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

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