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Current State Analysis of Counterfeit Medicine Detection in Pharmaceutical Supply Chains in Pakistan

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Abstract

Counterfeit medicines are a serious challenge in Pakistan's pharmaceutical supply chain, posing a serious threat to public health and economic stability, as well as the credibility of the health care system as a whole. This paper discusses the current status of counterfeit medicine detection mechanisms in Pakistan by using qualitative methods like an interview with industry leadership. The study deals with the examination of the present legacy systems; prevalence and effect of counterfeit medicines; and a gap in rules and technology that needs to be filled. Urgent need: modern technological integration, updated regulation frameworks, strategic solutions to overcome the growing danger of counterfeit drugs.

Introduction

Counterfeit medicines pose a global concern, and the country of Pakistan is one that faces major hurdles in detecting and preventing the dissemination of such medicines. These are often substandard, falsified, or even unregulated products that compromise the safety of the patient, bring about financial loss, and even damage public confidence in healthcare. The pharmaceutical supply chain in Pakistan is vulnerable on account of the weak regulatory framework, outdated systems of detection, and lack of technological integration. This study seeks to analyze the current systems of detecting counterfeit drugs in the pharmaceutical industry in Pakistan, uncover the strengths and

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weaknesses of the mechanisms, and determine the prevalence and impact of counterfeit drugs. The findings of this study will be used in recommendations for improvement in the counterfeit detection systems and suggest new technologies that can be integrated into the supply chain.

Literature Review

The use of counterfeit medications has been regarded as one of the most severe threats that the healthcare industry worldwide, particularly in developing countries such as Pakistan, faces. Several dimensions of this phenomenon have been studied at length, and problems pointed out present many issues and possible solutions. It has been reported that counterfeit drugs represent over 10% of the world pharmaceuticals market, and in almost all the less regulated regions, the figure is much higher [1], [2]. These drugs are usually impotent or contain harmful substances and, therefore result in adverse health effects and loss of people's confidence in the health services [3].

Literature on the issue: There is, therefore, evidence that traditional ways of detection have their limitations. Most of the systems currently in use rely heavily on human inspection and paper documentation, which are inefficient when there are high counterfeits that have evolved to even reproduce the packaging and authentication numbers [4], [5]. Such manual processes have been well eloquently described as ineffective; for example, it has been claimed that manual checking alone is not even sufficient to identify the counterfeit drugs produced using state-of-the-art forgery methodologies [6], [7]. Human judgment varies significantly and goes wrong, meaning that it hugely compromises the ability to detect them accurately [8].

Technologies offer solutions in the problem area of counterfeits in drugs. Research studies have analyzed the applicability of blockchain and QR codes in enhancing traceability and transparency in pharmaceutical

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supply chains. Blockchain, for example, because of its distributed and immutable ledger, is notably applied to provide the security and integrity of the transactions in a supply chain [9], [10]. Singh et al. [11] demonstrated that blockchain can significantly reduce risks of counterfeits by ensuring real-time tracking and verification of authenticity of the drugs. Similarly, it has been suggested that systems based on QR codes also trace the origin of drugs in an economical and cost-effective way to conduct authenticity checking at various stages of the supply chain [12], [13].

However, problems still surround their implementation in developing countries such as Pakistan. Ahmed et al. [14] indicate lack of infrastructure support, high implementation costs, and the amount of interference mainly as the significant barriers to the widespread adoption of these technologies. In addition, the introduction of new technology into existing infrastructure is always hostile towards stakeholders with the tradition of long-standing operation [15], [16]. However, recent research has begun to afford and promote the integration of contemporary technology solutions in supporting the identification of counterfeit drugs [17], [18]. Though regulatory environments help eradicate counterfeit medicine, most developing countries lack proper implementation mechanisms.

Yet another critical facilitator in spreading counterfeit medicines is the weak regulatory environment [19], [20]. The Drug Regulatory Authority of Pakistan, DRAP has been trying to enhance the regulatory mechanisms in Pakistan. However, it is observed that implemented selectively [21], [22]. It has been observed that effective regulatory mechanisms supplemented with enforcement systems are necessary for regulation of spurious drugs [23], [24]. The contemporary literature puts emphasis on increased regulatory surveillance and coordination amongst various stake holders [25], [26]. Public education and awareness also play

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key roles in combating counterfeits of medicines. Others have indicated that lack of consumer awareness often limits the ability to distinguish between the genuine product and the counterfeit one, especially in rural areas [27], [28]. Educational campaigns targeting the dangers of counterfeit drugs to the public about these dangers and how best to check authenticity have also been presented as integral aspects of a strategic anti-counterfeit approach [29], [30]. There is, however, a proposal for collaboration between pharmaceutical firms and health care professionals looking forward to an increase in the stock of knowledge of the public and raising detection sensitivity [31], [32]. Emerging studies from anti-counterfeit actions of pharmaceutical companies in issues are also emerging.

Companies are further investing in serialization as well as in digital tracking technology to protect their products against counterfeiting [33], [34]. Public and private sectors enhanced collaborations on medicines with the engagement of pharmaceutical firms in anti-counterfeit efforts, which are among the great steps for having a more potent defense against medicines being counterfeited [35], [36]. Such efforts need efficient exploitation of technological innovations and improvement in regulations to address the challenges of detecting counterfeit drugs in all its multifaceted dimensions [37], [38].

Methodology

This research-based study methodological framework has a qualitative nature. It utilized open-ended in-depth interviews of the key stakeholders from the pharmaceutical sector. The core objective was to obtain in-depth, descriptive insights into the existing practices and the challenges associated with the detection of counterfeit medicines. The three cities of Pakistan where the research was conducted include Islamabad, Lahore, and Karachi because of their vital role in the pharmaceutical supply chain.

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15 participants were selected for the survey. There were five participants from each city, which were Islamabad, Lahore, and Karachi. These participants included CEOs, Managers, and Directors of some of the top pharmaceutical companies. Therefore, insights obtained through this research would be industry-experience and strategic viewpoints from a higher level in the industry. The depth of understanding required through purposive sampling is therefore vital in achieving such an outcome.

Table 3.1: Participant Distribution

City	Number of Participants	Roles
Islamabad	5	CEO/Managers/Director
Lahore	5	CEO/Managers/Director
Karachi	5	CEO/Managers/Director
Total	**15**	

Face-to-face interviews were used in data collection to open up the issue of the practice and views with participants. Interview guides are mostly open-ended interviews that ensure discussions cover some crucial core areas with participants free to elaborate on details. This type of interview really helped capture complex and nuanced counterfeiting-practice detection and understanding.

Qualitative data were coded using thematic analysis. The iterative process of coding and categorization during the data processing phase helped elicit the key themes and patterns. It was carried out in a stepwise process involving stages: familiarization with the data, initial codes, themes search, reviewing themes, definition and naming, and the final report production. This way, the results became robust and reflective of the insights held by the participants.

