Improving Access to Drugs: The Critical Role of Supply Chain Risk

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A simple way of thinking about medical criticality, supply chain risk and their interactions can lead to more sustainable solutions for drug shortages.

When pharmacists in France walked out of their counters en masse and went into the streets on 30 May, it was not just about their compensation and prospects. Their strike – the first in 10 years – surfaced a far wider problem.

While Covid-19 shone the spotlight on drug shortages, the problem exists even in the absence of large demand and supply shocks. In France, the shortage has been known to involve thousands of drugs, sometimes for months. Unreliable drug availability means pharmacists spend considerable time and effort in finding alternative solutions for patients.

An increasing problem in Europe and other parts of the world, drug shortages not only pose significant challenges for healthcare professionals, but they also put public health at risk by making timely, optimal treatment impossible. In worst-case scenarios, patient care is disrupted. In **England**,

pharmacists have warned that drug shortages are at such critical levels that patients are at risk of immediate harm and even death. Key medicines for the treatment of type 2 diabetes, ADHD (attention-deficit/hyperactivity disorder) and epilepsy became **unavailable in the UK** in recent months. Outside of Europe, **amoxicillin** has been on the US Food and Drug Administration drug shortage database since October 2022.

Need for a structural, systemic solution

In fact, many countries have been facing structural challenges for years but have limited insight in how to resolve them. In the Netherlands, the estimated total cost of drug shortages is about **EUR220 million** in 2023. Drug shortage is a critical problem that needs a long-term solution.

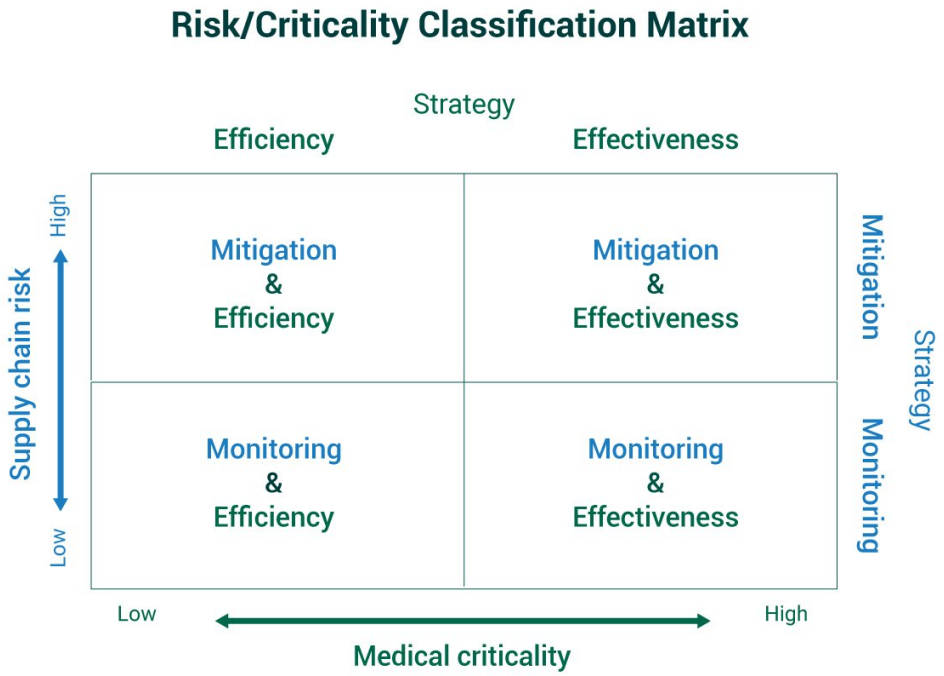
Unfortunately, most shortages are managed reactively, without accounting for the importance of supply chain risk. There is insufficient evidence of what works and little agreement among stakeholders on the causes of drug shortages. Overall, there is a lack of a systems view: stakeholders may propose interventions that may work well for a drug in the short term and in a specific country without considering the spillover effects in the long term, or on other drugs and other regions.

Those in charge of finding solutions are often stuck between a rock and a hard place: a high level of protection against shortages is expensive, while too little protection can reduce the quality of care of patients. In practice, blanket policies tend to be applied to all drugs, but this is not always feasible or cost-effective. For instance, while stockpiling would offer a high level of protection against shortage, it would have been prohibitively expensive for governments to stockpile all drugs.

We need a simple way to frame the differences between drugs and how that would lead to different interventions in addressing shortages.

Framing a two-dimensional issue

Together with researchers from five universities and the Norwegian Institute of Public Health, we embarked on a four-year study* of drug shortages in Belgium, France, Norway, Sweden, the Netherlands and the UK. As part of the study, we developed the Risk/Criticality Matrix (RCM) which consists of two dimensions: supply chain risk and medical criticality. Our matrix provides a pragmatic framework for classifying drugs and guiding decision-making.



