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# Pharmaceutical Shortages as a Multi-Level Governance Failure: An Exploratory Multi-Stakeholder Qualitative Study with Implications for EU and UK Policy

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## Abstract

# Background

Medicine shortages increasingly threaten patient safety and health system resilience across high-income countries. Despite expanding literature on supply chain vulnerabilities, the perspectives of frontline professionals, such as pharmacists and clinicians, remain underrepresented, and the multi-level governance dimensions of shortage management remain underexplored.

# Methods

We held a participatory multi-stakeholder workshop in March 2025 at the Università di Bologna, Italy. Eighteen participants from the UK and Italy took part in structured presentations and facilitated discussions. They included clinicians, pharmacists, procurement specialists, policymakers, industry representatives, and academic researchers. Recordings of the discussions were transcribed, anonymised, and analysed using thematic analysis in NVivo 15, with themes interpreted through a multi-level governance framework.

# Results

Five themes were identified: diversification and cooperation; transparency and trust; regulatory frameworks; demand-side pressures and public messaging; and national and regional security. Participants highlighted geographic concentration of manufacturing, fragmented supply chain communication, and rigid regulatory frameworks as structural causes of medicines shortages. Frontline professionals, particularly community pharmacists, were identified as bearing the greatest operational burden of shortages while having the least regulatory flexibility to respond. Proposed responses included expanded domestic manufacturing, real-time inventory systems, reformed procurement criteria, greater pharmacist dispensing flexibility, and strengthened international coordination.

# Conclusions

Our findings indicate that pharmaceutical shortages represent a systemic, multi-level governance failure rather than a purely logistical problem. Effective responses require coordinated action across supranational, national, and local levels. This should include regulatory reform such as expanded pharmacist dispensing flexibility; improved transparency and incentive-based early notification; and strategic investment in supply chain resilience to facilitate cross-sector stock redistribution. Reshoring and diversification strategies must also engage with the environmental governance implications of where and how medicines are manufactured. Our findings provide preliminary practitioner-informed

evidence relevant to EU and UK policy developments to address medicine shortages, including the Critical Medicines Act (CMA), while highlighting persistent gaps in their scope.

## Contributions to the Literature

- Medicine shortages are usually treated as logistics; we reframe them as a multi-level systemic governance failure, from frontline professionals to policymakers, making governance the decisive lever for protecting population health.
- Governance is dispersed across clinicians, pharmacists, procurement, industry and policymakers; an exploratory workshop showed shortages emerge where their decisions interact, beyond any single actor's control.
- Compounding drivers include concentrated drug-ingredient production, fragmented information flows, and inflexible regulation.
- Front-line professionals carry the heaviest burden yet have the least freedom to act.
- Incentivised shortage reporting and regional cross-sector coordination are promising, low-cost levers warranting evaluation.

## Introduction

This study aims to consolidate and critically examine solutions proposed by a broad range of stakeholders within the pharmaceutical sector to address the ongoing problem of medicine shortages. Responding to recent calls for a more comprehensive evidence base, including the perspectives of pharmacists, manufacturers, and clinicians (1), we conducted a structured multi-stakeholder workshop at the Università di Bologna, Italy. Participants representing diverse professional roles from the UK and Italy contributed insights on strategies to mitigate shortages, addressing all areas of the supply chain. Thematic analysis of these contributions enabled the identification and synthesis of key challenges and proposed policy and practice responses, with implications for UK and EU policy.

## Background

Pharmaceutical supply chains are structurally vulnerable because production is concentrated in a small number of countries. Around 60–80% of active pharmaceutical ingredients (APIs) for generic medicines in the EU are sourced from China (2), creating dependence on a limited supplier base. A 2024 Nuffield Trust report describes these as persistent systemic “fragilities” in global medicine supply networks (3). In the UK, Brexit has added further complexity by disrupting regulatory alignment and distribution systems previously integrated within EU frameworks (3). These structural weaknesses are intensified by acute external shocks, including the COVID-19 pandemic, geopolitical instability, and climate-related disruptions (4, 5). Medicine shortages have major consequences for patient safety, healthcare delivery, and system sustainability. In mid-2023, 57% of pharmacists in the UK reported that shortages had placed patients at risk within the previous six months, and 93% of pharmacy owners in England reported

increased procurement-related workload (6, 7). Beyond operational burdens, shortages generate psychological distress, damage patient-provider relationships, undermine long-term system sustainability, and increase the risk of falsified medicines entering supply chains when legitimate products are unavailable (8).

