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REGULATORY CHALLENGES TO TACKLE SHORTAGE OF MEDICINAL PRODUCT FOR MARKET AUTHORIZATION HOLDERS IN EU

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ABSTRACT

A "shortage" is defined as a disruption in the supply of a medicinal ingredient, and it is a worldwide issue. The study's main goal is to gather and publish information regarding drug shortages in European nations. This study covered countries like Belgium, the Netherlands, England, Italy, France, Germany, and Spain that had medicine shortage reporting systems. Information was gathered from publicly accessible internet reporting systems regarding the attributes of the drugs that are in limited supply as well as the reasons for the shortage. There were descriptive analyses carried out. Oral, branded medications that target various disease domains might be classified as drug shortages that are taken into account by the reporting systems under consideration. Generic injectables are more complex when critical medications and cancer treatments are taken into account. The reasons behind medicine shortages are not well acknowledged. If the reason is known,

production issues come first. Medicine shortages have an impact on patient care and healthcare services. For shortages to be effectively managed, there must be greater openness and information availability about current and upcoming shortages, as well as improved healthcare professional readiness. Across the globe, concerns about medication shortages are growing. Authorities in the European Union (EU) have started a number of initiatives to address this significant public health concern. Vaccines Europe (VE), a group that represents 14 European vaccine firms, carried out an analysis of the primary reasons of vaccine shortages in Europe in order to aid in the search for solutions. Six primary causes of vaccine shortages have been identified by Vaccines Europe. It will take a coordinated effort and communication with all important players to find solutions.

Keywords: Drug shortage, Drug supply, Health policy

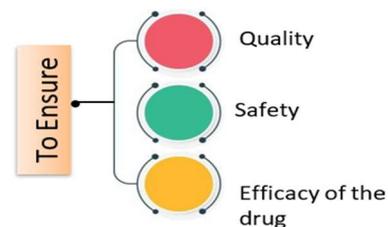
INTRODUCTION:

Medicine shortages, recognized by the European Medicines Regulatory Network (EMRN) and international organizations like the World Health Organization, have been a global issue for some time, affecting European countries and significantly impacting patient care. The EU is experiencing a serious shortage of medicines, mostly as a result of the coronavirus pandemic. There is now a greater chance of patient supply holdups, and new, expensive medications' accessibility and availability have become major political issues. The European Commission identifies a number of reasons for the scarcity of medications, such as production problems, industry restrictions, illicit trading, and economic considerations like cost [1].

The European Union (EU) boasts one of the most advanced and rigorous pharmaceutical regulatory frameworks globally, designed to

ensure the safety, efficacy, and quality of medicinal products available to its citizens [2].

Due to growing workloads and the migration to alternative therapies, drug shortages will have a



financial impact [3].

Importance of addressing medical product shortage:

- Patient Safety and Public Health
- Healthcare System Efficiency
- Economic Impact [4]

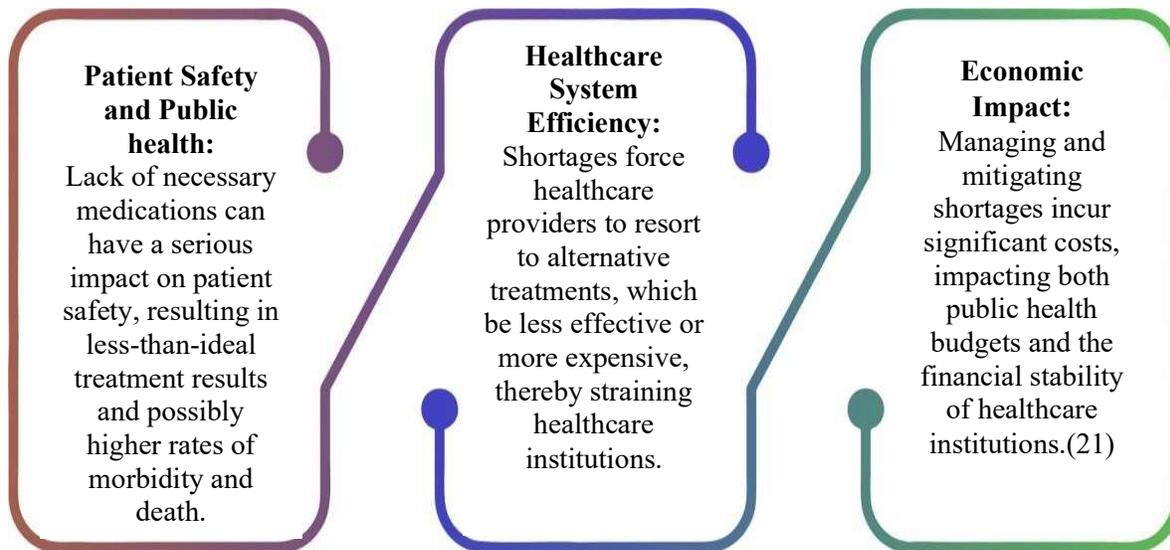


Figure 1: Importance of addressing medical product shortage

Challenges Faced by Market Authorization

Holders:

Market Authorization Holders (MAHs) play a crucial role in ensuring the continuous supply of medicinal products. However, they face several regulatory challenges that can contribute to shortages:

- Regulatory Compliance and Burden
- Supply Chain Vulnerabilities
- Economic Pressures
- Transparency and Communication
- Regulatory Harmonization [5]

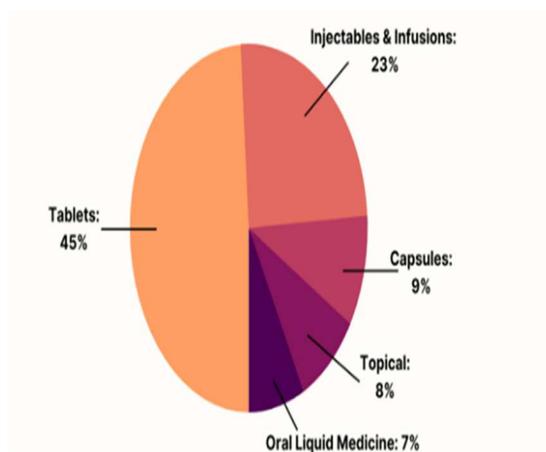


Figure 2: Top Five EU Drug Shortage Notifications by Different Dosage Forms

Strategies to Address Regulatory

Challenges:

To mitigate the regulatory challenges

contributing to medicinal product shortages, several strategies can be considered:

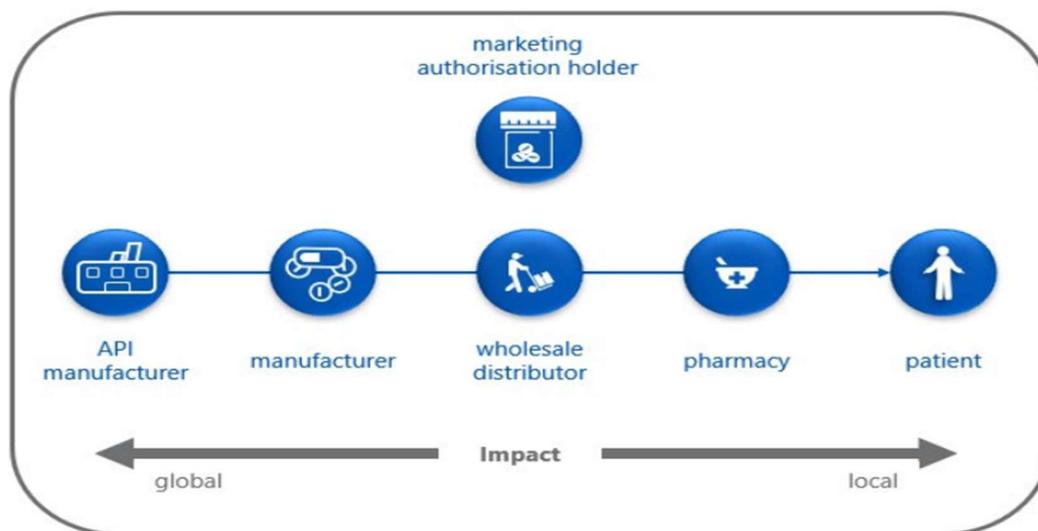
- Regulatory Flexibility and

- Innovation
- Enhanced Supply Chain Management
- Collaborative Approaches
- Regulatory Harmonization
- Incentives and Support [6]

authorizations, or MAHs, are tasked with monitoring the flow of their medications from the point of manufacture to the final consumer. They also have an obligation to guarantee that patients will continue to receive their medications as long as they fulfill their responsibilities [5].

Marketing Authorization Holder:

Those who possess marketing



Medicine Shortage and Availability issues:

Improving the quality of medications approved in the EU is a top priority for the European Medicines Agency (EMA) and the European Medicines Regulatory Network. The medicine supply chain is severely hampered by shortages or problems with medicine availability, which may endanger the health of humans and animals. Due to causes including production problems, quality problems, or rising demand, shortages of medications can have a major impact on

patient care. Working with regulatory bodies inside and outside of Europe, the European Medicines Regulatory Network seeks to avoid and reduce the effects of drug shortages on patients by:

- In order to handle their manufacturing and distribution problems as well as any potential emergencies, the person is currently working with pharmaceutical businesses.

