MEDICINES SECURITY INSTITUTE

Full working-paper manuscripts

Four conceptual and policy-analysis drafts | v0.1 | 13 October 2026

Independent technical review and accountable human authorship remain pending. No new empirical study is reported. Original introductory records remain separately available at medicines-security.org/publications.

Medicines Security: From Supply Continuity to National Resilience

1527 words in abstract and main text. Institutional draft; independent scholarly review pending.

Abstract

This conceptual working paper asks how medicines security should be understood when availability depends on institutions, industrial capability and international networks. It distinguishes current supply continuity from the capacity to anticipate, absorb, adapt to and recover from disruption. A ten-domain framework is proposed to connect governance, science, manufacturing, supply chain, investment, technology, geopolitics, regulation, people and future dynamics. Selected UK policy documents and recent scholarship provide context rather than a comprehensive evidence synthesis. The principal contribution is a proposed chain linking risk ownership, evidence, decisions and tested recovery options. Notification counts are treated as reporting-system observations rather than direct measures of patient harm. The paper sets out candidate indicators, a practical assurance approach and a prospective validation study. It does not claim a validated Index, exhaustive literature coverage or causal evidence for the recommendations.

1. Research question and scope

The question is whether medicines security can provide a useful analytical level between individual shortage management and broad national preparedness. An uninterrupted delivery is an outcome at a particular moment. A secure system is a continuing capability: it can identify dependencies, make accountable choices and preserve access under changing conditions. Those concepts overlap but are not interchangeable. A system may meet current demand while depending on one vulnerable production line; another may experience a temporary interruption yet recover through credible alternatives. The proposed distinction makes both present performance and future capability visible without treating every shortage as a national-security emergency.

2. Method and evidence selection

This draft uses purposive documentary reading and conceptual analysis. Sources were selected for direct relevance to UK medicines-supply governance, industrial capability, workforce and observed shortage consequences. Official policy texts establish institutional intentions; research articles provide contextual evidence. Searches and source checks were undertaken on 13 October 2026. This is not a systematic review: no exhaustive database strategy, duplicate screening, formal quality score or registered protocol is claimed. The argument proceeds by defining terms, examining the mismatch between reporting and system capability, proposing relationships and specifying how those relationships could be tested. The selected references permit readers to challenge the framing and trace its context.

3. What the selected evidence supports

The DHSC and NHS England supply paper explicitly connects medicines resilience with trade, international cooperation and industrial strategy [1]. Its accompanying data pack records notifications within a reporting system, including potential and confirmed supply issues and discontinuations, with acknowledged reporting limitations [2]. Santhireswaran and colleagues examine changes in medicine utilisation after supply disruption across studies with differing settings and measures [3]. These sources support examining medicines availability across institutional boundaries. They do not establish that MSI's framework is novel, comprehensive or superior to existing approaches. Those are questions for further review and comparison, not conclusions that follow from selecting a few relevant documents.

4. A working definition

Medicines security is proposed here as the sustained capability of a society to protect equitable access to quality-assured, clinically appropriate medicines through anticipated and unexpected disruption. Sustained capability implies maintenance, exercises and learning rather than a one-off stock purchase. Equitable access prevents the concept from becoming simply an aggregate volume measure. Quality assurance prevents physical availability from being treated as sufficient. Clinical appropriateness recognises that substitutes cannot be evaluated solely as commercial equivalents. The definition is intentionally testable and provisional. It should be refined through comparison with pharmaceutical resilience, essential-medicines access and health-security scholarship, including perspectives from patients and resource-constrained settings.

5. The ten-domain architecture

The ten domains provide an organising scheme rather than a validated causal model. Governance addresses authority; science concerns discovery and evidence; manufacturing concerns usable production; supply chain concerns movement and dependencies; investment concerns the resources maintaining capability. Technology concerns information and digital systems, geopolitics external constraints, regulation authorised quality and access, people the necessary skills and leadership, and future dynamics changing conditions. Each domain should be linked to a concrete question rather than filled with generic indicators. For example, a manufacturing assessment asks whether a critical product can actually be made and released during stress, with its inputs, workforce and authorisations available.

