

Drug Shortage Concepts among Stakeholders in Saudi Arabia

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Keywords

Knowledge · Practice · Satisfactions · Drug shortage · Reporting system · Saudi Arabia

Abstract

Introduction: The SFDA internal records showed that several pharmaceutical entities (National Unified Procurement Company (NUPCO) and Saudi Food and Drug Authority (SFDA) are overlapping in their tasks within the system of drug availability in the Saudi market. This may have led to difficulties in terms of contacting which entity when drug shortages occur. This study aimed to identify stakeholders' understanding of drug shortage, the internal process of reporting a drug shortage to the SFDA, and to evaluate the clarity of the communication channels and the stakeholder's satisfaction regarding drug shortage reporting system at SFDA. **Method:** A cross-sectional study conducted between December 2020 and August 2021. The study consisted of three separate surveys targeting the main stakeholders including healthcare institution (hospitals and pharmacies), NUPCO, and registered pharmaceutical companies/storage) with a response rate of (68.07%). The survey consists of three main parts: knowledge, practice, and perception of drug shortage reporting system at SFDA. **Results:** Healthcare institution defined drug shortages as unavailability of the product after confirmation of unavailability by the agent by 65.3% and low stock generic product by 44.9%. Nonetheless,

67.3% of healthcare institutions planned for inventory stock based on several factors such as the need of the stock/product and consumption of the products per different periods. Moreover, NUPCO identified the drug shortages by two factors when the stock of brand drug is zero and after pharmaceutical companies confirm the unavailability of the product. Additionally, all of the stakeholders were aware of SFDA communication channels for drug shortages. **Conclusion:** Based on our results, the internal workflow of stakeholders on the issue of drug shortages was reviewed and most responses provided a general overview of the internal processes for handling drug shortages, reporting steps, and submitting drug shortage reports. Nonetheless, when it comes to choosing the right provider for a healthcare facility, price and delivery time are major factors that influence their decision. In addition, it is recommended that further investigation of internal workflows be conducted to measure aspects that may affect the clarity and quality of services provided by the SFDA.

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Introduction

The United States Food and Drug Administration (FDA) defines drug shortage as “a period of time when the demand or projected demand for the drug exceeds the supply of that drug” [1]. A similar definition is used by

the Saudi Food and Drug Authority (SFDA): when a drug is in shortage or unavailable because supply from the warehouses of the official agent does not meet the needs of the health facilities [2].

Drug shortages pose a significant public health concern worldwide, considering that medications are the pillar of modern medical care. Drug shortages can lead to delays in treatment, thereby worsening patients' health outcomes and disease progression, increasing the cost of healthcare, and reducing patient satisfaction [3].

Some of the many factors that lead to drug shortages include large and sudden surges in demand, manufacturing and quality problems, insufficient quantities of raw materials, and discontinuation of ingredients [4]. During the coronavirus disease 2019 (COVID-19) pandemic, many hospitals and pharmacies could not cope with the large demand for critical medications such as propofol, midazolam, chloroquine, and hydroxychloroquine [5].

Few studies have investigated drug shortages in Saudi Arabia. One of these, a 2005 study conducted at the outpatient pharmacy of a tertiary referral teaching hospital in Riyadh, found that 9% of prescriptions went undispensed due to drug unavailability [6]. A cross-sectional study of 10 hospitals in Riyadh investigated the prevalence of drug shortages. The study showed that cardiac drugs such as beta blockers and renin-angiotensin blocking agents were reported to be in shortage by more than one-third of participants and that more shortages were reported of generic drugs than branded drugs. However, more than 50% of participants reported that drug shortages usually lasted less than a month [7]. Recently, another cross-sectional study published in Saudi Arabia assessed the impact of COVID-19 on essential drugs such as various antivirals (lopinavir/ritonavir) and steroids (dexamethasone, prednisolone, and hydrocortisone) and found that at least 8% of the participants experienced shortages of these essential drugs [8]. Finally, a study conducted in Riyadh to measure pharmacists' awareness of drug supply shortages showed that most participating pharmacists (53.7%) only learned that a drug was in short supply when it was at zero stock [6].

