Industrial Strategy for Secure Medicines Manufacturing

1506 words in abstract and main text. Institutional draft; independent scholarly review pending.

Abstract

This working paper considers how pharmaceutical industrial strategy can be evaluated through usable capability rather than announced investment alone. It distinguishes location, capacity and assured access, and proposes a capability contract linking public support to verifiable resilience conditions. The UK Life Sciences Sector Plan, current workforce policy and manufacturing-fund guidance provide context. The analysis develops a product-specific assessment of facilities, inputs, quality systems, workforce, commercial viability and recovery options. It proposes a comparative documentary study and a pilot assurance method without claiming new empirical findings. The paper argues that domestic capacity, trusted international cooperation and diversified sourcing should be considered as complementary options. Strategic support requires clear additionality, delivery milestones and a counterfactual. The proposed framework remains a research proposition, with trade-offs concerning cost, equity, international access and opportunity cost explicitly identified.

1. Research question and analytical scope

What makes an investment in medicines manufacturing a contribution to security? A new facility can increase economic activity without assuring supply of the medicines most exposed to disruption. A domestically located plant can depend on imported inputs and specialist equipment. A line capable of producing a medicine may not have a viable market, available staff or the necessary authorisations. This paper therefore asks how policy can distinguish announced capacity from maintained capability. It treats security as a product-specific and time-dependent question. The aim is to develop a transparent assessment for investment and governance decisions, not to recommend a particular company or subsidy.

2. Method and evidence base

The approach is conceptual policy analysis using selected official UK documents. The 2025 Life Sciences Sector Plan supplies the broad industrial context [1]. The 2026 Jobs Plan supplies current workforce context [2]. Official guidance for the Life Sciences Innovative Manufacturing Fund provides an example of an investment-policy instrument [3]. The medicines-supply paper and critical-imports strategy situate manufacturing within resilience and international networks [4,5]. Sources were checked on 13 October 2026. No comparative effectiveness analysis of subsidies, company financial assessment or plant inspection was undertaken. These documents establish policy direction and design, not achieved outcomes attributable to MSI’s proposed approach.

3. Current policy context

The Life Sciences Sector Plan connects research, company growth, investment, manufacturing and patient access [1]. The Jobs Plan makes skills and sector coordination explicit components of the delivery agenda [2]. Manufacturing-fund guidance demonstrates that government has a dedicated instrument supporting investment in life-sciences production [3]. Those policy developments create a basis for studying how capability is built and sustained. They do not establish that every supported investment strengthens supply resilience or that life-sciences growth and medicines security are identical. An evaluation should specify the relevant medicine, dependency or recovery function before interpreting investment as a security outcome.

4. Location is not assurance

The proposed assessment separates location, capacity and access. Location identifies where activities occur. Capacity identifies what can be made under stated conditions. Access identifies whether that capacity can supply the relevant population when needed. The distinctions matter because contractual allocation, authorisations, input availability and commercial priorities can affect access to a domestically located facility. Conversely, an overseas partner may offer credible access through verified arrangements. The research should therefore record the pathway from facility to usable medicine rather than assigning a positive score for national location alone. That pathway includes production, release, distribution and the authority to mobilise the response.

5. Define the capability need

A strategic investment case starts with an identified gap. The gap may concern a formulation, ingredient, quality-testing function, surge capability or specialist workforce. Each has different economics and timescales. A defined medicines basket should establish clinical criticality and alternatives through appropriate expertise. The investment case then asks what interruption would occur without intervention and which options could address it. Domestic production should be compared with qualified alternative supply, cooperation, process change and proportionate reserves. A fair comparison includes time to become usable, maintenance costs and residual dependencies. The framework should retain uncertainty rather than selecting the politically most visible option in advance.

6. Facilities and quality systems

A capability record should specify products, production processes, qualified lines, release arrangements and constraints. Rated capacity is insufficient unless the assumptions behind it are disclosed. Maintenance, changeover time, validation requirements and availability of necessary utilities determine what can actually be produced. Quality systems are part of security: rapid output that cannot meet authorised standards is not usable capability. A proposed assurance exercise should test the complete production-and-release pathway under a defined scenario. Records should distinguish independently verified capability, management statements and future plans. Public claims can then describe what has been demonstrated rather than presenting construction completion as the final outcome.

