Available online on 15 Sep, 2023 at https://ijdra.com/index.php/journal

International Journal of Drug Regulatory Affairs

Published by Diva Enterprises Pvt. Ltd., New Delhi
Associated with RAPS & Delhi Pharmaceutical Sciences & Research University

Research Article

Open Access

Exploring the Knowledge and Practices of Adverse Drug Reaction and Falsified Medicine Reporting Amongst the Community Pharmacists of India

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Abstract

Background: Adverse drug reactions (ADRs) and falsified medicines (FMs) pose significant threat to patient safety and public health. Understanding the knowledge, experiences, and perspectives of community pharmacists in India regarding ADRs and FMs is crucial for effective intervention and prevention strategies.

Objective: This study aimed to assess the knowledge, experiences, and perspectives of community pharmacists in India regarding ADRs and FMs. It sought to gather information on pharmacists' familiarity with the threats posed by ADRs and FMs, their understanding of relevant legislation, their personal encounters with ADRs and FMs, and their views on the distribution of FMs and the adequacy of existing legislation.

Method: A survey was conducted among community pharmacists in India, and data were collected using a questionnaire. The survey included questions related to knowledge, experiences, and perspectives on ADRs and FMs. The responses were analysed to identify trends and key findings.

Results: The analysis revealed that a significant majority of pharmacists demonstrated a fundamental understanding of ADRs and FMs. However, a relatively low percentage reported encountering ADRs as well as FMs in their practice, with an equally low proportion reporting these incidents to the appropriate authorities Majority of pharmacists believed that they plan an important role in reporting of ADRs but only half of the pharmacists' surveyed things that they plan an important role in tackling the issue of FMs.

Conclusion: The research highlights that community pharmacists in India have a good understanding of Pharmacovigilance and ADR reporting, although knowledge of Indian legislation needs improvement. Pharmacists demonstrate a positive attitude towards ADR reporting and promptly report encountered ADRs and FMs. Patient education, convenience of the reporting system, and strengthening FM legislation are areas that require attention. Major sources of FM distribution are online pharmacies and street hawkers. These findings contribute to enhancing pharmacovigilance practices and addressing FM distribution in India.

Keywords: Adverse Drug Reactions (ADRs), falsified medicines, community pharmacists, India, PvPI, pharmacovigilance

Article Info: Received 30 Jun 2023; Review Completed 28 Aug 2023; Accepted 29 Aug 2023

Cite this article as:
Kaj KH. Exploring the Knowledge and Practices of Adverse Drug Reaction and Falsified Medicine Reporting Amongst the Community Pharmacists of India. Int J Drug Reg Affairs [Internet]. 2023 Sep 15 [cited 2023 Sep 15]; 11(3): 22-32. Available from:
http://ijdra.com/index.php/journal/article/view/612

DOI: 10.22270/ijdra.v11i3.612
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1. Introduction

Pharmacovigilance

Pharmacovigilance, as defined by the World Health Organization (WHO), encompasses the science and activities involved in detecting, assessing, understanding, and preventing adverse effects and other drug-related problems. (1) While adverse drug reactions (ADRs) are a key focus, pharmacovigilance also addresses medication errors, substandard and counterfeit medicines / falsified medicines (FMs), low drug efficacy, drug abuse, and drug-drug interactions. However, the primary emphasis of pharmacovigilance remains on the detection and reporting of ADRs. (2)

The significance of pharmacovigilance is underscored by the fact that ADRs are a major cause of morbidity and mortality. (3) In India, approximately 3.7% of hospital admissions can be attributed to ADRs (4), highlighting their impact on patient health. Therefore, effective pharmacovigilance systems are crucial for ensuring patient safety and optimizing healthcare outcomes.

