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Assessment of Challenges in Combating Counterfeit, Substandard, and Adulterated Medicines in Private Pharmacy Business Management

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ABSTRACT

INTRODUCTION

The management of a pharmacy business is very crucial for providing better healthcare to society. All healthcare professionals and business personnel play a key role in overall business management. The role of pharmacists is crucial in managing the overall business landscape and ensuring the availability of quality medicines in society. Pharmacists are involved at various levels in the drug supply chain before the medicines are dispensed to the patients, and therefore play a pivotal role in protecting patients from counterfeit, substandard, spurious, and adulterated (CSSA) drugs. Keeping this in view, the challenges related to CSSA drugs were assessed to improve business management.

METHODS

A web-based cross-sectional survey was conducted by distributing a questionnaire to key personnel in the pharmacy business. The study respondents consisted of business personnel and pharmacists working in the private sector in different domains of pharmacy in Pakistan.

RESULTS

A total of 166 respondents participated in the study. The majority had been in the pharmacy business or domain for 11.19 ± 10.17 years. The majority acknowledged the presence of CSSA drugs in society, while less than half of the participants had previous exposure to these drugs in the past. About 74.1% participants held wholesalers/distributors responsible for the overall spread of these drugs. More than half of the respondents (55.4%) confessed that they did not get any training on pharmacy law and regulations.

CONCLUSION

The loopholes exist in the pharmaceutical supply chain system, which exacerbate the spread of CSSA drugs. There is a need for training and infrastructure development to ensure a secure supply chain and to minimize the prevalence of CSSA drugs.

Keywords: Pharmaceutical supply chain, Pharmacy business, Retail business, Substandard drugs, Pakistan

Introduction

The management of a pharmacy business is very crucial for providing better healthcare to society. All healthcare professionals and business personnel play a key role in the overall business management.^{1,2} However, the role of pharmacists is crucial in managing the overall business landscape and ensuring the availability of quality medicines in society. They are responsible for creating awareness among the masses and edu-

cating common men about the risks associated with counterfeit, substandard, spurious, and adulterated (CSSA) drugs, their sources, and taking appropriate measures to stop the spread of these drugs. Pharmacists as business managers, regulators, and policy makers can play a key role in legislation and enforcement of drug laws in their true spirit. They monitor the pharmaceutical manufacturing and sale of drugs by ensuring good manufacturing practices (GMP), good procurement practices, good storage practices, and good distribution practices by continuous monitoring and surveillance.^{3,4}

Numerous studies have found that the quality of medicines is not up to the required standards. A study demonstrated that about one-quarter of medicines failed quality standards. The study also highlighted weaknesses in sampling methods, regional disparities, and the need for standardized global protocols.⁵ The cross-border supply and trade of substandard drugs is also reported to be high, emphasizing the need for improvements in vulnerable supply chains.⁶ According to a previous study, the substandard medicine manufacturing is most often aggravated by unregistered and illegal manufacturers and by deviation from GMP by authorized manufacturers.¹ The weakness in regulatory enforcement, poor procurement practices, weak supply chain monitoring, corruption issues, and low public awareness have been reported as major causes of the existence of CSSA drugs in Pakistan.^{3,4,7}

Pharmacists are involved at various levels in the drug supply chain before the medicines are dispensed to the patients and therefore play a pivotal role in protecting patients from CSSA drugs.⁸ The role of pharmacists has been recognized in combating CSSA drugs in the literature, right from manufacturing quality medicines through quality assurance, regulators ensuring surveillance and regulatory oversight by securing the supply chain, and retail pharmacists being vigilant for any suspicion of counterfeit/spurious/substandard medicines.⁹ Pharmacists report any such suspicious/dubious drugs to the national regulatory authority and sensitize the patients about such drugs by creating mass awareness.^{10,11} The retail pharmacists are in direct contact with the general public and are directly responsible for overall pharmacy business management and for eliminating access to below-standard medications to patients or end users. They are part and parcel of the drug supply chain, personally handling the medicines after procuring them from reliable sources.

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The awareness of pharmacists about CSSA drugs is not up to the mark to play their effective role in society. It is incumbent upon regulators/policy makers to improve the awareness of the public and pharmacists about CSSA drugs. The World Health Organization has reported high prevalence of CSSA drugs in low- and middle-income countries and urged stronger regulations, supply chain integrity, and provision of training and guidance to promote awareness among the public.¹² The provincial government of Punjab took various initiatives after the “fake drug crisis 2012,” which included, among others, the establishment of the Provincial Drug Control Unit (PDCU) in 2017 and the revamping of Drug Testing Laboratories (DTLs), which are not only ISO certified but also prequalified by the World Health Organization to test and analyze drug samples. The PDCU has started the dissemination of information on the failed drug samples as safety alerts through its web portal for the public and health professionals. The national Drug Regulatory Authority of Pakistan (DRAP) also took various initiatives to combat the spread of CSSA drugs and to protect the public from the hazards of these medicines.¹³ Statistics on quality evaluation and issuance of drug safety alerts have been appreciated as an unprecedented positive step of information sharing in Pakistan; however, the impurity profiling is not conducted due to financial and skilled human resource constraints. The provincial and national drug authorities have clearly defined CSSA drugs and prohibited their use under any circumstances.¹⁴ However, the issue is prevalent to a large extent. Therefore, to address the research problem and to assess the challenges faced in the effective management of CSSA drugs, the views, perceptions, experiences, and practices of pharmacists in both the public and private sectors were explored.

Methods

Study Design and Setting

A descriptive exploratory study was conducted, which gathered insights from pharmacists actively engaged in the pharmacy business and provided a broader picture of views, experiences, preferences, and practices of pharmacists related to the CSSA medicines issues. A web-based cross-sectional survey was developed, and the questionnaire was distributed to the target population. The questionnaire was shared through social media to reach out to the maximum number of pharmacists. An online questionnaire was designed using Google Forms, and its online link was shared through various social media platforms. The participants could view the questions by simply clicking on the shared link and answering the questions.