6. Risk ownership and the decision chain

The proposed decision chain starts with a defined access risk and ends with an accountable choice. The first record identifies affected medicines, population, time horizon and consequences. The second records evidence and uncertainty. The third names the decision owner and available response options. The fourth records the chosen action, authority, review date and residual risk. Institutions should distinguish information ownership from decision authority: a supplier may hold operational data while a public body owns allocation policy. The chain is useful only if it resolves that boundary. A named coordinating committee without clear rights to act may improve communication while leaving critical decisions unresolved.

7. Criticality and proportionality

A national programme cannot treat every product identically. A defensible prioritisation process should consider clinical consequences, the availability and suitability of alternatives, substitution time and the burden on affected groups. The resulting basket should disclose its rationale and review triggers. Priority can change as clinical practice, demand and production evolve. A medicine with a small commercial market may nevertheless be essential for a narrowly defined population. Conversely, a high-volume product with several safe, available alternatives may need a different response. These judgements require clinical and patient expertise; the conceptual framework does not authorise MSI to make treatment or allocation decisions.

8. Capability evidence and exercises

An assurance system should record what can be done, by whom, within what time and under what assumptions. Inventory records alone cannot answer those questions. An alternative supplier may be technically qualified but lack allocated capacity; a reserve may be physically present but require distribution arrangements; a production line may be available while one specialist role is uncovered. A scenario exercise should therefore test the response chain using explicit constraints. The proposed output is a short capability statement distinguishing demonstrated responses from plans, assumptions and unresolved gaps. Exercises should include recovery and equitable distribution, with clinical decisions reserved to authorised professionals.

9. Measurement without misleading aggregation

Candidate measures include time to identify an exposure, time to authorise a response, coverage of critical dependencies, recovery time under a specified scenario and completeness of decision records. These measures need definitions, units and denominators before use. A count of notifications does not represent a count of patients denied treatment, and a rise may partly reflect changing reporting behaviour. A composite Index can conceal those distinctions. MSI should begin with a transparent domain profile and visible missing data. Any later aggregate measure needs evidence of construct validity, comparable observations, justified weighting, sensitivity analysis and an explanation of how decisions change because of the score.

10. Prospective validation design

A feasible next study would select several contrasting medicines or pathways through an explicit criticality process. Documentary analysis would establish responsibilities and response procedures; stakeholder interviews would examine how those procedures operate. Interviews require appropriate ethics review, informed consent and secure handling. A predeclared codebook would distinguish formal authority, information access, resources, escalation and learning. Negative cases should be sought: instances where visible capability did not prevent disruption, or where informal coordination enabled recovery. The framework would then be revised against the evidence. Sample size and recruitment would be justified by the question and access, rather than retrospectively chosen to support the model.

11. Practical implications

For public institutions, the immediate task proposed here is to align the medicines-risk register with named owners and response authority. For industry, it is to connect critical product dependencies to board assurance and verified recovery options. For researchers, it is to distinguish intentions, operational capability and outcomes. A useful first output is a small, inspectable assessment of a defined pathway, not a claim to rank entire countries. Workforce evidence should be integrated because critical capability rests with people as well as facilities; the 2026 Life Sciences Jobs Plan provides current policy context for that dimension [4]. These are proposed applications requiring evaluation, not proven intervention effects.

12. Limitations and conclusion

The source selection favours accessible English-language UK material and cannot represent every jurisdiction or scholarly tradition. No empirical test establishes the ten domains as exhaustive. Relationships between governance, capability and outcomes may be affected by resources, demand, clinical practice and market structure. National security language can also privilege domestic capability over equitable international access unless those values remain explicit. Medicines security is therefore offered as a disciplined research proposition. Its value will depend on whether it improves the clarity of questions, quality of evidence and accountability of decisions. The next step is methodological challenge and proportionate testing, with correction where evidence contradicts the framework.

Appendix: proposed institutional assessment worksheet

For a first assessment, record the medicine pathway, population, time horizon and scope exclusions on one page. Identify the accountable owner and the authority of each participating institution. Attach an evidence register showing source, observation date, access date, unit, confidence and missing information. Describe one disruption scenario and at least two feasible responses, including the time and resources each would need. Mark every capability as demonstrated, documented but untested, planned or unknown. Record which clinical, regulatory or contractual decisions sit outside the research team’s authority.