By systematically collecting and analyzing data on suspected ADRs, pharmacovigilance programs contribute to identifying previously unknown or poorly

understood adverse effects of medications. This information is vital for improving patient care, guiding regulatory decisions, updating drug labelling, and implementing risk management strategies. (3)

The ultimate goal of pharmacovigilance is to enhance drug safety by minimizing the risks associated with the use of medications and maximizing their benefits. It relies on the active participation of healthcare professionals, including pharmacists, who play a vital role in detecting, reporting, and preventing ADRs. Their contributions in recognizing ADRs through their clinical experience and communicating relevant risk data to other healthcare workers are invaluable in improving the overall pharmacovigilance process. (5)

1.1 Pharmacovigilance programme of India

The Pharmacovigilance Programme of India (PvPI) is a comprehensive drug safety monitoring program established in India. It serves as a crucial initiative to ensure the safe and effective use of medications in the country. The program is spearheaded by the Indian Pharmacopoeia Commission (IPC), which acts as the National Co-ordination Centre (NCC) responsible for overseeing and coordinating pharmacovigilance activities nationwide. (2)

In order to effectively monitor ADRs, selected medical colleges and hospitals are designated as ADR Monitoring Centres (AMCs) under the PvPI. These AMCs play a pivotal role in the collection, analysis, and reporting of Individual Case Safety Reports (ICSRs). They actively collaborate with healthcare professionals and encourage reporting of suspected ADRs from various sources, including hospitals, clinics, and community settings. (2)

The collected ICSRs are then submitted to the NCC for further evaluation and assessment. The NCC, in collaboration with other stakeholders, analyses the data to identify potential safety signals and assess the risk-benefit profile of drugs in the Indian market. This crucial information helps in making informed decisions regarding the regulation, labelling, and safety of pharmaceutical products. (3)

Through the PvPI, India aims to strengthen its pharmacovigilance system, enhance patient safety, and contribute to global drug safety initiatives. By actively monitoring and reporting ADRs, the program plays a vital role in promoting the rational use of medications and improving public health outcomes across the country. (3)

The below graph displays, the total number of ICSRs reported by various stakeholders to the AMCs under NCC-PvPI:

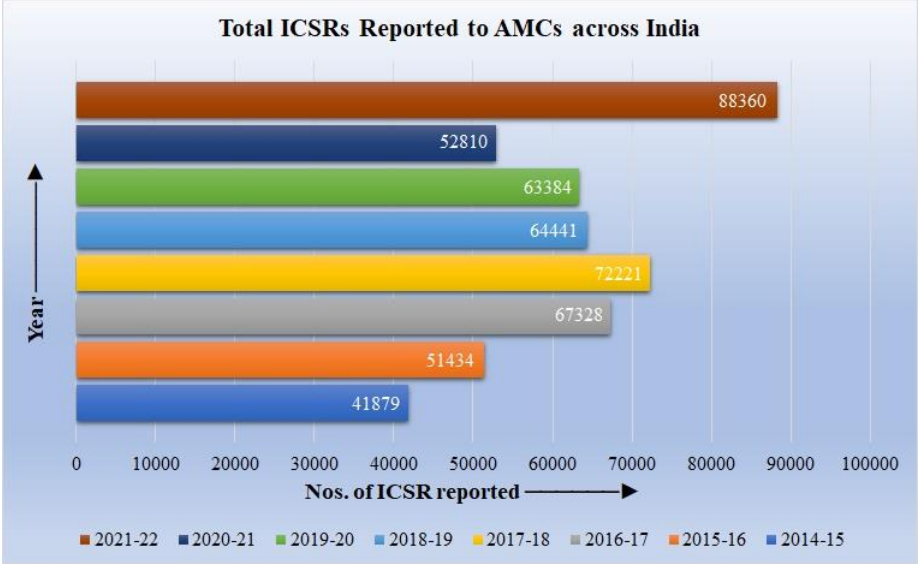

Figure 1. Total ADRs Reported to the NCC-PvPI (6-13)