- The objective is to provide knowledge about alternate supply sources to global partners.
- To help with decision-making, the program solicits feedback on the effects of medicine shortages from patients and medical professionals.
- putting policies in place to allow the use of substitute medications or suppliers [7]

Public information on shortages in the EU/EEA: improvements made among 2023:

1497 hospital pharmacists (HPs), doctors (PHYs), nurses (NRS), and other healthcare professionals participated in the survey (OHCPs). 86% of OHCPs and 95% of HPs said that shortages of medications were a continuous problem. The main reasons for the shortfall were issues with the supply chain (50%) and production (67%) as well as active medicinal ingredients (77%). In 2022, medical device shortages affected more than 60% of HPs. The main effect of medicine shortages was delays in care.

- ✓ **European Voluntary Solidarity Mechanism:** Launched on 24 October 2023 to address critical shortages in Member States.
- ✓ **Union List of Critical Medicines:** To be published by the end of 2023.

- ✓ **EU Guidance on Procurement:** To be issued by early 2024 [8]

Stepping up action to prevent shortages of medicines in Europe:

- ✓ Creating a list of essential medications for the EU.
- ✓ Organizing collaborative efforts to enable regulation exemptions in order to supply patients with medications.
- ✓ EU procurement guidelines to enhance supplier security.
- ✓ Purchasing medicines and respiratory virus treatments jointly by the EU for the upcoming winter.

Can the EU solve the drug shortage issue?

Theoretically, the EU ought to be more equipped than ever to handle a crisis affecting the entire bloc. It recently updated its laws to address dangers to public health, including as a shortage of prescription drugs. The EMA now has more authority to keep an eye on medication shortages. Additionally, a brand-new organization called the Health Emergency Preparedness and Response Authority (HERA) has been established, granting it the authority to acquire medications for the whole EU on the open market. The ability to ask suppliers for information on medicine inventories and manufacturing capacity as well as ideas on mitigating shortages would be granted to an

EMA steering group for shortages [9].

✓ To examine the challenges and opportunities in EU.

Objectives:

The objective of the study is,

✓ To develop Regulatory Flexibility for Emergency Use in EU.

✓ To evaluate Impact on EU Healthcare.

Methodology:

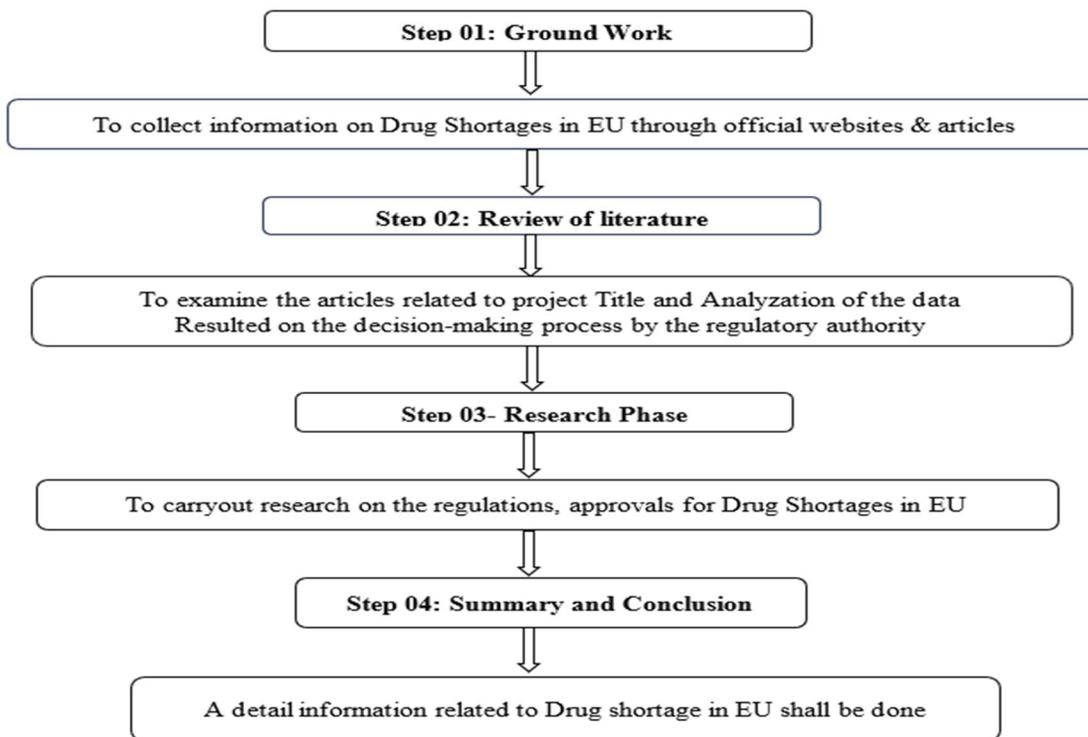


Figure 4: Methodology

RESULTS AND DISCUSSION:

The EMA defines a medicine shortage as "a situation in which the demand for a medicine exceeds its supply." Medicine shortages are recognized as a global problem by the **European Medicines Regulatory Network (EMRN)** and other international organizations such as the World Health Organization. For a while now, shortages have been a global

problem that has gotten worse in European nations, notably harming patient care [10].