The study was conducted between March 2025 and June 2025 among personnel involved in the private pharmacy business sector in Pakistan. The sampling frame included pharmacists, pharmacy owners, wholesalers, distributors, and managerial staff working in private retail and supply chain settings. The study reporting followed established best practices for cross-sectional observational research, with

a transparent description of study design, sampling approach, questionnaire development, measurement of variables, and descriptive statistical analysis, consistent with STROBE guidelines.

Inclusion Criteria

The study respondents consisted of business personnel and pharmacists working in the private sector in different domains of pharmacy business in Pakistan, including community pharmacists, hospital pharmacists, industrial pharmacists, regulatory pharmacists, supply chain pharmacists, and wholesale and distribution pharmacists. Participants from academia or regulatory institutions were included only if they had current or previous experience in the private pharmacy business or pharmaceutical supply chain activities.

Survey Development

The questionnaire /instrument was developed using information from a literature review and findings from qualitative and quantitative studies with respect to issues in combating CSSA drugs. Those studies captured attitudes, perceptions, knowledge, and experiences of business professionals, drug law experts, and pharmacists. The participants of the research highlighted the role of pharmacists to help in combating CSSA drugs and suggested various ways and means to counter this menace.

The questionnaire comprised structured items, including awareness of substandard and falsified (SF) medicines, perceived supply chain vulnerabilities, regulatory training exposure, and business governance practices. The questionnaire/instrument comprised four main components. Part A consists of demographic data of respondents. It included gender, residential area, education, and total years of experience in their sector of work. Part B consists of perceptions on training on drug regulations, prevalence of CSSA drugs, and perceptions of the participants regarding CSSA drugs.

The World Health Organization classifies poor-quality medicines under the umbrella term SF medical products. In Pakistan, however, national drug laws and regulatory practice employ legally defined categories referred to as CSSA drugs. To ensure legal accuracy and respondent comprehension, the questionnaire used the CSSA terminology as recognized under national regulations. These categories conceptually overlap with the WHO SF framework; however, reported prevalence in this study is based on CSSA categories rather than internationally standardized SF prevalence.

Questionnaire Validity

The instrument was tested for face and content validity by two researchers from the field of pharmacy practice and administration, who were experts in conducting qualitative as well as quantitative studies, especially in the areas of pharmacy policy and practice. For face validity, the questionnaire /instrument was evaluated and responses were collected from the other members

of the research team at Punjab University College of Pharmacy before launching the survey. Content validity was achieved by refinement of the questions during instrument/questionnaire development, keeping in view the data already collected, during the pilot stage. Content validity was assessed by two subject-matter experts in pharmacy practice and pharmaceutical regulation. The questionnaire was revised in the light of suggestions received. The instrument was pilot tested among a small group of pharmacy professionals to improve clarity and flow; no substantive content changes were made. Missing responses were handled using pairwise deletion, and denominators are reported for each item.

Sampling and Study Procedure

The convenience sampling method was adopted to reach out to the desired participants. The sample size was calculated by Raosoft calculator by assuming 5% margin of error, 95% confidence interval, and a prevalence of 50%. The sample size came out to be 351 participants. A total of 351 individuals were approached, of whom 166 accessed and completed the questionnaire, yielding a response rate of 47.29%. To improve the response rate, the questionnaire/instrument was designed to be succinct and pithy so that all areas relevant to the research were covered. The researcher made repeated phone calls to participants to persuade them to participate in the research, as the response rate was low. Web-based link was sent to pharmacists through WhatsApp groups, Facebook, and email, and reminded them time and again to fill out the questionnaire. As the questionnaire was a bit lengthy, people were reluctant to fill it out. However, the researcher personally contacted all the pharmacists and motivated them to participate in the research. Due to the use of convenience sampling and online recruitment, the sample may not be fully representative of all private pharmacy business stakeholders in Pakistan.

Data Analysis

The data were entered into the Statistical Package for Social Sciences (SPSS) software. The descriptive statistics were used to describe demographics and practice characteristics. Percentages and frequencies were used for categorical variables, while means and standard deviations were calculated for the continuous variables. The analysis was primarily descriptive, as the study aimed to explore perceptions and experiences.

Ethical Approval

Participation was voluntary, and informed consent was obtained electronically before survey initiation. No identifiable personal data was collected, and responses were anonymized. The study was approved by the Institutional Review Board (IRB) of the University of the Punjab, Lahore, Pakistan (Letter No: D/191/FIMS).

Results

Demographic Data

The total number of respondents was 166, out of which a major portion constituted male pharmacists; 75.3%

($n = 125$), while only 24.7% ($n = 41$) were females. The majority of the respondents were in the age group 36.48 ± 11.03 (SD), and the majority had been in the pharmacy business or domain for 11.19 ± 10.17 years. Most of the respondents, 30.1% ($n = 50$), belonged to community pharmacy, 19.9% ($n = 33$) were industrial pharmacists, whereas 15.1% ($n = 25$) were regulatory affairs pharmacists. Moreover, 12% ($n = 20$) pharmacists were also associated with the private teaching institutions. Persons related to sales and marketing were 10.2% ($n = 17$). The majority of participants, 83.7% ($n = 139$), hailed from urban areas, while 16.3% ($n = 27$) were from rural areas. The detailed demographics are given in Table 1.