7. Inputs and hidden concentration

The same input or specialist service can connect apparently separate plants. A project assessment should therefore map critical dependencies beyond direct suppliers, including materials, packaging, equipment maintenance and testing services. Evidence should identify actual production sources where lawful and practicable, rather than relying only on the address of a contracting intermediary. An investment may reduce one exposure while shifting it to another tier. The proposed risk register records the dependency, consequence, substitution process and recovery time. Disclosure may need restricted handling for commercial or security reasons, but the public evaluation should still explain its coverage and significant limitations.

8. Workforce as maintained capability

A facility cannot recover through stress without people who know its processes and hold the necessary responsibilities. Workforce assurance should identify critical roles, skills, qualified cover and time to competence. Headcount alone does not show whether specialist capacity is available when needed. Training and succession plans should be linked to the product pathway, including quality and regulatory functions. The proposed assessment distinguishes vacancies, reliance on particular individuals and institutional knowledge held outside formal records. Workforce policy provides context [2], but the actual security contribution needs evidence from the relevant operation. A project that adds equipment without sustaining those skills may leave its main bottleneck intact.

9. Commercial viability and additionality

Security capability has operating costs even when no emergency occurs. The investment case should explain how production and preparedness will be maintained after initial support. Proposed incentives might address demand uncertainty, qualification costs or response readiness, but each needs a justified intervention logic. Additionality asks what would happen without support. A project already commercially viable on the same terms may not need a security subsidy. Conversely, a critical capability with limited routine demand may require an explicit public-service arrangement. The framework does not assume that public support is inherently effective; it requires a counterfactual, milestones and a proportionate approach to underperformance.

10. A proposed capability contract

The capability contract is an analytical proposal, not a legal template. It would state the public objective, supported function, verification method, maintenance obligations and review triggers. Milestones should progress from investment commitments to qualified capability and, where relevant, exercised access arrangements. Public reporting should distinguish money announced, money committed, assets delivered and usable outcomes. Any response obligation must be lawful, commercially defined and operationally feasible. Independent review should examine whether the capability still addresses the original gap. Terms concerning repayment, change of ownership and discontinuation need qualified legal design; this working paper does not supply that advice.

11. Prospective comparative study

A useful research design would compare a small set of publicly supported manufacturing projects using a predeclared documentary template. Selection should include contrasting technologies and policy objectives, with explicit inclusion criteria. Evidence would be coded for additionality, milestones, input dependencies, workforce, quality, access and evaluation. Interviews with authorised stakeholders could explore gaps between formal commitments and implementation, subject to ethics approval. The study should seek negative and incomplete cases rather than select only successful projects. Findings would identify how policy design makes resilience measurable, while avoiding causal claims unless the evidence and comparison genuinely support them.

12. Trade-offs and conclusion

Domestic capability can be valuable, but it has opportunity costs and can remain dependent on international systems. Excessive duplication may divert resources from other access priorities; concentrated public support may also entrench market power. Cooperative capability needs credible arrangements rather than assumed goodwill. The proposed policy test is consequently functional: does an intervention improve the ability to provide defined medicines under defined stress, relative to feasible alternatives? The framework remains unvalidated and UK-centred. Its next step is comparative research and technical challenge. A credible industrial strategy should make the path from expenditure to usable, maintained and equitable access inspectable.

Appendix: proposed manufacturing capability record

A project record should identify the supported product or function, the reason it is strategically relevant, the alternative options considered and the counterfactual without intervention. Record investment commitments separately from delivered assets. Describe the usable production and release pathway, input dependencies, workforce, quality requirements, access conditions and maintenance costs. State which claims have independent evidence and which are management assertions or future milestones.

An assurance review should test whether the capability can operate under the defined stress scenario, whether the public objective is still relevant and what residual vulnerabilities remain. It should consider the recurring resources needed after initial support and the effects on competing access priorities. The review should document how underperformance will be identified and who has authority to respond. This is a proposed research template, not a grant application guarantee, facility certification or legal agreement. Appropriate technical and professional expertise is required before its findings inform consequential investment or manufacturing decisions. For example, a project that installs additional equipment should separately establish qualified production, release capacity and access arrangements before reporting a medicines-security outcome.

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