Re-shoring life sciences for a sustainable future

A qualitative inquiry into major challenges

forvis mazars

Contents

4 Foreword
6 Executive summary
9 Context and scope of the study
14 Turning compliance into competitiveness
17 Territorial planning for industrial sovereignty
20 Building a sustainable pharma value chain
23 Fuel for innovation and industrial growth
25 Unlocking the power of existing assets
29 Relocalising the health industry from ambition to reality
31 Closing remarks
32 Methodology
33 Annexes and key sources
34 Appendix

Foreword

In recent years, the idea of relocating part of Europe's life sciences industry has emerged on political agendas as a strategic necessity. While the covid-19 pandemic brutally exposed the sector's logistical vulnerabilities such as supply chain disruptions, dependence on Asia for active pharmaceutical ingredients (APIs) and the saturation of critical channels, it was merely the visible trigger.

Beyond this health emergency, pharmaceutical and medtech relocation addresses deeper objectives: reindustrialising regions, supporting skilled employment, reducing the trade deficit, strengthening economic sovereignty and preparing the industry for ongoing climate and geopolitical transitions. In a world of tightening border controls, industrial influence strategies and shifting trade configurations, the return of European-based production has become a matter of control, anticipation and, increasingly, survival.

This momentum is supported by ambitious policies worldwide. In the US, the Inflation Reduction Act is mobilising massive funding to accelerate strategic reshoring. In Europe, the Important Project of Common European Interest (IPCEI) Health initiative and the Health Emergency Preparedness and Response Authority (HERA) aim to build a collective health autonomy. In France, public announcements regarding the France 2030 plan signal a strong commitment to industrial revival.

For Europe, strategic reshoring policies offer some clear opportunities:

- Strengthening the resilience of supply chains to withstand future crises.
- Reducing the carbon footprint, particularly in logistics, through production closer to consumption hubs.
- Creating durable, locally anchored industrial jobs.
- Meeting regulatory requirements such as environmental, social and governance (ESG) reporting, now a structuring factor in tenders and corporate strategies.
- And more than ever, building long-term European industrial and health sovereignty.

Foreword

Yet beyond the opportunities, political momentum and headline declarations, industrial realities remain far more complex. Why are some projects slowed down or even abandoned despite visible public support? What economic, regulatory, land-use and logistical constraints are encountered on the ground? And what enables other projects to succeed?

To better understand this contrasted reality, Forvis Mazars conducted a unique qualitative study, based on a series of in-depth interviews with around 20 stakeholders representative of the sector: pharmaceutical companies (specialties and generics), medtechs, biotechs, contract development and manufacturing organisations (CDMOs), competitive clusters, investors and institutional experts.

All interviews were conducted confidentially and anonymously to guarantee participants' freedom of expression and to reflect the complexity of their positions — often situated between economic constraints, regulatory pressures, industrial pragmatism and strategic conviction. The aim of the study is not to settle the debate or offer a universal solution but to shed light on what health sector players are experiencing today - confronting political intent with practical feasibility.

This study examines the structural and operational barriers that must be addressed, the strategic levers that can be mobilised to overcome them and the long term scenarios that emerge when the objective is to design a relocation strategy that is sustainable, competitive and responsive to the imperatives of the 21st century.

It aims to provide a rigorous, evidence based contribution to this analysis, offering an informed perspective that reconciles political ambition with the practical realities of implementation.

Before delving into the details of this study, we would like to express our sincere gratitude to all interviewees for their openness, transparency and availability. Their diverse perspectives and approaches have enriched this qualitative study, offering a broader and more nuanced view of the industry's evolution worldwide, and in Europe in particular.

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Executive summary

In a context of increasing pressure on health sovereignty, accelerating ecological transition and evolving societal expectations, the reshoring of life science industries in Europe has emerged as a strategic priority. This momentum is driven by ambitious public policies such as the EU Critical Medicine Act, France 2030 Health & Life Sciences Track, PNRR Health & Research Missions in Italy, PERTE for Vanguard Health in Spain, Health Research Framework Programme & Zukunftspaket in Germany, HERA, IPCEI Health as well as others in European Member States. There are also heightened requirements in terms of corporate social responsibility (CSR) and converging global trends across, for example, the US and Asia.

On the ground, however, stakeholders describe a more nuanced reality:

- A regulatory framework deemed overly complex (environmental compliance, European Conformity (CE) marking) and inconsistent across Europe, which extends timelines and slows projects.
- A shortage of suitable industrial land combined with environmental constraints (Zero Net Land Take), making implementation difficult despite available subsidies.
- Unfavourable economic conditions with administered prices set too low, a heavy industrial tax burden and limited visibility on volumes and margins.
- Funding difficulties, especially in the scale-up phases, notably for biotech, medtech and deeptech projects with high capital requirements.
- A supply chain that remains highly globalised, characterised by strong dependence on foreign subcontractors and limited control over lead times, traceability or carbon footprint.
- Underutilised European assets: low-carbon energy, climate stability, hospital infrastructure, pools of skilled labour and high CSR standards.

The study also highlights the need to rethink the market model, shifting from a volume-based to a value-based approach, to better reward products with high medical and environmental impact and to redirect resources towards a sustainable value chain.

The message is clear: success in reshoring does not come from simply increasing subsidies but from achieving greater coherence between political ambition and industrial feasibility. This requires listening to field actors, simplifying regulations, providing economic visibility and promoting industrial models aligned with public health, sustainability and European sovereignty objectives.

A dense, layered and interdependent value chain

To grasp the dynamics of industrial reshoring, it is crucial to first examine the structure of the life sciences ecosystem; an analysis this study undertakes by exploring all of its key value-chain segments across Europe. The value chain extends from basic research to hospital and retail distribution, encompassing the production of APIs, formulation, device manufacturing, packaging, logistics, clinical and technical trials, as well as regulatory, financing and governance functions.

The ecosystem is built on a network of diverse actors: pharmaceutical companies (from biotech to large industry), medical device companies (from implantable devices to digital remote monitoring), industrial subcontractors (CDMOs and CMDOs), competitiveness clusters, regulatory authorities (ANSM, EMA, notified bodies for medical devices), specialised investors and hospital and academic institutions. This architecture combines long value chains (mature products, standard devices) with highly integrated models (innovative therapies, complex devices).

Europe has a high-level industrial and regulatory infrastructure but its flows remain highly globalised. A large share of components, raw materials and electronics is still imported, particularly from Asia. Conversely, exports of finished products to North America, the Middle East and Africa are growing. Centres of excellence are well established in both pharmaceuticals and devices: the trinational Rhine BioValley (Basel–Mulhouse–Freiburg), the Medicon Valley (Denmark–Sweden), the Cambridge–Oxford–London triangle and clusters such as Lyon-Gerland (including Lyon biopôle), Saclay–Villejuif and the Munich region, which concentrate expertise, innovation, production and testing capabilities.

Towards a coherent European strategy for medicines and medical devices

In response to the vulnerabilities exposed by the pandemic, growing geopolitical pressures and rising industrial sovereignty concerns, the EU and its Member States have placed reshoring at the top of their priorities. At the EU level, the Pharmaceutical Strategy, the HERA initiative, IPCEI Health and more recently the EU Critical Medicines Act provide a strategic framework to identify and secure the production of essential medicines and medical devices.

These programmes aim to create resilient, interoperable and better-coordinated production capacities across Europe while encouraging investment in both APIs and finished dosage forms, as well as in vitro diagnostics and medical devices. Several Member States, including France with its France Relance and France 2030 plans, Germany with vaccine and biologics capacity expansions and Spain with significant injectables projects, have mobilised massive funding to re-establish critical capacities on their soil.

Together, these initiatives illustrate a shared European ambition to reduce dependencies on third countries and strengthen strategic health sovereignty. Other countries throughout the world have taken similar measures. The US, through the Inflation Reduction Act and the Defense Production Act (DPA), strongly encourages the reshoring of critical medicines and devices (injectables, smart syringes, rapid diagnostics). Japan and India have launched comparable incentive plans, sometimes focused on medical electronics or API production.

Flagship examples of reshoring in Europe (pharmaceutical and medtech industries)

 Esteve – API expansion, Celrà (Girona, Spain)

Project: Construction of a new manufacturing unit at the Celrà (Girona) plant to produce APIs, including reaction and service buildings to boost production capability.