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Analysis

Legacy Systems for Counterfeit Medicine Detection

As far as counterfeit medicine detection in Pakistan is concerned, the reliance remains very much on legacy systems. Legacy systems-which involve predominant manual processes and physical inspections-are a stronghold of pharmaceutical regulation for decades now.

Strengths of Legacy Systems

One of the strengths of such legacy systems would be the fact that they come with established procedures. These, over time, have become highly entrenched in pharmaceutical companies' operating procedures and that of regulatory authorities. The experience and predictability associated with them are something these industry professionals rely on.

More than this, such systems are harmonized with the regulatory standards and guidelines at the national level to ensure that there is a uniform system under which the pharmaceutical companies are working. Harmonization with these national standards provides a form of compliance in a degree to uphold the supply chain integrity.

Additionally, experience-based detection methods utilized by seasoned professionals form another key strength. The seasoned professionals depend on intuition and their rich experience to identify counterfeits; sometimes they notice anomalies that other, less-experienced staff or systems may miss.

As one of the respondents put it,

"Our traditional ways and skilled workforce have helped us retain some kind of control over counterfeit products, but we know these are no match for more advanced techniques used by counterfeiters."

Another respondent said:

"Though our old methods have stood the test of time, it is time for something more complex in terms of counterfeiting techniques."

Third respondent said,

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"The manual processes have their benefits, especially with experienced inspectors, but we need to modernize to keep up with the challenges."

A visual representation of this aspect is shown below in table 4.1 and figure 4.1 (a) and (b).

Table 4.1: Strengths of Legacy Systems

Strengths	Percentage of Participants Mentioning
Established Procedures	60%
Regulatory Compliance	53%
Experience-Based Detection	47%

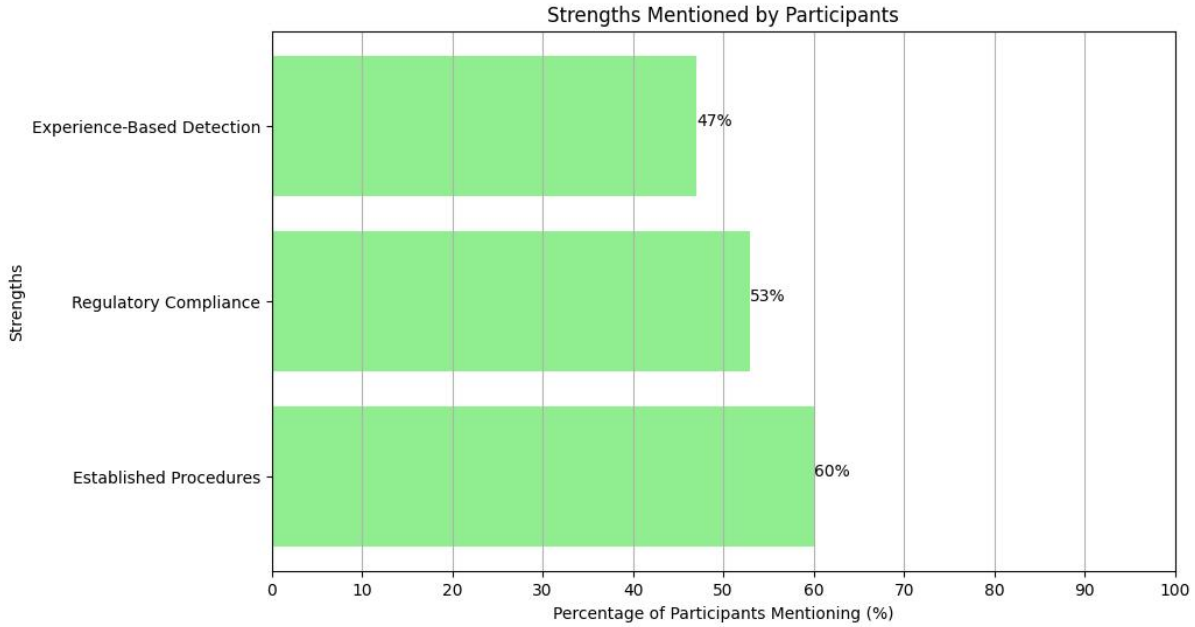

Figure 4.1 (a): Strengths of Legacy Systems

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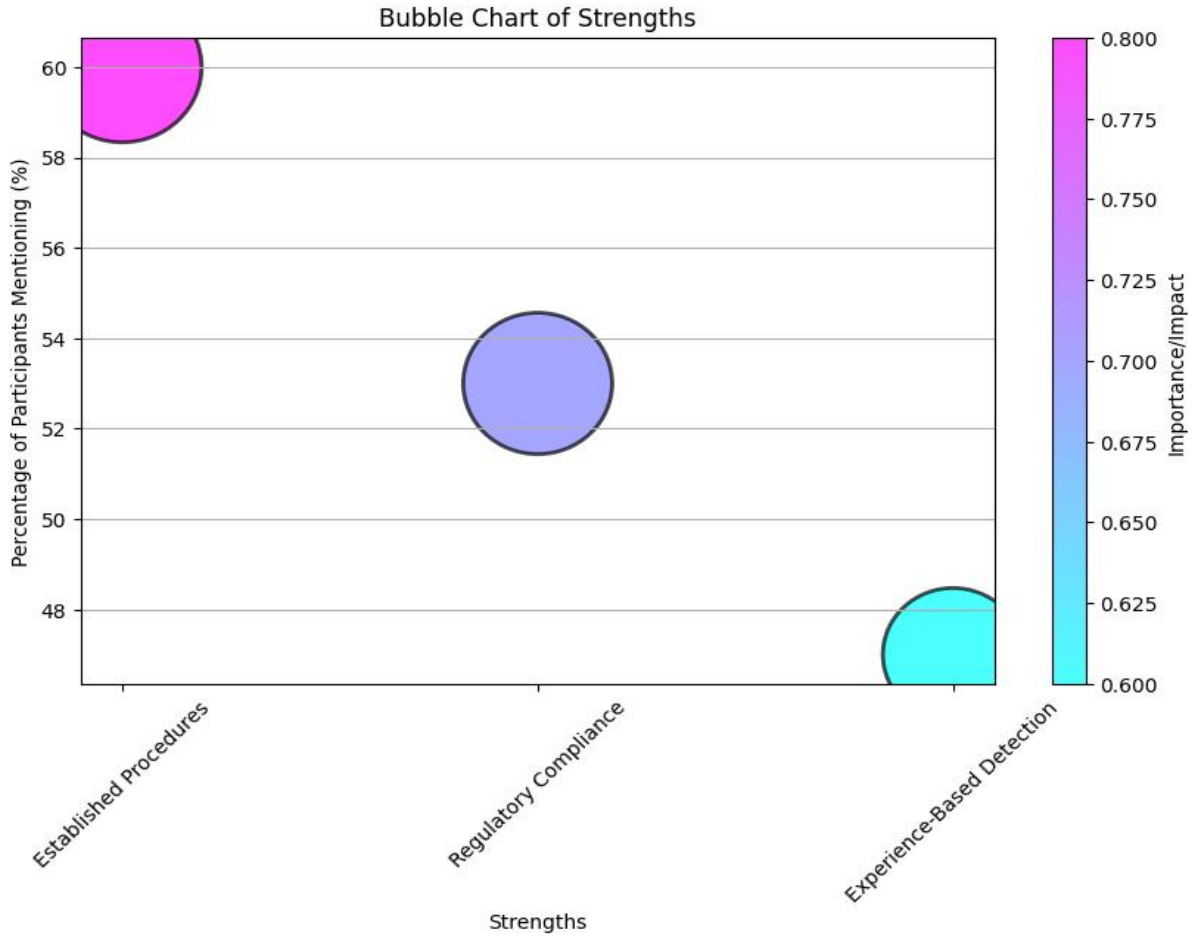