1.2 Legislation governing Pharmacovigilance in India

The regulation for pharmacovigilance in India is established in the Schedule-Y of The Drugs and Cosmetics Act 1940 and Rules 1945, which provides guidelines on reporting timelines and data elements for serious ADRs. (14) This regulatory amendment also made it a legal obligation to report ADRs during clinical trials, supporting India's Good Clinical Practice (GCP) guidelines. (14)

Regarding generic drugs, the regulations require generic drug manufacturers to collect, monitor, and report spontaneous ADRs, including the reporting of Suspected Unexpected Serious Adverse Reports (SUSARs) and the preparation of Periodic Safety Update Reports (PSURs) The amendment also mandates Indian pharmaceutical companies to establish adequate pharmacovigilance systems to ensure the reporting of ADRs. (14)

In addition, the Schedule-M of the D&CA 1940 and Rules 1945 provides a legal framework for handling complaints and adverse reactions in the pharmaceutical industry. It stipulates that all complaints regarding product quality should be reviewed, recorded, and investigated according to written procedures. Serious ADRs should be reported promptly to the relevant licensing authority, and there should be written procedures describing the actions to be taken and recalls being made for defective products. (15)

To ensure the smooth functioning of pharmacovigilance activities in the pharmaceutical industry, the IPC collaborated with the Central Drugs Standard Control Organization (CDSCO) to release the "Pharmacovigilance Guidance Document for Marketing Authorization Holders of pharmaceutical products" in October 2017. This document aims to assist Marketing Authorization Holders (MAHs) in establishing and maintaining effective pharmacovigilance systems at their manufacturing sites. (16)

Furthermore, the IPC published a guidance document in 2014 for the spontaneous reporting of ADRs for medicines, vaccines, and blood products. This document aims to encourage healthcare professionals to report ADRs and collect case reports and data, ultimately improving patient safety and reducing risks associated with drug products. (17)

1.3 Methods of Spontaneous Reporting of ADRs in India

In India, the reporting of ADRs is facilitated through various channels, as outlined by the IPC (17):

Patients can contact their healthcare providers who are required to fill out the "Suspected Adverse Drug Reaction Form," which is available on the official website of the IPC. The completed form can be submitted to the nearest AMC or directly to the NCC. (17)

Patients or their representatives can complete a "Medicines Side Effect Reporting Form" available on the official website of the IPC in multiple vernacular languages. The completed form can be sent via post or email to the NCC. (2)

A toll-free helpline number, 1800 180 3024, is available for individuals to report ADRs. (13)

Patients or their representatives can utilize a mobile phone application called "ADR PvPI," specifically designed for Android users, to report ADRs. (18)

These various reporting mechanisms aim to provide multiple avenues for individuals to report ADRs and contribute to the pharmacovigilance efforts in India. (18)

2. Falsified Medicines

The proliferation of falsified medicines (FMs) is a critical issue within the healthcare industry, necessitating immediate attention. FMs are counterfeit products deliberately designed to deceive consumers regarding their identity, composition, or origin, and they are illicitly promoted as genuine and authorized medications This illicit practice poses a substantial threat to public health on a global scale, emphasizing the urgent requirement for robust pharmacovigilance measures. (19)

To combat the issue of FMs effectively, pharmacovigilance plays a pivotal role by actively monitoring and detecting these fraudulent products. Pharmacovigilance systems contribute significantly to the identification and resolution of the presence of counterfeit medications in the market by collecting and analyzing data related to suspected FMs. Additionally, pharmacovigilance programs enhance awareness among healthcare professionals and the general public about the associated risks of purchasing medicines from unauthorized sources, such as online pharmacies or unlicensed medicine shops. (19)

2.1 Major concerns of Falsified Medicines in India

A concerning issue in the global pharmaceutical landscape is the contaminated, substandard quality, and presence of spurious medicines. According to a study by Khan et al. (2015), a significant proportion of medicines supplied globally are found to be contaminated, substandard, or spurious. The report further highlights that India contributed to approximately 75% of the cases of falsified medicines worldwide. (20)