Training of Pharmacists on Drug Regulations/CSSA Drugs

The study intended to explore the involvement of private sector pharmacy personnel in training on drug regulations. Most of the respondents, 55.4% ($n = 92$), confessed that they did not get any training on drug

Table 1 | Demographics of Surveyed Personnel ($n = 166$)

Demographics	Frequency (%)
Average age in years	36.48 ± 11.03
Average years of experience	11.19 ± 10.17
Gender	
Female	41 (24.7)
Male	125 (75.3)
Residence	
Rural	27 (16.3)
Urban	139 (83.7)
Qualification	
B.Pharm	19 (11.4)
B.Pharm, LLB	1 (0.6)
B.Pharm, M.Phil	32 (19.3)
B.Pharm, M.Phil, LLB	5 (3.0)
B.Pharm, MBA	2 (1.2)
Pharm.D	68 (41.0)
Pharm.D, LLB	2 (1.2)
Pharm.D, M.Phil	12 (7.2)
Pharm.D, MBA	2 (1.2)
Pharm.D, MBA, LLB	1 (0.6)
Ph.D	22 (13.3)
Sector of Work	
Academia	20 (12.0)
Business	1 (0.6)
Community Pharmacy	50 (30.1)
Distribution	4 (2.4)
Hospital	16 (9.6)
Industry	33 (19.9)
Regulatory Affairs	25 (15.1)
Sales and Marketing	17 (10.2)

regulations, while only 44.6% ($n = 74$) did. As to whether they had any previous formal training or education about CSSA drugs, 74.1% ($n = 123$) replied positively. Only 25.9% ($n = 43$) of the study sample had not previously received formal training regarding CSSA drugs. Furthermore, Figure 1 shows the types of education or training opportunities that the participants had in the past regarding CSSA drugs. The most common kinds of training were conferences and workshops (Figure 2).

Regarding the question of where participants received training in pharmacy law, the majority received training during their undergraduate studies and on-the-job (OJT) training, 21.7% and 14.5%, respectively (Figure 3). Regarding the questions where the training program or education should be provided on CSSA drugs, 53.6% ($n = 89$) respondents recommended ed-

ucation and training program during undergraduate degree at university level, 22.9% ($n = 38$) of the study population said that it should be OJT training, 14.5% ($n = 24$) said it should be during registration with pharmacy council and 9% ($n = 15$) preferred it to be imparted during postgraduate program like masters/PhD. Moreover, 44.6% ($n = 74$) liked that their education and training on CSSA drug issues be imparted through workshops, 24.7% ($n = 41$) preferred short certificate courses, and 22.9% ($n = 38$) preferred conferences as a mode of training. However, some participants, 5.4% ($n = 9$), selected distance learning as an appropriate mode of training (Table 2).

Degree of Perceived Prevalence of CSSA Drugs

The opinions of participants were sought about the de-

Conceptual mapping of Pakistan CSSA categories to WHO SF terminology

WHO Category	Pakistan Drug Law Term	Definition under the Pakistan Drugs Act, 1976
Substandard	Substandard drug	A drug that does not conform to the prescribed specifications or quality standards.
Falsified	Counterfeit drug	A drug whose label or outer packaging is an imitation of, or closely resembles, that of another manufacturer with the intent to deceive.
Falsified	Spurious drug	A drug that does not contain the stated active ingredient, or whose manufacturer is fictitious or non-existent.
Substandard / Falsified	Adulterated drug	A drug consisting wholly or partly of filthy, putrid, or decomposed substances, or manufactured, packed, or stored under unsanitary conditions.

Fig 1 | Mapping of CSSA with WHO SF terminology

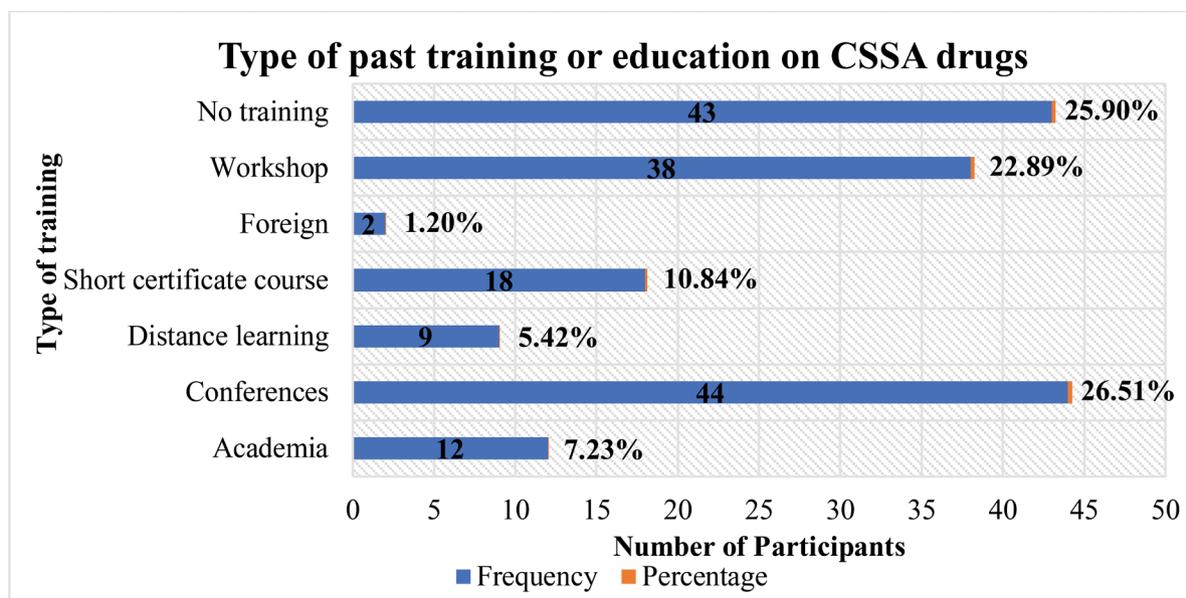


Fig 2 | Response of participants regarding the preference for the mode of training