Figure 4.1 (b): Strengths of Legacy Systems

Weaknesses of Legacy Systems

Despite these strengths, the legacy systems are fraught with several critical weaknesses that negate their effectiveness. One of the major issues is the lack of technological integration. The systems mostly operate in a vacuum, disconnected from modern technological advancements such as digital tracking and blockchain, thus limiting their ability to keep up with increasingly sophisticated counterfeit operations.

This also leads to inconsistent and incomplete records, especially when relying on manual record-keeping. These inconsistencies can mean that there is a huge lack of traceability of medicines that makes it extremely challenging to follow the movement of products through the supply chain. In addition, these manual processes are not scalable, which

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can be a rather serious limitation as there are significant volumes of medicines that need monitoring.

The most significant weakness would be human error. Since inspection and documentation are manual processes, the chance for error is enhanced, and these errors may critically affect the counterfeit medicine detection system. A heavy reliance on personal expertise means that the system may be quite erratic in terms of effectiveness due to the different skill levels of personnel.

A respondent pointed out that

"The paper-based record keeping and inspection mechanisms are not only time-consuming but also prone to errors. Advanced technological solutions should be developed and implemented to seriously fight counterfeit medicine."

Another one said,

"The inconsistency in manual records is big. We can't trace sources of some items because of missing gaps."

In a third, the interviewee said,

"Human error is a serious issue. Even the most experienced inspectors can err, and we cannot afford those mistakes."

This is shown below in table 4.2 and figure 4.2 (a) and (b).

Table 4.2: Weaknesses of Legacy Systems

Weaknesses	Description	Percentage of Participants Mentioning
Lack of Technological Integration	Minimal use of modern technology such as digital tracking and blockchain	67%
Inconsistent Record-Keeping	Manual processes often result in inconsistent and incomplete records	53%

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Limited Scalability	Manual inspections and checks are not scalable for large volumes	47%
Susceptibility to Human Error	High potential for human error in detection and documentation	60%

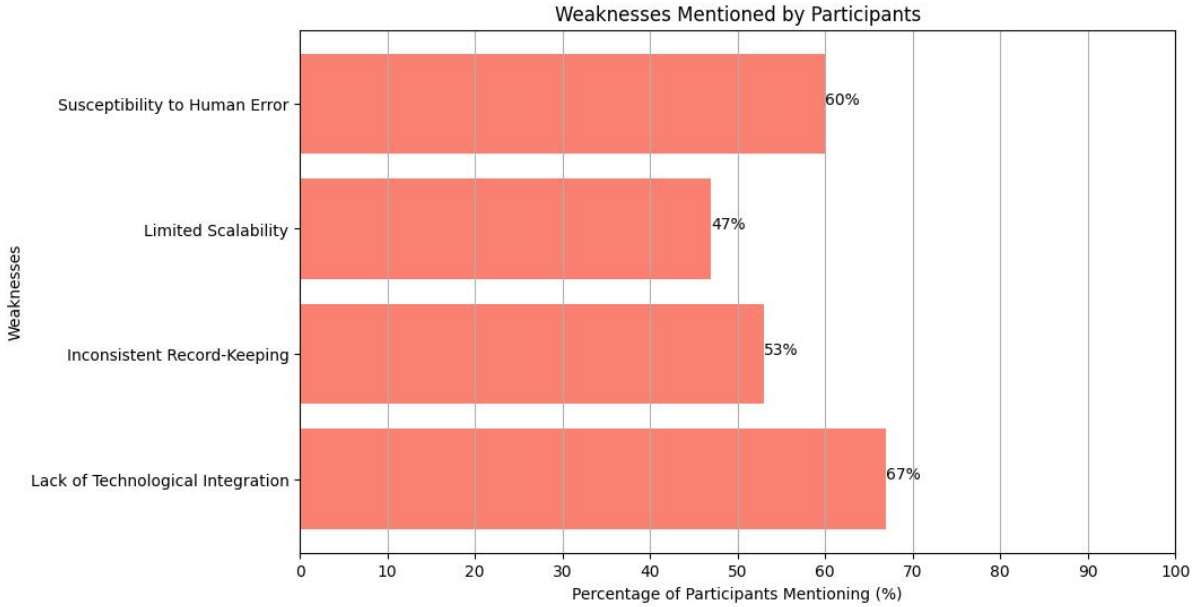

Figure 4.2 (a): Weaknesses of Legacy Systems

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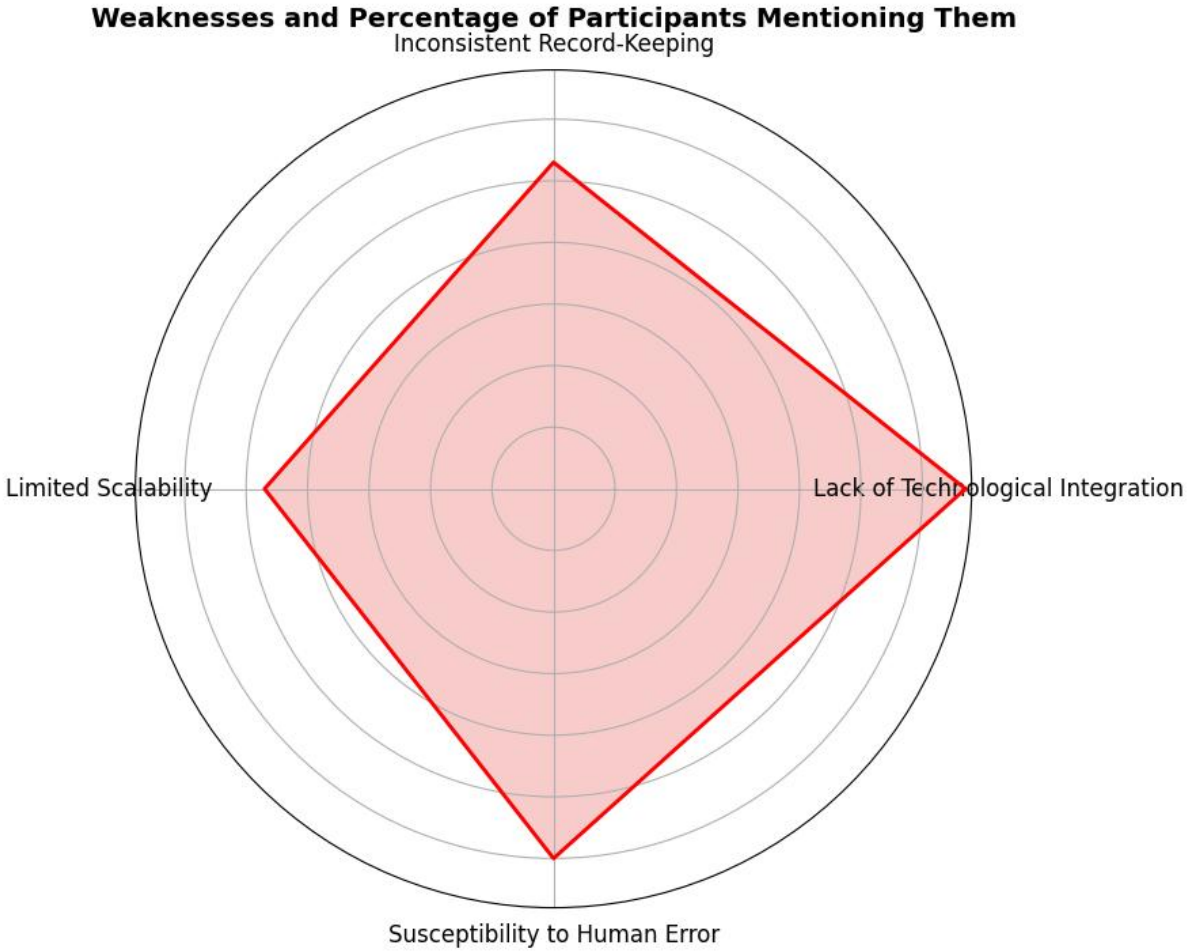