In 2007, a survey conducted by the Southeast Asia Regional Pharmaceutical (SEARPharm) Forum, a group of Pharmaceutical Associations of the International Pharmaceutical Federation (FIP) and the WHO, analysed 10,743 samples of medicines collected from 234 retail outlets in India. The survey revealed that about 31% of the samples were identified as spurious, and 0.3% did not meet the pharmacopoeial standards. (20)

To assess the issue of spurious and substandard drugs in India, the National Institute of Biologicals conducted a study in 2017. The study included 47,954 product samples of 224 drug molecules from various supply chains across 654 districts in 36 states and union territories. The samples were tested in Central and State Drug Testing Laboratories according to pharmacopoeial criteria. The results showed that out of the 47,012 samples tested, 13 samples were found to be spurious, and 1,850 samples were deemed "Not of Standard Quality" (NSQ). This indicates that 3.16% of drugs in India are NSQ, while the percentage of spurious drugs was found to be 0.0245%. (21)

2.2 Legislation addressing Falsified Medicines in India

In accordance with the Drug and Cosmetic Act, 1940, and Rules 1945 of India, the guidelines for substandard drugs are categorized into Sections 17, 17A, and 17B. (20)

In 2008, an amendment was made to the Drug and Cosmetic Act, 1940, and Rules 1945, which classified low-quality products into three categories (22):

Category A: This category includes spurious and adulterated drug products that are typically manufactured by unlicensed individuals involved in illegal activities. In some cases, these products may also be produced by licensed manufacturers.

Category B: Substandard drugs fall under this category when they fail the disintegration or dissolution test. Additionally, drugs in this category have an active pharmaceutical ingredient (API) assay result below 70% and may contain up to 5% of the permitted limit of thermolabile product for tablets or thermostable products for capsules.

Category C: This category covers products with minor defects, such as emulsion cracking, variations in net content, sedimentation in clear liquid preparations, failure of the weight variation test, uneven coating, presence of foreign matters, discoloured formulations, and errors in labelling.

As per this amendment, if an adulterated or spurious drug causes death, the manufacturer and seller may face imprisonment for a minimum of ten years or even a lifetime. They are also penalized with a minimum of 10 lakh Indian Rupees or three times the value of the confiscated drugs, whichever amount is higher, as a deterrent against illegal practices. (20)

2.3 Methods of reporting of Falsified Medicines in India

In India, the reporting of FM is directed to the state drug control administration. The Indian Government has established a "whistleblower scheme" to encourage individuals to come forward with information about FM producers and sellers. This scheme offers monetary rewards to individuals who take the risk of providing such information. (22)

Under the whistleblower scheme, informers who provide specific information that leads to the seizure of falsified, adulterated, misbranded medications, cosmetics, and medical devices can receive lucrative incentives. Additionally, officers of the CDSCO who provide relevant information leading to such seizures are also eligible for rewards. (22)

The purpose of this reward scheme is to incentivize individuals and authorities to actively participate in combating the production and sale of falsified products, thereby safeguarding public health, and ensuring the integrity of the healthcare system in India. (22)

Also, a healthcare professional can complain to the drug enforcement authority if they notice a FM in supply chain. (20)

3. Role of Pharmacists in reporting of ADRs and FMs

Pharmacists have the potential to contribute significantly to the reporting of ADRs by leveraging their unique clinical experience. Their distinct perspective allows them to identify ADRs that may differ from those observed by general medicine practitioners. By effectively communicating this risk data to other healthcare professionals, pharmacists play a crucial role in enhancing the pharmacovigilance process. (5) Furthermore, they establish connections between patients and other healthcare providers, enabling the development and dissemination of educational materials through drug information centres. These materials, such as newsletters, pamphlets, and publications, focus on drug warnings and promote drug safety. (5) Pharmacists also contribute to data collection for initiating pharmacoepidemiologic longitudinal studies. In one-on-one counselling sessions, they actively work to minimize medication errors and improve patient safety and quality of life. (5)