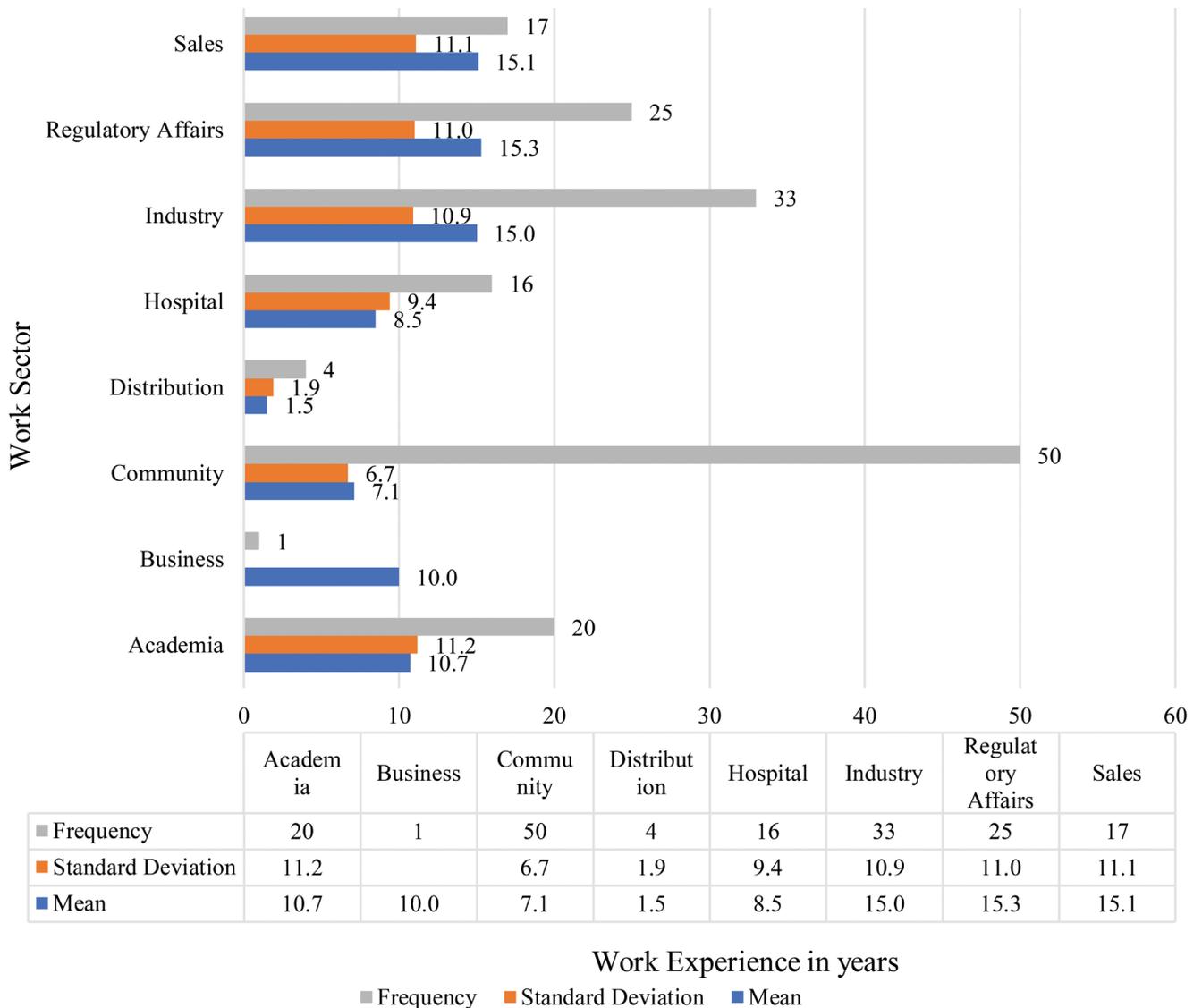


Fig 3 | Stratification of work experience into the sector of work

gree to which such drugs were present in the market. The majority, 74.7% ($n = 124$), acknowledged the presence of such drugs in society, whereas 18.1% ($n = 30$) declined to accept their presence, and 7.2% ($n = 12$) said that they did not know about it. The extent of perceived prevalence of substandard drugs in society was evaluated, and 28.9% ($n = 48$) of respondents considered the presence of substandard drugs in the range of 11%–30% in the pharmacy business sector, whereas 24.1% ($n = 40$) perceived it between 1%–10% and 31%–50%, respectively. However, 10.8% ($n = 18$) of participants believed it is in the range of 51%–70%, and 3.6% ($n = 6$) thought it is more than 70% in the market. Regarding the perceived prevalence of spurious drugs, 33.1% ($n = 55$) considered it in the range of 2%–10%, whereas 19.9% ($n = 33$) perceived it between 31% and 50%. However, 19.3% ($n = 32$) of respondents believed it is in the range of 11%–30%, and 13.3% ($n = 22$) think it is about 0%–1% in society. Similarly, for the perceived prevalence of counterfeit drugs, 38.6% ($n = 64$) considered it in the range

of 2%–10%, whereas 22.3% ($n = 37$) perceived it in between 11% and 30%. As far as the perceived prevalence of adulterated drugs is concerned, 31.9% ($n = 53$) considered it in the range of 0%–10%, whereas 15.1% ($n = 25$) perceived it in between 0%–1% and 31%–50%, respectively (Table 3).

Participants’ Experience of the CSSA Drug Issue

A significant number of participants had previous exposure to CSSA drugs in the past, 42.8% ($n = 71$), while the majority, 57.2% ($n = 95$), had no such experience in their professional life. As to whether pharmacy businesses operated and manned by pharmacists can play an effective role in combating CSSA drugs, 90.4% ($n = 150$) endorsed this viewpoint, and only 9.6% ($n = 16$) did not agree with this statement. Participants were also asked to opine about the effectiveness of drugs manufactured by multinational companies (MNCs) and imported drugs compared to locally manufactured drugs. The majority, 59.6% ($n = 99$), considered the drugs manufactured by MNCs to