Amount: Approx. €100m investment.

Objective: Strengthen Europe's API manufacturing base, increasing domestic production to reduce reliance on external suppliers and support long-term supply security.

Benefits: ~45 % increase in local API production capacity, enhancing European self-sufficiency. 15 % growth in Esteve's global production capacity, supporting overall resilience. Creation of specialised manufacturing infrastructure and skilled technical jobs in the region. Enhances supply chain sustainability by localising critical production.

 Seqens – Paracetamol, Roussillon (Isère, France)

Project: Construction of an API production unit for paracetamol on the Roussillon chemical site.

Amount: €100m investment, supported by the French State under the France Relance plan.

Objective: Secure supply of an essential medicine previously produced mainly in Asia.

Benefits: Reduced strategic dependency, creation of skilled industrial jobs, lower carbon footprint through shorter supply chains.

 Pfizer, Grange Castle (Dublin, Ireland)

Project: Large-scale biomanufacturing expansion, including drug substance production.

Amount: ~€1.2bn investment.

Objective: Increase production capacity for biologics and novel therapies, including mRNA platforms.

Benefits: Creates ~400 new jobs, strengthens Ireland's reputation as a leading biopharma hub, supports EU independence in advanced medicines.

 Sandoz, Kundl (Austria)

Project: Continued production and upgrading of Europe's last integrated penicillin API plant.

Amount: ~€150m public-private investment with Austrian state support.

Objective: Preserve Europe's only remaining large-scale penicillin API source and reduce reliance on China.

Benefits: Safeguards a strategic antibiotic, maintains ~1,000 jobs, strengthens EU health sovereignty.

 Hovione, Seixal & Loures (Portugal)

Project: Construction of new "Hovione Tejo" campus with expanded particle engineering and drug product capacity.

Amount: €200m+ (phased).

Objective: Expand European API and drug product production to meet global demand.

Benefits: ~300 jobs, boosts Portugal's positioning in the global CDMO landscape, enhances EU supply security for critical drugs.

 Rentschler Biopharma, Laupheim (Germany)

Project: Expansion of bioproduction capacities for monoclonal antibodies and gene therapies.

Amount: €500m, with support from the German federal government under IPCEI Health.

Objective: Establish a European hub for manufacturing strategic biopharmaceuticals.

Benefits: Industrial upscaling, skilled jobs, strengthens European autonomy in advanced therapies.

International examples of industrial reshoring in health (outside Europe)

Phlow Corp., Virginia (United States)

Project: Creation of an API and production site for critical generic medicines.

Amount: +$350m via the DPA and the Biomedical Advanced Research and Development Authority (BARDA).

Objective: Build a strategic API reserve for the US market.

Benefits: Securing essential molecules, continuous flow production, creation of local skilled jobs.

Samsung Biologics, Incheon (South Korea)

Project: Construction of the world's largest biopharmaceutical manufacturing plant (Plant No. 5).

Amount: $1.8bn (Phase 1), announced in 2022.

Objective: Massively increase monoclonal antibody production capacity for major pharmaceutical groups.

Benefits: Consolidation of Asia's leadership in bioproduction, reduced manufacturing lead times, regional sovereignty.

Kissei Pharmaceutical, Nagano (Japan)

Project: Repatriation of renal medicine production from China to a new integrated site.

Amount: ~€90m, via a public industrial resilience fund.

Objective: Internalise sensitive production in the context of growing regional tensions.

Benefits: Supply chain robustness, quality control, preservation of local expertise.

Serum Institute, Pune (India)

Project: Construction of a manufacturing hub for vaccines and injectable components (including smart syringes).

Amount: $2bn over several phases, partly via the Production Linked Incentive (PLI) Scheme.

Objective: Reduce import dependency, strengthen national and export manufacturing capacity.

Benefits: Vaccine self-sufficiency, regional economic development, exports to the Global South.

Reshoring as a driver of sustainable transformation

Beyond industrial resilience, reshoring is now viewed as a lever for sustainable transformation. It makes it possible to:

- Bring production sites closer to end markets, delivering both logistical and public health benefits.
- Reduce transport-related emissions, particularly for fragile products or those with a high carbon footprint.
- Create skilled jobs, especially in regions undergoing industrial reconversion.
- Better control quality, traceability and regulatory compliance, particularly with regard to European regulations for medical devices (MDR/IVDR).
- Shorten time-to-market — a critical factor in times of hospital supply pressure.
- Improve environmental performance, in line with low-carbon trajectories, eco-design initiatives or EU taxonomy requirements.
- These benefits form part of a broader CSR logic, directly linked to several UN Sustainable Development Goals (SDGs):
- SDG 3: Health and well-being/access to care
- SDG 8: Decent work and economic growth/skilled employment
- SDG 9: Industry, innovation and infrastructure
- SDG 12: Responsible consumption and production
- SDG 13: Climate action

In both pharmaceuticals and medical devices, industrial players and public contracting authorities are increasingly integrating these CSR criteria into tenders, procurement strategies and ESG reporting.

Many stakeholders also emphasise that Europe's high environmental, social and quality regulatory standards, while often perceived as a constraint, in fact act as a de facto barrier to market entry for non-compliant producers. These standards reward companies that can operate under such requirements and provide partial protection to the European market against lower-cost but less regulated competitors. This protection is particularly relevant in the pharmaceutical and medical device sectors, where the Medical Device Regulation (MDR) and the In Vitro Diagnostic Medical Devices Regulation (IVDR), Good Manufacturing Practices (GMP) and environmental compliance rules significantly increase the threshold for accessing the EU market.

This situation creates a tangible opportunity for reshoring. Because all life science actors already comply with stringent quality requirements, Europe's differentiator lies in its broader regulatory ecosystem, including - but not limited to - carbon reduction targets, eco-design obligations, workforce protection rules and ESG reporting duties. Companies able to internalise these additional standards can use reshored production sites not only to ensure supply security but also to align with European procurement strategies that increasingly integrate sustainability and ESG criteria. For example, several Member States have called for hospital tenders to include 'green procurement' clauses, potentially giving preference to suppliers with lower CO_2 emissions in logistics, recyclable packaging or verified ESG reporting. Similar approaches are under discussion in the context of EU joint procurement initiatives coordinated by HERA.

Reshoring therefore enables firms to: (i) secure preferential access to public tenders where CSR and environmental performance are weighted heavily; (ii) capture demand from hospitals and health systems seeking low-carbon, traceable, 'made in Europe' supply chains; and (iii) strengthen their reputational positioning by demonstrating leadership on sustainability and sovereignty. In this sense, compliance with Europe's demanding framework becomes a competitive advantage — transforming regulation into a lever for industrial renewal and market growth.

A dynamic momentum but still limited in practice

Despite unprecedented political alignment, strong public statements and mobilised funding, industrial reshoring is still struggling to take shape on the ground. The case of paracetamol production by Seqens in Roussillon (Isère) illustrates this tension: announced in 2020 as a symbol of restored sovereignty, the project took over three years to reach operational phase and remains one of the few fully committed examples in France.

At the European level, important initiatives have been launched from the **IPCEI Health programme**, which supports projects such as the Rentschler Biopharma investment in Germany to expand monoclonal antibody production. Also, the newly introduced **EU Critical Medicines Act** which, for the first time, provides a dedicated regulatory and financial framework to identify, prioritise and secure the manufacture of medicines most vital for European public health. These measures mark a turning point by embedding sovereignty objectives directly into EU-wide industrial policy. (previous initiatives in Appendix 1)

Yet, large-scale projects that have actually been implemented remain relatively few compared to the level of ambition expressed. The gap between political intent and concrete execution forms the starting point of this study. By giving voice to industry stakeholders, we sought to understand what is holding back reshoring and how to better align political commitments and regulatory frameworks with real-world industrial and operational realities.

Reshoring? Yes - but under what conditions?

The five issues developed in this chapter stem directly from insights gathered in the field. They are based on in-depth listening, cross-analysis of perspectives and structured review of feedback from stakeholders representing the entire pharmaceutical and medtech value chain in Europe. Each of these themes emerged repeatedly during the interviews, reflecting tangible operational tensions as well as potential levers for action.