Figure 4.2 (b): Weaknesses of Legacy Systems

Presence and Impact of Counterfeit Medications

Mainly, the research participants illuminated that counterfeit drugs are a matter of widespread concern in the pharmaceutical market of Pakistan. These drugs penetrated urban and rural areas owing to various underlying factors.

Prevalence

In return, participants note that weak and ineffective regulatory law enforcement is also a major characteristic of the very widespread presence of counterfeit medicines in the market. Regulatory bodies also lack the human and financial capacities to enforce thorough checks and balances. This lacks is further hindered by practices of corruption and bribery, as these further create weaknesses in law enforcement.

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Therefore, regulatory law officials can sometimes be bribed to ignore those counterfeit products once they have gotten into the marketplace.

The demand for cheap alternatives is the other contributing factor. Many of the consumers who come from a low socio-economic background will search for cheaper drugs. These customers do not understand the danger in using fake medicines, hence providing an excellent opportunity for the counterfeiter who can use gaps in the supply chain to pass his products as the original drug.

One of the respondents put it thus,

"The regulatory bodies are under-resourced and often compromised by corruption, which makes it easy for counterfeit medicines to slip through the cracks."

Another respondent commented,

"Consumers looking for cheaper alternatives end up with counterfeit products, unaware of the risks they are taking."

A third respondent added,

"The lack of stringent enforcement and the demand for low-cost drugs create a perfect storm for counterfeiters."

This is shown below in table 4.3 and figure 4.3 (a) and (b).

Table 4.3: Factors Contributing to the Prevalence of Counterfeit Medicines

Factors	Description	Percentage of Participants Mentioning
Weak Regulatory Enforcement	Lack of resources and authority to enforce stringent checks	73%
Corruption and Bribery	Bribery of regulatory officials to overlook counterfeit products	67%

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High Demand for Cheaper Alternatives	Consumer demand for 60% affordable medications, often unaware of associated risks