Pharmacists hold a significant responsibility as healthcare professionals as they are the final custodians of medicines before they are dispensed to patients. They ensure the proper use and administration of medications, playing a vital role in patient care. Additionally, pharmacists actively participate in managing the supply chain of medicines, overseeing processes from manufacturing to procurement, with a focus on maintaining quality and ensuring authenticity. (19)

The expanding market for falsified products, driven by shortages, high costs, and weak regulatory systems, highlights the critical role of pharmacists. They are essential in strengthening procurement processes and educating patients about the risks associated with purchasing medicines from unauthorized sources such as online pharmacies, unlicensed medicine shops, or street vendors, including illiterate hawkers. Pharmacists actively report any observed changes in the efficacy of drug products, contributing to the detection and prevention of FMs. (19)

4. Limitations

A study conducted by Mohmoud et al., regarding the knowledge of ADR reporting found that 23% of the pharmacists involved in the study were familiar with the ADR reporting process while 77% of the pharmacists had never registered any ADRs due to the lack of awareness about the reporting process. (5)

The major limitation for a pharmacist in the identification and detection of FMs is their lack of knowledge and training in the supply chain of pharmaceuticals. (19) Another issue is the selling of medicines through online pharmacies. People have a belief that the online purchase of medicines is convenient and economical. Many times, the online pharmacies make false advertisements claiming to sell drugs that have a magic effect such as immediate weight loss, curing baldness, and to cure erectile dysfunction. However, in fact, these medicines contain substandard or falsified drug substance that has no effect or sometimes-adverse reactions on its consumers. (23)

A study by Chambliss et al. in 2012 suggests that by increasing awareness, recognizing training materials with specific advice, and enforcing guidelines to ensure the integrity of the supply chain can help pharmacists to tackle the issue of FMs. (24)

5. Objective of the study

Globally, the role of pharmacists in pharmacovigilance varies country-wise. But in the recent decade, the role of pharmacists has evolved from just dispensing of drugs to the full fledge reporting of ADRs. (25) Pharmacists are considered as the most accessible health care professionals especially in India where the access of general physicians in remote areas is limited. (4)

The present study aims at investigating the knowledge of Community Pharmacists of India in reporting ADRs to the NCC-PvPI, their understanding of the regulations of pharmacovigilance and the practice of “spontaneous” reporting the ADRs in their respective countries by conducting survey and interviews. (25)

Spontaneous reporting means the reporting of ADRs by any healthcare worker as it is observed, voluntarily. (26) It is also known as individual case safety reports (ICSRs), and it is the most frequently used method of post-market surveillance of medicines all around the world. (27)

The study will also investigate knowledge of FMs, and the action taken by the community pharmacists of India to report them as it has become a global issue. Ironically, no studies were carried out previously which measures the knowledge, attitude, and practice of reporting of falsified medicines. Thus, it made a new exploratory field to conduct the study. (27)

The reason for selecting the community pharmacists of India as a study group because India is a leader in pharmaceutical industries. This will provide us answers on whether the safety surveillance in dispensing field of pharmaceuticals is as standardized as that in the development of medicines. (27)

6. Method and material

The study utilized a cross-sectional, observational approach to assess the knowledge and attitude of community pharmacists in India regarding the reporting of ADRs and FMs. Data collection was conducted through an online survey distributed among community pharmacists in India. The online platform "Survey Planet" was utilized, with a paid "Pro" plan to access premium features and analysis tools.

The survey consisted of 21 questions divided into two sections: Pharmacovigilance & ADR reporting and FMs. The questionnaire was developed based on previous studies and literature and covered various topics such as pharmacovigilance knowledge, ADR reporting, sources of knowledge, legislation, encounters with FMs, reporting of suspected FMs, patient awareness, and opinions on the role of pharmacists. Most questions had close-ended options, including multiple-choice responses, while some questions allowed for open-ended responses to gather participants' opinions.

A total of 470 emails containing survey links were sent to community pharmacists in India, ensuring compliance with Indian regulations requiring registration with state pharmacy councils. The response rate was 13.4%, with 63 pharmacists participating in the study.