The SFDA has a system to report drug shortages and track all drugs registered in Saudi Arabia through a program called the Drug Track and Trace System (RSD). It is worth mentioning, however, that very few of the drug shortage studies investigated here discussed issues around this system. The objective of the RSD is to ensure and enhance the safety and availability of all medications by tracking them from manufacture to delivery to the patient [9]. Stakeholders including hospitals, com-

munity pharmacies, pharmaceutical and biopharmaceutical companies, and the National Unified Procurement Company (NUPCO) are expected to report any drug shortage to the SFDA. However, the presence of several entities with overlapping tasks in the Saudi drug industry has resulted in discrepancies and lack of consensus on the meaning of drug availability. It is necessary to study these variations and to apply the results of this study to achieve a more unified concept of drug availability in Saudi Arabia. In addition, the results of this study could provide an important building block for legislation regarding drug availability in Saudi Arabia, which in turn aligns with the SFDA's vision of protecting and promoting public health.

Therefore, this study aims to assess the knowledge and concepts of drug shortage among key stakeholders in Saudi Arabia and evaluate satisfaction toward drug shortage reporting system in the SFDA. Evaluate, understand the internal stakeholder process of reporting a drug shortage to the SFDA, and identify reporting challenges in the system.

Materials and Methods

Methods

A cross-sectional study was conducted, consisting of three separate surveys targeting the signed point of contact at the key stakeholders/healthcare providers in Saudi Arabia registered in the Drug Track and Trace System (RSD) and Saudi Vigilance as shown in Figure 1. Stakeholders were categorized under the following four groups:

- Private/governmental/semigovernmental hospitals of all sizes.
- Community pharmacies (all pharmacies that deal directly with people in their local areas and have responsibilities including counseling, checking, and dispensing of prescription drugs to patients).
- Pharmaceutical and biopharmaceutical companies.
- The NUPCO (a healthcare supply chain company based in Riyadh that centralizes procurement, storage, and distribution of pharmaceutical/medical supplies and devices to healthcare supply chain management in Saudi Arabia).

The three surveys distributed among the stakeholders were as follows:

- A survey assigned to groups A and B evaluating drug shortage concepts among hospitals and pharmacies.
- A separate survey sent to group C assessing drug shortage concepts among pharmaceutical and biopharmaceutical companies.
- A third survey sent to group D evaluating drug shortage concepts in NUPCO.

The survey links were emailed to the targeted participants in each category described above. All participants were given 1 week to complete the survey after the links were sent. For those participants