Despite this policy urgency, the existing evidence base has notable gaps. Much of the published literature focuses on supply chain logistics, regulatory frameworks, or industry perspectives, with comparatively little systematic attention to the views of frontline healthcare professionals who manage the day-to-day consequences of shortages in practice (1). This is a significant omission: frontline professionals hold practical knowledge of local solutions, regulatory constraints, and patient impacts that are rarely captured in upstream supply chain analyses. The policy context is also rapidly evolving. The European Commission's proposal for a Critical Medicines Act (CMA) represents the most significant supranational legislative response to date, aiming to strengthen supply chain monitoring, pooled procurement, and critical medicine designation processes (4). However, how these policy developments address the multi-level governance dimensions of shortage management remains underexplored from an empirical, multi-stakeholder perspective.

This study addresses these gaps by applying a multi-level governance framework to pharmaceutical shortage management and contributing original qualitative evidence from a diverse stakeholder workshop. The study had three specific objectives: (1) to examine perspectives on the drivers of medicine shortages from across the pharmaceutical supply chain; (2) to identify stakeholder-proposed mitigation strategies; and (3) to analyse these findings through a multi-level governance framework to assess implications for EU and UK pharmaceutical policy.

## Methods

We conducted a 7.5-hour participatory workshop in March 2025 (9). This approach was selected because shortage governance involves interdependencies between manufacturers, regulators, distributors, procurers, and frontline professionals, where structured group discussion methods would allow us to capture the trade-offs and shared priorities that individual interviews may not. We adopted an exploratory design because the multi-level governance dimensions of shortage management are under-theorised empirically. The study was not designed to test pre-specified propositions. Its purpose was to surface hidden mechanisms and policy levers, grounded in practitioner experience, that can be further studied in future comparative work.

# Participants and recruitment

Eighteen participants took part in total. Fourteen external participants were recruited through purposive sampling to ensure representation of the full range of professional roles involved in pharmaceutical supply chains, including clinicians, pharmacists, procurement specialists, policymakers, and pharmaceutical industry representatives, predominantly Italy-based (Table 1). Four author-researchers

also participated in their professional capacity: two UK-based academics with expertise in supply chain management and global health policy, and two Italy-based clinicians with expertise in health systems. This combination ensured representation of both frontline practitioner perspectives and policy-analytical expertise across two distinct European regulatory contexts. While the sample size is modest, qualitative research of this design prioritises conceptual adequacy over statistical representation, and the professional diversity of participants ensured that multiple, sometimes conflicting, perspectives on the same governance challenges were represented and interrogated.

Table 1
Participants Workshop

| Participant | Area | Country |
|---|---|---|
| 0001 | Policy | Italy |
| 0002 | Procurement | Italy |
| 0003 | Clinician | Italy |
| 0004 | Pharmacy | UK |
| 0005 | Pharmacy | Italy |
| 0006 | Clinician | Italy |
| 0007 | Academia | UK |
| 0008 | Industry | Italy |
| 0009 | Pharmacy | Italy |
| 0010 | Policy | Italy |
| 0011 | Pharmacy | Italy |
| 0012 | Clinician | Italy |
| 0013 | Academia | UK |
| 0014 | Policy | Italy |
| 0015 | Procurement | Italy |
| 0016 | Clinician | Italy |
| 0017 | Pharmacy | Italy |
| 0018 | Pharmacy | Italy |

## Workshop structure

The participatory workshop consisted of two components. First, invited speakers delivered short presentations followed by questions from the audience. Second, participants took part in a structured group discussion aimed at identifying and refining potential solutions to pharmaceutical shortages. Discussion topics were organised around issues raised in the earlier presentations, enabling participants to collectively examine challenges and co-develop strategies.

## Data collection

Data included audio recordings of the group discussion, researchers' notes taken during and immediately after the session, and speaker presentations. Audio files were transcribed using automated transcription software and subsequently anonymised before analysis. Only the research team had access to the anonymised materials, which were stored securely on university servers. Participants provided written informed consent and were informed that discussions would be audio-recorded and anonymised no later than two weeks following the workshop. They retained the right to withdraw consent at any point before anonymisation was completed.