Table 2 | Training of Participants on the Regulation of CSSA Drugs

Sr.	Questions	n (%)
1	Have you ever obtained any formal training in pharmacy law and education?	
	No	92 (55.4)
	Yes	74 (44.6)
2	Where did you receive training?	
	During Master's/Ph.D.	2 (1.2)
	During registration with the pharmacy council	12 (7.2)
	During undergraduate	36 (21.7)
	On-job training	24 (14.5)
	Not received	92 (55.4)
3	Have you ever obtained any formal training or education about counterfeit, spurious, substandard, and adulterated drugs?	
	Yes	123 (74.1)
	No	43 (25.9)
4	Which of the following education or training opportunities have you undertaken regarding counterfeit, substandard, spurious, and adulterated drugs?	
	Academia	12 (7.2)
	Conferences	44 (26.5)
	Distance learning	9 (5.4)
	Short certificate course	18 (10.8)
	Foreign	2 (1.2)
	Workshop	38 (22.9)
	No training	43 (25.9)
5	Where would you believe an education or training opportunity specifically about counterfeit, substandard, spurious, and adulterated drugs should be provided?	
	During Master's/Ph.D.	15 (9.0)
	During registration with the pharmacy council	24 (14.5)
	During undergraduate	89 (53.6)
	On-job training	38 (22.9)
6	Do you think that there should be a center for professional development for drug regulators to optimize their performance and effective working?	
	No	9 (5.4)
	Yes	157 (94.6)
7	Which type of education or training opportunity would you prefer to undertake regarding counterfeit, substandard, spurious, and adulterated drugs?	
	Conferences	38 (22.9)
	Distance learning	9 (5.4)
	Foreign	4 (2.4)
	Short certificate course	41 (24.7)
	Workshop	74 (44.6)

be more effective, while 40.4% ($n = 67$) did not agree with the statement. Similarly, 56% ($n = 93$) perceived that imported drugs were more effective compared to local drugs, but 44% ($n = 73$) did not consider local drugs inferior to imported drugs. The perception of participants regarding the current law and legislation, and the quantum of punishment, was also evaluated. The majority, 59% ($n = 98$), considered the penalties of CSSA drugs as insufficient, whereas 41% ($n = 68$) were satisfied with the current penalties awarded to drug law offenders (Table 4).

Role of Wholesalers/Distributors in the Spread of CSSA Drugs

The majority of participants (74.1%, $n = 123$) hold wholesalers/distributors responsible for the overall spread of CSSA drugs, while 25.9% ($n = 43$) do not consider them responsible. The vast majority, 82.5% ($n = 137$) hold wholesalers /or distributors liable for violation of drug laws along with the pharmaceutical manufacturers, while 17.5% ($n = 29$) did not agree with this notion. Similarly, 89.8% ($n = 149$) were of the view that medicines should only be sold

Table 3 | Perceived Prevalence of Counterfeit, Substandard, Spurious, and Adulterated Drugs

Sr.	Questions	n (%)
1	Do you think these types of drugs are commonly available in society?	
	Don't know	12 (7.2)
	No	30 (18.1)
	Yes	124 (74.7)
2	In your opinion, what is the perceived prevalence of substandard drugs in society?	
	Don't know	14 (8.4)
	1%–10%	40 (24.1)
	11%–30%	48 (28.9)
	31%–50%	40 (24.1)
	51%–70%	18 (10.8)
	More than 70%	6 (3.6)
3	What do you think is the perceived prevalence of spurious drugs in society?	
	Don't know	15 (9.0)
	0%–1%	22 (13.3)
	2%–10%	55 (33.1)
	11%–30%	32 (19.3)
	31%–50%	33 (19.9)
	51%–70%	8 (4.8)
	More than 70%	1 (0.6)
4	What do you think is the perceived prevalence of counterfeit drugs in society?	
	Don't know	15 (9.0)
	0%–1%	9 (5.4)
	2%–10%	64 (38.6)
	11%–30%	37 (22.3)
	31%–50%	30 (18.1)
	51%–70%	8 (4.8)
	More than 70%	3 (1.8)
5	What do you think is the perceived prevalence of adulterated drugs in society?	
	Don't know	13 (7.8)
	0%–1%	25 (15.1)
	11%–30%	29 (17.5)
	2%–10%	53 (31.9)
	31%–50%	25 (15.1)
	51%–70%	14 (8.4)
	More than 70%	7 (4.2)

to retail outlets and health care establishments by a pharmaceutical manufacturer/authorized agent (distributor)/importer/indenter and not by unauthorized wholesaler/stockist. Almost 86.7% ($n = 144$) of respondents were of the opinion that multiple intermediaries/middlemen/stockists in the pharmaceutical supply chain facilitate the supply of SF drugs to pharmacies. About 86.7% ($n = 144$) also considered the warranty of medicines issued by wholesalers without being an authorized agent of the manufacturer as illegal (Table 4).

Role of Media and Anti-Counterfeiting Technologies in Combating CSSA Drugs

The majority, 67.5% ($n = 112$), perceived that the media was not playing a positive or responsible role regarding news about CSSA drugs. Similarly, the majority, 81.9% ($n = 136$), considered the use of information technology tools like 2D barcode, RFID, and hologram technology as useful in combating CSSA drugs. Regarding the responsibility of the spread of CSSA drugs in society, the majority, 53.01% ($n = 88$), believed that unlicensed /unknown manufacturers are responsible for the prevalence of CSSA drugs. Almost 11.44%

Table 4 | Perceptions of Respondents About Counterfeit, Substandard, Spurious, and Adulterated Drugs

