for ecosystem-dependent sectors with large economies of scale like pharma. **Strategic sectors require concentration of effort, not symbolic distribution.** ■

Belgium as a strategic frontrunner

Belgium should frame itself as a frontrunner ecosystem. The country is small enough to organise operational reform faster than the EU as a whole, but specialised and large enough for success or failure to be noticed internationally.

Why Belgium matters

Belgium's relevance in biopharma is measurable, not symbolic. It shows up in exports, jobs, R&D, clinical trials, tax revenues, patient access, logistics, international standing and company portfolios. A country with roughly €73 billion in pharmaceutical exports, around 45,000 direct jobs, nearly 141,000 total jobs and more than €6 billion in annual R&D should not treat biopharma as a niche.

For Belgium, biopharma is a pillar of its export base, innovation economy, fiscal capacity and global positioning. Losing momentum here would weaken one of the few areas where Belgium is genuinely world-class. That is precisely why Belgium should be more ambitious.

The relevant benchmark is not whether Belgium performs well compared with its own past. The benchmark is whether **Belgium can be one of the best places in Europe to launch, test, manufacture, finance and anchor biopharma innovation.** Frontrunner status requires current and future performance, not retrospective pride.

Belgium has a practical advantage: reform can be concrete. **One accountable interface, faster trial start-up, coordinated data feasibility, predictable access pathways, targeted resilience procurement and better scale-up finance** are not abstract continental dreams, they can be **organised nationally and then linked to European coalitions**.

Where the erosion risk is real

The first risk is access predictability. If companies no longer see Belgium as a credible early-access or launch country, they will update their entire investment picture. MFN policies compound this issue, because low-price or slow-launch signals now also interact with global pricing strategy.

The second risk is capital and scale. Compared with the United States, Belgium and Europe still struggle to finance €100 million scale-up rounds, even though domestic savings and institutional capital are substantial. The issue is not to push households blindly into risk. The issue is that Belgium has not built enough credible pathways between savings, pension and insurance capital, public instruments, specialised funds and biopharma scale-ups. Without those pathways, science is generated here but monetised and controlled elsewhere.

The third risk is cost and talent. Belgian personnel costs have risen strongly, while STEM shortages and

demographic pressure are tightening. A high-cost ecosystem can remain competitive only if it performs at the top of its class on speed, predictability, quality and problem-solving. If Belgium is expensive, talent-constrained and slow, its competitiveness erodes.

The fourth risk is governance. International location decisions do not experience Belgium as one coherent state. They experience multiple authorities, multiple contact points and fragmented accountability. Complexity may be constitutionally familiar, but it is not competitively neutral.

The fifth risk is clinical-trial erosion. Belgium can remain excellent in selected domains, but excellence has to be renewed operationally. Every lost trial weakens patient access, hospital expertise, data generation and future anchoring decisions.

None of these risks is destiny. They are the result of policy choices, governance choices and investment choices. Belgium can still be a frontrunner, but only if it acts like one and updates its policies accordingly.

Where the roundtable pointed next

The discussion pointed toward the need for a comprehensive economic & life sciences growth strategy. Innovations with a high therapeutic value added deliver health outcomes and high-quality jobs, while supporting industrial clusters. Economic ambition and public health advance together rather than against each other.

Participants emphasized the need for a transversal economic growth strategy rather than sector-specific quick fixes. Key priorities relate to Belgium's attractiveness as an investment location, market access and predictable approval procedures, simplification and less red tape and a balanced consideration of economic parameters in the policy debate. They also left open what Belgium can realise on its own and what needs EU-level action, stressed that a positive strategy must engage the whole ecosystem, not only the largest players, and must stay measurable over time.

Advocating these directions is where the roundtable stopped. Translating them into a economic growth strategy, with policy priorities and indicators to track, is the task that follows, not of this report, which records the discussion rather than pre-empting its conclusions. ■

Call to action

The government's choice is now explicit. Belgium can either manage gradual erosion through business as usual, or it can develop and implement a frontrunner strategy. The latter option can build on the legacy strength of the sector and the innovation potential it carries. It impliestreating biopharma as strategic infrastructure and organising policy around four pillars.

The four pillars

1. Access and launch predictability

Treat the 180-day Transparency Directive limit as a ceiling, not as the ambition. Belgium should aim to beat it for valuable innovation. Build capacity for faster assessment, reduce avoidable clock-stops, organise earlier dialogue before formal filing, make early-access routes credible, coordinate approval-pricing-reimbursement steps and expect company discipline in return. Belgium should be a country where valuable medicines can reach patients predictably and early.

2. Clinical trials, health data and evidence execution

Make Belgium the fastest practical clinical-trial ecosystem in Europe for selected priority domains. Implement one ethics opinion per trial wherever possible, standard contracts, fast site activation, lawful and quick data feasibility, patient-recruitment support, real-world evidence capability and one accountable national front door.