Together, these five issues form the framework for the conditions needed to achieve sustainable industrial reshoring. They encompass regulatory, economic, fiscal, technological, systemic and behavioural dimensions. Through their exploration, the aim is to understand not only why reshoring remains marginal despite ambitious rhetoric but also how to better align public ambitions with industrial realities.

Can an industry be rebuilt on a regulatory foundation that has become a labyrinth?

Among the most unanimously cited themes in the interviews is the issue of regulatory complexity. Industrial players acknowledge the importance of a rigorous framework to ensure the safety, quality and traceability of health products. However, they also point to the layering, instability and slowness of this framework, which directly hinders industrial investment in both France and Europe. Without clarification, simplification and coherence of regulations, reshoring will remain a political objective that is difficult to achieve within the stated timelines. with real-world industrial and operational realities.

Regulatory agility and bottlenecks

Conversely, some international initiatives show that more agile regulatory frameworks can accelerate industrial deployment. In Germany, the Digital Health Applications (DiGA) scheme, which enables the rapid integration of digital health apps into the reimbursement system, has stimulated investment in healthtech by facilitating market access. At the EU level, the new Health Technology Assessment (HTA) Regulation, in force from 2025, aims to streamline and accelerate the evaluation of innovative medicines and certain high-risk medical devices by creating a joint European assessment, thereby reducing duplication and speeding up patient access across Member States. In the US, the Food and Drug Administration's (FDA) Framework for Regulatory Advanced Manufacturing Evaluation (FRAME) programme adapts regulation to advanced manufacturing processes such as continuous manufacturing, thereby reducing deployment times.

These examples illustrate that a clear, stable and responsive framework can transform regulation into a strategic lever — an essential condition for the success of reshoring projects.

> "Each new regulation adds a layer without ever removing the previous one."

Similarly, the time required to obtain, for example, Classified Installations for Environmental Protection (ICPE) permits, longer evaluation cycles, notably for medical devices subject to the Medical Device Regulation (MDR) or the multiplication of regulatory layers such as GMP and ESG, make industrial decision-making particularly risky, with ever-lengthening timelines.

Several projects mentioned in the interviews have been suspended or relocated for these reasons alone. The time required to obtain ICPE or MDR authorisations is often considered incompatible with industrial schedules. But it is not just processing times that are the problem: the associated administrative burden, the complexity of the dossiers to be prepared and the difficulty in providing all the required supporting documents are also major obstacles to project progress.

The median time to obtain CE marking under the MDR in Europe is now averaging between 13 and 18 months, according to MedTech Europe (equivalent to approximately 400–540 days). While in the US, FDA processes can, in practice, allow pre-marketing decisions in under 90 days. This regulatory asymmetry imposes a significant competitive disadvantage on European producers.

Turning compliance into competitiveness

In addition, industrial stakeholders denounce a lack of medium-term visibility. Uncertainty surrounding the transposition of European directives, such as the Corporate Sustainability Reporting Directive (CSRD), makes it difficult to anticipate future compliance requirements. This lack of clarity is compounded by other texts currently being discussed or progressively enforced, including the Corporate Sustainability Due Diligence Directive (CSDDD), the revision of Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulations, the Waste Framework Directive (with stricter requirements on pharmaceutical packaging and recycling obligations) and the EU taxonomy for sustainable activities. Each of these initiatives carries potentially significant operational, reporting or investment consequences. Their evolving scope and staggered timelines make it difficult for companies to forecast compliance costs and integrate them reliably into business plans. Moreover, as regulations progress in parallel and with different implementation dates, companies struggle to model their combined impact. This regulatory uncertainty undermines the attractiveness of French and European sites compared to other regions where compliance frameworks are more stable and predictable.

Added to this is institutional fragmentation, characterised by the coexistence of several decision-making levels (local authorities, national agencies, European bodies) without sufficient coordination. This superposition makes administrative processes opaque and slows the concrete implementation of projects. It is not uncommon for a stakeholder to receive strategic support at national or European level while facing regulatory or operational blockages locally, particularly in relation to land-use planning or environmental constraints.

Finally, the regulatory issue is not limited to the law: it is also about people. The multiplication of procedures diverts internal resources towards compliance functions, sometimes to the detriment of innovation or production. The shared perception is that of a growing gap between political ambition and the administrative system’s operational capacity to deliver on it.

Forvis Mazars' expert view

Current regulatory complexity is holding back industrial investment, even in projects with significant societal impact. An effective reshoring policy requires simplified, transparent and predictable governance built at European level. It also means prioritising regulatory requirements so that compliance does not become a deterrent.

To achieve this, several pragmatic levers can be activated:

- Streamlined permitting procedures: establish 'fast-track' channels for strategic health projects (e.g. ICPE permits, MDR certification), with guaranteed timelines and clear escalation paths when delays occur.
- Regulatory convergence and single interfaces: reinforce coordination between local, national and European levels by creating 'one-stop shop' authorities for industrial health investments, avoiding contradictory requirements and reducing administrative opacity.
- Predictable compliance roadmap: publish forward-looking EU implementation calendars for directives such as CSRD, CSDDD, REACH, Waste Framework and EU taxonomy — giving companies sufficient lead time to integrate compliance costs into investment planning.
- Proportionality of requirements: adapt the depth of reporting and documentation obligations to the risk level of the project, so that compliance effort is focused on high-risk areas (safety, patient protection, environmental impact) without diverting resources unnecessarily from production and innovation.
- Link regulation to demand-side tools: embed sustainability and sovereignty criteria into EU and national procurement (e.g. green hospital tenders, joint EU purchasing under HERA) so that firms investing in reshoring are rewarded with market access advantages.
- Skills and administrative capacity: invest in training and staffing for notified bodies, environmental agencies and compliance authorities to reduce bottlenecks and ensure that rules are enforceable without paralysing decision-making.

Finally, it is essential to consider regulating demand as well as supply: encouraging more responsible consumption of medicines and medical devices, fighting waste in hospital procurement and incentivising sustainable prescribing practices. This dual approach — aligning regulation with pragmatic industrial facilitation while shaping demand — helps create the conditions for a sustainable balance between quality of care, budgetary sustainability and industrial reshoring.

Territorial planning for industrial sovereignty

Relocating an industry requires physical production capacities. Yet, in a context of land-use sobriety, strict environmental policies and growing local tensions, finding space to produce has become a strategic challenge. Access to industrial land, the acceptability of projects by local communities and environmental regulatory requirements are now structural factors determining feasibility. Relocalisation cannot succeed without a coherent and coordinated territorial planning strategy.

The availability of industrial land has become a decisive factor in the ability to relocate production, far beyond purely real estate considerations. Several projects, sometimes supported by ambitious public schemes (France 2030, regional subsidies, IPCEI), have failed to materialise due to the lack of classified land under ICPE regulations or because of constraints imposed by the Zero Net Land Take (ZAN) policy.

Originating in the European Green Deal and the EU Biodiversity Strategy, the principle of 'no net land take by 2050' is progressively being transposed into national legislation across Member States. In France, the 2021 Climate and Resilience Act introduced the Zéro Artificialisation Nette framework, which aims to drastically limit the consumption of natural, agricultural and forested land. In Germany, the federal government has committed to reducing land take to 30 hectares per day by 2030, while Austria has adopted a national soil protection strategy that seeks to limit soil sealing through federal–regional agreements. While the environmental objectives are legitimate, the rigid implementation of these frameworks creates tensions in industrial planning, particularly for new production sites or logistics extensions. Moreover, the rules often remain unclear for both local authorities and industrial players, adding uncertainty to investment decisions.

> "Without available land, all our projects remain theoretical."

These regulatory obstacles are compounded by particularly long permitting timelines, often deemed incompatible with economic imperatives. One industrial stakeholder interviewed reported taking more than 24 months to secure a plot of land in the region before even being able to apply for a building permit. In an environment where international groups compare execution speeds across global sites (countries), such delays weigh heavily on the territory's attractiveness.

Beyond procedures and timelines, the social and political dimensions of industrial siting are becoming decisive factors. The 'not in my backyard' phenomenon is present in many projects, including in the health sector at large. Several interviewees mentioned strong local pressures, even for projects with controlled and limited environmental impact. This growing territorial sensitivity requires a more structured and proactive dialogue with elected officials, residents and civil society stakeholders to build projects that are accepted and sustainable.