Risk/Criticality Classification Matrix

Medical criticality refers to the clinical value of a drug. Life-saving drugs should always be considered high criticality (e.g. insulin, blood thinners, antibiotics for the treatment of sepsis, etc.), while drugs that improve lifestyle tend to be low in medical criticality. Other criticality factors include the number of people dependent on the drug and whether good substitutes exist.

The other dimension, supply chain risk, captures the likelihood of mismatches between supply and demand. The probability of demand shocks, the connectedness and agility of the supply chain, as well as the availability of information and coordination are the deciding factors.

Our matrix invites relevant stakeholders – particularly governments and international organisations responsible for securing access to drugs – to consider how medical criticality and supply chain risk interact dynamically. In practice, it takes a multidisciplinary team with the relevant skills and training to evaluate where each drug stands.

Even when a drug is accurately characterised and placed in the most relevant quadrant, the interdisciplinary team needs to consider the context, regulations and costs to determine the most appropriate intervention – one that is not too expensive nor jeopardises patient care.

Tackling the shortage of drugs classified as high in medical criticality requires effective, full control, which may involve continuous scans of the entire supply chain, and acting pre-emptively with speed. On the other hand, strategies to address shortage of low criticality drugs such as erectile dysfunction medications are focused on efficiency. Occasional shortages would be acceptable in exchange for substantial cost savings.

For drugs with low supply chain risks, the supply chains should be monitored, prioritising preparedness for unlikely shortages and having responsive mechanisms to address shortages should they occur. As for drugs with high supply chain risks, mitigation is the priority. This should focus on reducing the risk of shortages through measures such as stockpiling or reshoring production, while monitoring the supply chains and having reactive systems in place at the same time.

Arriving at appropriate interventions

Based on where the drug is placed in the matrix, the most appropriate interventions can be determined, depending on whether the focus is on monitoring vs. mitigation and efficiency vs. effectiveness. These are potential interventions for each classification:

- **Monitoring and efficiency**: establish monitoring system to maintain a lean supply chain and develop contingency plans to respond to unlikely shortages.
- **Mitigation and efficiency**: leverage data-driven forecasting to optimise inventory levels (while balancing shortage and costs) and diversify supplier base.
- **Monitoring and effectiveness**: employ rapid response protocols and surveillance systems, as well as have collaboration networks in place to ensure collective effectiveness.
- **Mitigation and effectiveness**: establish pre-emptive stockpiles and continuously invest in reducing supply chain risks e.g. relocate upstream manufacturing to nearby locations.

The matrix is by no means a static tool. It represents the first step in a continuous improvement loop that ensures interventions stay effective and aligned as conditions change. For instance, when a pandemic strikes, demand for medicines that may have been considered low in medical criticality (such as paracetamol) might quickly become critical. Or, when a brand-name drug becomes generic, it changes the supply chain structure (the number of suppliers and their geographical location/concentration) which may in turn alter the supply chain risk.

A tool to foster alignment and a systems view

Drug supply chains involve many stakeholders with potentially vastly different perspectives, incentives and objectives. Naturally, we can expect strong differences in opinions among doctors, distributors, manufacturers and other actors. Yet, a system cannot function properly if stakeholders are not aligned and committed to an agreed-upon intervention.

Bringing different stakeholders together in open discussion based on the matrix can foster mutual understanding. This leads to more constructive negotiations and improved alignment, which are essential in creating a shared understanding of the required resources, timeline, responsibilities and KPIs.

The approach proved useful to the **Dutch government**, which used our analyses on stockpiling in revising its drug stockpiling policy. From 1 January this year, the minimum stock requirement only applies to medicines that cost less than EUR 15 per pack, which run out about three times more frequently than more expensive drugs.

Indeed, when diverse stakeholders are able to look beyond their own perspective and interests, it increases the probability that the most appropriate intervention can be identified. This can also provide opportunities for learning and collaboration, and potentially improved access to drugs at a wider, regional scale. For instance, Iceland, Norway, Denmark are small countries that often face difficulties in securing supply. However, together, they are stronger; **collaboration among these Nordic countries** have increased knowledge and purchasing power, and as such, reduces supply risk.

The complexity and sometimes opaqueness of drug supply chains demand a systems approach. Our matrix provides a simple tool with concrete steps to

help stakeholders (such as a government or cross-industrial network) move towards a systems view. Every effort to gather more evidence, better align the many stakeholders and to move to a systems view will pay off.

** The research is a collaboration among: **Thomas Breugem**, Tilburg University; **Iman Parsa** and **Luk Van Wassenhove**, INSEAD; **Kim van Oorschot** and **Marianne Jahre**, BI Norwegian Business School; **Christine Oline Årdal**, Norwegian Institute of Public Health; **Nonhlanhla Dube** and **Kostas Selviaridis**, Lancaster University; and **Harwin de Vries** and **Stef Lemmens**, the Rotterdam School of Management.*

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About the research

Measures for Improved Availability of Medicines and Vaccines (**MIA**) is a study funded by the Research Council of Norway.

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