3. Resilience and strategic depth

Stop procuring critical medicines on lowest price alone. Pay explicitly for reliability, quality, dual sourcing and strategic redundancy where security of supply is at stake. Go beyond stockpiles: keep the capacity to discover, test, scale, manufacture, regulate, reimburse and decide in Europe. You cannot stockpile innovation.

4. Capital, IP anchoring and European scale

Mobilise scale-up finance through better use of savings, pension and insurance capital, public-private funds and specialised instruments. Protect the fiscal and legal conditions that keep IP and decision centres in Belgium. Use EU instruments where useful and coalitions of the willing where EU27 consensus is too slow.

These pillars should be governed through one accountable political and administrative structure – a "one stop" point of contact. Belgium should not confront investors and innovators with an administrative maze. It should offer a front door with authority, deadlines and escalation power.

Real change is needed and possible

The fiscal objection is real but not decisive. Fiscal space should be created through prevention, early detection, appropriateness of care and reduction of low-value spending, not by simply delaying valuable innovation. **Delayed access is not a sustainable cost-cutting strategy, it is a hidden transfer from today's patients and tomorrow's competitiveness to today's budget line.**

Belgium does not need another declaration of strategic relevance. It needs a decision. **Either biopharma becomes a national priority, with accountable execution on access, trials, health data, resilience, capital and IP anchoring, or Belgium will gradually become a niche high-quality supplier inside value chains controlled elsewhere, geopolitically exposed, economically vulnerable.**

The country still has the assets to lead, but assets are not strategy. What is missing is disciplined execution of policies built for the geopolitical, socio-economic and technological realities of this century. **Frontrunner status is not inherited from yesterday's strengths, it is built by the decisions Belgium makes now and lost by the decisions it postpones.** ■

Appendix: Sources and Validation

This position paper combines Itinera's closed expert roundtable of 2 March 2026 with public data, regulatory documents and policy sources available at the time of drafting. The roundtable was used as an input source for diagnosis and prioritisation.

Belgian biopharma baseline

The Belgian sector figures should be read with a clear distinction between the strong **2024 baseline** and the **weakening in the 2025 update.**

- Pharma.be's *Pharma Figures 2025*, which reports **2024 data**, gives roughly **€79 billion in pharmaceutical exports**, around **15.5% of Belgian exports**, more than **€6 billion in annual R&D investment**, and nearly **141,000 direct, indirect and induced jobs.**
- *Pharma.be's more recent 2026 communication* reports a weaker **2025** picture: **exports declined by 6.8%** but still reached **€73.1 billion,** while employment, researcher numbers, patent applications, R&D investment and production also declined. That is why the report integrates both points: Belgium starts from a strong biopharma base, but that base is no longer self-perpetuating.
- Where the body text refers to direct employment, the most precise public figure from the 2024 baseline is **44,738 direct jobs** provided by Pharma.be.

Access and availability

The access figures are based primarily on the **EFPIA Patients W.A.I.T. Indicator 2024 Survey** and related EFPIA/CRA work on the root causes of unavailability and delay.

- The *2024 W.A.I.T. survey* reports that the EU **average availability of centrally approved innovative medicines** was **46%**, and that the average EU time from central marketing authorisation to availability was **578 days**. Belgium's median time to availability is reported as **476 days**. W.A.I.T. measures real-world time to patient availability, usually reimbursement-listing availability, and should not be confused with the narrower legal decision clock for pricing and reimbursement.
- The comparison with the United States should be treated as directional rather than as a strict W.A.I.T.-equivalent measurement. *Recent Reuters reporting* states that Americans have access to roughly **80%** of new drugs, compared with less than **50%** in Europe. This supports the report's strategic point that US availability remains materially higher, but the methodological basis differs from the EFPIA W.A.I.T. survey.

Root causes of access delay

The statement that access delay is driven by multiple actors and process steps is supported by the **EFPIA/CRA European Access Hurdles Portal**. The *2025 Portal report* shows that delays include both the time from EMA approval to pricing and reimbursement filing and the time from filing to national pricing and reimbursement decisions. It also reports that reasons for non-filing are distributed across health-system infrastructure, economic viability, pricing and reimbursement process issues, and value-assessment issues.

Economic viability

The "around 1 in 7" estimate on medicines becoming economically non-viable to launch in Europe should be read as **directional expert input from the Itinera roundtable**. Public **EFPIA/CRA evidence supports the broader point** that economic viability is a major launch barrier: across categorised reasons for non-filing for pricing and reimbursement, **economic viability accounts for 37%**, alongside health-system infrastructure, pricing and reimbursement process issues, and value-assessment-process issues.