Territorial planning for industrial sovereignty

Some companies work around these obstacles through proactive measures: early consultation, landscape integration, High Environmental Quality (HQE) certification and local social clauses. However, these approaches require internal resources and time, which are not accounted for in current support schemes.

There are also weak but positive signals. Some metropolitan areas or regions are setting up local industrial support desks, pre-identifying ‘strategic interest zones’ or actively supporting high-impact health projects. In France, the Grand Est region has launched a dedicated biocluster around Strasbourg, linked to the BioValley France competitiveness cluster. In Belgium, Flanders has positioned itself as a European biopharma hotspot, supported by the Flemish Agency for Innovation & Entrepreneurship (VLAIO). In Spain, Catalonia drives biotech and medtech growth through Biocat, a regional coordination and funding platform. In Germany, Bavaria has consolidated the BioM cluster in Munich as a major European hub for biotech innovation. These local dynamics are sometimes backed by targeted regional subsidies that complement national schemes (such as France 2030) or European programmes (IPCEI, the European Regional Development Fund). However, coordination between these different levels of support remains limited and project sponsors still struggle to navigate a fragmented aid ecosystem, with no single entry point and no overarching strategic clarity.

Forvis Mazars' expert view

Industrial land is no longer just a siting parameter; it has become a strategic asset, on par with patents, skills or energy. To achieve successful reshoring, it is essential to embed the health industry within a coherent, transparent and prioritised territorial planning vision. This requires stronger alignment between urban planning, environmental objectives and actual industrial needs.

Projects must also be anchored in regions with qualified technical and scientific talent pools. It is equally crucial to define which part of the value chain is to be relocated. Several interviewees emphasised that it is often more relevant and realistic to relocate innovation (R&D, trials, formulation) rather than heavy production which is more capital-intensive, riskier and harder to gain local acceptance.

For example, relocating fine chemicals or API manufacturing involves ICPE-equivalent classified installations, significant environmental impacts and demanding territorial dialogue. In contrast, establishing development or packaging capabilities can prove faster, more acceptable and a generator of skilled jobs. More broadly, within the pharmaceutical and medical device value chain, certain activities are typically easier to anchor in European territories: formulation and fill-finish, packaging and labelling, quality control laboratories, clinical trial logistics, digital health and data platforms, as well as after-sales services and refurbishment of medical devices. These activities combine a high ratio of skilled employment with a comparatively lower environmental footprint, while contributing directly to industrial sovereignty and regional attractiveness. This approach is consistent with the objectives of the **European Green Deal** and the **EU Biodiversity Strategy** (targeting no net land take by 2050). It complements industrial policy instruments such as the **EU Critical Medicines Act**, which explicitly encourages the localisation of essential, but territorially acceptable, manufacturing capacities.

Land-use decisions must therefore factor in public health sovereignty and industrial self-sufficiency objectives, without overlooking their territorial and environmental impacts: local employment, urban integration and social acceptability. We therefore recommend fully integrating 'sustainable public health' into land-use planning logics, on par with food and mobility, especially in high-pressure or reconversion areas.

Can the price of medicines remain low without compromising the balance of the entire value chain?

Many of the industrial players we interviewed state it plainly: relocating to France or Europe is economically unviable in a large number of cases. Between very low regulated prices, squeezed margins, heavy taxation and the absence of a clear economic trajectory, the conditions for profitability are rarely met. While public support is useful, it is not enough to offset the structural imbalances that weaken the production base and hold back commitment to long-term projects.

The issue of medicine pricing emerged as a significant point of tension in all the interviews conducted. Several stakeholders, particularly in the generics sector, described a situation in which official prices are often too low to cover production costs in a European context, where labour, energy and compliance costs are significantly higher than in Asia. This challenge is compounded in many Member States by budgetary control mechanisms such as safeguard clauses or clawback systems that cap public spending on medicines but introduce major financial uncertainty for manufacturers.

Across Europe, mature molecules frequently fall into a low-price trap: national health systems push for sustained price reductions while production costs rise, eroding margins and undermining investment capacity. According to industry surveys, countries such as France, Italy and Spain consistently rank among the lowest-priced markets in Europe for many off-patent medicines. Under these conditions, restarting a production line often means operating at a loss unless substantial public support is provided. Even then, the medium-term viability remains uncertain without structural reform of procurement and pricing models.

By contrast, some markets illustrate alternative approaches. In Germany, the Pharmaceuticals Market Reorganisation Act (AMNOG) framework for new medicines combines early benefit assessment with price negotiation, giving greater predictability to manufacturers compared to blunt price caps. In the Nordic countries, pooled procurement models — particularly for hospital medicines — integrate not only price but also supply-security and sustainability criteria, creating more balanced incentives. These counterexamples show that European medicine pricing is highly fragmented. More coherent alignment could help reconcile the dual objectives of affordability for health systems and viability for manufacturers.

> “Producing locally is becoming an act of activism, not an economic model.”

In the medical devices sector, the situation is similar. Price pressure in hospital tenders frequently disadvantages local production, which is more expensive than standardised products imported at low cost. Several companies interviewed spoke of a ‘scissors effect’ with rising production costs (energy, compliance, wages) against fixed or even declining contractual prices, leaving little prospect of economic balance.

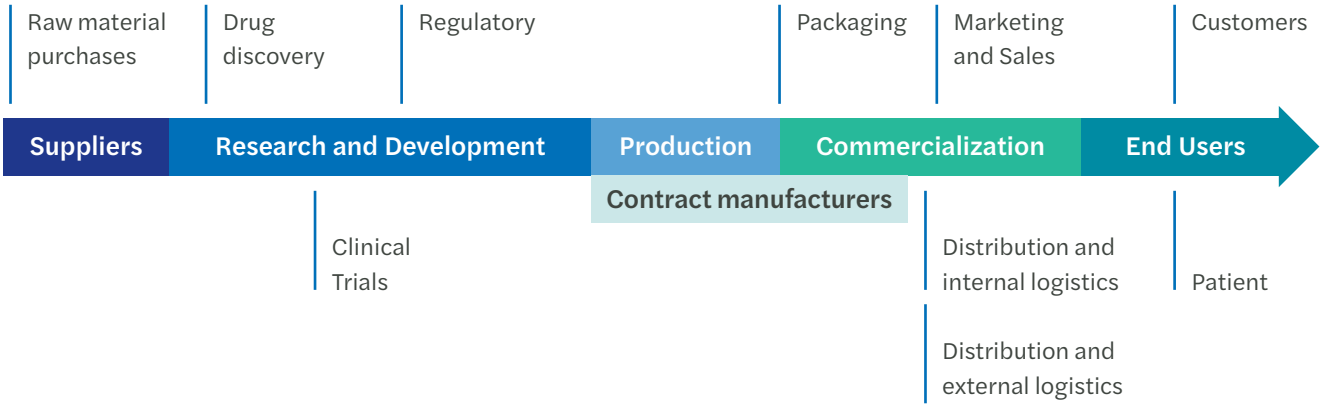
On top of pricing pressures comes structural fiscal pressure. Stakeholders across Europe point to the weight of industrial taxation — including production taxes, employer social charges and property taxes on industrial sites and equipment. These levies directly raise the cost of producing medicines and medical devices in Europe, while reducing the resources available for reinvestment in new lines, digitalisation or sustainability improvements. The competitiveness gap is accentuated when compared to jurisdictions with lighter or differently structured tax regimes: in several Member States, the combined burden of payroll charges and industrial property taxation can exceed that of neighbouring countries by 20–30%. By contrast, countries such as Germany or Ireland apply more favourable rules, either by limiting the taxation of production equipment or by maintaining lower employer contributions. This asymmetry creates distortions within the Single Market itself. It makes Europe as a whole less attractive compared to global hubs where labour, energy and fiscal regimes are structurally less costly.