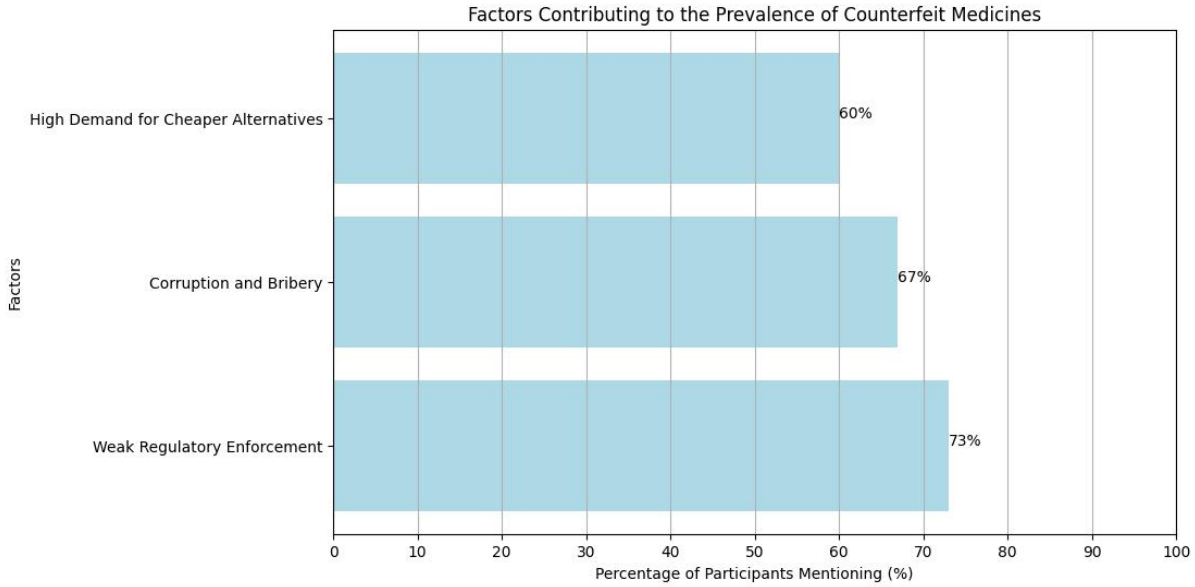

Figure 4.3 (a): Factors Contributing to the Prevalence of Counterfeit Medicines

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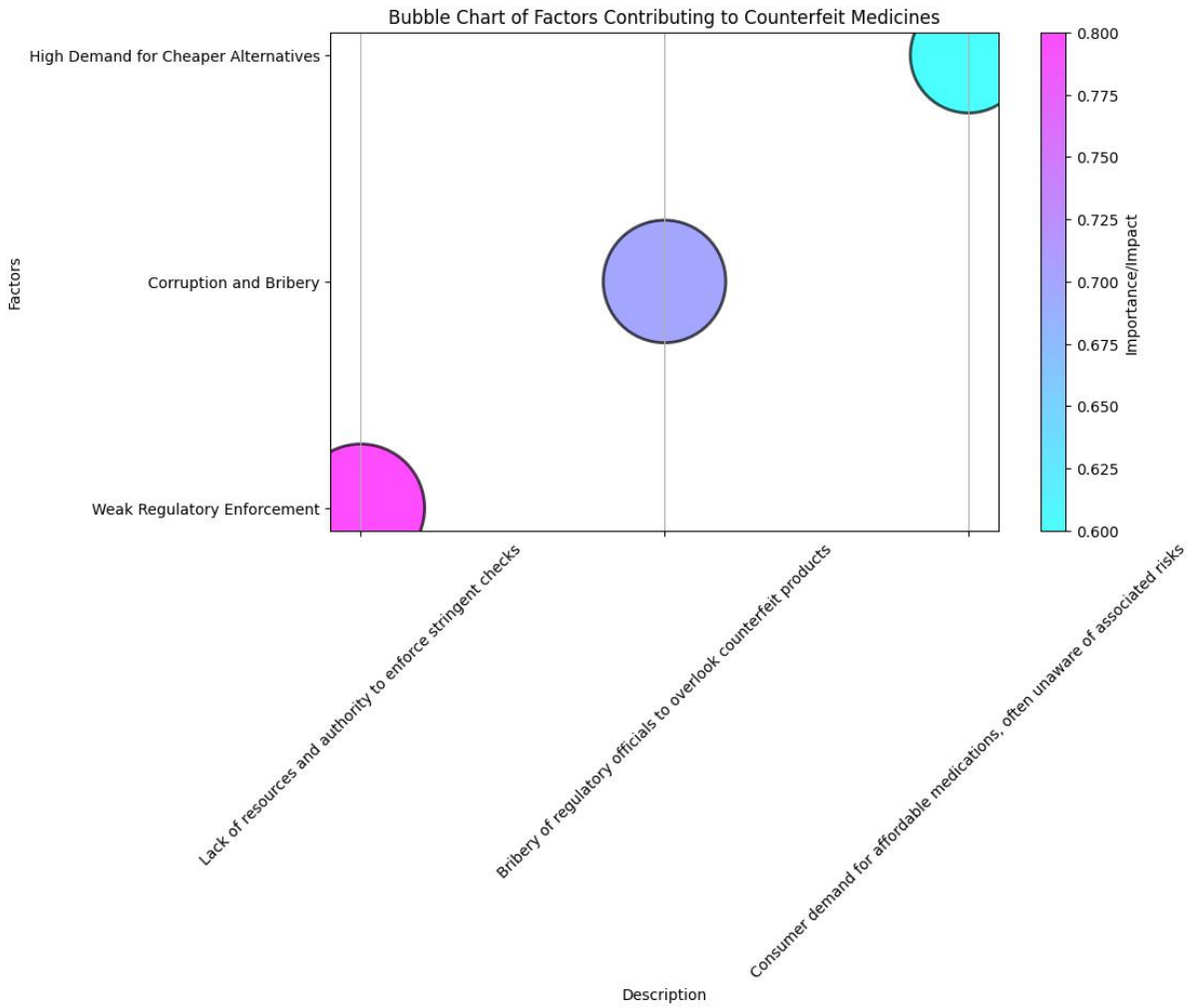

Figure 4.3 (b): Factors Contributing to the Prevalence of Counterfeit Medicines

Effects

The effects of counterfeit medicines are multifaceted and of a deep concern. From the viewpoint of public health, the use of counterfeit drugs can result in serious health dangers. Patients might suffer adverse effects or get a wrong treatment leading to a long illness or death. In some cases, patients may not experience any side effect, but still, their health is endangered since the drug may lack active ingredients or have dangerous substances.

Economically, counterfeit drugs also result in serious losses for real pharmaceutical firms since they heavily invest in research and

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development, along with quality control, to eventually lose the same market shares. The cost also goes beyond lost sales revenue because of costs of fighting counterfeit medicines and the regaining of their brand value.

Another key outcome is the erosion of public trust. Patients feel let down and lose confidence in the healthcare system and the pharmaceutical industry when they take counterfeit medicines. Loss of trust is likely to lead to non-adherence to treatments prescribed for them and fear of going to the healthcare delivery facilities, which worsens public health further.

A respondent pointed out

"The financial and reputational damage caused by counterfeit medicines is immense. It not only affects our bottom line but also erodes trust among patients, which is difficult to rebuild."

Another participant noted,

"The health risks are severe. We've had cases where patients suffered because of counterfeit drugs, which is unacceptable."

A third interviewee remarked,

"When patients lose trust in our products, it's not just about lost sales. It's about a loss of faith in the entire healthcare system."

This is shown below in table 4.4 and figure 4.4.

Table 4.4: Effects of Counterfeit Medications

Effects	Description	Percentage of Participants Mentioning
Health Risks	Severe health risks including adverse reactions and ineffective treatment	80%
Economic Losses	Substantial financial losses to legitimate pharmaceutical	67%

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	companies	
Erosion of Trust	Diminished public trust in the healthcare system and pharmaceutical industry	73%

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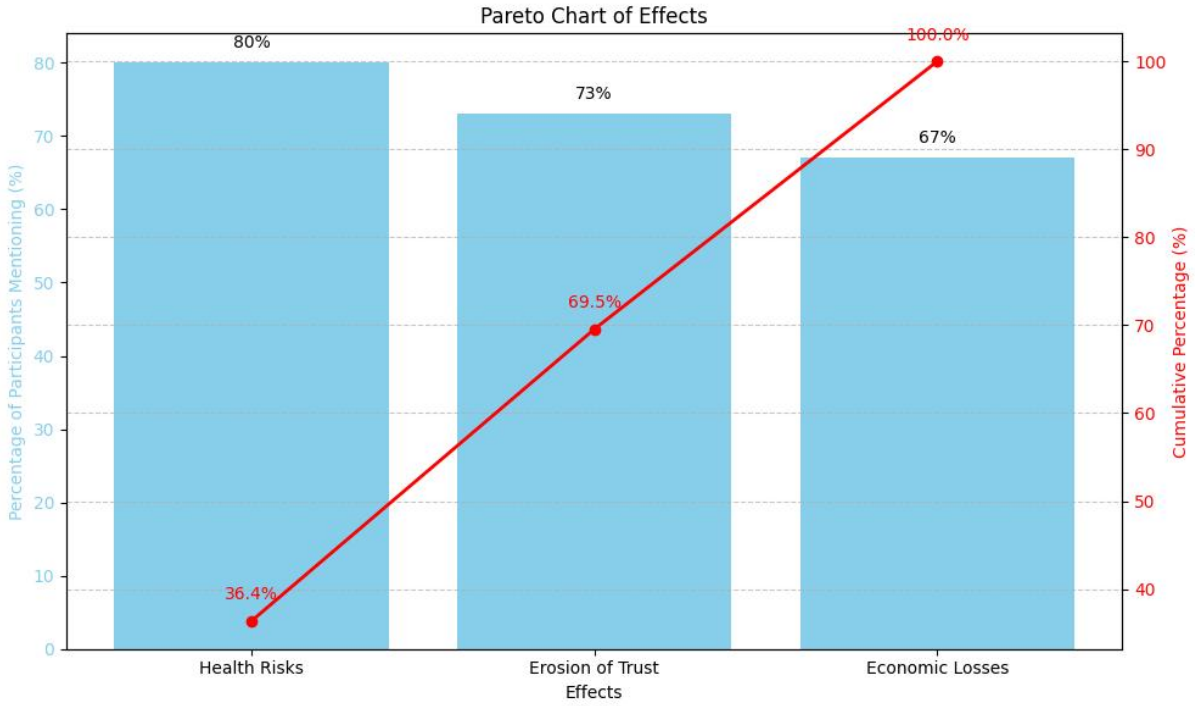

Figure 4.4: Effects of Counterfeit Medications

The thematic analysis of the interview data revealed several critical themes that encapsulate the current state of counterfeit medicine detection in Pakistan.

