



Regulatory Approaches To Mitigating Drug Shortages: Strategies And Policy Solutions

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ABSTRACT

Drug shortages are emerging as a serious challenge to the global healthcare delivery system, irrespective of economic jurisdictions. This review provides an insight into the current scenario of drug shortages in a global perspective, with prominent focus on affected therapeutic classes and major factors that contribute to drug shortages, such as failure in manufacturing quality, lack of raw materials, economics, and inefficient regulatory policies. The effects of drug shortages, in terms of patient safety, economics, and human aspects, especially in low- and middle-income countries, are described, and their need and importance in different settings are emphasized. This review particularly focuses on regulatory affairs concerning drug shortages, and it describes how regulatory policies in jurisdictions need to allow transparency and focus on strategies to counter drug shortages due to their significant impact in health access and delivery worldwide.

1. INTRODUCTION

Medicines are vital to healthcare, and access to essential medicines is recognized as a fundamental human right. The World Health Organization (WHO) defines essential medicines as those that meet the priority health care needs of the population. However, persistent drug shortages pose major challenges to health systems worldwide.

Drug shortages are not a recent phenomenon. The earliest recorded shortage dates back to the insulin crisis of the early 1920s. Since then, shortages have become increasingly common across the globe. In 2012, Gray and Manasse reported drug shortages in 21 countries, while the University of Utah Drug Information Services documented 129 medicine shortages in the United States alone in 2020.

Drug shortages affect high-, middle-, and low-income countries, though their causes differ. In high-income countries, shortages are often linked to manufacturing problems, business decisions, raw material scarcity, and regulatory issues. Despite the implementation of various policies, reporting systems, and guidelines by governments and professional organizations, shortages continue to create serious health and economic consequences.

Low- and middle-income countries also experience some unique challenges such as pseudo-drug licensings, unavailability of raw drugs to local producers, smuggling of drugs, and unfavorable tax policies. A study conducted in these countries emphasizes the importance of better government policies and information solutions to minimize shortages. Low-income countries are not conducting much research, while the policies in such places are not ideal. Stock out of critical drugs and tuberculosis drugs, ketamine, as well as anti-HIV

drugs, have been reported to frequently occur in countries such as Malawi, Egypt, and Uganda, and in some countries of Africa.

Impacts associated with a drug shortage include delayed or inadequate treatment, intensified monitoring, longer lengths of hospitalized stay, elevated rates of hospitalization, deferred or abandoned procedures, and, in several instances, death. Healthcare practitioners, on the other hand, also suffer greatly due to shortages. These effects have been observed through surveys held in Europe.

This review will assess the global situation regarding medicines shortage, discuss its causes and consequences in different economic environments, and outline how some measures can be taken globally to improve healthcare systems and benefit overall public health.

2. DEFINITIONS OF DRUG SHORTAGES

General Definition

A drug shortage refers to a situation in which the supply of a drug is insufficient to meet the current or projected demand, potentially compromising patient care, delaying treatment, or requiring the use of less effective or riskier alternatives.

United States Food and Drug Administration (US FDA)

"A drug shortage is a situation in which the total supply of all versions of a medically necessary drug available at the user level will not meet the current or projected demand at the patient level."

European Medicines Agency (EMA)

"A drug shortage occurs when supply does not meet the demand for a medicine at the national level."

World Health Organization (WHO)

"A medicine shortage exists when the supply of medicines, health products, or vaccines identified as essential is insufficient to meet public health and patient needs."

Health Canada

"A drug shortage is when a drug manufacturer cannot meet the demand for a drug currently marketed in Canada."

India – Central Drugs Standard Control Organization (CDSCO)

India does not have a standardized legal definition like the FDA or EMA, but:

CDSCO identifies shortages as non-availability or restricted availability of scheduled essential medicines. Recent policies focus on real-time monitoring of essential drugs through the National List of Essential Medicines (NLEM).

Although there is no single universally adopted definition, most agencies agree that a drug shortage involves the unavailability of essential or medically necessary medicines due to supply not meeting demand. Definitions vary slightly based on jurisdiction, scope, and policy frameworks but share common concerns about patient safety and public health.