Building a sustainable pharma value chain

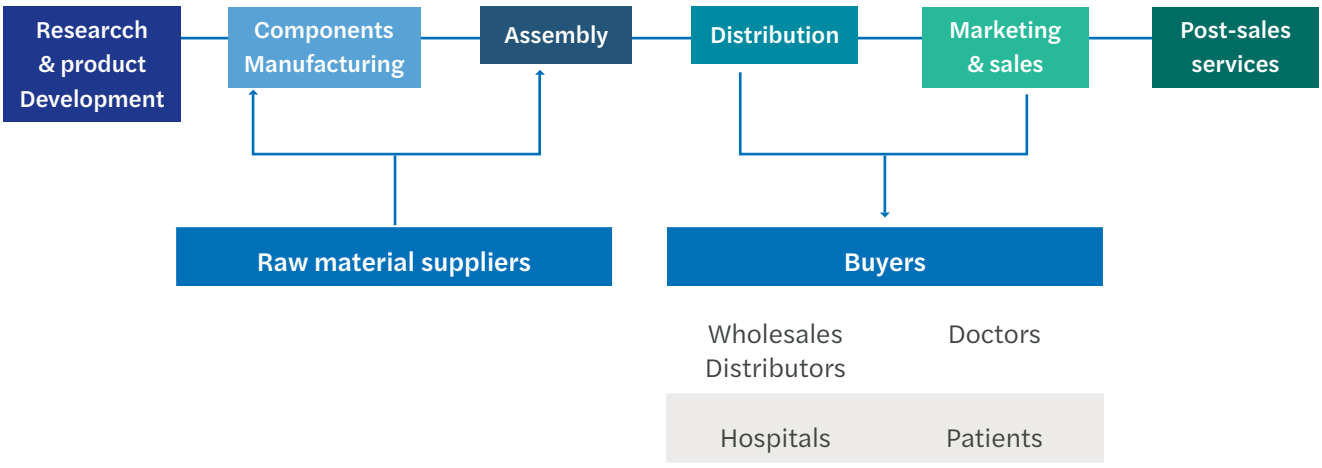
More broadly, the system is perceived as unpredictable. Prices are not re-evaluated over time, public aid is ad hoc and support mechanisms do not cover operating costs. This makes it difficult to project over a 5–10 year horizon, which is the minimum period required to recoup an industrial investment.

Finally, some interviewees put forward another avenue for reflection; acting upstream on consumption. Working on the relevance of prescriptions, prevention and waste reduction would allow public funding to be directed towards products that are truly necessary, thereby better supporting strategic producers without destabilising the overall budget balance.

Drug Value chain



Medical device Value chain



Forvis Mazars' expert view

The current economic model for medicines often struggles to provide the stability needed for long-term industrial decision-making. Particularly for mature products, generics or standard devices, administered price levels and budget constraints weigh heavily on industrial viability. It is becoming essential to define clearer, more stable price trajectories aligned with the real costs of local production to offer minimum visibility to industrial operators and investors.

Industrial taxation is another lever for rebalancing. Better recognition of productive investments, in terms of employment, infrastructure, ecological transition or health sovereignty, could help build a more competitive economic environment, while aligning with European sustainability objectives.

Finally, beyond prices and costs, the very model of medicine consumption needs to be reconsidered. Several interviewees stressed that reshoring cannot succeed without addressing the excessive volumes placed on the market and ensuring they are aligned with real patient needs and prevention strategies. This calls for a set of complementary levers:

- More appropriate packaging, reducing wastage and the risk of incomplete treatments.
- Awareness and education for healthcare professionals and patients to encourage more targeted prescribing, guided by actual use and clinical effectiveness.
- ·Health spending strategies oriented by impact rather than volume, ensuring that resources are directed where they deliver the most value.
- A value-driven approach across the entire production and procurement chain, from manufacturers to payers.

> "To take our biotech to Phase III, we'd need €60m – and no European investor is willing to take that risk."

By reducing unnecessary or non-relevant consumption, financial resources could be reallocated to higher value-added products — often manufactured locally — while easing price pressures that currently strain the value chain. In this sense, controlling consumption is not about limiting access but about creating the structural conditions to reconcile budgetary discipline, industrialsovereignty and the sustainability of the European healthcare system.

Industrial sovereignty begins in the laboratories

One of Europe's major paradoxes lies in its ability to generate breakthrough innovations without always being able to industrialise them locally. While Europe has a dynamic research ecosystem, strong clusters and robust early-stage support mechanisms, financing for the advanced stages of development (late-stage) remains fragmented, risky and insufficient. To achieve sustainable reshoring, it is necessary not only to produce but also to structure an 'innovation-to-industry' continuum capable of supporting biotech, medtech and start-ups all the way through to market launch.

Industrial production reshoring cannot be separated from the ability to finance innovation. Yet the European landscape remains fragmented, particularly for biotech, medtech and deeptech start-ups seeking to raise funds as they approach late clinical phases or industrialisation.

Interviewed stakeholders describe an asymmetric situation in Europe with a very favourable early-stage ecosystem with numerous public support mechanisms (European Innovation Council Accelerator, regional grants, French Public Investment Bank, etc.) but a shortage of specialised pan-european private equity investors for tickets above €30–50m. This leads many companies to raise funds outside Europe, often in the US or Asia, with the risk of partially or entirely relocating industrial capacities.

In the medical device sector, the situation is similar. The cost of CE marking under MDR, compliance requirements and extended testing timelines requires heavy investments, sometimes without any guarantee of immediate market access. Financing the 'time-to-market' is considered too risky by most European funds, except for a few highly specialised investors.

The project-based approach — driven by calls for expressions of interest or public funding windows — remains useful but it does not replace an integrated sector-wide vision. Several interviewees advocate for a public–private financing continuum, with structured co-investment between the European Investment Bank, European Investment Fund, HERA, specialised funds and industrial players themselves.

> "AI, continuous bioproduction, cell therapy: these are breakthroughs. But without specialised funds, they will leave Europe."

Some examples demonstrate that this model can work. Projects carried out under IPCEI Health, co-financing through France 2030 and industrial hub initiatives (Saclay, Lyon-Gerland, Medicon Valley in Denmark–Sweden) create an environment conducive to the emergence of industrial scale-ups.

Other European initiatives deserve highlighting. In Germany, targeted support for bioproduction via public investment bank KfW and the integration of biotech into federal innovation plans has allowed players such as BioNTech to build industrial capabilities domestically. In Belgium, the ecosystems of Leuven and Liège leverage a dense network of universities, institutional investors and integrated production sites, helping to maintain local capacities. In Scandinavia, public–private funds such as those in the Medicon Valley invest in health technologies in a coordinated way, with regional governance involving industry, research and public agencies alike.

However, scale effects will remain limited unless Europe also strengthens its culture of patient capital, capable of supporting biotechs over 8 to 10 years. The risk is not a shortage of innovation but that these innovations will be realised elsewhere.

Fuel for innovation and industrial growth

Forvis Mazars' expert view

Europe's industrial competitiveness will largely depend on its ability to finance technological innovation over the long term. It is imperative to strengthen co-financing mechanisms between public and private actors, simplify access to funding in post-seed phases and build effective bridges between research, industry and finance.

This also means leveraging existing mechanisms in Europe to promote technology transfer between academia and industry. Several countries have set up specific tools such as technology transfer offices, technology maturation platforms or mixed public–private entities. This is the case in France, for example, with the Sociétés d'Accélération du Transfert de Technologies (SATT) or the structures integrated into competitiveness clusters which facilitate the transformation of research projects into industrialisable innovations. Better support and connecting these ecosystems would accelerate the reshoring of strategic technological building blocks.

We also recommend fostering the emergence of pan-European funds specialising in health and disruptive technologies that are capable of supporting a fully sovereign industrial ambition and scaling European players to the global level.

Europe does not lack infrastructure but recognition of its strategic value

Reshoring is often seen as a lever for sovereignty. But for a growing number of companies it is equally a way to strengthen the alignment between their CSR commitments, climate objectives and industrial model. More than just a question of location or geographical proximity, it reflects a broader ambition for a responsible and resilient value chain: controlling flows, reducing carbon footprint, anticipating climate-related risks, ensuring full traceability, guaranteeing responsible production conditions and embedding ethical governance.

Some stakeholders interviewed go even further than the 'made in' concept, making location a strategic choice aligned with their core purpose. In this context, Europe's structural assets, if properly leveraged, can become powerful accelerators of differentiation.