Identifying the root causes of medicines shortages:

Stakeholders in the supply chain collaborated to determine the underlying reasons behind pharmaceutical shortages. A partial summary of the main factors contributing to drug shortages is provided in the table below, which is arranged by category [11].

Table 1: Summary of root causes of medicines shortages

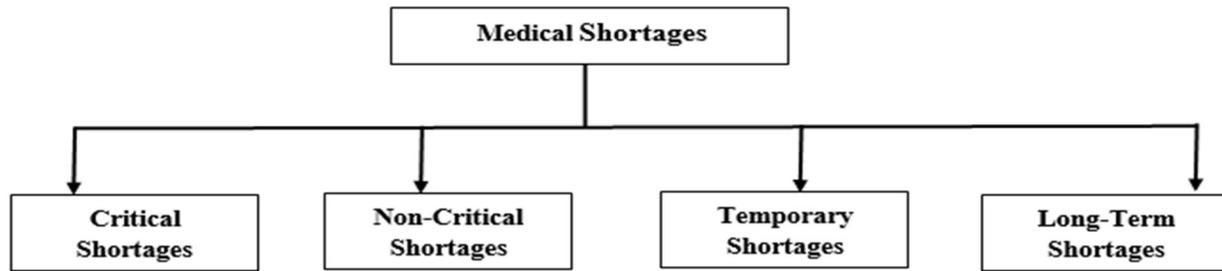
		Regulatory	Manufacturing and quality	Economic	Supply chain
Products not authorized		Regulatory time lag	NA	NA	NA
Products authorized but not launched		National requirement	Manufacturing capacity Natural disasters	Market conditions	NA
Products authorized and marketed but unavailable due to shortages	Temporary	NA	Manufacturing lag times GMP issues Surges in demand API and excipient supply	Pricing mechanisms Tender practices Cost-containment measures	Supply quotas and parallel export Logistical inefficiency
	Permanent	NA	Manufacturing capacity	Commercial withdrawals	NA

Defining and Understanding Medical Product Shortages:

Shortages of medications can be caused by issues with production, issues with medication quality, or a rise in demand. To combat this, the EMA works with pharmaceutical firms to address problems related to production and

delivery, exchanges knowledge about alternate supply sources worldwide, solicits feedback from patients and medical professionals, and permits the use of substitute medications or suppliers when required.

Classification of Medical Product Shortages:



➤ **Critical Shortages:**

These involve products essential for treating life-threatening or severe conditions with no available alternatives. Immediate action is required to address these shortages.

➤ **Non-Critical Shortages:**

These involve products where alternatives are available, or the conditions treated are not life-threatening. The impact is less severe, and the response can be more measured.

➤ **Temporary Shortages: or Short Term**

These are expected to be resolved within a short timeframe. Communication with healthcare providers and stakeholders is essential to manage the interim period.

➤ **Long-Term Shortages:**

These are expected to last for an extended period and may require long-term strategic planning, including finding alternative sources or increasing production capacity [12].

A comprehensive characteristic of different type of Shortages: -

Table 2: characteristic of different type of Shortages

Critical Shortages	Non-Critical Shortages	Temporary Shortages	Long-Term Shortages
Definition: Involves drugs essential for treating life-threatening or severe conditions with no available alternatives.	Definition: Involves drugs where alternatives are available or the conditions treated are not life-threatening.	Definition: Expected to be resolved within a short timeframe.	Definition: Expected to last for an extended period.
Impact on Health: High impact, as the unavailability can lead to significant adverse health outcomes or increased mortality.	Impact on Health: Moderate impact, as alternative treatments or solutions are available.	Impact on Health: Short-term impact on supply and healthcare delivery.	Impact on Health: Long-term impact on healthcare delivery and patient outcomes.
Urgency: Requires immediate intervention to address the shortage.	Urgency: Less urgent compared to critical shortages, allowing for a more measured response.	Urgency: Requires prompt but temporary measures to manage the shortage.	Urgency: Requires strategic long-term planning and intervention.
Regulatory Action: Often necessitates urgent	Regulatory Action: Standard regulatory	Regulatory Action: May involve temporary	Regulatory Action: May require changes in