Understanding these definitions is critical for regulatory bodies, policymakers, and healthcare providers to respond effectively to drug shortages and develop preventive strategies.

3. DRUGS REPORTED IN SHORTAGE

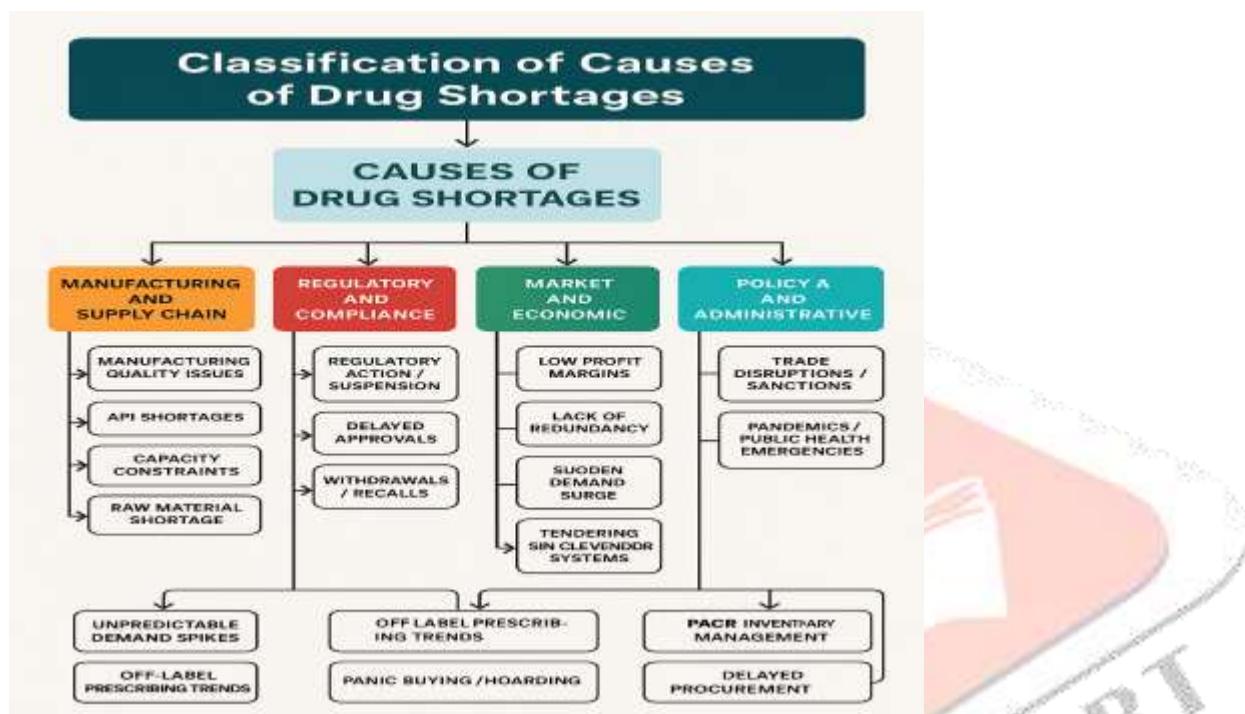
Drug shortages impact a wide range of therapeutic areas and drug classes. The shortages may involve injectables, oral solids, vaccines, biologics, or medical gases, and often include critical, life-saving drugs. The issue is more severe in low- and middle-income countries, but even developed nations like the USA, UK, and Germany face frequent shortages.