Indeed, several stakeholders emphasise that reshoring cannot be approached solely from the 'made in' perspective. It must also take into account the quality of production conditions, control over the supply chain and alignment with the company's CSR commitments. For some organisations, production location becomes a strategic choice based on values: reducing carbon footprint, ensuring traceability, working conditions and ethical sourcing. This approach goes beyond simple geographical proximity to embrace overall coherence between product, impact and mission.

It is particularly along the supply chain that reshoring challenges become tangible. The COVID-19 crisis and geopolitical tensions have highlighted the structural dependence on imports of active ingredients and components, especially from Asia. This dependency creates uncertainty in lead times, costs and quality, as well as in the environmental and social standards applied at each link in the chain.

European logistical fragmentation is also seen as a barrier: cross-border flows lack harmonisation, transport costs are difficult to pool and standards differ by destination. Several manufacturers note that a successful reshoring project, beyond the site itself, often requires a broader reorganisation of subcontracting and distribution flows.

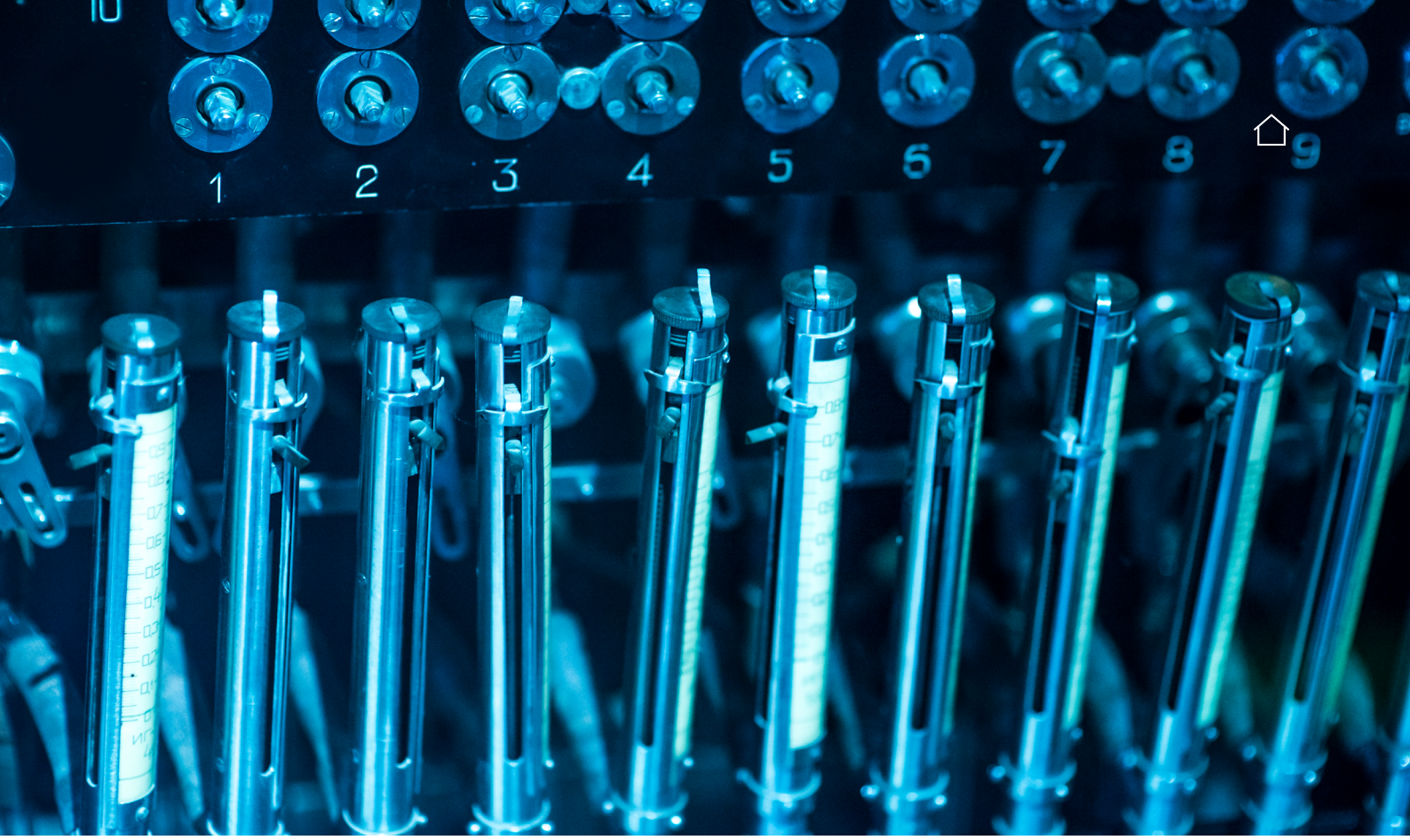
The role of CDMOs is central here. While these partners offer valuable flexibility, they can also be points of vulnerability: capacity saturation, prioritisation of strategic clients and lack of control over timelines. Some companies are considering partially reinternalising certain critical steps to secure their value chain and reduce dependency.

Finally, Europe has underutilised structural assets that could serve as powerful levers for reshoring. These include: a low-carbon electricity mix (notably in France, the Nordic countries, Central Europe), a high density of hospital and research centres, a robust regulatory culture valued for its rigour and stability and dynamic regional ecosystems combining infrastructure, innovation and local governance.

Unlocking the power of existing assets

Another decisive factor is access to pools of qualified labour in many European regions. The health industry requires specific skills — industrial pharmacists, specialised operators, data scientists, process engineers, maintenance technicians — which some territories have managed to preserve or develop thanks to long-standing industrial traditions. For example, the Basel region (Switzerland and Alsace, France) has historically been a global hub for chemistry and pharmaceuticals, maintaining a dense ecosystem of process engineers and industrial pharmacists. Leuven and Antwerp in Flanders (Belgium) concentrate expertise in biomanufacturing and vaccine production, reinforced by universities and companies like GSK and Janssen. Saxony and Thuringia in Germany have built a reputation in medical technology and diagnostics since the German Democratic Republic period, sustaining specialised operators and engineers in imaging and lab equipment. In Denmark, the Copenhagen/Kalundborg region has become a reference for bioproduction, with Novo Nordisk anchoring a skilled workforce in biologics and insulin manufacturing. In Ireland, the Cork–Dublin corridor has developed deep expertise in pharmaceutical manufacturing and biologics through decades of investment by multinationals. This availability of trained talent, often nurtured by strong public education and training systems, is a significant asset for manufacturers looking to set up or expand capacity on the continent.

When these elements are coherently mobilised within a structured industrial strategy, they make it possible to offer a competitive proposition based not on price but on the overall value of the product (environmental, social, ethical and territorial). This model of responsible competitiveness is one that many stakeholders now wish to strengthen.



Forvis Mazars' expert view

Reshoring should not be thought of solely in terms of cost or sovereignty but as an opportunity to strengthen the overall coherence of the health value chain. Europe has a unique foundation for combining industrial competitiveness and sustainability: low-carbon energy, high-quality standards, proximity to consumer markets and demanding CSR frameworks.

To this can be added an often underestimated advantage: Europe's generally lower exposure to acute climate risks compared to other major global industrial regions. This relative environmental stability reduces the likelihood of physical damage to facilities, limits operational disruptions caused by floods, hurricanes or heatwaves and allows for more predictable insurance and maintenance costs. By contrast, in regions more exposed to climate volatility, companies face production shutdowns, higher logistics uncertainty, accelerated equipment wear and rising insurance premiums. In the context of escalating climate risks globally, Europe's relative stability is becoming a strategic criterion increasingly taken into account by industrial players when deciding where to locate or expand their production capacities.

The most committed companies are thus developing a distinctive approach, based not on 'made in' as an end in itself but on a production model aligned with their purpose: traceability, resource efficiency, local impact and real sustainability. It is time for industrial policies and support mechanisms to recognise this diversity of trajectories, by valuing not only location but also the quality, robustness and coherence of production chains.

The interviews conducted confirm that the barriers to reshoring are neither occasional nor isolated. They reflect a persistent gap between political will and operational reality, across five major issues: governance, land availability, taxation, innovation financing and alignment with CSR objectives.

Sovereignty cannot be conceived at the level of a single state. In a globalised industry, strategic autonomy must be built at the European scale through enhanced coordination.