Regulatory and Policy Gaps

There is a recurring theme in the discussions, which refers to the serious gaps in the regulatory policies and their enforcement. Participants constantly indicated that the existing legislation is ineffective in preventing the counterfeit activities. The laws existing are often criticized as being old-fashioned and too lenient. They do not address the nature of modern operations in counterfeiting. Enforcement challenges further complicate these problems. Regulatory authorities frequently lack the

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personnel and technical capacity to inspect thoroughly and monitor compliance well. The extreme corruptness in these regulatory bodies works against the ability of those bodies to operate impartially and thus rigorously, leaving doors open to counterfeit medicines.

As an interviewee put it,

"The laws are archaic and enforcement is weak. We need a complete overhaul of the regulatory framework to effectively fight counterfeit drugs."

Another respondent noted,

"Our regulatory bodies don't have the resources they need to enforce the laws. This gap allows counterfeit medicines to flourish."

A third respondent said,

"Corruption is a major problem. Even when there are laws in place, they're not always enforced due to bribery."

This is shown below in table 4.5 and figure 4.5.

Table 4.5: Regulatory and Policy Gaps

Gaps	Description	Percentage of Participants Mentioning
Inadequate Legislation	Outdated laws insufficient to deter modern counterfeit operations	73%
Enforcement Challenges	Under-resourced regulatory bodies lacking personnel and technical capabilities	67%
Corruption	Pervasive corruption undermining effective enforcement	60%

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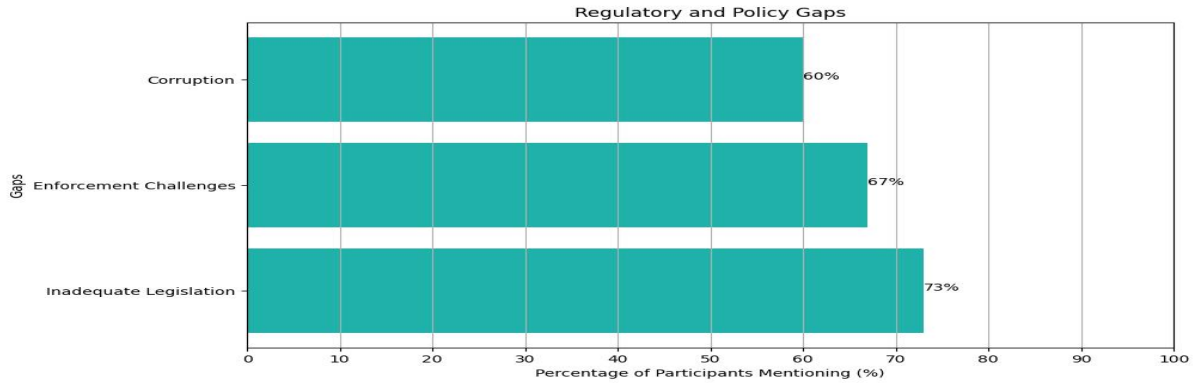

Figure 4.5: Regulatory and Policy Gaps

Technological Deficiencies

Another major theme highlighted was that there is a clear need for technological advancements in the identification of counterfeit medicines. The fact that digital tracking systems, such as blockchain or QR code-based verification, did not exist was considered the most significant shortfall. Such technology would immediately permit tracking and tracing in real-time, making detection and prevention much more effective in terms of delivery of counterfeit goods.

The participants also identified the woeful lack of investment by pharmaceutical companies and regulatory bodies in technology. There is lag in implementing modern solutions that can easily help to streamline operations and enhance the overall efficiency of counterfeit detection.

One participant observed that

"The lack of investment in modern technologies like blockchain is a major obstacle. We need to embrace these technologies to stay ahead of counterfeiters."

An interviewee noted:

"Without sophisticated tracking systems, it is quite challenging to monitor the supply chain effectively. We need to invest more in technology."

A third participant said,

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"Digital tracking and verification technologies can revolutionize our ability to detect counterfeits, but we're not investing enough in them."

This is shown below in table 4.6 and figure 4.6.

Table 4.6: Technological Deficiencies

Deficiencies	Description	Percentage of Participants Mentioning
Lack of Digital Tracking	Absence of modern digital tracking systems like blockchain or QR codes	67%
Insufficient Technological Investment	Low investment in technology by pharmaceutical companies and regulatory bodies	60%

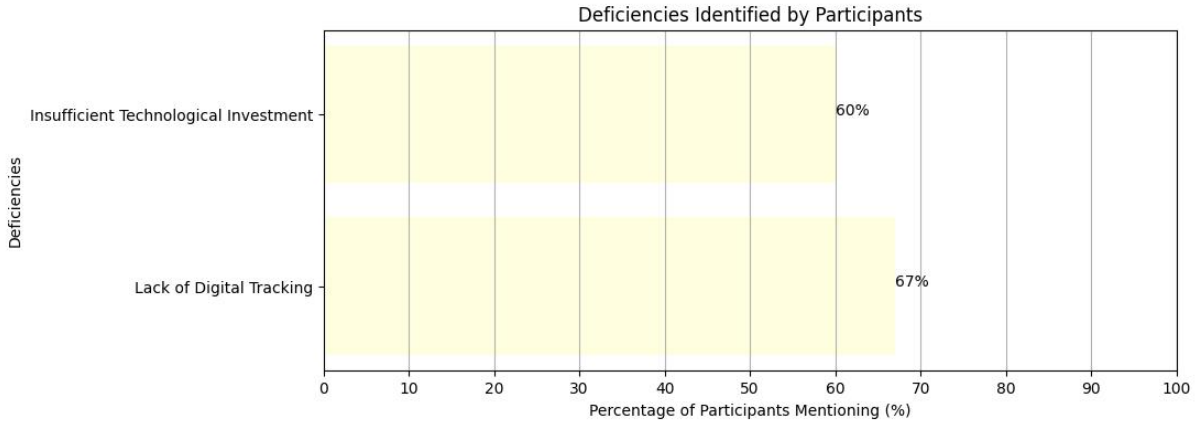

Figure 4.6: Technological Deficiencies

Supply Chain Vulnerabilities

The complexity of the pharmaceutical supply chain was the other major theme that emerged. The distribution networks in Pakistan often involve a multiplicity of middlemen and points of transfer. This complexity allows for numerous points of entry of counterfeit products in the supply chain. The poor controls at point of sale in retail outlets are a significant weakness. Most retail pharmacies do not have strong verification

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systems, thus it is quite easy for spurious drugs to reach the hands of the end user. Such slack checks at the point of delivery compromise the integrity of the whole supply chain.