Therapeutic Category	Examples of Drugs	Reasons for Shortage	Geographic Examples
Oncology Drugs	Cisplatin, Carboplatin, Methotrexate, Doxorubicin	<ul style="list-style-type: none"> - Manufacturing quality issues - Limited sterile injectable capacity - API supply constraints 	USA, India (AIIMS reports), EU
Antibiotics / Antimicrobials	Amoxicillin, Penicillin, Cefazolin, Vancomycin	<ul style="list-style-type: none"> - API shortages - Few generic manufacturers - Surge in demand due to outbreaks 	India, UK (Strep A), USA
Cardiovascular Drugs	Atropine, Nitroglycerin, Metoprolol injection	<ul style="list-style-type: none"> - Production delays - Raw material shortage - Short shelf-life of injectables 	Global
Anesthetics & Sedatives	Propofol, Midazolam, Fentanyl, Ketamine	<ul style="list-style-type: none"> - COVID-19 ICU usage spike - Controlled drug regulations - Limited producers 	USA, EU, India
IV Fluids & Electrolytes	Sodium chloride IV, Dextrose, Potassium chloride	<ul style="list-style-type: none"> - Natural disasters affecting manufacturing plants - High-volume production demand 	USA (Puerto Rico plant disruption), India
Pediatric Formulations	Amoxicillin syrup, Paracetamol syrup	<ul style="list-style-type: none"> - Seasonal infections - Low profitability - Fewer child-specific manufacturers 	India, USA
Vaccines	Rabies, Influenza, HPV, BCG	<ul style="list-style-type: none"> - Long production lead times - Cold chain logistics - Global demand fluctuations 	WHO data, India (rabies vaccine), Africa
Psychiatric / Neurology	Sodium valproate, Clonazepam, Risperidone	<ul style="list-style-type: none"> - Supply chain issues - Regulatory halts - Growing patient demand 	UK (Sertraline), India, USA
Hormonal Drugs	Insulin, Thyroxine, hCG	<ul style="list-style-type: none"> - Cold storage dependency - Market competition - Patent-related production gaps 	USA, India, Canada
Emergency Medications	Epinephrine auto-injector (EpiPen), Albuterol	<ul style="list-style-type: none"> - Supply plant closures - Raw material shortage - High demand 	USA (FDA Shortages List)
Diabetes Medications	Ozempic (Semaglutide), Insulin analogs	<ul style="list-style-type: none"> - Off-label demand (e.g., weight loss) 	USA, Australia

		- Limited production capacity	
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4. CAUSES OF DRUG SHORTAGES

There may be different causes for the shortage of drugs. These causes may depend on the type, nature, and category of the drug. Overall, the causes for the shortage of drugs may be classified into supply factors, demand factors, and regulatory factors, as depicted in the Figure. Drug shortage causes may be diverse. These causes are due to various factors. These factors may include production, finances, shortage of raw materials, and the concept of just in time inventory, which are recognized as basic causes for the shortage of medicines in the advanced member states of the EU, the United States, Saudi Arabia, and other developing states like Pakistan and Fiji.



Supply Issues

Supply-related causes are a leading cause of drug shortages resulting from the inability or unwillingness of manufacturers to produce supplies that are adequate to meet demand. These disruptions result from manufacturing failures, raw material shortages, economic disincentives, and logistical constraints. A lot of specific issues related to medicine availability include equipment failures, contamination, noncompliance with regulatory requirements, delayed shipment, and incomplete distribution systems. These are managed in high-income countries through buffer stockpiling, oversight of regulatory systems, and diversified supply sources, whereas LMICs have more significant potential risks due to financial limitations, dependence on imports, poor levels of domestic production, inadequate forecasting systems, and delayed procurement processes, hence reducing access with poorer outcomes.

Manufacturing Issues

Manufacturing issues are consistently reported as one of the major roots of drug shortages in various parts of the world. The European Medicines Agency, along with studies from multiple countries, has reported manufacturing failure to be one of the key contributors. In middle-income countries, shortages—particularly of sterile injectables—are often related to declining manufacturing incentives and quality concerns, while low-income countries face additional challenges due to weak regulatory enforcement, poor infrastructure, and limited financial capacity.

i. Quality Problems

Quality-related problems are one of the main reasons for drug shortage and can be detected through inspection or surveillance studies. Quality-related problems can trigger recalls and interrupted production in various drugs. Common problems in drug quality are microbial or particulates, endotoxins, poor disintegration of tablets, and drug-packaging incompatibility. Breaches in Good Manufacturing Practice (GMP) rules add to the drug shortages. In the United States, quality-related problems contributed to almost two-thirds of drug shortages in 2012 and 2013.

ii. Competing Manufacturing Priorities

Small production capacity compels the manufacturing company to produce one product at the expense of another. Low profit medicines, more so generics and injectables, are usually low on the priority list regardless of their clinical significance. Injectable products also involve complicated and expensive manufacturing processes, hence less attractive to produce. This often makes the manufacturing company focus on high-margin products, leading to the shortage of essential medicines as it happens currently in the United States and Brazil.