The assessment should conclude with the decision that the evidence can support now, the residual uncertainty and the evidence required for the next decision. A reviewer should check whether the options address the same access objective and whether important populations are missing. This worksheet is a proposed research instrument. Its usefulness needs testing with practitioners before it is adopted as an institutional standard. It is designed to expose assumptions, not certify that a medicines system is secure.

References and publication record

1. DHSC and NHS England (2025). Managing a robust and resilient supply of medicines.
https://www.gov.uk/government/publications/managing-a-robust-and-resilient-supply-of-medicines/managing-a-robust-and-resilient-supply-of-medicines
Accessed 13 October 2026.

2. DHSC (2025). Managing a robust and resilient supply of medicines: data pack.
https://www.gov.uk/government/publications/managing-a-robust-and-resilient-supply-of-medicines-data-pack/managing-a-robust-and-resilient-supply-of-medicines-data-pack
Accessed 13 October 2026.

3. Santhireswaran, A., Chaudhry, S., Ho, M. et al. (2025). Impact of Supply Chain Disruptions and Drug Shortages on Drug Utilization: A Scoping Review. Pharmacoepidemiology and Drug Safety 34(7), e70178. doi:10.1002/pds.70178.
https://onlinelibrary.wiley.com/doi/full/10.1002/pds.70178
Accessed 13 October 2026.

4. UK Government (2026). Life Sciences Jobs Plan.
https://www.gov.uk/government/publications/life-sciences-jobs-plan/life-sciences-jobs-plan-web-version
Accessed 13 October 2026.

Authorship, funding, interests and AI use

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Artificial Intelligence and Medicines Security

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Abstract

This working paper proposes a decision-centred approach to AI in medicines-security systems. It examines how forecasting, document analysis, dependency mapping and scenario support could contribute to resilience without confusing computational performance with operational benefit. Recent healthcare supply-chain scholarship is used to identify the gap between modelling and evaluated deployment, while WHO guidance provides governance context. The contribution is a proposed assurance sequence covering decision definition, data readiness, comparator selection, prospective testing, human escalation and maintenance. A distinction is made between source-grounded research assistance and operational early-warning systems. The paper proposes a limited pilot using retrospective records followed by silent prospective observation. It does not report a tested model, quantified benefit or validated shortage prediction. It concludes that AI should be judged by the quality and timeliness of authorised decisions and equitable access outcomes, with explicit reporting of failures and uncertainty.

1. The research problem

AI is frequently discussed as though a better prediction automatically creates a more resilient medicines system. That assumption overlooks the steps between an output and a response. An alert must concern the right decision, arrive early enough to matter, be understood by an accountable person and connect to a feasible action. A warning about an unavoidable interruption may still have value, but that value differs from prevention. The central question is therefore not whether AI can detect patterns. It is whether a defined application improves a defined decision under operational conditions, compared with an appropriate alternative and without creating unacceptable new dependencies.

2. Method and source boundaries

This draft combines conceptual analysis with purposively selected research and governance documents. The 2026 review by Espinosa and colleagues provides a recent examination of AI in healthcare supply chains, with its evidence search extending to May 2024 [1]. WHO’s 2021 and 2024 guidance supplies a governance foundation for health AI and large multi-modal models [2,3]. These sources were checked on 13 October 2026. No new systematic review or model experiment was performed. Healthcare supply chains include products beyond pharmaceuticals, so findings cannot be transferred to medicines without qualification. The assurance sequence proposed below is MSI’s analytical contribution and remains to be tested.

3. Evidence maturity matters

Espinosa and colleagues identify a substantial gap between proposed computational models and real-world evaluation within the literature they reviewed [1]. That bounded finding cautions against treating simulation results as demonstrated clinical or operational benefit. It does not prove that every current implementation is ineffective, particularly because the search period precedes publication. A research register should classify evidence as conceptual, simulated, retrospectively tested, prospectively observed or operationally evaluated. These categories ask different questions. A model may be technically promising while still lacking evidence that staff can use it, that an alert produces a timely response or that any benefit persists after deployment.