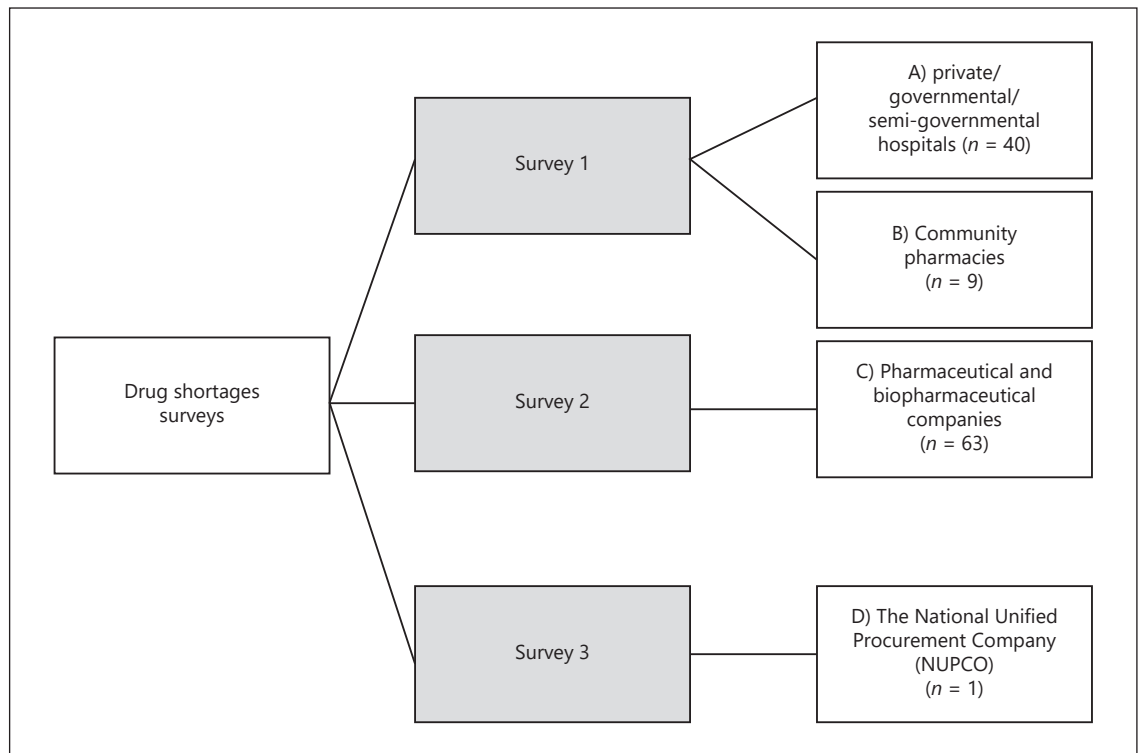


Fig. 1. Surveys distribution diagram.

who did not fill out the survey, three reminders were given via emails and phone calls before they were withdrawn from the study. The participants did not receive any financial or nonfinancial incentives.

Survey Contents

Surveys were developed by the authors based on previous research [10, 11] as well as frequent questions reported from stakeholders to the SFDA's drug availability department.

The surveys were then revised by a panel of experts including researchers and pharmacists. The surveys were validated by face validity and piloted among 20 participants from the study population who answered the electronic survey via email to ensure the initial data input, management, and coding were appropriately addressed. All three surveys are attached in the online supplementary data (for all online suppl. material, see www.karger.com/doi/10.1159/000529168).

Measurements

Knowledge and Perceptions regarding Drug Shortage Reporting System

In this part, we aim to understand and focus on the internal process of reporting drug shortages from the stakeholder's point of view. Therefore, several questions related to the internal process concept have been included.

The internal process concept of the stakeholders was assessed by asking 2 questions: (1) In terms of delivering the best care to patients and/or operating the pharmacy, are drug shortages a problem in the institution you work in? and (2) Approximately

how often does your institution experience drug shortages? A Likert scale was used to assess frequency with the following choices: Never, Sometimes, Often, Always.

For the following five questions, a dichotomous scale with answers Yes and No was used: (1) Do you search the SFDA's published list of registered human medications for a generic product before reporting a drug shortage? (2) Are you aware of the SFDA's drug shortage list? (3) Do you utilize it? (4) Are you aware of the official communication lists with pharmaceutical companies' agents in case of a drug shortage? (5) Are you aware of these circulars/forms (23615, 71295) regarding medication shortages?

One question utilized a three-point scale with answers Yes, No, and Occasionally: In case of a drug shortage, do you communicate with agents through the official communication (email) lists?

Various other questions relating to the concept were also included, such as the definition of the drug shortages, whether the stakeholder submitted drug shortage reports or reported drug shortages to the SFDA, how often the institutions experienced drug shortages, and when the institutions took stock of pharmaceutical products. All of these questions are available and categorized according to the measurement instruments used.

Practice regarding Drug Shortage Reporting System

Evaluating stakeholders' awareness of the available guidelines and system of reporting channels is an essential part of this study. Therefore, several survey questions were provided to assess the stakeholders' awareness of the SFDA drug shortage list and available

channels that provide them with all information and steps related to drug shortage reporting. For this, a dichotomous scale with answers Yes and No was used for the following 2 questions: (1) Do you consider prescribing a generic product before filing a drug shortage report? and (2) Do you search the SFDA's published list of registered human medications for a generic product before reporting a drug shortage?

Stakeholders' Feedback on the Clarity of the SFDA Communication Channels and Their Satisfaction regarding the SFDA Drug Shortage Reporting System

Clarity implies delivering a specific message to stakeholders. To understand this concept, we assessed the clarity of the provided circulars and channels from the SFDA to the stakeholders, by asking several questions related to all relevant channels and circulars. In addition, satisfaction is an essential factor to be measured; therefore, we used questions to rate the stakeholders' satisfaction with the service provided through the RSD.

For clarity, a Likert scale was used with the following answers: Very clear, Somewhat clear, and Not clear. (1) In terms of reporting steps, is the circular/form (23615/the reporting process for drug shortages)? and (2) In terms of reporting steps, is the circular form (71295/the reporting process for shortages in registered drugs)?