regulatory approvals or fast-tracking alternative solutions.	procedures suffice; no need for urgent action.	regulatory adjustments or allowances.	regulatory policies, approvals for new manufacturers or sources.
Stakeholder Involvement: High level of coordination required among healthcare providers, regulators, and manufacturers.	Stakeholder Involvement: Involves healthcare providers and patients to manage and switch to alternatives.	Stakeholder Involvement: Coordination with manufacturers and suppliers to expedite resolution.	Stakeholder Involvement: Involves extensive coordination among regulators, manufacturers, and international bodies.
Risk Management: High priority on risk management and mitigation strategies.	Risk Management: Lower priority on risk management compared to critical shortages.	Risk Management: Short-term risk management strategies to bridge the gap.	Risk Management: Comprehensive risk management and mitigation strategies for long-term stability.

Regulatory related root causes:

In Europe, the pharmaceutical regulation guarantees the efficacy, safety, and quality of medications. For this reason, each pharmaceutical product sold in the European Union needs to have a current Marketing Authorization (MA).

"When supply falls short of demand at the national level, there is a shortage of a medicinal product for human or veterinary use."

There are two specific instances when shortages can be linked to the time required to meet regulatory requirements:

1. Regulatory time lag
2. National requirements (e.g. different pack size in the context of the decentralized method)

Manufacturing and quality related root causes:

Producing pharmaceuticals is difficult and necessitates highly advanced infrastructure, protocols, and highly skilled personnel to guarantee the effectiveness, safety, and quality of the

resulting drugs.

Manufacturing capacity

- Manufacturing lead delays,
- Gmp problems



- Demand spikes as well as api and
- Excipient supplies

Economic related root causes:

accumulating data about the underlying economic reasons of the shortage of medications. The supply chain for pharmaceuticals involves a number of economic players. In many European markets, the buyer also sets the prices, a phenomenon known as a monopsony. The reasons of economic-related shortages are multifaceted and intricately interact with one another as well as with other underlying causes.

- Market circumstances,

- pricing guidelines,
- tender procedures,
- cost-cutting techniques, and
- commercial withdrawals

Supply chain related root cause:

To make sure the proper medication reaches the right patient, a variety of stakeholders with a shared interest are involved in the supply chains for medicines. It is probable that problems relating to these elements will cause drug shortages because of the intricacy of the supply chain, the economic relationships between the various parties involved, and the difficulty of manufacturing, storing, distributing, and dispensing medicines.

- ✓ **Supply quotas and parallel export.**
- ✓ **Logistical inefficiency [11].**

Drug Information Services (UUDIS)

▪ **Determinants of drug shortages:**

Drug shortages were described by the interviewees as a complex and multifaceted problem. They were asked to identify the true causes of drug shortages and consider the typology of drug shortages given in Birgli's report. Of the many reasons for the drug shortages mentioned in the report, the most significant ones are listed below in decreasing order of frequency by the interviewees

- Manufacturing issues,
- Restricted production capacity,
- Parallel distribution,
- Shortages and limitations on raw materials, and
- Non-compliance with regulations are the first five issues.