# Data analysis

Data were analysed using thematic analysis (10). Researchers familiarised themselves with the data through repeated reading of the anonymised transcripts, notes and workshop materials, which were then initially coded using NVivo Version 15. Codes were iteratively developed inductively into broader organising themes and overarching themes, which were then refined and agreed upon collectively for data triangulation. This approach enabled us to systematically identify recurring themes in the discussion. The resulting themes were subsequently interpreted through a multi-level governance (MLG) framework (11, 12), to situate themes within the governance structure of pharmaceutical supply. This framework was applied to examine the governance dimensions of participants' accounts (11, 12).

The research team comprised academics from UK and Italian universities, with professional backgrounds spanning supply chain management, global health policy, pharmaceutical policy, and health systems research. Four members of the research team also participated in the workshop in their professional capacity, contributing data alongside external participants. To manage the potential for bias arising from this dual role, author-participant contributions were analysed by non-participant authors in the same manner as all other participant data, without privileged weighting. Participant identities, including those of author-participants, were anonymised prior to analysis.

## Results

Participants described the broad consequences of pharmaceutical shortages, including financial pressures, environmental harms, workforce strain, and patient distress. Sourcing alternatives was reported to disrupt hospital workflows, increase costs, and generate additional transport emissions through fragmented procurement. Participants highlighted the strain on healthcare workers, particularly

the emotional and practical burden of managing patient expectations while avoiding communication that could encourage stockpiling. Patients were identified as experiencing the greatest impact, including distress, delayed treatment, and reduced quality of life, informing participants' perspectives on the themes below.

# Diversification and cooperation

I think what they're saying is diversifying the manufacturing to make sure that it's not [a] monopoly

Participants repeatedly emphasised the concentration of pharmaceutical manufacturing as a major driver of medicine shortages. Participants highlighted that this dependency is especially pronounced in the UK and EU, where a substantial proportion of APIs are sourced from non-European manufacturers, most notably in China, thereby heightening exposure to external shocks, trade disruptions, and geopolitical risks. In response to these challenges, participants argued for expanding domestic and regional manufacturing capacity. Strengthening local production could be a mechanism to enhance resilience, as well as ensuring more balanced partnerships with producers in other regions. However, they noted that increasing local manufacturing capacity does not eliminate vulnerability to supply chain disruptions, such as flooding or other climate-related events.

The implications of European stockpiling could be reduced availability for other countries

That should be [done] in a very careful way, because we all know that the supply chain is a global supply chain and that it's very interconnected

Centralised regional procurement was also discussed as a mechanism to improve purchasing efficiency, reduce duplication, build medicine reserves, and promote equitable regional access to medicines. However, ethical concerns were raised regarding the global implications of increased stockpiling, particularly for low- and middle-income countries with limited production capacity. While some participants supported prioritising local supply resilience, they emphasised the need for more cooperation and global equity.

We need more global action and more coordinated actions

More broadly, participants expressed the need for increased international cooperation to address the systemic drivers of medicine shortages. Strengthening global coordination was viewed as necessary to support earlier detection of disruptions, promote more equitable distribution of scarce products, and reduce the over-reliance on single-country manufacturing hubs. Participants argued that coordinated global efforts, supported by transparent information flows and collaborative governance structures, would be critical for enabling pharmaceutical supply systems to better withstand future shocks.

## Transparency and trust

There is […] little understanding of the inventory held within community pharmacies […] one community pharmacy will not know what is held within another unless they speak to each other on the phone.

Participants consistently emphasised that limited communication across different segments of the pharmaceutical supply chain contributes to delayed recognition and management of emerging shortages. In the UK, substantial gaps were reported between community pharmacies, wholesalers, and manufacturers, with fragmented information systems preventing real-time visibility of stock levels. Improved stock control and electronic inventory systems were highlighted as potential mitigations.

National oversight of the stock in community pharmacy is […] almost zero.

Without centralised inventory visibility, pharmacies must contact each other individually to locate supplies, which was characterised as a time-consuming and operationally inefficient process. Participants also highlighted the limited direct engagement between community pharmacies and manufacturers, noting that communication is typically mediated through a small number of wholesalers. This multilayered structure was viewed as restricting the flow of accurate and timely information about impending shortages and limiting opportunities for proactive mitigation measures, such as early therapeutic substitution or patient messaging.

