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BIA submission to the House of Lords inquiry into the UK's ability to predict and prevent medicine supply issues

About BIA

The BioIndustry Association (BIA) is the voice of the UK's innovative life science and biotech industry, and our mission is to enable and connect the UK ecosystem so that businesses can start, grow, and deliver world changing innovation. The BIA has a diverse membership, counting over 600 members including start-ups, scale-ups and established global companies, as well as universities, research centres, and investors. BIA is also connected to the European ecosystem through our membership of EuropaBio¹, the European trade association for biotechnology.

Summary

- The medicines supply chain is inherently global and the UK is highly reliant on overseas production; both of active pharmaceutical ingredients, excipients and other components.
- Although global supply chains are unavoidable, UK resilience to supply issues can be improved by increasing UK-based medicines developers, producers and manufacturers
- Approximately 70% of medicines² in development globally are produced by smaller companies, as opposed to larger established companies, and many specialists manufacturers are SMEs, ensuring the UK is a fertile place for them is key.
- The UK has a highly skilled workforce across life sciences and pharmaceutical manufacturing, with world-class expertise in research, development, and advanced therapies. However, gaps remain in key areas that affect supply chain resilience.
- Capital funding gaps compared to the US, high operating costs, limited tax and investment
 incentives, lengthy trial set-up times, and dual batch release testing reduce the UK's
 competitiveness as a company scale-up environment and manufacturing base.
- Policies to grow the UK life sciences sector, including small, medium and large companies, combined with continued investment in innovative medicines is crucial to increasing medicines supply chain resilience for the UK.

Responses to questions

Causes of medicine supply chain issues

1. What are the causes of medicine supply chain issues in the UK?

¹ Home - Europabio

² Emerging Biopharma's Contribution to Innovation - IQVIA

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The medicine supply chain is global, with ingredients and parts passing through multiple countries throughout their lifetime to produce the end manufactured product, and then on to the end-user. The complexity of medicines means this global chain is unavoidable in almost all cases. Supply chain challenges in the UK can therefore stem from both global and domestic factors.

Internationally, the UK is highly reliant on overseas production of active pharmaceutical ingredients and excipients, particularly from the US, India and China, leaving it vulnerable to local supply and manufacturing disruptions in those countries and outside of the UK's influence, as well as export controls, and global logistics disruptions. Geopolitical tensions can also occasionally cause disruption.

Domestically, structural barriers that limit sovereign manufacturing capacity may reduce resilience to these external pressures. Pricing and reimbursement frameworks, combined with limited incentives for onshore production, can make the UK a less attractive market for manufacturers, and thus increase reliance on overseas supply chains. Parallel trade can also mean some medicines are exported out of the country where they can fetch a higher price, although we are not aware of this for new and innovative medicines treating defined patient populations, e.g. cell therapies. Regulatory and procurement processes can also be complex and slow, compounding risks during periods of disruption.

Research by the Office of Health Economics (OHE) has found that medicines with single suppliers can be more prone to medicine shortages. Single-supplier markets often occur in rare disease medicine markets due to a lack of competition and treatment alternatives. OHE's research also found that the risk of medicines shortages is more amplified in the rare disease space, as these treatments often involve complex manufacturing processes that can be volatile to market shocks.

a) What are the impacts of medicine shortages on patients and frontline services when they occur? And what is the significance of the impact when they do occur?

Supply shortages can result in treatments being interrupted or reduced for patients, harming their health. For some patients with chronic and seriously debilitating diseases, this can result in rapid deterioration in health. This was set out in a recent OHE report which cited a number of studies on the impact on patients of supply shortages of treatments for rare diseases, including Gaucher Disease, Fabry Disease and Pompe Disease. ⁴ These studies found that even short interruptions to treatments led to a worsening in patients' symptoms.

Shortages can also affect the wider health system, impacting overall efficiency and resource allocation.

2. What are the current and possible future threats facing the UK medicine supply chain?

A current threat is that the UK is highly reliant on overseas production; both of active pharmaceutical ingredients, excipients and other components, as described above, and for the end high-value advanced medicinal products, which the UK may not have managed to secure manufacturing facilities for due to being outcompeted by other nations. There is strong international competition to attract investment into new medicines manufacturing facilities, which has intensified further following the pandemic, and the UK has not

³ OHE: The Importance of Diversity of Supply in Rare Diseases Markets (2025)

⁴ Ibid.

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historically been competitive for these. However, recent efforts are improving this situation (described below in answer to Question 8).