Data collection was conducted using the "Survey Planet" online tool, chosen for its efficiency and accuracy. The collected responses were analysed using Microsoft Excel 2019 and IBM SSPS Statistics 23 software. The data analysis involved the use of frequency and percentages to describe the responses and provide insights into the knowledge and attitudes of community pharmacists.

Ethical considerations were addressed in the study, as it posed no risks to the participants. Full transparency was maintained throughout the research process, and participants were provided with an introductory note explaining the purpose of the study, emphasizing voluntary participation, ensuring anonymity, and estimating the completion time of the survey. Informed consent was obtained from all participants in the beginning of the survey.

7. Results

7.1 Pharmacovigilance & ADR reporting

This is the first part of the survey questionnaire and is divided into four sub-sections.

a. Demographic information of Pharmacists

The survey responses received were categorized into four groups based on the years of practical experience of the participating pharmacists. The groups were defined as follows:

- Group A: Pharmacists with less than 5 years of experience.
- Group B: Pharmacists with 5-10 years of experience.
- Group C: Pharmacists with 11-20 years of experience.
- Group D: Pharmacists with more than 20 years of experience.

This categorization allowed for an analysis of the survey results by comparing the responses among pharmacists with different levels of experience. It provided an opportunity to identify any potential variations or trends in their responses based on their years of practical experience in the field. By examining the data within each experience group, the study aimed to gain insights into the knowledge, attitudes, and practices of pharmacists at different stages of their professional careers.

Table 1. Demographic information of Pharmacists

Q. no.	Question	Data received				
1	How many years have you been registered as a pharmacist?	**< 5 years** % (n)	**5-10 years** % (n)	**11-20 years** % (n)	**> 20 years** % (n)	**Total** % (n)
		60.32 (38)	25.4 (16)	7.94 (5)	6.35 (4)	100 (63)

The analysis of the survey results revealed that the majority of respondents, accounting for 60.32% of the total, had less than five years of work experience as a Certified Pharmacist. This group may include newly registered pharmacists who are relatively new to the field.

The second-largest group of pharmacists, comprising 25.4% of the total responses, had work experience between 5-10 years. These pharmacists have gained a moderate level of experience in their professional careers.

The group with the third-highest representation consisted of pharmacists with work experience between 11-20 years, making up 7.94% of the total responses. These individuals have accumulated a substantial amount of experience throughout their careers.

Finally, pharmacists with more than 20 years of work experience constituted 6.35% of the respondents. This group represents pharmacists with extensive practical experience, likely having witnessed significant changes and developments in the field over the years.

b. Knowledge of Pharmacovigilance

The questionnaire aimed to assess the knowledge of community pharmacists regarding the following aspects:

Understanding of Pharmacovigilance: Assessing the pharmacists' comprehension of Pharmacovigilance and its key components, including ADRs, FMs, medication errors, off-license drug use, abuse and misuse, lack of efficacy, poisoning, drug-drug/food interactions, expired stock destruction, and drug-related mortality.

Knowledge Acquisition: Gathering information on how pharmacists acquired their knowledge of Pharmacovigilance, including their pharmacy training, continuing education programs, professional development activities, or any other sources that contributed to their understanding of Pharmacovigilance.

Knowledge of Legislation: Evaluating the pharmacists' knowledge of the legislation related to Pharmacovigilance in India, including their familiarity with relevant laws, regulations, guidelines, or directives governing the practice of Pharmacovigilance in the country.

Knowledge of the Pharmacovigilance System in India: Determining the pharmacists' awareness and understanding of the Pharmacovigilance system in India, including their knowledge of reporting systems, regulatory authorities responsible for Pharmacovigilance oversight such as the PvPI, and any other pertinent information regarding the implementation of Pharmacovigilance in the country.