I would ask [industry] to be a lot more honest and transparent about the causes of shortages

If we really want to solve the problem with shortages, we need trust. You need to trust the suppliers, and suppliers need to trust you.

Additionally, the importance of trust emerged as a central component of effective communication. Participants on the demand-side emphasised that more transparent and detailed information from suppliers, such as the nature, expected duration, and underlying causes of shortages, could help foster greater trust across the supply chain. From the supplier perspective, the stability and security of procurement contracts were described as essential for incentivising information sharing and supporting reliable supply. Improved contractual certainty was seen as a mechanism to encourage longer-term planning and reduce the incentives for withholding information about vulnerabilities or production challenges.

## Regulatory frameworks

Participants identified three interrelated regulatory challenges: jurisdictional asymmetries in compliance standards, restrictions on cross-sector stock redistribution, and the rigidity of existing prescribing frameworks.

Contracts and resources should be spent on getting the right medicine to patients, not on bureaucratic process.

Participants noted that regulatory actions themselves may shape the emergence and severity of shortages, particularly when requirements differ substantially across jurisdictions. For example, stricter Environmental, Social and Governance (ESG) related compliance standards in Italy and, more broadly, in the EU were viewed as creating asymmetries in competitiveness between manufacturers, potentially slowing production or complicating distribution relative to countries with less stringent requirements. Legal constraints within national systems, such as language of packaging, were also reported to limit the capacity for rapid, coordinated responses during shortages.

In the times of shortages then we have a lot more […] collaboration, but it's still legally very constrained.

Although collaboration between stakeholders tends to increase during periods of acute disruption, participants emphasised that existing legislative structures continue to restrict the movement of stock between sectors, such as between hospitals and community pharmacies, thereby prolonging or intensifying supply challenges. Nonetheless, in Italy, there are regionally organised processes to move stock across hospitals and community pharmacies, through centralised procurement management.

The [solution] is flexibility to be able to transfer medicine stock from one place to another without the legal constraints.

Enhancing cooperation between clinicians and pharmacists was identified as essential for ensuring safe and timely substitution, especially when considering the use of unlicensed medicines. Participants noted that hospitals are typically better positioned to procure unlicensed medicines than community pharmacies, suggesting that strengthened cross-sector coordination could help overcome regulatory and procurement barriers that currently constrain access to alternative products. Participants also noted that some community pharmacies may already have informal protocols in times of shortages and ensure stock availability for their patients.

Ideally there would be legislative changes allowing them more flexibility and more freedom to provide an alternative therapy.

*Serious Shortage Protocols…give community pharmacies extra powers to amend a prescription when there is a known national shortage. […] What would have been very helpful is a Serious Shortage Protocol allowing community pharmacies to substitute […] an unlicensed version when […] they run out of stock.*

In the UK, alternative prescribing is legally possible under a Serious Shortage Protocol, whereby the Department of Health and Social Care (DHSC) issues potential substitutions for medicines in shortage (13). However, these are time-limited, restricted to only certain alternatives, and only for severe national shortages. Participants argued that this framework could be expanded, giving community pharmacists more flexibility during a critical shortage.

[Clinicians] will hold very strong prescribing habits […] Making them aware of the different therapeutical therapies, developing a multidisciplinary clinical context in which these skills and competencies of pharmacists and clinicians [can] work together is at least the part of this solution

Finally, participants observed that entrenched prescribing habits by clinicians can hinder the adoption of alternative therapies during shortages. They suggested that better education of clinicians on the variety of therapeutic options could lead to prescribing practices that can be more adaptive during a shortage.

# Demand-side pressures and public messaging

Demand can rapidly change for a number of reasons.

Sometimes it is difficult […] for a pharma[ceutical] company to have an idea of what is the real demand, where the product is used

Participants identified increased and unpredictable demand as a significant contributor to medicine shortages. Related to the previous theme of transparency, participants noted that manufacturers often lack visibility over how and where products are used and what epidemiological trends are emerging, making it difficult to adjust production volumes in a timely manner. This misalignment between real-time demand signals and manufacturing responsiveness can create delays across the supply chain as companies attempt to scale production or reallocate stock.

[Patients] need the assurance. If we don't give them the assurance, they provide their own assurance, which is stockpiling.