4. Specify the decision before the model

A suitable use-case record states the owner, decision, lead time, affected population and available actions. For example, an institution may wish to identify products requiring additional supplier investigation within a defined planning period. The output should support that investigation, not claim to predict patient harm directly. The decision record should identify the consequence of missing a signal and the cost of investigating a false alert. When those consequences differ markedly, a single accuracy statistic is inadequate. A deliberately simple baseline may be sufficient for a first deployment; complexity should be justified by useful improvement, not by the appeal of the technology.

5. Data readiness and provenance

An input catalogue should record who produced each observation, when it was available, how it was revised and whether it may be used for the intended purpose. Medicines-security data can refer to products, ingredients, manufacturing sites, suppliers or incidents; those entities must not be silently conflated. Missingness should remain visible. Training records must distinguish what was known at the decision date from information added after an event. Otherwise, apparent predictive success may result from leakage. Access rights and confidentiality are also methodological requirements: a model based on data unavailable to the operational user cannot be evaluated as though those inputs will always be present.

6. Forecasting and classification

A proposed forecasting pilot should compare performance across products and time periods, including disruptions unlike the training examples. Demand and supply signals should be evaluated separately because an observed shortage may have several explanations. Classification outputs should include uncertainty and a route to inspect the supporting record. The study must specify how outcomes are labelled and when they become observable. Changes in reporting practice can alter those labels without an equivalent change in underlying risk. The pilot should report false alerts, missed signals, calibration and useful lead time, alongside operational workload. It should not convert model confidence into an unexplained national resilience score.

7. Document analysis and generative systems

Generative AI can assist with source discovery, extraction drafts and structured summaries, but its fluent output is not evidence. A source-grounded workflow should preserve the exact document version and passage supporting each material claim. The reviewer should verify entities, dates, units and whether the passage supports an observation or an interpretation. Retrieval should not be described as verification merely because a link exists. Documents can contain irrelevant or adversarial instructions, so research systems should treat their text as data rather than authority to change the task. Sensitive supplier, patient or interview information should remain outside unapproved systems.

8. Human accountability and escalation

WHO’s guidance places ethical governance and accountability at the centre of health AI [2,3]. In this proposed operational framework, every application needs an owner who can challenge the output, pause its use and explain the decision taken. Escalation rules should cover disagreement, missing evidence, unexpected behaviour and system outage. Staff need a usable alternative when the application fails. Human review should be designed as substantive judgement rather than routine approval of automated suggestions. The organisation should record where the model affected a decision and where it was rejected. That record supports learning and prevents accountability from becoming diffuse between supplier, software and institution.

9. Security and dependency risks

An AI application can improve one part of a system while creating a new single point of failure. Concentrated vendors, opaque model updates, inaccessible logs or dependence on one external service may weaken continuity. A deployment assessment should consider data access, model portability, cyber response, outage tolerance and contractual exit. Those questions are distinct from predictive validity, but both determine whether the application is usable during stress. The institution should test recovery without the model and define which tasks can continue manually. An early-warning system that becomes unavailable during the event it is intended to support has failed an essential capability test.

10. A prospective pilot design

The proposed pilot begins with a defined product group and documented historical observations. Stage one builds an auditable baseline using simple rules. Stage two compares the candidate model using temporal holdout data and predefined metrics. Stage three operates silently alongside normal practice, recording alerts without changing clinical or procurement decisions. Only after independent review should a controlled operational phase be considered. The evaluation should measure whether alerts reach authorised owners, whether actionable options exist and how staff workload changes. Any later outcome study would need a credible comparison and attention to confounding. No stage should be represented as complete before evidence has been collected.

11. Equity, adoption and workforce

Efficiency alone cannot determine success. A model may prioritise products with richer data while overlooking small populations or fragmented supply pathways. Evaluation should therefore ask whose risks become visible and whose remain unobserved. Accessibility, training and staff capacity affect whether outputs are acted upon. A warning dashboard can consume attention without improving decisions if it is not integrated into existing work. The proposed adoption record includes the target user, training, authority, response resources and feedback channel. Changes should be reviewed with relevant practitioners and patient perspectives, rather than assuming that one workflow fits every institution.