Additionally, stakeholders' satisfaction regarding the drug shortage reporting system at the SFDA was assessed by asking 2 questions with a 3-point Likert scale (Satisfied, Neutral, or Dissatisfied): (1) How satisfied are you with the response timeline for your drug shortage request by the SFDA? and (2) How satisfied are you with reporting drug shortages through the Saudi Vigilance system? For two related questions, a dichotomous scale with answers Yes and No was used: (1) If your institution ever reported a drug shortage, did the SFDA close your drug shortage report? (2) Do you have any suggestions or recommendations to improve the process of reporting a drug shortage?

Sample Size

The targeted stakeholders were recruited from the SFDA's RSD registry and Saudi Vigilance. The drug availability department at the SFDA provided the stakeholders' contact information (emails and phone numbers) with a response rate of (68.07%). A pilot survey for the three questionnaires was administered to 10% of the total sample population to test the clarity of the survey.

Statistical Analysis

A descriptive analysis including percentages and frequencies was performed to evaluate the knowledge and practice of the targeted stakeholders. Data analysis was conducted with SPSS version 26.0 software.

Results

A total of 166 participants in different healthcare institutions (hospitals and community pharmacies), pharmaceutical companies, and NUPCO were approached. Of these, 113 (68.07%) participants completed the surveys. More details are presented in Table 1.

Stakeholder Internal Drug Shortage Concepts/Work Process regarding Drug Shortage Healthcare Institutions

More than half of the healthcare institution participants (53.1%) stated that they face continuous drug shortage issues; in fact, half (51%) of the healthcare institutions said they experience shortages monthly. When given multiple choices to define "drug shortage," 65.3% of respondents defined it as unavailability of the product after confirmation of unavailability by the agent, 44.9% as low stock of generic product, and 30.6% as zero stock of generic drug, as shown in Table 2. In addition, approximately half (57.1%) of healthcare institutions reported to the SFDA when the agents confirmed that the product was unavailable.

Nonetheless, 67.3% of healthcare institutions planned for stock based on their demand for the stock/product, as shown in Table 2. Most healthcare institutions assessed their consumption for product restock monthly (38.8%) or every 3 months (32.7%) as shown in Table 2.

The vast majority (93.95%) of healthcare institutions depended on the SFDA registered human drug list to identify available registered medications. Furthermore, prescribing an alternative for the unavailable drug was one of the most common practices in healthcare institutions, as 89.8% considered prescribing a generic product before filing a drug shortage report with the SFDA.

Over half of the participants reported experiencing drug shortages in the following therapeutic groups: infectious diseases, oncology/hematology, anesthetic cardiovascular, emergency medications, endocrine, respiratory transplant, and other groups, as shown in Figure 2. Selecting suitable suppliers for healthcare institutions was affected by various factors: price (49%), supply time (30.1%), and other reasons (20.4%). More details are presented in Table 2.

National Unified Procurement Company

NUPCO identified two key factors in determining a drug shortage: (1) when the stock of a branded drug is zero, and (2) after pharmaceutical companies confirm the unavailability of the product. NUPCO stated that it had faced ongoing drug shortage problems. It also indicated that drug shortages occur every month, and that shortages occurred in all of the following therapeutic groups: infectious diseases, oncology/hematology, cardiovascular, emergency medications, and endocrine, as shown in Table 3.

NUPCO determined its stock availability according to the demand and the availability of the product in question. After assessing a shortage in drug supply, NUPCO

Table 1. The response of all participants/ stakeholders

Participants	Survey number	Response, N (%)
Healthcare institutions (hospitals and pharmacies)	97	49 (50.52)
Pharmaceutical companies	69	63 (91.30)
NUPCO	1	1 (100)
Total	166	113 (68.07)

NUPCO, National Unified Procurement Company.

Table 2. The healthcare institution response on the concepts/work process regarding drug shortage

Questions	N (%)
Which of the following statements describe the definition of drug shortage in your institution?	
When the stock of brand drug is zero	6 (12.2)
When the stock of generic drug is zero	15 (30.6)
Low stock of the brand product	4 (8.2)
Low stock of the generic product	22 (44.9)
Unavailability of the product after confirmation of unavailability by the agent	32 (65.3)
Other	4 (8.2)
Which situation(s) do you rely on to determine your institution's stock of pharmaceutical products?	
Stock/products demand	33 (67.3)
Stock/products availability	25 (51)
Stock projection	23 (46.9)
Other	2 (4.1)
How often does your institution estimate/assess the expected needed stock of pharmaceutical products?	
Consumption per 12 months	2 (4.1)
Consumption per 3 months	16 (32.7)
Consumption per 6 months	7 (14.3)
Consumption per month	19 (38.8)
Other	5 (10.2)
What is the most common reason for selecting different suppliers than those requested by pharmacies (wasfaty)/ hospitals?	
Supply time	15 (30.6)
Supplier history	9 (18.4)
Price	24 (49)
Other	10 (20.4)

indicated that appropriate suppliers were chosen according to the price. Moreover, the registered human medication list for generic products was the first source it consulted before reporting a drug shortage.