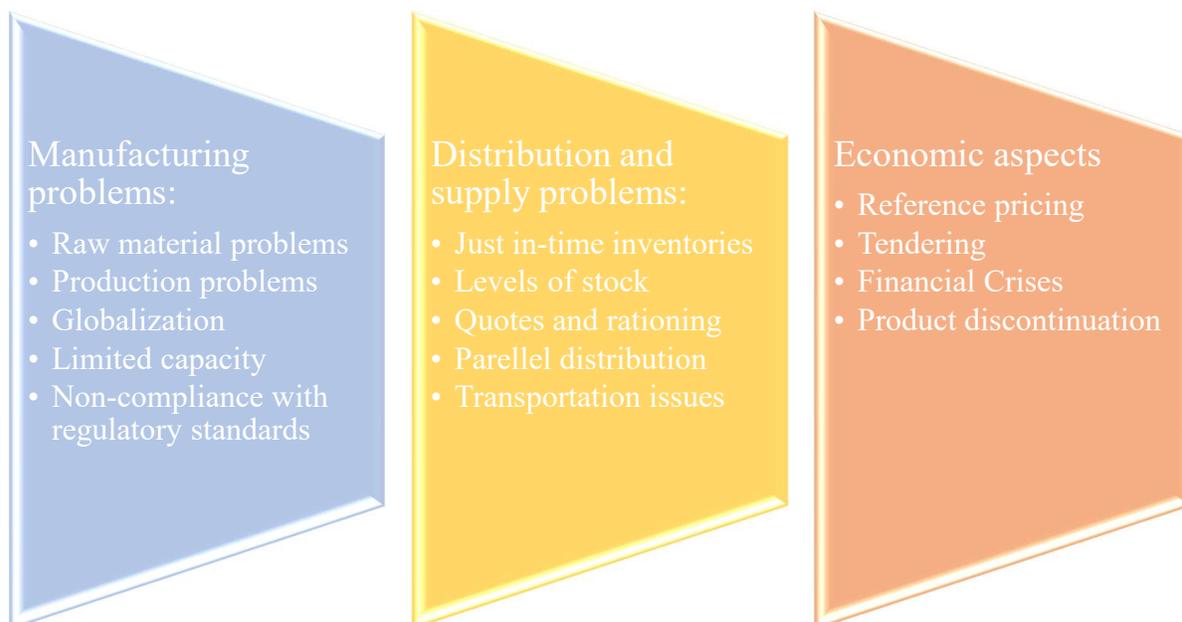


Figure 5: Categories and sub-categories of the reported determinants of Drug Shortage

Issues with raw materials, manufacturing facilities, global sourcing, production quality, manufacturing capacity, and non-compliance with regulatory norms can all lead to manufacturing challenges [13].

Management of Current Drug Shortage:

- **Restrictions on the use of current stock:** The A4R framework is a crucial tool for limiting drug stock in healthcare facilities, prioritizing patients receiving restorative therapy, children, cancer patients, clinical study participants, and those following treatment plans that improve survival, especially for anticancer, emergency, and rare generic medications in Fijian institutions.
- **Use of products with minor defects:** The US FDA has approved minor flaws in medications, such as particulate matter, incorrect packaging, labeling errors, glass particles in injectables, and non-registered drugs, provided they are handled appropriately and risk assessed.
- **Increase of expiry date:** The US FDA has extended the shelf life of coral snake antivenin due to shortages, as the manufacturer stopped producing the medication.
- **Redistribution of available stock:** Manufacturers must ensure consistent drug supply redistribution in case of

shortages, requiring effective communication, transparency, and a robust reporting system for efficient and equitable distribution.

- **Development of the medical expert platform:** A medical expert platform can help manage medication shortages by pharmacists, doctors, and nurses. The platform should manage current shortages, inform about upcoming shortages, and explore alternative therapies. It should enhance dialogue between institutions and other ones. The US has established a framework for anticipating and analyzing shortages. High-risk medications may have serious side effects, and cancer patients should only take off-label medications.
- **Wastage management:** Small dosages frequently result in medication waste while treating chronic illnesses, especially in pediatric and cancer patients because of their limited shelf lives. In order to deal with this, US hospitals group patients for chemotherapy appointments on particular days, and anesthesia departments employ the twin syringe method. This tactic aids in overcoming shortages, stops medication waste, and instructs carers on managing shortages [14].

Improvement in Operations:

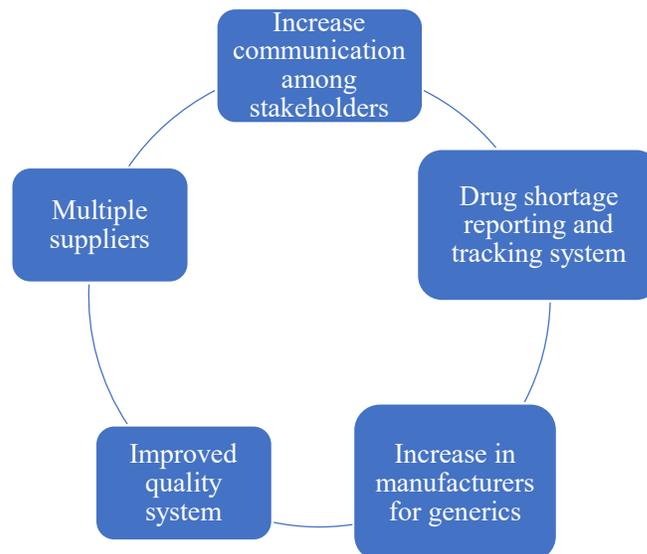


Figure 6: Different categories in Improvement in Operations

Medication shortages require coordination between national and international regulatory bodies and stakeholders. A tracking and reporting system can help report information about the duration, frequency, drugs involved, causes, effects, managing methods, and forecasting future shortages. Some medications, like injectables and generics, are more likely to run out due to low prices and high costs due to GMP regulations. An incentive pricing system is needed to encourage more producers to produce these medications. Quality of a drug can be compromised during production, storage, shipping, and administration. Manufacturers should contact multiple suppliers for a specific raw material and regulatory bodies should consider medications with only one

source at the moment [15].