12. Limitations and research agenda

The framework has not been tested and cannot establish that its sequence improves outcomes. Selected sources do not cover every AI technique or implementation, and rapid technical development can outpace published evaluation. Retrospective data may be incomplete, while prospective interruption outcomes may be rare. These constraints argue for precise, small studies with honest negative findings. Future work should investigate the relationship between technical performance, useful lead time and decision quality. Medicines-security AI should be assessed as a maintained institutional capability. Its contribution is credible when the evidence shows what improved, for whom, under which conditions and at what cost.

Appendix: proposed AI use-case assurance record

Record the intended decision, user, owner, relevant medicine group, planning horizon and permitted actions. Document source rights, version dates, missingness and the point at which each input becomes available. State the baseline comparator and the outcomes used for evaluation. Predefine how false alerts, missed signals, calibration, lead time and staff workload will be assessed. Record which populations or product categories have weak data coverage and how that affects use.

Before any operational phase, document human escalation, pause authority, monitoring, outage procedures and a practical non-model alternative. Keep a log of accepted and rejected outputs and the reasons for decisions. Specify how changes to data sources, model versions or operational conditions trigger review. Independent assessment should challenge evidence quality, generalisability and whether an apparent technical improvement changes an authorised response. This record is a proposed assurance instrument, not a validated certification checklist. It does not remove the need for appropriate data protection, clinical, regulatory and organisational review.

References and publication record

1. Espinosa, O., Basto, S., Ordóñez, A. et al. (2026). A review of artificial intelligence in healthcare supply chains: untapped potential? BMC Health Services Research 26, 742. doi:10.1186/s12913-026-14559-2.
https://link.springer.com/article/10.1186/s12913-026-14559-2
Accessed 13 October 2026.

2. WHO (2021). Ethics and governance of artificial intelligence for health.
https://www.who.int/publications/i/item/9789240029200
Accessed 13 October 2026.

3. WHO (2024). Ethics and governance of artificial intelligence for health: Guidance on large multi-modal models.
https://www.who.int/publications/i/item/9789240084759
Accessed 13 October 2026.

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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.

References and publication record

1. UK Government (2025). Life Sciences Sector Plan.
https://www.gov.uk/government/publications/life-sciences-sector-plan/life-sciences-sector-plan
Accessed 13 October 2026.

2. UK Government (2026). Life Sciences Jobs Plan.
https://www.gov.uk/government/publications/life-sciences-jobs-plan/life-sciences-jobs-plan-web-version
Accessed 13 October 2026.

3. UK Government. Life Sciences Innovative Manufacturing Fund: Expression of Interest. Current official guidance accessed 13 October 2026.
https://www.gov.uk/government/publications/life-sciences-innovative-manufacturing-fund-lsimf
Accessed 13 October 2026.

4. DHSC and NHS England (2025). Managing a robust and resilient supply of medicines.
https://www.gov.uk/government/publications/managing-a-robust-and-resilient-supply-of-medicines/managing-a-robust-and-resilient-supply-of-medicines
Accessed 13 October 2026.

5. Department for Business and Trade (2024). Critical imports and supply chains strategy.
https://www.gov.uk/government/publications/uk-critical-imports-and-supply-chains-strategy/critical-imports-and-supply-chains-strategy-html-version
Accessed 13 October 2026.

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Governing Global Pharmaceutical Dependencies

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Abstract

This working paper examines when international pharmaceutical dependence becomes a strategic vulnerability and how institutions can govern it without assuming self-sufficiency is achievable or desirable. It proposes a dependency-assessment approach based on criticality, concentration, substitutability, correlated exposure and recovery time. Selected UK supply-chain and medicines policy documents provide context. The contribution is a proposed dependency record and escalation process that connects network evidence to authorised decisions. Diversification is treated as a property of underlying production and response capacity, not simply the number of contracting suppliers. The paper considers trusted cooperation, reserves and domestic capability as options to compare for a defined access risk. It proposes a product-pathway case-study method and highlights uncertainties in trade and supplier data. No national dependency score, causal intervention effect or current geopolitical forecast is reported.

1. Research question and framing

International production and exchange create access to scientific capability, specialised processes and economies of scale. Dependence is therefore not automatically evidence of failure. The research question is when a dependency becomes sufficiently consequential, difficult to substitute or exposed to common shocks that it requires deliberate governance. A framework must distinguish ordinary commercial interdependence from a vulnerability affecting critical access. It must also ask who has the authority and resources to respond. This paper proposes an assessment organised around the medicine pathway and decision horizon, avoiding the assumption that national ownership or domestic location by itself establishes security.