Sr.	Questions	No—n (%)	Yes—n (%)
1	Do you think that drugs manufactured by multinationals are more effective than local drugs?	67 (40.4)	99 (59.6)
2	Do you think that imported drugs are more effective than local drugs?	73 (44.0)	93 (56.0)
3	Do you think current law and legislation are sufficient to combat counterfeit, substandard, spurious, and adulterated drugs?	117 (70.5)	49 (29.5)
4	Do you think penalties for counterfeit, substandard, spurious, and adulterated drugs are sufficient?	98 (59.0)	68 (41.0)
5	Do you think that the wholesalers and/or distributors are responsible for the spread of counterfeit, substandard, spurious, and adulterated drugs?	43(25.9)	123 (74.1)
6	Do you think that the wholesaler/distributor is also liable, along with the pharmaceutical manufacturer, for drug law violations?	29 (17.5)	137 (82.5)
7	Do you think that medicine should be sold to retail outlets and health establishments by a pharmaceutical manufacturer/authorized agent (distributor)/importer/indenter and not by an unauthorized wholesaler/stockist?	17 (10.2)	149 (89.8)
8	Research has shown that multiple intermediaries/middlemen/Stockists in the pharmaceutical supply chain facilitate the supply of substandard and falsified drugs to pharmacies and medical stores in Pakistan. Do you agree?	22 (13.3)	144 (86.7)
9	Do you think that wholesalers issuing a warranty without being an authorized agent of the manufacturer is illegal?	22 (13.3)	144 (86.7)
10	Do you think pharmacies manned by qualified graduate pharmacists can play an effective role in combating the menace of counterfeit, substandard, spurious, and adulterated drugs?	16 (9.6)	150 (90.4)
11	Do you think the amendments made by the Punjab Government in the Drugs Act 1976 are effective in curbing the menace of counterfeit, substandard, spurious, and adulterated drugs in Punjab?	56 (33.7)	110 (66.3)
12	Do you think Drug Testing Laboratories (DTLs) in Punjab are equipped with the latest equipment and trained personnel for drug analysis?	80 (48.2)	86 (51.8)
13	Do you think the Appellate Laboratory, National Institute of Health (NIH), is equipped with the latest equipment and trained personnel for drug analysis?	84 (50.6)	82 (49.4)
14	Are you satisfied with the performance of the Punjab Quality Control Board (PQCB)?	99 (59.6)	67 (40.4)
15	Are you satisfied with the performance of District Quality Control Boards (DQCBs) in Punjab?	98 (59.0)	68 (41.0)
16	Are the Drug Courts playing an effective role in convicting the Drug law offenders?	104 (62.7)	62 (37.3)
17	Do you think training of Regulators and other stakeholders is essential to combat the menace of counterfeit, substandard, spurious, and adulterated drugs?	22 (13.3)	144 (86.7)
18	Have you had any experience with counterfeit, substandard, spurious, and adulterated drugs?	95 (57.2)	71 (42.8)
19	Do you think that the implementation of a warranty system, i.e., a warranty issued by the manufacturer or his/her authorized agent and importer/indenter, helps curb the menace of counterfeit, substandard, spurious, and adulterated drugs from society?	34 (20.5)	132 (79.5)
20	Do you think information technology tools like 2D barcode, RFID, hologram technology, etc., can be used to curb the menace of counterfeit, substandard, spurious, and adulterated drugs in the country?	30 (18.1)	136 (81.9)
21	Is the media playing a positive/responsible role regarding news about counterfeit, substandard, spurious, and adulterated drugs in the country?	112 (67.5)	54 (32.5)

($n = 19$) of respondents considered unauthorized wholesalers to be responsible for this spread (Table 4).

Discussion

The study was designed to evaluate the challenges faced in the management of pharmacy business operations and address the issues related to CSSA drugs. The understanding, knowledge, and experiences of business professionals in the pharmacy profession were evaluated. The study was performed by employing digital social media and electronic channels and approached a wide spectrum of respondents. The study highlighted various loopholes in the prevalence and spread of CSSA drugs.

The study found that a significant percentage of participants had previous experience with CSSA drugs, mainly due to greater exposure and engagement in surveillance, monitoring, and evaluation of drug quality. The study suggests that there is no organized system of communication about CSSA drugs. It underpins the

need for more training about CSSA drugs so that public health safety can be ensured by stopping the use of CSSA drugs. It is evident from the fact that less than half of the participants reported receiving any formal training on pharmacy law, which is an alarming sign warranting the need for policymakers and regulatory bodies to focus on capacity building of concerned professionals.

The majority of study participants preferred to get education or training at the university level, besides workshops, short courses, and conferences, and more than 90% endorsed the need for the establishment of a center for professional development to optimize performance and effective working, which showed their readiness to embrace the change through future training or education. Similar results have been corroborated in a previous study conducted on counterfeit medicines.¹⁵ The study showed that the majority of participants recognized the presence of CSSA drugs in the market. This shows that business professionals

are more skeptical about substandard drugs, and they believe these are available in abundance in the market. Similar is the case for counterfeit, spurious, and adulterated drugs. This is in contradiction to the previous study, in which one of the respondents reported that substandard and spurious drugs are not very prevalent in society.³ The respondents were of the view that this high prevalence of CSSA drugs is the result of media portraying such news without any evidence, just to grab the attention of the general public to increase the circulation of their newspapers and higher ratings of electronic media. This is corroborated by the fact that the majority of participants believed that the media was not playing a responsible/scrupulous role regarding CSSA drugs, respectively, as news reporters are not technical people and are not aware of drug issues.

The majority believed the quality of MNC products is superior to that of local drug manufacturers. Similarly, the majority also believed the quality of imported drugs to be better than locally manufactured drugs. Similar findings were observed in a study conducted in Iraq, where participants had a strong preference for imported products over national or generic products.¹⁶ However, in a study, it was found that the main driver for preference of patients for imported drugs was physicians' recommendations (38.3%), whereas 87.5% and 66.7% of pharmacists indicated that patients preferred imported products for prescription and non-prescription products, respectively, which was consistent with our study.¹⁷ Likewise, most of the participants did not repose any confidence in the current law and legislation to combat the menace of CSSA drugs. These findings are consistent with similar studies conducted in Pakistan, wherein weak legislation was declared as

the top contributing factor in the spread of CSSA drugs in the country.^{16,18}

Three-quarters of participants considered the wholesalers/distributors to be mainly responsible for the spread of CSSA drugs, which indicates that this sector should be strictly regulated without any laxity, as distributors/wholesalers are the main players in the drug supply chain, responsible for ensuring the integrity of the products. The majority of participants perceived the wholesalers/distributors as liable, along with the pharmaceutical manufacturer, in drug law violations. Almost 90% respondents were of the view to improve the supply chain system and advocated the provision of medicines either directly through the pharmaceutical manufacturer or by authorized agent(distributor)/ importer/indenter and not by poorly regulated and unauthorized wholesaler/stockist. They were also in agreement with the fact that multiple intermediaries and stockists in the pharmaceutical supply chain facilitate the supply of SF drugs. This practice is prevalent in the whole country, where multiple wholesalers are found in the supply chain and claim to be the agent of the manufacturer without any documentary evidence. These results are consistent with the news clipping wherein illicit Canadian pharmaceutical wholesaler SB Medical Inc./TC Medical group was convicted and fined \$75 million for conspiracy to smuggle misbranded and counterfeit medications into the United States from 2011 to 2014.¹⁹