Changes in Governmental Policy

- uniform definition,
- advance notification systems,
- pricing, and
- changes to government policies and initiatives.
- Rapid medication evaluation [14]

PROPOSE SOLUTIONS TO TACKLE SHORTAGES:

1. Shortage Prevention Plans:

Implementing robust plans to prevent shortages:

The European Medicines Agency (EMA) is actively addressing medicine shortages through the European Shortages Monitoring Platform (ESMP). This platform gathers

information about medicine supply and demand in the European Union (EU) and European Economic Area (EEA) to prevent, detect, and manage shortages. Here's how it works:

Role of the Platform:

- ✓ During crisis situations (such as public health emergencies or major events), the ESMP monitors critical medicines' supply, demand, and availability.
- ✓ EMA publishes a list of these critical medicines for each crisis situation.
- ✓ Outside crises, the platform helps:
- ✓ Monitor supply and availability when requested by EMA's Executive Steering Group on Shortages and Safety of Medicinal Products.
- ✓ Prevent and manage shortages that could lead to public health emergencies.
- ✓ Enable marketing authorization holders to routinely report shortages of centrally authorized products.
- ✓ Development and Milestones:
- ✓ EMA follows an Agile approach, gradually adding features to the platform over time.
- ✓ the first version of the ESMP will be available by February 2025.
- ✓ Key developments include adopting Regulation (EU) 2022/123 and

registering industry single points of contact for medicine supply and availability [16].

2. Transparency:

The European Medicines Agency (EMA) has increased transparency in stock levels and demand since 1995, publishing detailed information on its scientific assessment work and explaining its decisions and procedures. The Agency has proactively released updates on its activities and allows the public to request information and documents in accordance with its rules on access to documents and information, balancing commercially confidential information and personal data protection [17].

3. Mandatory safety stocks:

The European Union is implementing mandatory safety stocks for marketing authorization holders (MAHs) to ensure the availability of essential medicines in case of supply disruptions. The European Medicines Agency (EMA) recommends strategies to prevent shortages, diversify suppliers, and enhance manufacturing capacity. MAHs must monitor supply and demand, communicate openly with operators, and handle any shortages. Directive 2001/83/EC requires MAHs to notify authorities of anticipated disruptions for early action and contingency planning [7].

4. Early Notifications:

The European Medicines Agency (EMA) has provided Marketing Authorization Holders (MAHs) with instructions on identifying and alerting authorities to potential shortages using uniform reporting templates. Task forces have been established to improve coordination and response to drug shortages. Legislation proposals aim to improve supply chain resilience and ensure the availability of essential medications by reinforcing early reporting regulations. Finland has demonstrated the effectiveness of financial incentives in incentivizing prompt reporting of shortages through increased notification fees. However, member state early warning requirements vary widely, and a significant percentage of shortages are reported on the day they start or later. The EU's approach aims to minimize patient care effects and maintain vital medication supply [18].

5. EU Coordination:

The European Union has implemented strong coordination mechanisms to manage and prevent drug shortages, involving cooperation between the European Medicines Agency, the European Commission, and Member States. In 2022, the EMA extended its mandate to improve coordination with the pharmaceutical industry during crises, focusing on quick meetings and regular engagement to address

supply issues. The pharmaceutical sector plays a crucial role in providing safe, modern, and affordable therapies for disease diagnosis, treatment, and prevention. However, innovative therapies may not reach all patients across Europe at the same speed, leading to shortages. The coronavirus pandemic underscored the importance of crisis-resistant systems and ensuring availability of medicines. The EU faces rising disease burdens, rising health threats, and increasing dependence on non-EU countries for importing medicines and active ingredients. The Communication on a Pharmaceutical Strategy for Europe aims to address these challenges and adapt the EU pharmaceuticals system [19].

EFFECT OF SHORTAGES:

Drug shortages have an impact on a wide range of stakeholders, including patients, researchers, administrators, buyers, and medication safety officials. The adverse consequences can be broadly classified into two groups: clinical and economic.

1. Economic Effects: 99% of respondents reported at least one drug shortage in the previous six months, demonstrating the substantial impact drug shortages have on health systems. More shortages are anticipated to occur in larger facilities. In US hospitals, the annualized human expenses for

handling medication shortages came to almost \$216 million. Nevertheless, this estimate does not account for the whole cost of staff or the expenditures incurred by patients and society as a whole due to medication shortages. Moreover, rising commodity prices are a further economic worry. According to a Premier Healthcare Alliance poll, 98% of participants reported that there was a shortage that increased prescription costs, frequently as a result of off-contract purchases.

clinical risk to patients. The number of patients affected is difficult to quantify due to the lack of a national reporting system. Data on patient harm is mainly based on case reports or surveys. Medication shortages increase the risk of medication errors and adverse patient outcomes. High vulnerability areas exist in the medication use process, particularly when purchasing a different brand or concentration of medication or ordering unfamiliar medications [20].