A respondent commented,

"The supply chain is very complicated and involves too many points through which counterfeit products can slip. Verification processes need to be enhanced at every stage, especially at the retail level."

Another interviewee pointed out,

"Retail pharmacies are a weak link. Without proper checks, counterfeit medicines can easily make their way to consumers."

A third participant added,

"The complexity of the distribution network makes it very difficult to ensure that all products are genuine. We need to simplify and secure the supply chain."

This is visible in table 4.7 and figure 4.7.

Table 4.7: Supply Chain Vulnerabilities

Vulnerabilities	Description	Percentage of Participants Mentioning
Complex Distribution Networks	Multiple intermediaries and points of transfer creating opportunities for counterfeits	67%
Weak Point-of-Sale Controls	Lack of robust verification mechanisms at retail pharmacies	60%

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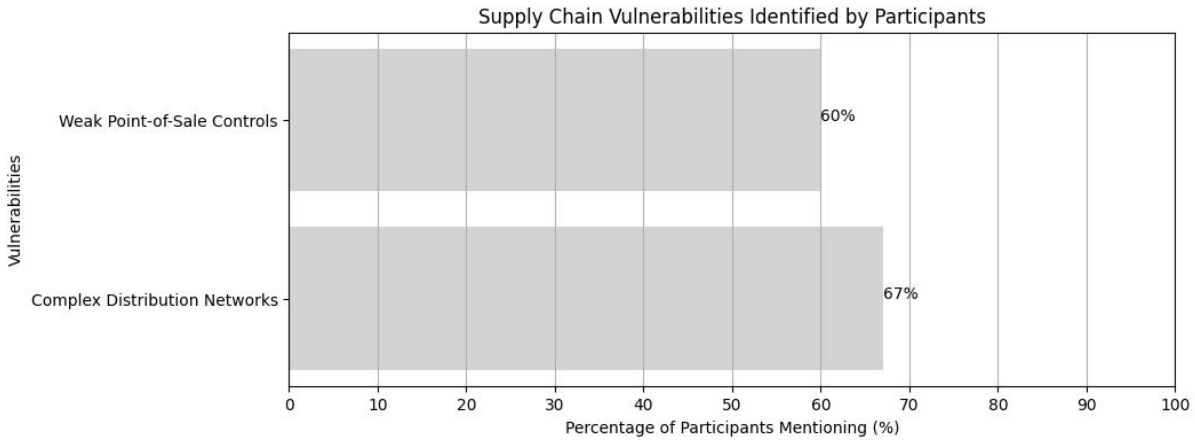

Figure 4.7: Supply Chain Vulnerabilities

Discussion

The findings from this study offer a comprehensive overview of the challenges and deficiencies within the current systems for detecting counterfeit medicines in the pharmaceutical supply chains of Pakistan. Reliance on legacy systems may offer some advantages in terms of established procedures and regulatory compliance, but it cannot be considered satisfactory for the current modern challenges by sophisticated counterfeit operations.

Thematic analysis brings into sharp focus the need for urgent reform along different dimensions. In this respect, there is an urgent need for updated legislation, which takes cognizance of the present reality of production and distribution of spurious drugs, to address policy and regulatory loopholes. To ensure compliance, effective mechanisms that are corruption-free and well resourced should be in place.

Technological advancement is one of the major requirements to improve the detection ability of pharmaceutical supply chains. Promising solutions that could improve traceability and transparency in supply chains are blockchain and QR codes, among others. However, successful implementation requires heavy investment and commitment to modernize the existing systems.

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The vulnerabilities of the supply chain, especially point-of-sale, must be mitigated through strong verification processes and improved oversight. The retail pharmacies need to have the right tools and protocols in place to verify the authenticity of medicines so that counterfeit products cannot reach the consumer.

One of the participants aptly summarized the situation:

"We must have a holistic approach to solve this problem. The law should be updated, investment in technology should be done, and the supply chain must be secured."

Another interviewee emphasized,

"The solution is not simple, but it is doable with coordination among all the stakeholders."

A third participant noted,

"By filling up the gaps and investing in the right areas, we can reduce the presence of counterfeit medicines by a great extent."

This is shown below in table 4.8 and figure 4.8 (a), (b) and (c).

Table 4.8: Summary of Key Findings and Recommendations

Key Findings	Recommendations	Percentage of Participants Mentioning
Regulatory and Policy Gaps	Update legislation, strengthen enforcement, combat corruption	73%
Technological Deficiencies	Invest in digital tracking systems, implement blockchain and QR code verification	67%
Supply Chain Vulnerabilities	Improve supply chain transparency, enhance point-of-sale verification processes	67

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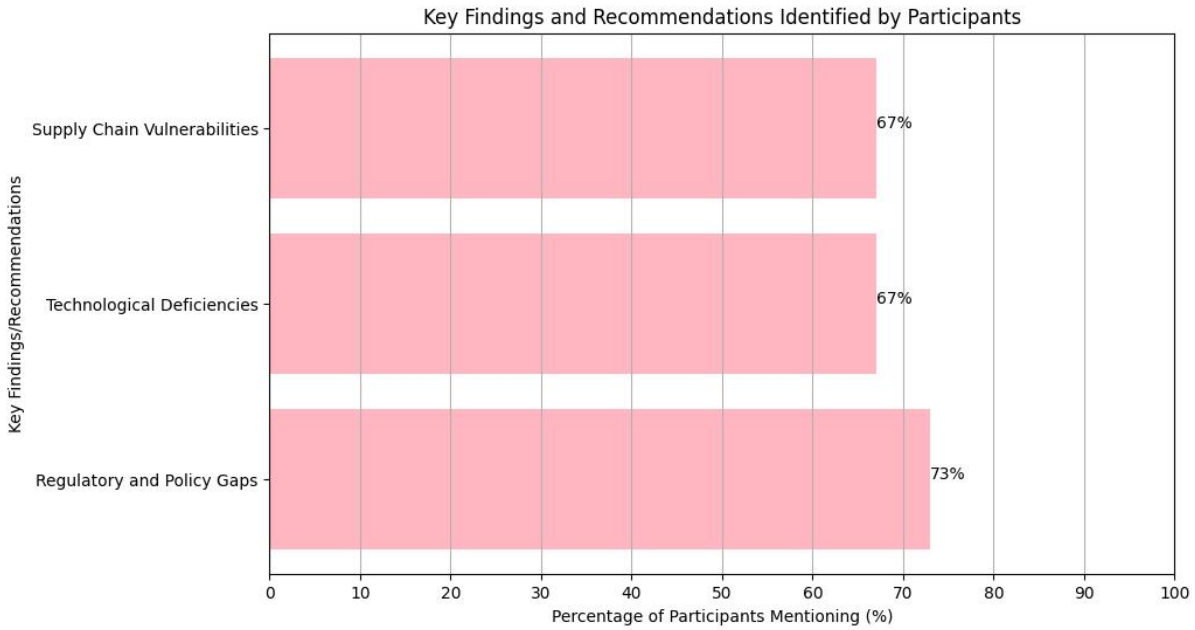

