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

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