US market weight and MFN

The strategic weight of the US and North American markets is based on EFPIA industry figures and recent policy developments. EFPIA's Pharmaceutical Industry in Figures 2025 reports that North America accounted for **54.8%** of estimated world pharmaceutical sales in 2024, compared with **22.7%** for Europe. EFPIA also reports that **66.9%** of sales of new medicines launched during 2019–2023 were on the US market, compared with **15.8%** in the top five European markets.

Recent Reuters reporting has linked MFN-related uncertainty and US price-cut deals to delayed or reconsidered European launches and tougher European pricing negotiations, because low European prices may become relevant to US pricing exposure.

EU pharmaceutical reform

The EU pharmaceutical reform reference concerns the broader *reform of EU pharmaceutical legislation*, not a completed reform of the Transparency Directive's national pricing and reimbursement clock. EMA and Commission communications describe the December 2025 political agreement as aimed at improving access, supply security, competitiveness, innovation and regulatory efficiency.

EMA indicates that adopted acts are expected to enter into force in 2026, with a transition phase through 2028. As of this drafting, the current pharmaceutical package has not reduced the 180-day national pricing and reimbursement ceiling. Earlier attempts to revise the Transparency Directive did explore shorter pricing and reimbursement timelines.

Clinical-trial competitiveness

The clinical-trial competitiveness argument is supported by *EFPIA/IQVIA analysis* showing a **sharp decline in Europe's global commercial-trial share**. The EEA share of global commercial trials fell from **22% in 2013** to **18% in 2018** and **12% in 2023**, while China's

role expanded significantly. EFPIA also links Europe's declining attractiveness to slower set-up, more fragmented execution and less favourable operating conditions compared with the US and China.

China market access

The China market-access point is based on evidence that China combines large market potential with strong price pressure. China's National Reimbursement Drug List dynamics can create rapid reimbursement inclusion for selected medicines, but often after substantial negotiated price reductions.

Reuters reported that medicines added to China's state insurance list in a recent round faced an average price cut of **63%**, illustrating why China can be both attractive and demanding for innovative medicines. This supports the framing of China as a large opportunity, but not an easy high-price market. China's scale, speed and reimbursement pressure allow companies to learn quickly and expand access, while also forcing strong value demonstration and price concessions.

China/EMA clinical-evidence examples

The China/EMA clinical-evidence examples are based on EMA regulatory documents.

- For **Cejemly/sugemalimab**, EMA's public assessment report states that the **pivotal Phase III** study CS1001-302 was **conducted exclusively in China**, screened 846 patients, randomised 479 patients, and enrolled **patients exclusively of Asian origin**. This supports the report's statement that Cejemly is an emblematic case of China-generated clinical evidence supporting European market access when EMA considers the evidence reliable and applicable to European patients.
- For **Tizveni/Tevimbra/tislelizumab**, EMA product information describes specific Phase III NSCLC studies, including BGB-A317-304 and BGB-A317-307, with patients **100% Asian and all enrolled in China**. These studies provide the clearest pre-Cejemly precedent for the pattern discussed in the report.
- EMA's later **Cejemly stage III NSCLC variation** assessment refers to study CS1001-301 / GEMSTONE-301 as a Phase III study conducted in China and **refers to several previous applications based on studies conducted exclusively in China**. This supports the report's claim that the signal had become a recognisable regulatory pattern rather than an isolated case.
- For **Aumseqa/aumolertinib**, EMA material records EU marketing authorisation on 12 February 2026. The EMA assessment report states that the **majority of clinical studies were conducted in China, that non-Chinese patients represented less than 5% of the clinical development population, and that no patient was included in the EU**. This supports the report's claim that the trend broadened beyond PD-1/PD-L1 antibodies.
- **Ryzneuta** and **Fruzaqla** should be treated as early, weaker signals, not as clean Cejemly-type precedents.

- EMA's Ryzneuta assessment **relied on a broader evidence package, with one Asian-only study**, SP11631, **playing a supporting role.**
- Fruzaqla's EU approval was based primarily on the global Phase III FRESCO-2 study, even though **China-generated evidence formed part of the broader development** story. They are useful context for the trend, but the cleaner China-only/all-Asian oncology precedents are tislelizumab and Cejemly.

Confidential expert input

The confidential example on clinical-trial staffing in Belgium is based on Chatham House input from the Itinera roundtable and is not independently verifiable from public sources. It should therefore be retained only as an illustrative expert input, not as a public statistical benchmark. ■

About Itinera

As an independent think-tank, linera has been working since 2006 on solutions to the social and economic challenges of our time. Its work is based on scientific analyses and published debate.

It inspires and encourages policymakers, entrepreneurs, and citizens to overcome the obstacles that hinder ideas.

This means focusing on three pipelines: they are the same as before, but best suited to entrepreneurs. Together with societal stakeholders, linera critically examines policy with a solution-oriented approach. By addressing these issues, we will have a positive impact, and we will also create a positive impact.

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