2. Method and evidence boundaries

This is a conceptual working paper using purposively selected policy documents and published research. The UK critical-imports strategy frames resilience in relation to analysis, response and collaboration [1]. The medicines-supply paper places pharmaceutical resilience within wider institutional and international activity [2]. The accompanying data pack and recent utilisation review help distinguish supply-system observations from consequences for medicine use [3,4]. These sources were checked on 13 October 2026. No complete supplier network, proprietary trade dataset or original stakeholder evidence was analysed. The proposed dependency record is therefore a research instrument to test, not a representation of verified UK exposure.

3. The unit of analysis

A useful dependency assessment defines the medicine, formulation, pathway, jurisdiction and period. The unit cannot remain an unspecified national import percentage. An ingredient, packaging component, testing service or production process may create the relevant bottleneck. One component can support several products, and one product can use several pathways. The record should identify those relationships explicitly. Clinical criticality and the availability of suitable alternatives must be assessed by appropriate experts. A research assessment may describe the decision problem, but it should not recommend individual treatment substitutions or allocation. Scope must also show whose access is being protected and how international consequences are considered.

4. Five proposed assessment dimensions

The proposed dimensions are criticality, concentration, substitutability, correlated exposure and recovery time. Criticality concerns the consequences of interruption. Concentration concerns reliance on shared sources, entities or functions. Substitutability concerns the feasibility of moving to another qualified pathway. Correlated exposure asks whether nominal alternatives can fail together. Recovery time concerns the interval required to restore access under specified assumptions. These dimensions should be documented separately before any scoring is considered. A highly concentrated pathway may have credible alternatives, while a dispersed network may depend on one common input. A single composite number can obscure that distinction and should not substitute for the underlying explanation.

5. Map beyond contracting relationships

Two distributors may obtain a product from the same production site. Different finished-dose manufacturers may share an ingredient source. Separate countries may depend on the same specialist equipment or logistics corridor. Counting direct suppliers alone can therefore overstate diversification. The proposed map distinguishes contracting entity, production source, critical input and delivery pathway wherever evidence permits. Each edge should have provenance, observation date and confidence. Unknown tiers should remain unknown rather than being inferred from a company’s headquarters. Commercial sensitivity may limit public disclosure, but an assessment should still explain which tiers were covered and how missing information affects the conclusions.

6. Correlation and scenario design

Dependency becomes more consequential when alternatives are exposed to the same event. The research should identify plausible common constraints rather than assign a generic country-risk label. A scenario may concern a utility failure, quality interruption, border delay, cyber incident or sudden demand change. Its assumptions must be stated, including duration, affected functions and the time at which institutions learn of the event. Scenarios are tools for testing response, not predictions that a particular shock will occur. An exercise should ask whether the alternatives remain available under those assumptions and whether authorisation, production and distribution can be coordinated in time.

7. Substitution and recovery

The presence of another source is different from the ability to use it. Substitution can require qualification, contractual allocation, regulatory action, process adaptation or clinical guidance. A dependency record should identify which steps are necessary and who can authorise them. The recovery estimate should distinguish technical minimum time, likely operational time and uncertainty. If the alternative capacity is already committed elsewhere, that constraint should be visible. The framework proposes testing recovery options through documentary evidence and exercises rather than accepting unqualified statements of supplier availability. Changes to medicines and patient care remain governed by authorised clinical and regulatory processes.

8. Compare response options

Options may include qualifying alternative pathways, maintaining reserves, supporting domestic capability or developing reciprocal access arrangements. Their merits depend on the defined risk. A reserve buys time but requires rotation, storage and distribution; alternative supply requires usable capacity; domestic production still requires inputs and skills. The proposed comparison records response time, recurring cost, residual dependency, implementation authority and effects on other users. An option should not be called a resilience improvement merely because it reduces an import ratio. It should improve a specified access function under plausible stress, with uncertainty and opportunity costs stated.