Pharmaceutical Companies

Drug shortages occurred among 64.6% of pharmaceutical companies; of those, 69.8% reported them to the SFDA directly, while 22.2% searched for other options to overcome drug shortages. As for assessing drug demand in the Saudi market, 41.3% of pharmaceutical companies evaluated demand every 3 months, while 14.3% evaluated monthly and 27% used different periods, as

shown in Table 4. The most commonly reported reason for drug shortages among pharmaceutical companies was demand issues (65.1%), followed by manufacturing issues (60%) and raw material shortages (38.1%), as shown in Figure 3.

Using Available Reporting Channels for Drug Shortages

Healthcare Institutions

Most healthcare institutions (79%) were aware of the SFDA communication channels for drug shortages, and 51% of respondents used these channels for communicating with the suppliers (pharmaceutical companies) to

Table 3. NUPCO representative response's on the concept/work process regarding drug shortage

Questions	N (%)
Which of the following statements describe the definition of drug shortage in your institution?	
When the stock of brand drug is zero	1 (100)
Unavailability of the product after confirmation of unavailability by the agent	1 (100)
In terms of delivering the best care to patients and/or operating the pharmacy; are drug shortages considered a problem in your institution?	
Always	1 (100)
Approximately how often does your institution experience drug shortages?	
Monthly	1 (100)
Which of the following therapeutic groups does your institution commonly experience a shortage with?	
Infectious diseases	1 (100)
Oncology/hematology	1 (100)
Cardiovascular	1 (100)
Emergency medicines	1 (100)
Endocrine	1 (100)
Which situation(s) do you rely on to determine your institutions stock of pharmaceutical products?	
Stock/products availability (time needed to order stock, price, reliability of supplier)	1 (100)
Stock/products demand (patients need, fast moving medicine, sessional diseases)	1 (100)
How often does your institution estimate/assess the expected needed stock of pharmaceutical products?	
Consumption per month	1 (100)
What is the most common reason for selecting different suppliers than those requested by pharmacies (wasfaty)/hospitals?	
Price	1 (100)
Do you search the Saudi Food and Drug Authority's published list of registered human medicine to look for generic products before reporting a drug shortage?	
Yes	1 (100)