Do not stockpile […] can be a public health message as opposed to [a] scare message

Demand side pressures were reported to interact with public behaviour where uncertainty about medicine availability has the potential to induce patient stockpiling. This behaviour can generate sudden spikes in demand that further strain supply chains, amplifying the severity of shortages. Participants highlighted the role of targeted public health messaging to discourage unnecessary ordering and reduce waste, but also to reassure patients and reduce uncertainty about medicine availability. At the local level, healthcare professionals bear the primary responsibility for managing demand-side pressures, yet lack the communication infrastructure and policy mandates to do so effectively. This is a governance gap operating across national and local levels simultaneously.

# National and regional security

It's a national security issue

Participants emphasised that governments have a responsibility not only to manage consumption but also to ensure adequate domestic production capacity. They cited the case of Australia, which has limited local manufacturing capacity particularly for antibiotics, making it highly dependent on imports and vulnerabilities in the global supply chain.

Governments should make sure that they [have the] ability to provide medicines for their citizens

Participants proposed reframing pharmaceutical shortages as a national security concern in order to elevate political prioritisation and secure sustained government investment. Shortages were described as having the potential to undermine public trust, intensify public frustration, and create broader social and political instability if essential medicines become unavailable. In addition, the increasing digitisation of pharmaceutical supply systems was associated with emerging cybersecurity risks, highlighting the need for stronger digital protections to safeguard supply chain continuity.

## Discussion

This study examined multi-stakeholder perspectives on pharmaceutical shortages through a participatory workshop conducted at the Università di Bologna, Italy, in March 2025. The findings suggest that medicine shortages are not primarily a logistical or technical failure, but a consequence of fragmented information flows, concentrated manufacturing capacity, demand-side pressures, and regulatory rigidity operating across supranational, national, and local levels. The discussion situates these findings within the broader policy and governance literature, drawing on the MLG framework to examine how failures at different levels interact to produce systemic supply vulnerabilities.

# Transparency and information fragmentation

At the supranational and national levels, the governance of pharmaceutical information flows remains fragmented, lacking visibility over manufacturing locations, API sourcing, production capacity, and inventory levels across the supply chain (14). Participants consistently identified information asymmetry as a central driver of shortages. Medicines supplied to the UK, Italy, and the broader European market rely on complex transnational production networks, yet critical upstream vulnerabilities are not routinely disclosed, limiting stakeholders' ability to anticipate and mitigate risks (14).

Participants emphasised that transparency requires not only formal reporting mechanisms but also trust-based relationships across the supply chain. In practice, pharmacists and GPs frequently rely on informal networks or decentralised platforms such as Community Pharmacy England's reporting tool, which may not feed systematically into a coordinated national response (15). This fragmentation limits early detection and monitoring of stock levels and contributes to delayed interventions.

At the manufacturer level, the picture is similarly poor: following the EU's 2019 early notification requirement, only 5.2% of shortages were reported 60 days in advance, while over 56% were reported on or after the start date (16). In the UK, while manufacturers are legally required under the Health Service Products (Provision and Disclosure of Information) Regulations 2018 to notify authorities of anticipated shortages, no national framework exists to support proactive shortage management at the local NHS level (15).

An incentive-based mechanism has been trialled in Finland, showing that notification failures are not intractable. They introduced financial penalties for late reporting, which increased the proportion of early notifications from 3% to 20% (16), indicating that modest economic incentives can drive some

improvements in compliance. Strengthening the capacity of regulatory national or supranational bodies, such as the UK's Medicines and Healthcare products Regulatory Agency (MHRA), to oversee increasingly globalised supply networks, combined with incentive-based notification frameworks, could represent a practical and scalable path toward improved early warning (17). Improved demand forecasting and targeted public health messaging to discourage stockpiling were also identified as necessary complements to supply-side interventions.

# Regulatory flexibility and cross-sector coordination

At the local level, community pharmacies bear the operational and financial consequences of governance failures originating at higher levels of the system, yet existing national regulatory frameworks provide insufficient flexibility to respond adaptively to shortages in practice. In the UK, Serious Shortage Protocols (SSPs) permit pharmacists to supply alternatives without prescriber reauthorisation but are issued case-by-case by the Secretary of State, apply only to named products over fixed periods, and are widely described as bureaucratic and slow to activate (13, 15). Community Pharmacy England and the Royal Pharmaceutical Society have called for pharmacists to be empowered to make limited prescription amendments without SSP activation or prescriber approval (5, 15, 18).