9. Cooperation without assumed endorsement

The critical-imports strategy emphasises collaboration between public institutions, business, academia and international partners [1]. For pharmaceutical pathways, a proposed cooperation arrangement should identify what information or capability is shared, when access can be requested and who retains decision authority. Statements of goodwill are different from exercised arrangements. Partners may face simultaneous pressure, so reciprocal obligations and constraints need careful design. MSI’s role at this stage is research and convening: citing a public institution does not create a partnership. Any future programme should record permissions, funding and conflicts before representing relationships, and publish the relevant boundaries of responsibility.

10. The dependency-to-decision register

The proposed register contains a risk statement, affected pathway, evidence sources, confidence, exposure mechanism, recovery options, owner, trigger and review date. It should separate factual records from judgement and proposed action. A trigger might concern a material change in capacity, authorisation or the availability of an alternative, but its threshold must be justified for the pathway. The owner should have either the authority to act or a defined escalation route. The register becomes valuable when it changes a decision and records the result. It should be maintained as conditions change, with historical versions supporting accountability and learning.

11. Data limitations and prospective study

Trade records can identify product flows without fully identifying upstream ingredients, ownership, capacity or contractual allocation. Commercial data may also vary in coverage and update frequency. A proposed case study would select several medicine pathways and triangulate public documents with authorised supplier evidence and interviews. The analysis would code each dependency dimension and record disagreement rather than force consensus. Ethics and confidentiality arrangements would precede interviews. Findings should compare how the proposed register performs against existing risk practices and whether it reveals actionable gaps. No claim of comprehensive national mapping should be made from a small set of cases.

12. International equity and conclusion

A national response can move pressure elsewhere. Purchasing reserves or claiming scarce production capacity may affect another population’s access. The framework should therefore include distributional consequences and cooperation options, not just domestic assurance. Medicines security is proposed as governed interdependence: visibility of critical relationships, accountable choices and credible recovery pathways. The argument is provisional, and international perspectives may identify missing dimensions or challenge its priorities. The next research task is to test the register on bounded pathways and document where it fails. A defensible dependency policy should preserve the benefits of exchange while addressing demonstrable vulnerabilities through proportionate and transparent action.

Appendix: proposed dependency and recovery record

Record the medicine pathway, clinical criticality assessment, source entities, production functions and evidence dates. Map known input tiers and identify unknown relationships explicitly. For each material dependency, describe concentration, substitutability, correlated exposure and recovery time without combining them into an unexplained score. State the scenario assumptions and identify which alternatives remain feasible under them.

Each response option should record authorisation steps, operational capacity, time, cost, uncertainty and effects on other populations. A decision owner should review the comparison and record the selected action, residual risk and review trigger. Independent challenge should check that contracting diversity has not been mistaken for production diversity and that evidence from one period or country has not been silently generalised. The register should retain previous versions to support learning. This is a proposed research instrument requiring validation, not a complete map of national dependencies or a recommendation to change an individual patient’s treatment. For example, two suppliers using the same upstream input should be recorded as a shared dependency until production evidence establishes meaningful independence. Uncertainty about that relationship should trigger investigation rather than an optimistic diversity assumption.

References and publication record

1. Department for Business and Trade (2024). Critical imports and supply chains strategy.
https://www.gov.uk/government/publications/uk-critical-imports-and-supply-chains-strategy/critical-imports-and-supply-chains-strategy-html-version
Accessed 13 October 2026.

2. DHSC and NHS England (2025). Managing a robust and resilient supply of medicines.
https://www.gov.uk/government/publications/managing-a-robust-and-resilient-supply-of-medicines/managing-a-robust-and-resilient-supply-of-medicines
Accessed 13 October 2026.

3. DHSC (2025). Managing a robust and resilient supply of medicines: data pack.
https://www.gov.uk/government/publications/managing-a-robust-and-resilient-supply-of-medicines-data-pack/managing-a-robust-and-resilient-supply-of-medicines-data-pack
Accessed 13 October 2026.

4. Santhireswaran, A., Chaudhry, S., Ho, M. et al. (2025). Impact of Supply Chain Disruptions and Drug Shortages on Drug Utilization: A Scoping Review. Pharmacoepidemiology and Drug Safety 34(7), e70178. doi:10.1002/pds.70178.
https://onlinelibrary.wiley.com/doi/full/10.1002/pds.70178
Accessed 13 October 2026.

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