Finally, reshoring does not necessarily mean bringing back all production: for many actors, the challenge is to relocate intelligently. For example, by focusing on certain critical links, innovation or logistics while building value chains that are sustainable, resilient and coherent.

Unlocking the power of existing assets

While the five levers apply across the life sciences industry, their relative impact differs markedly between subsectors — with traditional pharma constrained primarily by pricing and regulation, biotech by financing gaps, and medtech by regulatory delays and procurement models. The table below provides a comparative overview.

Comparative impact of reshoring challenges by subsector			
Lever	**Traditional Pharma**	**Biotech**	**Medtech**
Turning compliance into competitiveness	Stable GMP/EMA processes but still heavy burden.	Uncertainty on scaling new therapies.	**High impact**: MDR/ IVDR delays and costs.
Territorial planning for industrial sovereignty	ICPE/ZAN rules constrain API/ chemicals sites.	Cluster siting and talent pools decisive.	Facility acceptance delays market entry.
Building a sustainable pharma value chain	**Critical issue**: low prices squeeze margins.	Less about price, more about funding continuity.	Procurement overly price-driven, ESG underused.
Fuel for innovation and industrial growth	Large groups self-finance incremental innovation.	**Critical gap**: late-stage (€30–60m+) financing.	Heavy MDR costs + testing/scale-up hurdles.
Unlocking the power of existing assets	Strong base: low-carbon energy, industrial skills.	Dependence on bioproduction infrastructure/ CDMOs.	Opportunity in repair, refurbishment, digital flows.

This layout gives a visual signal at first glance:

- = structural barrier / critical pain point
- = moderate challenge / conditional risk
- = opportunity / existing strength to leverage

Relocalising the health industry from ambition to reality

Since the COVID-19 pandemic, the issue of industrial reshoring has emerged as a strategic priority both for reasons of health sovereignty and as part of a sustainable transition. The ambition expressed by many EU Member States, as well as by the European Commission, converges towards a common goal: to strengthen production capacity on European soil, secure supply chains and meet citizens' new expectations for traceability, responsiveness and transparency.

Reshoring is thus part of a global movement, where health is now recognised as a strategic public good at the intersection of industrial, environmental and social challenges. It benefits from several levers: ambitious public policies (France 2030, IPCEI Health, HERA), targeted European funding, increasing territorial engagement and the consolidation of CSR frameworks that integrate industrial proximity as a factor of overall performance. Internationally, the US, India, Japan and Germany have also implemented proactive policies to re-anchor part of their critical production domestically.

However, behind this momentum, the lessons from the field reveal a more nuanced reality. Stakeholders welcome the intentions but point to a series of structural constraints: regulatory unpredictability, administrative delays, price pressure, penalising taxation, scarcity of land, fragmented support mechanisms, increased logistical dependency and a lack of funding for growth phases. Europe, despite its undeniable structural assets (decarbonised energy mix, climate stability, high regulatory compliance standards), still struggles to turn these strengths into a driver for industrial investment.

This dissonance is not a disagreement in principle but an urgent need for convergence between the long timelines of industrial investment and the short cycles of public decision-making; between companies' environmental ambitions and the budgetary logic of public procurement; between different governance at local and European level which must speak with one voice when it comes to health sovereignty.

In this respect, sovereignty cannot be considered in isolation, country by country. In a profoundly globalised industry, reshoring must be planned, financed and coordinated at the European level, integrating industrial complementarities and logistical interdependencies between territories.

Interviews also reveal that reshoring is not limited to physical production. In some cases, relocating innovation, R&D, critical logistics or upstream industrialisation proves more realistic and higher value-added. Many companies have already launched inspiring initiatives: internalising certain production steps to secure supply chains, adapting packaging to reduce waste, co-investing public and private capital in targeted stages and building industrial hubs anchored in dynamic regions.

But to create the conditions for sustainable reshoring, the consumption model itself must also be rethought. Several professionals stressed the counterproductive nature of a market driven exclusively by volumes. Particularly in France, where overly low prices render some products unprofitable and divert industrial investment. Moving from a volume-based market to a value-based market is essential. Linking price to medical service provided, environmental performance and supply chain sustainability would not only reconcile budgetary discipline with sovereignty but also align industrial practices with CSR commitments.

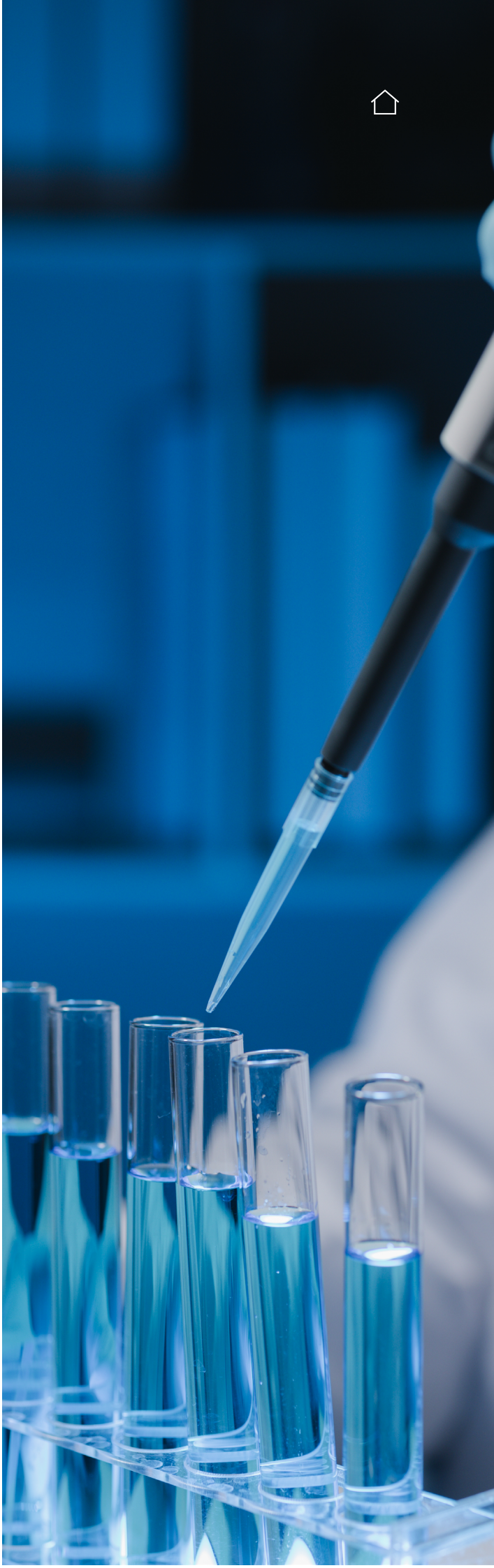
The pathways identified in this study go beyond one-off subsidies. They call for a structural transformation of the operating framework:

- Simplify and harmonise the regulatory framework at the European level.
- Provide multi-year economic visibility, especially on prices and volumes.
- Integrate sustainability into the evaluation criteria of health policies.
- Better align industrial strategies, territorial planning and land management.
- Promote virtuous models based on resilience, traceability and CSR coherence.

Relocalising the health industry from ambition to reality

These findings highlight the limits of current support mechanisms: low disbursement rates for aid, lack of coordination between programmes and the absence of clear monitoring indicators. This reflects a broader challenge across Europe: moving from a logic of political intention to a logic of execution which is measurable, shared and effectively managed over time.

Reshoring does not mean reproducing the past. It means building a competitive, sustainable European model, aligned with health needs, social balance and environmental constraints. Listening to industrial stakeholders means acknowledging the complexity of reality without abandoning ambition. It means aligning public policies with the concrete conditions for success and making reshoring a forward-looking strategy in the service of European citizens' health.



Closing Remarks

Pierre Courteille
Abivax, Chief Business Officer, HealthTech for Care, Co-founder & Chairman

On behalf of the Board of the HealthTech For Care Endowment Fund, I warmly welcome this timely study on the strategic reshoring of the life sciences industry in Europe, and extend my sincere thanks to Forvis Mazars for this valuable initiative.

At the center of this debate must remain the European patient—whose access to innovative, safe, and timely care is directly shaped by our industrial and policy choices.