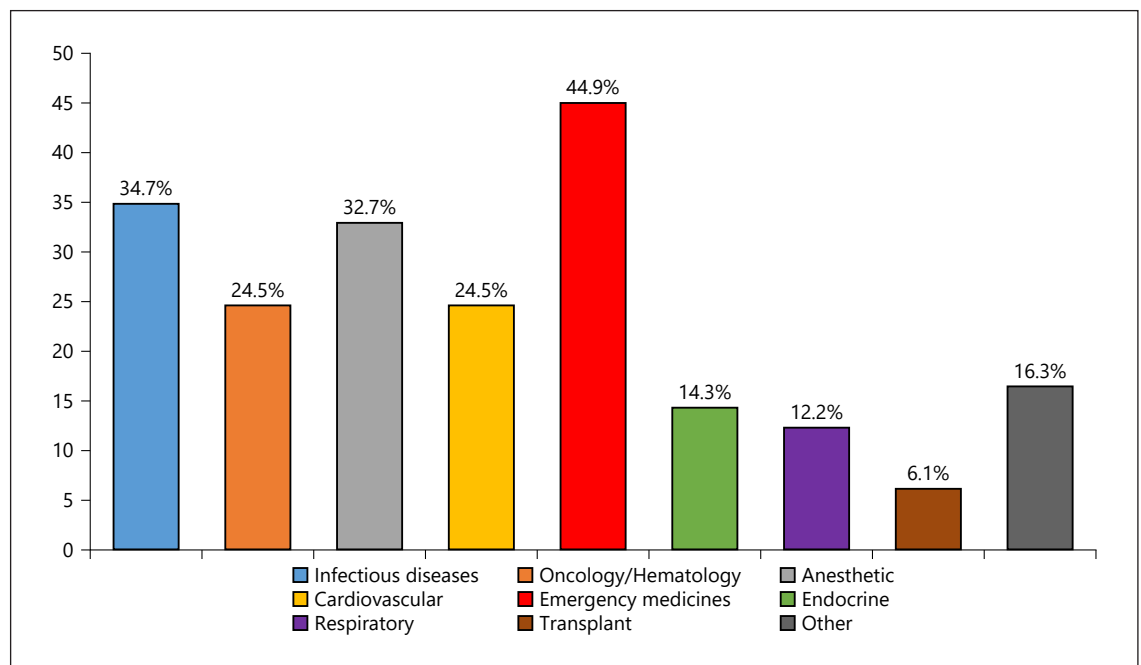


Fig. 2. The percentage of drugs in shortage according to their therapeutic groups based on healthcare institution responses.

Table 4. Pharmaceutical companies' response concepts/work process regarding drug shortage

Questions	N (%)
How often do you determine the Saudi Market Demand for your registered pharmaceutical products?	
Every 12 months	4 (6.3)
Every 3 months	26 (41.3)
Every 6 months	16 (25.4)
Other	17 (27)
When do you submit a report of drug discontinuation or expected drug shortage via drug track and trace system for pharmaceutical products (RSD)?	
After contacting SFDA and inquiring about the availability of the drug	13 (20.6)
At least 6 months before a drug discontinuation or a drug shortage is expected	34 (54)
Zero stock (brand and generic)	5 (7.9)
Other	11 (17.5)

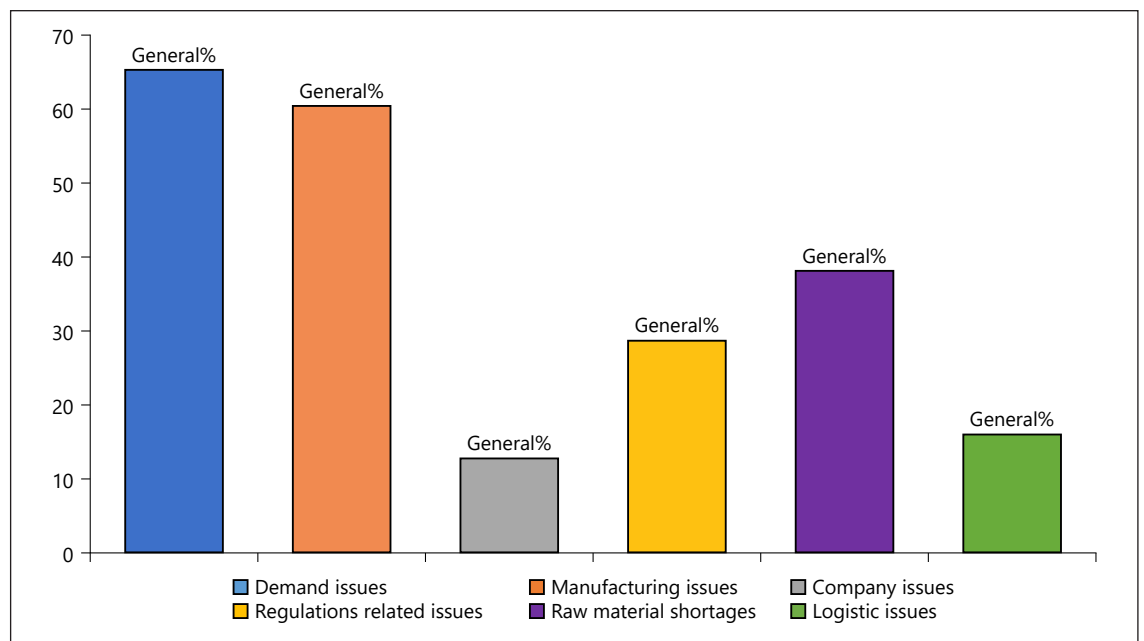


Fig. 3. Reasons for drug shortages among pharmaceutical companies.

address drug shortages. Approximately half of health-care institutions (49%) received the SFDA drug shortage circulars.

National Unified Procurement Company
NUPCO (100%) was aware of all the communication channels and was always able to use them to communicate with suppliers regarding drug shortages.