Unavailability of Raw Materials

Shortages of active pharmaceutical ingredients (APIs), excipients, or packaging materials are one of the key causes of drug shortages. Dependence on API supply companies from different countries such as India and China makes them prone to political turmoil, trading barriers, natural calamities, as well as pandemics. Moreover, the COVID-19 pandemic highlighted this situation because of export restrictions, road blockages, and customs hold-ups. Dependence on a limited number of companies aggravates the shortages. Shortages of raw materials of medications have been documented extensively across different countries such as Saudi Arabia, Canada, and Pakistan.

Business Issues

Economic and related factors also play important roles in influencing the availability of drugs. The low profit margins, squeezing prices, and increased regulatory costs for manufacturers contribute significantly towards halting the manufacture and supply of 'non-profitable products,' such as generic injectables. In LMICs, lack of efficiency, as well as poor planning, lead to shortages and added pressures on constrained budgets, increasing pressures on meager budgets spent on health care.

5. REGULATORY CAUSES OF DRUG SHORTAGES

Drug regulatory authorities have a vital role in ensuring the availability of medicines that are safe, effective, and of high quality. Weaknesses in regulatory systems can, however, make a significant contribution to drug shortages. In many LMICs, the regulatory framework is rigid, poorly defined, and lacks flexibility. Delays in the registration and approval of medicines, the lack of comprehensive pharmaceutical policies, inadequate coordination among different regulatory bodies, and among manufacturers, distributors, and providers of healthcare, together with a failure to update essential medicines lists on a regular basis, disrupt the procurement and supply chain planning process, thereby resulting in frequent shortages.

Another impact of inefficiencies in regulatory mechanisms is the uncertainty in pharmaceutical markets. Unclear or outdated regulations obstruct timely decision-making, discourage the entry of manufacturers, and also impose limitations on proper resource allocation. Secondly, a lack of transparent reporting and monitoring systems facilitates early detection of possible shortages, thereby reducing the ability to apply timely mitigation strategies by the authorities.

The deployment of anti-counterfeiting and traceability technologies like the serialization of drugs, as well as electronic verification systems, could further put pressure on manufacturing and distribution capabilities. This is because a lot of investment will go into such initiatives.

Another major challenge is that a universally accepted definition of drug shortage does not exist. There are no standardized definitions when it comes to the assessment and reporting of drug shortages in different areas. Moreover, a lack of effective monitoring of the drug chain and inefficient inventory management methods in health institutions, especially in major hospitals, lead to drug shortages in the healthcare setting.

In conclusion, although regulatory control is necessary for ensuring the safety and quality of medication, rigid procedures, slow approvals, poor coordination, and regulatory gaps can inadvertently contribute to, rather than alleviate, a global medication shortage.

6. IMPACT OF DRUG SHORTAGES

Shortages of drugs trigger far-flung implications in the health care system, having ramifications for both patients and health care providers or institutions, pharmaceutical companies, and the government. Although developed countries have made policies to counter the impact of drug shortages, their impact is considerable. Rather, the lack of collectively formulated strategies in low- and middle-income countries heightens the problems associated with drug shortages in all aspects of health care delivery.

Economic Impacts

Shortages of drugs cause substantial economic burden, especially among patients in the fee-for-service model. Unavailability of the drug and the subsequent surge in demand cause price escalation, thereby compelling patients to opt for pricey alternatives. Other economic burdens include treatment of patients over an extended period, using compounded drugs, and traveling to obtain access to drugs. Hospitals experience economic burden owing to emergency purchases, education of staff, and storage of the drug. The cost of operation rises for the distributors and manufacturers because of searching for scarce raw materials, changing priorities of manufacturers, and poor market regulations. National economic burden occurs when countries import drugs due to national shortages.