This research also found that this supply chain is a real bone of contention wherein these self-claimed "wholesalers" are involved in the manufacturing and sale of CSSA drugs and frequently avoid the clutches of law by exploiting the loopholes in the system. In this

Risk–Control Matrix for CSSA Drugs Management in the Private Pharmacy Supply Chain

Identified Risk	Governance / Control Measures	Responsible Actors	Expected Business and Compliance Outcomes
Multiple intermediaries	Vendor accreditation procedures and track-and-trace systems	Wholesalers and distributors	Reduced entry of counterfeit medicines into the supply chain
Weak warranty verification	Mandatory warranty documentation checks and QR-code verification	Pharmacy procurement teams	Improved assurance of medicine authenticity
Limited staff training	Regular training workshops on CSSA identification and reporting	Pharmacists and pharmacy staff	Enhanced staff competency and risk awareness
Poor documentation	Standard operating procedures (SOPs) and periodic internal audits	Pharmacy management	Improved traceability and regulatory compliance
Under-reporting of cases	Dedicated reporting mechanisms and regulatory hotlines	Regulatory authorities	Faster detection and removal of CSSA-related threats

Fig 4 | Risk control measures in the private pharmacy supply chain

regard, it is pertinent to mention here that a similar situation was handled in the USA by the introduction of the Drug Supply Chain Security Act of 2013, which had to be fully implemented in 10 years.²⁰ The situation is more critical as the business of medicines in our country is in the hands of individuals with limited formal education, who mostly do not bother to buy medicines from a reliable source and are always trying to maximize profits in whatever manner. The findings are consistent with similar studies, where it is mentioned that medicines pass through multiple transactions, going back and forth, before reaching the supply point.²¹ The risk of CSSA drugs reaching patients increases with the increasing length and complexity of the supply chain.^{22,23} A closed and secure drug distribution system, ensuring the integrity of products, is a real solution.

More than 90% participants emphasized that the presence of qualified persons at the drug sale point can be a game changer, as the pharmacist can play an effective role in combating the problem of CSSA drugs by ensuring procurement through reliable sources. The study suggests that more than half of the participants were not satisfied with the functioning of regulatory bodies. For the conviction of drug law offenders, their role is very crucial, which must be transparent, based on merit, without any iota of nepotism and corruption. The study also found the training of regulators/stakeholders, implementation of a warranty system, and 2D barcode IT-based intervention as crucial, besides the development of infrastructure and logistic support to curb the menace of CSSA drugs (Figure 4).

From a pharmacy business management perspective, the findings highlight governance and compliance gaps across the private pharmaceutical supply chain. The findings reflect principal-agent problems within the pharmaceutical supply chain, where information asymmetry and weak monitoring increase the risk of CSSA medicines. Applying supply chain risk management and compliance frameworks highlights the need for governance mechanisms such as vendor accreditation, warranty verification, and structured training as risk-mitigating investments rather than operational costs. The perceived role of distributors reflects principal-agent challenges, where weak oversight and misaligned incentives increase quality risks. Limited regulatory training suggests underinvestment in human capital, despite the potential return on investment through reduced regulatory penalties, reputational damage, and patient harm. Adoption of track-and-trace technologies, standardized supplier audits, and structured compliance training programs may strengthen risk management within private pharmacy businesses.

Study Limitations

This study has several limitations. First, the reported prevalence values reflect respondents' perceptions and experiences rather than the objectively measured prevalence of CSSA medicines. Second, the use of

convenience sampling via social media may have introduced selection and nonresponse bias, limiting generalizability. These limitations are inherent to exploratory surveys but are acknowledged to ensure appropriate interpretation. The responses were self-reported; therefore, the study may be subject to recall and social desirability bias. Also, the cross-sectional design precludes causal inference, and findings reflect perceptions rather than objectively verified supply chain data.

Conclusion

The study highlighted that loopholes exist in the pharmaceutical supply chain system, which exacerbate the spread of CSSA drugs. The study emphasized the need for training and infrastructure development, and ensuring the secure supply chain through a robust regulatory system, coupled with a clear vision and policy based on merit and transparency instead of empty rhetoric.

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Questionnaire for assessment of challenges in combating counterfeit, substandard, and adulterated medicines in private pharmacy business management

Tick (✓) Appropriate Box

Demographics (Personal information and educational experiences)

- 1.0 Gender Male Female
- 2.0 What is your age? _____(years)
- 3.0 Residence area Urban Rural
- 4.0 Where and when you first obtained your first degree in Pharmacy University
_____Year _____
- 5.0 What is your qualification
- 6.0 B.Pharm
Pharm D
M.Pharm
M.Phil
PhD(Pharm)
M.B.A
LLB
M.S.(TQM)
Any other _____
- 7.0 In which year did you first obtain your Pharmacy Council Registration as a Pharmacist:

- 8.0 Your experience of working in pharmacy settings in years
0-5
6-10
11-15
16-20
21-25
over 25
- 9.0 In which sector do you work
Industry
Regulatory Affairs
Community Pharmacy
Hospital
Sales and Marketing
Other, Explain _____
Training on Drug Regulations
- 10.0 Have you ever obtained any formal training about the Pharmacy/Drug law & legislation?
Yes
No
- 11.0 Where did you receive training?
During an undergraduate degree
During Master's/PhD
On-the-job training
During registration with the pharmacy council
Not received
- 12.0 Have you attended any formal education or training regarding counterfeit, substandard, spurious and adulterated drugs?
No
Yes
how many times _____
- 13.0 Which of the following education or training opportunities have you undertaken regarding counterfeit, substandard, spurious and adulterated drugs?
Workshop
Conferences
Distance learning
Short certificate course
Academia
Foreign training
Other
(please specify) _____
- 14.0 Where would you believe an education or training opportunity specifically about counterfeit, substandard, spurious, and adulterated drugs should be?
During an undergraduate degree
During Master's/PhD
On-the-job training
During registration with the pharmacy council
- 15.0 Do you think that there should be a center for professional development for Pharmacists to optimize their performance and effective working?
Yes
No
Other
Please specify _____
- 16.0 Which type of education or training opportunity would you prefer to undertake regarding counterfeit, substandard, spurious, and adulterated drugs?
Workshop
Conferences
Distance learning
Short certificate course
Foreign
Other (please specify) _____
Prevalence of counterfeit, substandard, spurious, and adulterated drugs
- 17.0 Do you think these types of drugs are commonly available in the society?
Yes
No
I do not know
- 18.0 In your opinion, what is the prevalence of substandard drugs in the society?
0%-1%
1%-10%
10%-30%
30%-50%
50%-70%
More than 70%
I do not know
- 19.0 What do you think prevalence of spurious drugs in the society is:
0%-1%
1%-10%
10%-30%

- 30%–50%
- 50%–70%
- More than 70%
- I do not know
- 20.0 What do you think is the prevalence of counterfeit drugs in the society?
- 0%–1%
- 1%–10%
- 10%–30%
- 30%–50%
- 50%–70%
- More than 70%
- I do not know
- 21.0 What do you think is the prevalence of adulterated drugs in the society is:
- 0%–1%
- 1%–10%
- 10%–30%
- 30%–50%
- 50%–70%
- More than 70%
- I do not know
- Other
- Please specify _____
- Perceptions about counterfeit, substandard, spurious, and adulterated drugs
- 22.0 Do you think that drugs manufactured by multinationals are more effective than local drugs?
- No
- Yes
- No difference
- I do not know
- Other
- Please specify _____
- 23.0 Do you think that imported drugs are more effective than local drugs
- No
- Yes
- No difference
- I do not know
- Other
- Please specify _____
- 24.0 Do you think current law and legislations are sufficient to combat counterfeit, substandard, spurious, and adulterated drugs?
- Yes
- No
- Other
- Please specify _____
- 25.0 Do you think penalties and punishments for counterfeit, substandard, spurious, and adulterated drugs are sufficient?
- Yes
- No
- Other
- Please specify _____
- 26.0 What is the role of wholesalers/distributor in supply chain system and do you think that the wholesalers and the middleman are responsible for the spread of counterfeit, substandard, spurious, and adulterated drugs?
- Yes
- No
- Other
- Please specify _____
- 27.0 Do you think that the wholesaler/distributor is also liable, along with the pharmaceutical manufacturer, for drug law violations?
- Yes
- No
- Other
- Please specify _____
- 28.0 Do you think that medicine should be sold to retail outlets and health establishments by a pharmaceutical manufacturer/ his authorized agent (distributor)/importer/indenter and not by unauthorized wholesaler/stockiest?
- Yes
- No
- Other
- Please specify _____
- 29.0 Do you think that wholesalers giving warranty without being authorized agent of the manufacturer are illegal?
- Yes
- No
- Other
- Please specify _____
- 30.0 Do you think pharmacies manned by qualified graduate pharmacists can play effective role in combating the menace of counterfeit, substandard, spurious, and adulterated drug?
- Yes
- No
- Other
- Please specify _____
- 31.0 Do you think amendments made by the Punjab Government in the Drugs Act 1976 are effective to curb the menace of counterfeit, substandard, spurious, and adulterated drugs in Punjab?
- Yes
- No
- Other
- Please specify _____
- 32.0 Do you think the 18th constitutional amendment has affected the drug regulatory process in the country?
- Yes
- No
- Other
- Please specify _____
- 33.0 Do you think DTL's in Punjab are equipped with the latest equipment's and trained personnel for drug analysis?
- Yes
- No

- Other
Please specify _____
- 34.0 Do you think the Appellate Laboratory NIH is equipped with the latest equipment's and trained personnel for drug analysis
Yes
No
Other
Please specify _____
- 35.0 Are you satisfied with the performance of PQCB
Yes
No
Other
Please specify _____
- 36.0 Are you satisfied with the performance of DQCB's in Punjab
Yes
No
Other
Please specify _____
- 37.0 Are the Drug Courts playing an effective role in convicting the Drug law offenders?
Yes
No
Other
Please specify _____
- 38.0 Do you think training of Regulators and other stakeholders is essential to combat the menace of counterfeit, substandard, spurious and adulterated drugs?
Yes
No
Other
Please specify _____
- 39.0 Have you had any experience with counterfeit, substandard, spurious, and adulterated drugs?
No
Yes
How many times and name any

- 40.0 The counterfeit/spurious drug encountered belongs to class:
CVS
Asthma
- GIT
CNS
Antibiotics
Anticancer
Analgesic
Other
Please specify _____
- 41.0 Who is mainly responsible for counterfeit/substandard/spurious, and adulterated drugs in society
Unlicensed/unknown manufacturer/
Sub-Distributor/Wholesaler/stockiest
(Unauthorized)
Licensed Manufacturer
Authorized Distributor
Medical stores
Other
Please specify _____
- 42.0 Do you think that implementation of a warranty system, i.e. warranty issued by manufacturer or his/her authorized agent and importer/indenter, is helpful in curbing the menace of counterfeit, substandard, spurious, and adulterated drugs from society?
Yes
No
Other
Please specify _____
- 43.0 Do you think information technology tools like 2D barcode, RFID, halogram technology, etc., can be used to curb the menace of counterfeit, substandard, spurious, and adulterated drugs in the country?
Yes
No
Other
Please specify _____
- 44.0 Is the media playing a positive/responsible role regarding news about counterfeit, substandard, spurious, and adulterated drugs in the country?
Yes
No
Other
Please specify _____