Pharmaceutical Companies
The majority of the pharmaceutical companies (76.2%) were aware of the SFDA update feature for already-submitted

reports. Additionally, 42.9% used the RSD system to update submitted reports. 60.3% of pharmaceutical companies indicated that they received guidelines for drug shortages or discontinuations via the RSD, while 81% of pharmaceutical companies said that they received SFDA circulars for drug shortage reporting steps.

Stakeholders' Satisfaction with and Feedback on the Clarity of the SFDA Communication Channels
Healthcare Institutions
Healthcare institutions had different responses toward the clarity of reporting steps: 38.8% described them as

clear, while 6.1% said they were somewhat clear and 4.15% not clear. The SFDA drug shortage reporting steps were satisfactory to 85.7% of healthcare institutions, while 69.4% of healthcare institutions indicated that the SFDA facilitated drug shortage reporting process.

Only 10.2% of healthcare institutions were dissatisfied with the Saudi Vigilance system as a drug shortage reporting portal, while 46.9% were satisfied and 34.7% were neutral. Similarly, the SFDA response timeline for drug shortage reports was found mostly satisfactory by 46.9% of respondents and unsatisfactory by 10.2%.

National Unified Procurement Company

NUPCO (100%) found the SFDA reporting channels not clear, and the reporting steps somewhat clear. Additionally, NUPCO (100%) was dissatisfied with the SFDA reporting channels and steps. In fact, they stated that they had seen minimal improvement in the SFDA reporting system.

Pharmaceutical Companies

Approximately three-quarters (77%) of pharmaceutical companies found the SFDA reporting system to be clear. Slightly over half (52.4%) of the pharmaceutical companies described their satisfaction level as neutral, while 42.9% were satisfied and 4.8% were dissatisfied.

Discussion

The aim of this study was to evaluate stakeholders' internal concepts and work processes regarding drug shortages, and to understand the awareness, practice, and satisfaction regarding the SFDA's drug shortage reporting channels. The definition of drug shortage has not been systematically studied in existing literature. In light of this information, this study focused on the stakeholders who were dealing with constant drug availability issues or shortages. In this study, the questions were tailored to target key stakeholders including healthcare institutions, NUPCO, and pharmaceutical companies, which showed similarities in their definitions of drug shortage. In order of frequency, the factors identified as describing drug shortages were confirmation of product unavailability by the agent, low stock of generic product, zero stock of branded drug, and after pharmaceutical companies confirmed the unavailability of the product.

These results showed similarities with the definitions of both the SFDA and the FDA in terms of shortage or unavailability occurring when quantities available from

official agents' warehouses do not meet the needs of the health facilities drug [1, 2]. Understating these definitions is crucial to understand the gaps between Saudi regulatory authorities and key stakeholders. Our results showed that both healthcare institutions and NUPCO defined a drug shortage as stock falling to zero for branded products or generic stock becoming low. These results might raise concerns in terms of drug availability, especially in crises such as COVID-19, as they could lead indirectly to a significant impact on patient care. This impact has been well demonstrated in previous studies, which focused how shortages of injectable and other drugs affected patient care [12, 13].

Moreover, one study highlighted the role of the Saudi drug and medical equipment supply chain in drug shortages, implying that one possible reason is inadequate communication between the different health institutions and the SFDA about the status of drug shortages in these institutions [10]. The reason for stating this gap and performing this study was to demonstrate the SFDA's needed role in addressing drug shortages in healthcare institutions.

In contrast to previous studies which focused primarily on the perspective of healthcare institutions (hospital and pharmacies), this study also sought to understand how pharmaceutical companies evaluate the demand for their drugs. The results point to two main indicators, stock/product demand (67.3%) and monthly stock consumption/demand monitoring (38.8%).

To overcome drug shortages worldwide, the World Health Organization has introduced a strategy to control how shortages are dealt with. Therefore, internal work process is considered in this study as an important indicator for drug shortages for healthcare institutions, NUPCO, and pharmaceutical companies. All stakeholders were surveyed on various aspects of these processes, such as the reporting process; planning strategies including inventory check, pricing, supplier selection, and selecting alternative therapies; and choosing the best suppliers for raw materials. This is the first study to focus on the internal process by which regulators and industry players address drug shortages.