Participants argued that strengthened multidisciplinary collaboration between pharmacists and prescribers could similarly enable safer and more adaptive clinical responses in the UK context, particularly where shortages require rapid therapeutic substitution. Rigid legislation also restricts stock redistribution between hospitals and community pharmacies, creating inefficiencies that more flexible frameworks could mitigate. Participants' accounts suggest that the absence of an adaptable coordination mechanism represents a governance failure: stock held in one sector cannot be redistributed to another. In such circumstances, regulatory barriers can prevent medicines from being transferred to where they are most needed.

# Procurement and environmental and social governance

At the supranational level, the prevalence of lowest-cost procurement criteria across EU Member States reflects a structural governance failure in which individually rational purchasing decisions collectively produce a fragile supply architecture (19). This fragility results from the fact that European pharmaceutical regulation has historically focused on product safety and affordability rather than supply chain resilience or geographic diversification of production (20, 21). In the UK, Community Pharmacy England has called for reform of the price concession system, which frequently fails to reflect real-time acquisition cost volatility and may require pharmacies to dispense at a financial loss (15, 18). Proposed reforms in the UK include a strategic review of medicine pricing and supply policy, greater transparency in NHS procurement, and investment in digital infrastructure such as real-time shortage information platforms (15, 18).

Any regulatory reform to procurement must also be accompanied by safeguards against unintended competitive consequences. Stricter environmental and compliance standards in the EU and UK, if applied asymmetrically, risk displacing manufacturing to lower-regulation jurisdictions. Studies have

shown that API production concentrated in low-and-middle-income countries (LMICs) has been associated with significant environmental pollution, with antibiotic concentrations in treated effluents from Indian and Chinese facilities substantially exceeding those recorded in the US and EU (22). Strategies to reshore or diversify production must therefore continue to enforce environmental and social governance alongside supply security.

# Geopolitical framing and global equity

Beyond national and supranational governance frameworks, participants situated pharmaceutical supply resilience within a global governance context, highlighting the tension between domestic supply security and international equity. Participants framed pharmaceutical supply resilience as a national and regional security imperative. However, participants also acknowledged the global equity implications of this framing: EU-level reshoring may reduce demand for APIs from LMIC suppliers, intensify competitive pressures on manufacturers in LMICs, and redirect investment away from established export-dependent pharmaceutical sectors (23). Resilience achieved at the EU level therefore risks redistributing scarcity globally rather than addressing its structural causes. This tension between national resilience and global equity represents a fundamental governance challenge that current pharmaceutical policy has yet to fully address.

# The Critical Medicines Act

At the supranational level, the proposal for a Critical Medicines Act (CMA) has been the EU's most significant institutional response to the governance failures identified in this study. The CMA addresses fragmented coordination, inadequate supply chain monitoring, and procurement frameworks that prioritise cost over continuity (4). Its key provisions include an obligation on contracting authorities to refrain from relying solely on lowest-price criteria in public procurement, support for collaborative procurement between member states, and the designation of strategic industrial projects aimed at boosting the manufacture of critical medicines and their active ingredients within the EU. The scope was also expanded to include orphan medicinal products in certain key areas, and the agreement clarifies the use of a voluntary solidarity mechanism to enable data exchange on contingency stocks and voluntary reallocation of critical medicines between member states.

However, the CMA's scope remains constrained: it applies primarily to medicines designated as "critical" and does not provide a direct mechanism to address the coordination of reimbursement and pricing that influence supplier participation. The Act also lacks specific provisions to prevent excessive price increases for consumers, and the coordination mechanism currently focuses primarily on industry and governmental actors, with limited inclusion of frontline healthcare professionals. Concerns have also been raised that the CMA may add a further governance layer without resolving the underlying coordination failures, particularly given divergent national priorities and limited EU-level funding.

# UK post-Brexit pharmaceutical policy

The UK faces a distinct set of governance challenges. Its departure from the EU has added complexity to pharmaceutical supply governance by disrupting the previous alignment of regulatory and distribution systems with EU frameworks (3, 24). Although the UK is not subject to the Critical Medicines Act, the governance issues identified in our analysis—including siloed information, limited prescribing flexibility, the need for procurement reform, and weak coordination across sectors—remain relevant to the UK context and are reinforced by the current UK policy literature, including (15, 18).