Figure 4.8 (a): Summary of Key Findings and Recommendations

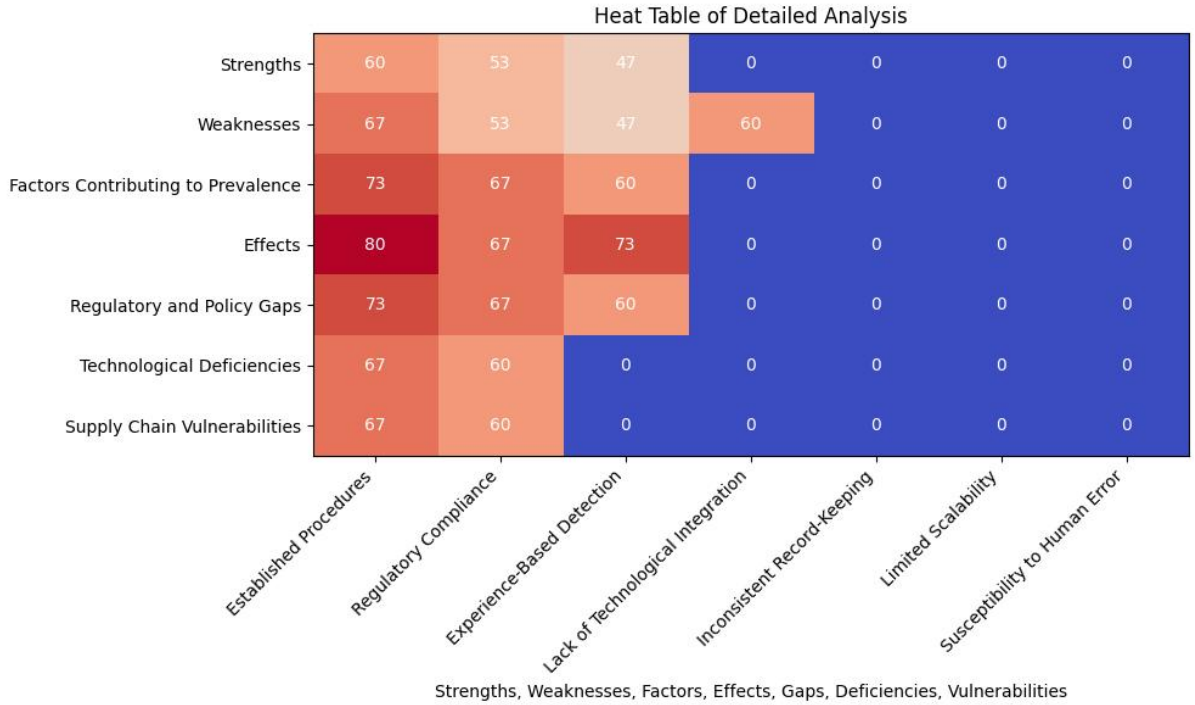

Figure 4.8 (b): Summary of Key Findings and Recommendations

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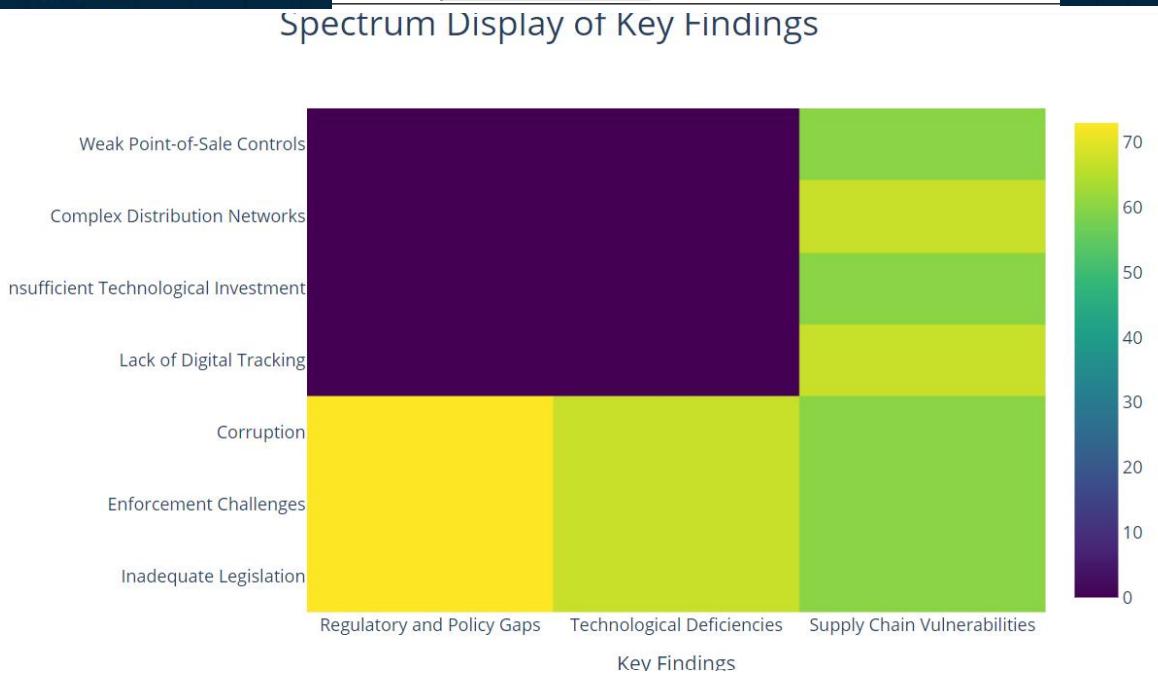

Figure 4.8 (c): Summary of Key Findings and Recommendations

Conclusion

An in-depth analysis of current status regarding the detection of counterfeit medicine produced within Pakistan's pharmaceutical supply chains has been provided in this article. Using qualitative research method and getting insights from industry experts, we find some significant gaps and vulnerabilities in Pakistan's existing systems. Findings highlight an urgent need for technological advancements, strengthening regulatory frameworks, and then enhancing enforcement to combat the menace of counterfeit medicines effectively.

The solution proposed aims to bridge these gaps by integrating modern technologies in a move to enhance the regulatory compliance and strengthen integrity of the supply chain. In this regard, through collaboration between all stakeholders, including the regulatory bodies, pharmaceutical companies, and retail pharmacies, it is possible to build a stronger and more reliable system for the detection of counterfeit medicines in Pakistan.

Future research would be aimed at assessing the efficacy of proposed technological solutions and finding other strategies for strengthening

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regulatory frameworks and supply chain transparency. By continuous improvement and adaptation, the fight against counterfeit medicines can be significantly advanced and ensure the safety and well-being of patients across Pakistan.

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