This leaves the UK vulnerable to local supply and manufacturing disruptions in those countries and outside of the UK's influence, export controls, and global logistics disruptions. Geopolitical tensions can also occasionally cause disruption. This threat is exacerbated by a reliance on single suppliers for many medicines, especially for biologics and advanced therapies, which have complex manufacturing processes, making it much more difficult to switch production on and off compared to small molecule markets.

A significant potential future threat is the impending US pharmaceutical tariffs which aims to incentivise manufacturers to move production to the US, which could result in less investment in UK manufacturing.

a) Overall, how resilient is the UK supply chain to these different threats?

The UK supply chain shows resilience in certain advanced modalities, supported by innovative SMEs that are building specialist manufacturing capacity. Touchlight, for example, has developed an enzymatic DNA platform that supplies high-purity starting materials for RNA therapeutics, addressing a critical bottleneck in RNA manufacturing and supporting faster, more reliable clinical timelines. Similarly, Sensible Bio is developing a cell-based platform for industrial-scale mRNA production, offering a scalable alternative to enzyme-based methods that could enhance flexibility and reduce costs. ⁵ It is companies like this that stepped in during the early days of the COVID-19 pandemic to scale-up the manufacture of potential vaccines that went on to have a pivotal role in addressing the global threat, as described by Dame Kate Bingham in her book about the Vaccine Taskforce. ⁶

While these companies highlight the UK's strengths and capacity for innovation, the overall manufacturing base remains too narrow and dependent on imports for essential components. To achieve greater resilience, the UK must broaden and diversify its domestic manufacturing capacity, alongside supporting these highgrowth, innovative SMEs.

Procurement strategies

6. What impact do procurement policies within primary and secondary care have on supply chain resilience and how could these be improved?

Health technology assessment (HTA), pricing and reimbursement, and procurement policies can help reduce barriers to the availability of medicines and supplier diversity. Value-based assessment of innovation should be complemented by recognition of the value added by supplier diversity and supply resilience.

The UK's current approach to spending on branded medicines is increasingly seen as a barrier to global pharmaceutical investment. Despite medicines accounting for a relatively small share of NHS spending, around 9% compared to 17% in Germany and Italy, and 15% in France, the UK imposes significant commercial constraints on industry.

⁵ mRNA Revolution: A New Generation of Medicine

⁶ The Long Shot: The Inside Story of the Race to Vaccinate Britain, Dame Kate Bingham 2023

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Proposals to raise repayment rates for newer medicines under the statutory scheme—from 15.5% to 32.2% in 2025, are seen as disproportionate. These payments, made in addition to normal taxation, are considered excessive relative to international benchmarks and contribute to growing concerns about the UK's commercial environment.

This policy direction has direct implications for investment in domestic manufacturing and supply chain resilience. High, unpredictable clawbacks make the UK a less attractive location for launching new medicines or building onshore production capacity.

In a competitive global landscape, countries that offer more commercially sustainable and stable conditions are more likely to attract long-term pharmaceutical investment. Without a shift in direction, the UK risks falling behind in efforts to strengthen its life sciences sector and secure more resilient access to critical medicines.

The UK Medicines Market

8. To what extent is the UK an attractive market for investment at all stages of the pharmaceutical supply chain, including research, manufacturing, and supply?

The UK life sciences sector is vibrant and diverse, composed of small. medium and large companies. An ecosystem that works for all these is key to economic growth and medicines supply chain resilience.

As approximately 70% of medicines in development globally are produced by smaller companies, as opposed to larger established companies, ensuring the UK is a fertile place for them is key. These smaller emerging companies are dependent on external private finance to grow, as they may be too early-stage or small to generate sustainable revenues. Although the UK is a strong performer in attracting venture capital into these smaller companies compared to European competitors (consistently accounting for approximately 30-40% of the continent's annual total⁸), compared to the US, the sector receives much lower levels of investment, even when accounting for GDP. The British Business Bank's latest Equity Tracker showed the US life sciences sector raises 59% more investment relative to GDP than the UK sector, and that this is the biggest sectoral funding gap seen in British venture capital.⁹

Seed funding for UK life sciences is relatively strong, with levels comparable to the US. ¹⁰ However, the funding gap emerges at early and late-stage VC rounds (Series B+/£20m+), where most investment comes from foreign—primarily US—investors.

Irrespective of where the funds are coming from, the fundamental barrier to translating UK science into manufacturing, supply, and eventually globally successful companies, is a lack of scale-up capital. The data clearly demonstrates that the fault does not lie with the quality of UK innovation, but with a financial system that fails to provide a complete pipeline of investment.

While the UK has strong scientific and R&D capabilities, its attractiveness as a base for medicines manufacturing – much of which is and can be delivered by SMEs – is undermined by structural disincentives.