The policy paper 'Managing a Robust and Resilient Supply of Medicines', published by the Department of Health and Social Care, represents a welcome step in the right direction (25). The policy paper proposes enabling community pharmacists to modify the formulation and strength of prescribed medicines to improve patient access and experience. Our findings support this recommendation and highlight the importance of strengthening multidisciplinary collaboration between community pharmacists and prescribers. Such collaboration could provide a practical and proportionate governance response to medicine shortages at the local level.

Despite representing a step forward, the proposal, as recommended by the Royal Pharmaceutical Society, should be supported by sustained national investment (26). Future reforms should prioritise access to real-time inventory data, incentive-based early-notification requirements, and a regulatory mechanism for cross-sector redistribution to address the governance failures identified in this study. These recommendations are derived from the governance analysis presented in this study rather than from data collected from UK workshop participants, as UK representation at the workshop consisted predominantly of academics.

## Conclusion

This study provides a multi-stakeholder perspective on the systemic drivers of pharmaceutical shortages and identifies coordinated strategies to strengthen supply chain resilience. The findings indicate that shortages are not primarily a logistical failure but a multi-level governance challenge, shaped by regulatory rigidity, manufacturing concentration, transparency gaps, and demand-side pressures, with pervasive consequences for patients, healthcare workers, and health systems. In doing so, the study makes three contributions to the literature: a multi-level governance analysis of pharmaceutical shortages; original qualitative evidence from a multi-stakeholder design; and empirical grounding for ongoing EU and UK pharmaceutical policy developments.

Effective policy responses require vertical alignment across governance levels, combining regulatory mandates, procurement standards, and strategic investment, alongside horizontal coordination mechanisms such as real-time information platforms and cross-sector forums. Transparency, regulatory flexibility, procurement reform, and international coordination are each necessary but insufficient in isolation, and must be accompanied by engagement with the geopolitical, environmental, and equity dimensions of pharmaceutical resilience. Specifically, the workshop generated four propositions for further policy development and evaluation: (1) strengthening mandatory early notification requirements

with financial penalties; (2) expanding pharmacist dispensing flexibility during declared shortages; (3) developing cross-sector stock redistribution frameworks at regional or national level; and (4) explicitly integrating global equity dimensions into domestic supply resilience strategies.

Several limitations should be noted. The sample of 18 participants, while purposively selected to maximise professional and sectoral diversity, is modest and predominantly Italy-based. UK representation comprised two academic researchers and one frontline practitioner, which limits the empirical depth of UK-specific claims; UK policy implications are therefore grounded primarily in existing literature rather than participant data.

As a single-session workshop, the data represent a cross-sectional snapshot rather than longitudinal or iterative perspectives, and findings may not fully capture broader organisational practices or informal norms within participants' sectors. Four author-researchers participated in the workshop in their professional capacity; steps taken to manage potential bias are described in the methods.

Notwithstanding these limitations, the professional diversity of participants, including frontline practice, procurement, industry, policy, and academia across two European regulatory context, supports the conceptual adequacy of the findings and their transferability to other high-income country settings facing comparable challenges. Future research should include larger comparative studies across EU countries, difference-in-differences designs exploiting variation in policy adoption timing, and qualitative longitudinal work tracking patient adaptation during recurring shortages and the feasibility of data-sharing agreements between manufacturers and regulators.

# Declarations

### Ethics approval and consent to participate

All procedures were conducted in accordance with the Helsinki declaration. Ethical approval for this study was obtained from the UCL Life and Medical Sciences Research Ethics Committee (Project ID 0482). All participants provided written informed consent to participate in the study and for publication.

### Data availability statements

The datasets analysed are available from the corresponding author on reasonable request.

### Declaration of competing interest

The authors declare that they have no competing interests.

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### Authors' contributions

RC and AC designed the study, conducted the data collection, guided the analysis, and drafted the manuscript. KG analysed the transcripts and contributed to manuscript drafting. AHE and PT conducted the policy and literature review and contributed to manuscript drafting. FC and VA contributed to the study design, data collection, and manuscript drafting.

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