The COVID-19 pandemic revealed critical vulnerabilities: Europe's heavy dependence on imports of active pharmaceutical ingredients and medical devices left patients exposed to shortages, delays, and uncertainty. Reshoring is therefore not merely an industrial policy—it is a public health imperative.

By relocating production within Europe, we can secure supply chains, cut carbon emissions, and create highly skilled jobs. In doing so, we reinforce both health sovereignty and sustainability—two pillars essential to maintaining patients' trust in our healthcare systems.

Yet, as the study rightly emphasizes, significant obstacles remain. Complex and inconsistent regulations hinder access to innovation. Limited industrial land, lengthy permitting processes, and fragmented financing constrain the development of critical infrastructure. For patients, this means slower access to medicines and technologies that could save or transform lives. Europe must respond with greater coherence, ambition, and urgency.

Reshoring also calls for a fundamental rethinking of our economic model. Current pricing policies often render European production of essential medicines unviable. Patients cannot be the collateral victims of policies that inadvertently fuel shortages. Value-based approaches are needed to balance affordability with long-term sustainability.

Financing represents another decisive challenge. Too many promising biotech and medtech projects risk stalling before reaching patients due to insufficient late-stage capital. Stronger public–private co-investment frameworks are essential, along with innovative investment policies capable of attracting long-term investors willing to take risks.

Encouragingly, flagship initiatives already under way—from Spain to Ireland—prove that reshoring can expand capacity, create jobs, and strengthen resilience. These examples should inspire a comprehensive European strategy, guided first and foremost by patients' needs.

Ultimately, reshoring is not only about sovereignty or economics. It is about health equity. Every patient in Europe, regardless of country, deserves timely access to innovative, high-quality medicines and technologies.

Europe has the assets to succeed—world-class science, regulatory expertise, and vibrant clusters of innovation. What is now required is clear political will, regulatory alignment, and sustained investment at the European level.

At HealthTech For Care, we remain fully committed to fostering dialogue between researchers, healthTech companies, pharmaceutical firms, CDMOs, investors, patients, and policymakers to ensure that reshoring delivers on its greatest promise: a stronger, fairer, and more resilient healthcare system for the benefit of every European patient.

Methodology

A qualitative, exploratory and multi-stakeholder approach

This study is based on a qualitative approach, built on a series of exploratory interviews conducted between March and June 2025 with a diverse panel of stakeholders from the pharmaceutical, biotech and medical device ecosystems across Europe.

In total, 20 semi-structured interviews were carried out using a prepared framework that was deliberately flexible, allowing for open expression. This open posture made it possible to bring out sometimes unexpected elements and to capture the nuances of a topic that is at once technical, strategic and human. The feedback gathered reflects both personal perceptions and more structured organisational positions, often situated at the intersection of operational constraints, industrial vision and political dynamics.

The interviews were conducted confidentially and anonymously to ensure the sincerity of exchanges. No personal names, company names or product names are mentioned in this study unless the information was already public. This confidentiality allowed for a greater freedom of expression and a richer analysis.

Broad coverage of the value chain

The interviewee panel was designed to reflect the diversity of links in the value chain, from research through to distribution, also including support functions, public stakeholders and investors. It included:

- Pharmaceutical laboratories (large groups, generic drug producers, hospital suppliers)
- Medical device companies (medtech)
- Biotechs and deeptech start-ups
- Industrial subcontractors (CDMOs)
- Regional competitiveness clusters
- Specialised investors
- Institutional representatives and public authorities

All of the organisations represented are based in Europe, with some belonging to international groups with multi-site operations in Europe. This deliberately broad scope makes it possible to cross-reference European and global realities, while keeping the main focus on the dynamics of reshoring to Europe.

In addition to the interviews, the analysis was enriched by targeted desk research based on public sources (official reports, specialised press, sector publications, European databases). These inputs helped to contextualise certain comments and shed light on the systemic issues underlying them.

A study anchored in reality, without scientific pretension

This study is not intended to produce a theoretical model or a universal truth. It is not based on a statistically representative sample, nor on quantitative data. It is intended to be pragmatic, empirical and grounded in field realities by reporting on the obstacles, levers and tensions experienced by stakeholders on a daily basis.

It highlights the diversity of viewpoints, depending on the size of the organisations, their position in the value chain, their degree of industrial integration or their strategy regarding reshoring.

In this sense, it provides a structured basis for reflection, supported by verbatims, observations and concrete examples, aimed at fuelling the debate on the feasibility and conditions for sustainable and competitive industrial reshoring in Europe.

Annexes and key sources

European Initiatives and Institutions

- **EU Critical Medicines Act** – European Commission press release and legal text
- **Pharmaceutical Strategy for Europe** – European Commission
- **HERA (Health Emergency Preparedness and Response Authority)** – European Commission
- **IPCEI Health (Important Project of Common European Interest – Health**) – European Commission overview
- **EU Critical Medicines Alliance** – European Commission announcement
- **Union List of Critical Medicines (2023/2024 updates)** – European Commission
- **EMA extended shortages mandate (2023)** – European Medical Agency (EMA) news
- **Health Technology Assessment (HTA) Regulation (2025 application)** – European Commission
- **STEP Regulation (Strategic Technologies for Europe Platform, 2024)** – European Commission fact sheet

National/regional initiatives

- **France 2030 Plan** – French Government
- **Italy – PNRR Health & Research Missions** – Italian Government Recovery Plan
- **Spain – PERTE for Vanguard Health** – Spanish Government PERTE Health
- **Germany – Zukunftspaket / Vaccine & Biologics Capacity** – German Federal Government

Industry reports and barometers

- **LEEM Barometer 2024 (France & European pharma industry)** – LEEM publications
- **MedTech Europe Reports (CE marking timelines, MDR impact)** – MedTech Europe

Regulatory and environmental frameworks

- **CSRD (Corporate Sustainability Reporting Directive)** – EU info
- **CSDDD (Corporate Sustainability Due Diligence Directive)** – European Commission
- **REACH Revision** – European Chemicals Agency
- **EU Waste Framework Directive** – European Commission
- **EU Taxonomy for Sustainable Activities** – European Commission
- **European Green Deal** – European Commission
- **EU Biodiversity Strategy (No Net Land Take by 2050)** – European Commission

Digital and regulatory innovation

- **Germany – DiGA Scheme ('Apps on Prescription')** – BfArM Official Portal
- **FDA FRAME Program (Advanced Manufacturing)** – FDA initiative

International comparisons

- **US Inflation Reduction Act (2022)** – White House fact sheet
- **US Defense Production Act (Health, APIs, Injectables)** – US DoD
- **Japan – Pharma Resilience Funds** – METI Japan
- **India – PLI Scheme for Pharmaceuticals** – Government of India

Preceding EU-level initiatives toward industrial sovereignty

1 **Reform of pharmaceutical legislation and EMA's shortages mandate**

In 2023, the EU extended the mandate of the EMA to better monitor and manage medicine shortages PGEU+5GoodLifeSci+5medicinesforeurope.com+5.

Alongside, the revision of pharmaceutical legislation introduced new resilience mechanisms to strengthen supply chains across Europe Ropes & Gray+3European Parliament+3vfa.de+3.

2 **Critical Medicines Alliance and Union List of Critical Medicines**

In 2024, the Commission launched the Critical Medicines Alliance, uniting Member States, industry, patients and civil society to address pharmaceutical vulnerabilities Ropes & Gray+10European Parliament+10medicinesforeurope.com+10.

By late 2023, the first EU-wide Union List of Critical Medicines—comprising over 270 active substances—was published and later updated in 2024 European Parliament+1.

3 **IPCEI Health and joint procurement via HERA**

The IPCEI on Health supported concrete production projects—such as Rentschler Biopharma's expansion of monoclonal antibody capacity in Germany—to bolster domestic manufacturing European ParliamentCrowell & Moring - Home.

Meanwhile, HERA coordinated joint procurement and stockpiling strategies for critical health products across Member States Crowell & Moring - Home.

4 **Broader industrial sovereignty tools (STEP regulation)**

In 2024, the EU adopted the STEP regulation, which identifies and supports key strategic sectors—such as advanced manufacturing technologies—that may underpin sovereign capacity in life sciences hsfkramer.com.

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