⁷ Emerging Biopharma's Contribution to Innovation - IQVIA

⁸ BIA: UK biotech finance report (2023)

⁹ British Business Bank: Small business equity tracker (2024)

¹⁰ BIA-Finance-report-2024-Q2.pdf

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These include higher operating costs compared to international competitors, limited tax and investment incentives, and regulatory challenges such as dual batch release testing. Companies often choose to commercialise manufacturing activities overseas, where the environment is more competitive and supportive of scale-up. The Life Science Innovative Manufacturing Fund (LSIMF) is an important step towards making the UK a more attractive place to start, grow and scale. Without reforms to improve competitiveness through fiscal incentives, streamlined regulation, and long-term policy support, the UK risks losing high-value manufacturing opportunities even when discovery and early development are based here.

Addressing both private capital investment shortfalls currently stymying domestic business growth and improving the fiscal competitiveness of the UK to attract and retain manufacturing will significantly improve UK medicines supply chain resilience.

a) How effectively does the UK promote research and development in the pharmaceutical industry? And
 b) What Government policies or strategies could be implemented to improve investment in the UK pharmaceutical industry?

With scale-up capital holding back growth of domestic medicine developers and manufacturers, unlocking new sources of funding would help bridge this gap. Pension funds are well placed to increase their exposure to late-stage VC funds and growth-stage public market deals. The capital-intensive and long R&D timelines of the life sciences sector align well with the longer-term investment horizon of pension funds. Action by government to address this lack of investment through pension reform will help close the funding gap between the UK and US by unlocking a significant new source of domestic capital.

The Mansion House Accord is an enormous step forward for the UK's financial services industry. UK pension funds have a significantly lower allocation to private equity and infrastructure assets (around 6% combined) than many of their peers (Canadian public sector pensions 34%, Finnish pensions 17%, and Australian supers 14%). It is, therefore, critical that government continues to give this agenda, and the Accord, its full backing and maintain pressure on the pensions industry to change its behaviour in the interests of the country.

In addition, R&D tax credits, introduced by the Labour government in 2000, have been critical to the growth and success of UK life sciences and biotech. BIA members regularly cite them as the most important support they receive from government. Crucially for pre-revenue companies, they reduce the cost of investing in R&D with cash payments, so that the level of investment required is more proportionate to the level of risk, thus incentivising private (often venture capital) investment into start-ups and scale-ups.

9. To what extent is the supply chain workforce suitably trained and resourced to produce and supply medicines?

The UK has a highly skilled workforce across life sciences and pharmaceutical manufacturing, with world-class expertise in research, development, and advanced therapies. However, gaps remain in key areas that affect supply chain resilience. Skills shortages are most prominent in roles like process operators, quality assurance and regulation. While larger companies can invest in training and retention, SMEs and manufacturers often face difficulties recruiting and retaining talent, particularly in regions outside established life sciences clusters. To ensure the workforce is equipped to meet future demand, the UK should prioritise investment in training programmes, apprenticeships, and upskilling initiatives that align with emerging technologies and modalities,

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as well as ensuring the visas systems are promoted and well understood, run efficiently and appropriate for the life sciences sector.

10. What is the current state of the UK's domestic manufacturing capability for producing medicines and their components (e.g., active pharmaceutical ingredients, excipients, or key ingredients)?

The UK's domestic manufacturing capability for innovative medicines has expanded in recent years. Government investments, such as the establishment of the UK RNA Centre of Excellence¹, have played a crucial role in developing capabilities that were previously unavailable domestically. Following the COVID-19 pandemic, BIA produced an mRNA explainer¹¹ to ensure the supply chain for RNA vaccines and therapeutics was captured and accessible.

UK contract development and manufacturing organisations (CDMOs) cover a wide range of drug types, from scale-up to commercialisation. However, the UK has been stymied in developing commercial capability, and largely failed to capture the opportunity of biologics manufacturing in the 2000s. It risks repeating this for advanced therapies now (described further below). This is largely due to a lack of UK business, as companies choose to commercialise elsewhere in response to non-competitive external factors such as tax incentives, pricing and reimbursement structures, clinical trial set-up times, and dual batch release testing caused by the absence of UK–EU mutual recognition. In summary, the UK has some strong capabilities, but it must become more competitive to ensure that these capabilities are extended, retained and strengthened.

a) Does this differ across different drug types?