2. Clinical Effects: Drug shortages in the United States pose a significant economic and

Reporting Template for drug shortage:

Drug identity				
Name	Active substance	Dose	Company	
Drug classification				
Brand or generic? <input type="checkbox"/> Brand drug <input type="checkbox"/> Generic drug	Prescription drug <input type="checkbox"/> Yes <input type="checkbox"/> No	Route of administration <input type="checkbox"/> Oral <input type="checkbox"/> injectable <input type="checkbox"/> Insert or implant <input type="checkbox"/> Topical or dermatological	Distribution <input type="checkbox"/> Community pharmacy <input type="checkbox"/> Hospital use only	
ATC code	Marketing authorization obtained via centralized procedure? <input type="checkbox"/> Yes <input type="checkbox"/> No	Drug classified as essential medicine by the WHO? <input type="checkbox"/> Yes <input type="checkbox"/> No		
Characteristics of the drug shortage				
Start date	End-date	Cause	Existence of alternative (generic) drugs <input type="checkbox"/> Yes <input type="checkbox"/> No	Source

Figure 7: Reporting Template for drug shortage

SUMMARY AND CONCLUSION:

The ongoing drug shortage problem in the US is a form of healthcare rationing affecting clinicians and patients daily. Stakeholders and the FDA are working on potential solutions, with progress made due to companies reporting problems earlier to the FDA. Remediation efforts and additional capacity are underway at large manufacturing facilities, and it is anticipated that shortages will decrease in the coming years. Further exploration is being conducted to determine if incentives are needed for firms to maintain adequate quality and encourage backup plans and redundancy. The use of quality metrics is another area being explored by the FDA and other organizations. Economic globalization has promoted the delocalization and gathering of manufacturing sites of drug substances and medicinal products, stressing the resilience of the pharmaceutical supply chain to shortages. Stronger coordination at the EU-level and harmonization of communication, risk-assessment, and risk-management strategies are desirable and urgent.

REFERENCES:

- [1] Scholz N. BRIEFING EPRS | European Parliamentary Research Service.
- [2] Medicines Agency E. Guidance on detection and notification of shortages

of medicinal products for Marketing Authorisation Holders (MAHs) in the Union (EEA) [Internet]. 2019. Available from: www.ema.europa.eu/contact

- [3] Pauwels K, Huys I, Casteels M, Simoens S. Drug shortages in European countries: A trade-off between market attractiveness and cost containment? BMC Health Serv Res. 2014 Sep 26;14(1).
- [4] Addressing the root causes of medicines shortages Supply chain Stakeholders' views on root causes and solutions. 2019.
- [5] Medicines Agency E. Good practices for industry for the prevention of human medicinal product shortages [Internet]. Available from: www.ema.europa.eu/contact
- [6] McKinsey & Company. Regulatory Strategy.
- [7] Website (EMA). Medicine shortages and availability issues.
- [8] Addressing medicine shortages in the EU today, tomorrow and beyond.
- [9] Website (EMA). Europe is running out of medicines.
- [10] Acosta A, Vanegas EP, Rovira J, Godman B, Bochenek T. Medicine Shortages: Gaps Between Countries

- and Global Perspectives. *Front Pharmacol.* 2019 Jul 19;10.
- [11] Addressing the root causes of medicines shortages Supply chain Stakeholders' views on root causes and solutions. 2019.
- [12] Ravela R, Airaksinen M, Lyles A. State of the European Union's early notification obligation for drug shortages: enforcement and compliance in eight European countries (2020–2022). *J Pharm Policy Pract.* 2023 Dec 1;16(1).
- [13] Bogaert P, Bochenek T, Prokop A, Pilec A. A qualitative approach to a better understanding of the problems underlying drug shortages, as viewed from Belgian, French and the European Union's perspectives. *PLoS One.* 2015 May 5;10(5).
- [14] Shukar S, Zahoor F, Hayat K, Saeed A, Gillani AH, Omer S, *et al.* Drug Shortage: Causes, Impact, and Mitigation Strategies. Vol. 12, *Frontiers in Pharmacology.* Frontiers Media S.A.; 2021.
- [15] Website (EMA). European Shortages Monitoring Platform.
- [16] Website (EMA). Transparency.
- [17] Website (European Commission). Critical shortages of medicines: by name and by nature, a pressing EU topic.
- [18] Website (EMA). A Pharmaceutical strategy for Europe.
- [19] Fox ER, Sweet B V., Jensen V. Drug shortages: A complex health care crisis. Vol. 89, *Mayo Clinic Proceedings.* Elsevier Ltd; 2014. p. 361–73.