Clinical Impacts

Also, drug shortages can cause disruptions in patient care. For healthcare professionals, drug shortages mean the potential use of unfamiliar drugs and this raises concerns about medication errors. Lack of vital drugs such as antibiotics, anesthetics, cancer drugs, and drugs for chronic illnesses may cause delayed procedures, longer stay in hospitals, failure of treatment, and even death. Moreover, when there is inadequate use of antimicrobial agents, it leads to the growth of resistant microorganisms. Moreover, in countries such as those in the LMICs group, drug shortages cause the progression of diseases and increased rates of complications even in life-threatening infectious diseases like cancer and HIV/AIDS.

Humanistic Impacts

The negative impact of drug shortages on the psychological and social wellbeing of patients may be manifested as anxiety, frustration, and distrust in healthcare systems. Limited access to medicines means that long travel with additional financial burden may be necessary. Handling shortages, prioritizing patients, or conducting suboptimal care also places a heavy toll on healthcare professionals through moral distress, stress, and burnout. In resource-poor environments, these pressures stretch provider-patient relationships and diminish overall quality of care.

7. MITIGATION STRATEGIES

The problem of drug shortages has been widely explored and tackled in more developed continents like the United States of America, Canada, the European Union, and Oceania. In other Asian and African nations, the lack of extensive research and discussion on the problem is a serious gap identified among low- and middle-income countries. Despite the help given by global bodies like the World Health Organization and the International Pharmaceutical Federation, the problem of drug shortages continues to be an international problem, stressing the need for flexible and universally applicable solutions.

In terms of addressing shortages on an institutional level, hospitals and community pharmacies deal with medication shortages by looking for alternative formulations, using divergent suppliers, formulary changes, and catering to most critically in-need patients. Shortages can also be handled through controlled consumption of available supplies, redistribution of these supplies, extending expiry dates based on scientific rationale, and strategies for waste reduction, especially in expensive medications.

There are operational improvements like: strengthening communication among stakeholders, centralized drug shortage reporting systems, incentives for generic drug manufacturing, upgraded quality control measures, and diversification of raw material suppliers. Policy interventions become imperative because there is a need for binding advance notification of supply disruptions. Establishment of dedicated governmental units must be considered. There should also be the adoption of a uniform definition for drug shortage, formulation of national and international guidelines, credible pricing models, and fast-track regulatory approvals for essential medicines.

Education and awareness of the pharmaceutical supply chain are considered key components of effective shortage management, good patient communication, and the minimization of medication errors for a number of professions, particularly within the field of pharmacy.

8. MITIGATION STRATEGIES: A REGULATORY AFFAIRS PERSPECTIVE

From the perspective of regulatory affairs, managing drug shortages requires prospective surveillance, legal enforcement, policy flexibility, and effective stakeholder coordination. At the center of it all, regulatory authorities monitor supply chains through national databases of shortages and early notification requirements for anticipated supply chain disruptions. Accelerated approval pathways, emergency importation, and risk-based regulatory flexibility-including temporary GMP waivers, expiry extensions, or emergency use authorizations-support continued access to lifesaving medicines in emergency situations. This transparency along the supply chain, including disclosure of manufacturing sites and sources of raw materials, helps enable early intervention and equitable distribution. Regulators can also incentivize manufacturers to produce low-profit essential medicines through fee waivers and expedited reviews. Global regulatory harmonization, effective risk communication, integration of pharmacovigilance with shortage monitoring, and ethical allocation frameworks further strengthen preparedness and patient safety in the context of severe shortages.

9. CONCLUSION

Medicines shortages have emerged as an important global concern posing threats to patients receiving adequate care within healthcare settings. Medicines shortages have emerged due to several factors, some of which include quality failures, raw material shortages, regulatory hurdles, economic inefficiencies, and supply chain challenges. Considering regulatory affairs, the key to effective management of medicines shortages lies in monitoring, mandatory reporting, accelerated approvals, regulatory flexibility, and transparency of the supply chain. In long-term solutions, the key lies in improving policies, local medicine manufacturing, global regulatory standards, and effective risk communication.

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