Pharmaceutical products are subject to market forces, and fluctuating medication prices might affect the supply chain in hospitals and pharmacies [8]. Multiple studies explored different factors behind drug shortages in low- and middle-income countries; the results showed that inadequate funding was one factor contributing to the problem of drug stock in these countries' healthcare facilities [14]. Therefore, the cost of

medication can also be a factor in selecting the supplier. In our study, participants were asked what factors would affect their choice of medication supplier; 49% of respondents agreed that price would be a factor. Thus, the cost of medication is one area that requires further study.

Since this study touches on some aspects related to a regulatory authority, it is important to assess the usage of reporting channels available to stakeholders on the SFDA website, including its curriculars, guidelines, and systems. Most of the survey questions related to participants' awareness of available communication channels, such as emails and phone numbers. Results indicated that all stakeholders were aware of the channels provided through the SFDA website. Despite this, however, the official communication channels remained underutilized; increasing their utilization could provide earlier predictions of essential drug shortages and is an important topic to explore.

In addition, most of the findings related to the clarity of the SFDA circulars were understandable. However, the way information and circulars are delivered to the stakeholders needs further assessment.

NUPCO's results were similar to those of the healthcare institutions since they shared the same survey questions. However, in the satisfaction part, NUPCO was dissatisfied with the reporting channels and steps, and it did not notice any improvement in the SFDA reporting system. Moreover, the clarity of the reporting steps and the communicating channels ranged from somewhat clear to not clear. Further investigation from the SFDA drug availability department could help to improve the services provided by the SFDA.

Although this is the first study to understand drug shortage concepts among stakeholders in Saudi Arabia from the SFDA's point of view, the gap left by previous studies provides an opening for our study as it lets us understand the entire process of reporting and dealing with drug shortages among stakeholders. To further improve the process of dealing with future drug shortages, more in-depth questions might be formulated to offer a broader picture for the process of reporting to the SFDA.

Our study has some limitations. First, this was a cross-sectional study including only institutions registered with RSD and Saudi Vigilance and therefore does not represent all the healthcare institutions (hospitals, pharmacies, and pharmaceutical companies) in Saudi Arabia. Therefore, we may not generalize the responses given by our participants to the entire country. Additionally,

outdated contact information provided by the stakeholders to RSD and the vigilance department caused obstacles in contacting the designated employee. Out of 166 participants, only 113 (68.07%) participants completed the surveys; we would need more information from other institutions, including those outside the 166 registered with RSD, to generalize the concept for all measurements.

Summary and Future Direction

The internal work process of the stakeholders regarding drug shortages was examined via a variety of survey questions. Most of the responses provided a general idea of the internal process of handling drug shortages, reporting steps, and submitting drug shortage reports. Nonetheless, price and supply time were the main factors that affected the healthcare institutions' selection of suitable suppliers. Additionally, more than half of the healthcare participants had positive feedback regarding the services of the drug availability department, and pharmaceutical companies affirmed the contribution of the SFDA to facilitating the availability of pharmaceutical products. Healthcare institutions were satisfied with the response timeline for drug shortage requests by the SFDA and with the process of reporting drug shortages through the Saudi Vigilance system. The pharmaceutical companies were satisfied with reporting drug shortages through RSD. Exploring more in the internal work process is recommended to measure different aspects that might affect the clarity and the quality of the services provided by the SFDA. In addition, future studies are recommended to assess the impact of the recent guidelines related to the reporting systems targeting drug availability in the SFDA.

Statement of Ethics

This study protocol was reviewed and approved by Saudi Food and Drug Authority Ethics Committee (approval number 2021_09). The need for informed consent was waived by the Saudi Food and Drug Authority Ethics Committee.

Conflict of Interest Statement

The views expressed in this paper are those of the author(s) and do not necessarily reflect those of the SFDA or its stakeholders. Guaranteeing the accuracy and the validity of the data is the sole responsibility of the research team..

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Author Contributions

Malak Almutairi: survey construction, methodology, analysis, writing – original draft, and visualization; Salwa Almomen: survey construction, writing – review, and editing; Haya Alhazzani:

survey construction data collection, review, and editing; Radwan Hafez: survey construction, methodology, and writing – review and editing; Bushra Almutairi: data collection, review; and Arwa Alenzi; survey construction and review. All the authors approved the final manuscript.

Data Availability Statement

All data generated or analyzed during this study are included in this article and its online supplementary material. Further enquiries can be directed to the corresponding author.

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