The UK's manufacturing landscape differs depending on the drug type and modality. For example, in viral vectors used for gene delivery, the UK has significant AAV (Adeno-associated Virus) manufacturing capacity, with contributions from companies such as Cobra Biologics, Pharmaron Biologics, OXB, and eXmoor Pharma. However, there remains a distinct lack of capability for lentiviral vector manufacturing.

Continued investment in high-potential modalities is essential. Prior to 2020, the UK had no domestic mRNA manufacturing capability. Government investment has since enabled the development of this capacity, ensuring the UK is better prepared to respond to future health threats using mRNA technology. Manufacturing capacity must be flexible to adapt to future emerging trends

b) What is our capacity for upscaling production of medicines in the face of supply issues or surges in demand?

The UK's current capacity to upscale production is limited and uneven across modalities. While there are strong capabilities in advanced therapies and biologics, gaps remain in areas such as APIs, excipients, and certain viral vectors. Upscaling is often constrained by a lack of commercial-scale facilities, fragile supply chains, and regulatory barriers.

To ensure resilience, the UK should promote private investment to generate a diverse and vibrant life sciences sector, prioritise public investment in flexible manufacturing infrastructure, create a more competitive

¹¹ mRNA Revolution: A New Generation of Medicine

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environment for commercialisation, and address structural barriers that drive production overseas. By doing so, the UK can strengthen its ability to rapidly respond to supply issues and future surges in demand.

11. The UK Government has pledged £520 million to grow the UK's life sciences manufacturing capacity and strengthen supply chain resilience. How far can the UK 'reshore' its medicine supply chain within the UK?

The government's commitment to the £520 million life science innovative manufacturing fund (LSIMF) is welcomed by BIA. It is an essential fund for ensuring the ability to domestically manufacture lifesaving medicines and pandemic preventing vaccines. Innovation is the key to a healthy workforce and prosperous economy, and SMEs are at the heart of our innovative sector. The BIA recommends that LSIMF and future capital grant programmes are designed to:

1. Support SMEs through accessible and fair funding mechanisms

SMEs are a vital part of the UK's life sciences innovation pipeline, yet they face disproportionately high barriers when accessing government funding programmes, including the LSIMF. To address this, we recommend:

- **Simplifying application processes** for SMEs, with clear guidance and less burdensome documentation.
- Removing requirements for parental or bank guarantees, which many SMEs cannot meet despite having credible and strategic business plans.
- Increasing and clearly stating the grant intervention rate upfront—for example, offering up to 50% capital contribution to make investment decisions feasible for early-stage companies and to make the UK a competitive place to invest.
- Recognising non-job creation benefits, such as regional supply chain growth, follow-on investment, and enabling ecosystem development, in grant assessments.
- Ring-fencing a portion of the LSIMF for SMEs or allocating based on company maturity, ensuring that the fund remains accessible and proportionate to business scale and needs.

2. Ensure even and predictable distribution of funds

Companies need clarity and time to plan capital-intensive investments. Unpredictable application windows or the rapid exhaustion of funds can discourage participation, particularly from time and resource-constrained SMEs. Therefore, we recommend:

- Distributing funds evenly over the entire spending review period, with clear, well-publicised
 application windows or competitions that are always open and have publicly-advertised assessment
 dates throughout the year.
- Publishing transparent allocation data, showing how much funding is available for different company sizes and types (e.g., large pharma vs SMEs).

a) To what extent is it possible to reshore all stages of the manufacturing process, including the production of medicinal components such as active pharmaceutical ingredients (APIs)?

The UK can strengthen elements of its medicine supply chain through targeted investment, but full reshoring is neither practical nor desirable given the globalised nature of pharmaceutical manufacturing.

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The areas most suited to reshoring are the most innovative and complex medicines, where the UK already has a strong scientific and industrial base. Advanced therapies, biologics, and mRNA are clear examples. The UK has significant clinical cell therapy capacity, established academic base in monoclonal antibody R&D and biologics production, and recognised strengths in fill—finish operations. Recent investment in RNA capabilities has shown how quickly domestic capacity can be established when strategic priority and funding are aligned. Applying this approach to cell therapy by building significant domestic commercial-scale supply would strengthen the UK's position as a global leader in this modality and enhance its attractiveness to US and EU partners.

However, for products such as active pharmaceutical ingredients, excipients, and generics, the UK will continue to depend on international supply. These markets are highly cost-sensitive and dominated by large-scale production hubs in Asia. Attempting full reshoring in these areas would not be commercially viable and not be as effective as establishing UK dominance in innovate medicines and therapeutics.

A realistic approach is therefore a targeted strategy of reshoring and expanding critical capabilities where security of supply is essential, while strengthening international partnerships and diversifying overseas sources for inputs where global reliance will remain.

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