Table 2. Responses related to the knowledge of pharmacovigilance amongst pharmacists

Q. no.	Question	Respondent with a 'Yes' % (n)
2	Do you possess a basic knowledge of the term "Pharmacovigilance"?	95.24 (60)
3	From where did you achieve basic knowledge of Pharmacovigilance?	
	➢ College/University	84.13 (53)
	➢ Refresher Courses hosted by Pharmacy council / society	4.76 (3)
	➢ UMC Online courses	3.17 (2)
	➢ Others	3.17 (2)
	➢ Unanswered	4.76 (3)
4	Are you aware of the pharmacovigilance legislation of India?	50.79 (32)

Based on the evaluation of the survey results, the following observations were made:

Understanding of Pharmacovigilance: A majority of pharmacists (95.24%) demonstrated a basic understanding of pharmacovigilance, indicating a widespread familiarity with the concept and its components among the surveyed pharmacists.

Sources of Pharmacovigilance Education: The primary source of pharmacovigilance education for pharmacists was their college/university education, with 84.13% of respondents reporting it as their source of knowledge. Refresher courses hosted by pharmacy councils/societies also played a significant role, as reported by 4.76% of pharmacists. Other sources, including work practice, contributed to the pharmacovigilance education of 3.17% of pharmacists. Online courses hosted by the Uppsala Monitoring Centre (UMC) were reported by 3.17% of respondents.

Knowledge of Indian Pharmacovigilance Legislation: The survey findings revealed that only 50.79% of pharmacists surveyed possessed knowledge of the Indian pharmacovigilance legislation. This suggests that a considerable proportion (49.21%) of pharmacists may lack awareness and understanding of the specific legislation governing pharmacovigilance practices in India.

In conclusion, while most pharmacists demonstrated a basic understanding of pharmacovigilance, there is room for improvement in terms of their awareness and knowledge of the specific pharmacovigilance legislation in India. Efforts can be made to enhance education and training on pharmacovigilance, particularly regarding the legal framework surrounding it.

c. Knowledge, attitude, and practice of ADR reporting

The objective of this section of the questionnaire was to collect data on the awareness and attitude of pharmacists towards ADRs. Specifically, the questionnaire aimed to assess the following aspects:

Awareness of ADRs among Patients: The survey sought to determine the pharmacists' perception of patient awareness regarding ADRs. This could include their observations of patients reporting ADRs or expressing awareness of the potential side effects of medications.

Awareness of the ADR Reporting System: The questionnaire aimed to assess the pharmacists' awareness of the ADR reporting system in place. This could include their knowledge of the reporting mechanisms, such as how and where to report ADRs.

Personal ADR Reporting: The survey sought to determine whether the pharmacists themselves have reported any ADRs. This would provide insights into their engagement in monitoring and reporting ADRs.

By gathering this information, the questionnaire aimed to evaluate the pharmacists' level of awareness and

involvement in ADR monitoring and reporting, as well as their perception of patient awareness regarding ADRs.

Table 3. Responses related to the knowledge, attitude, and practice of ADR reporting amongst the pharmacists

Q. no.	Question	Respondent with a 'Yes'% (n)
5	Do you know what Adverse Drug Reactions (ADRs) are?	95.24 (60)
6	Do you think reporting of an ADR should be mandatory for safety surveillance of the drug product?	84.13 (53)
7	Do you think that the patients are aware of ADR reporting?	26.98 (17)
8	Are you aware of the ADR reporting system of PvPI	82.54 (52)
9	Which of the following ADRs reporting methods are you aware of?	
	➢ ADR Reporting form for healthcare professionals	58.73 (37)
	➢ Side effects reporting form for patients	15.87 (10)
	➢ Toll-free number	9.52 (6)
	➢ ADR PvPI Mobile App	7.94 (5)
	➢ Others	3.17 (2)
	➢ Unanswered	4.77 (3)
10	Have you reported any ADR?	17.46 (11)

Upon analyzing the results, the following observations were made:

Understanding of ADRs: The survey results indicate that the majority of pharmacists (95.27%) possess a basic understanding of ADRs. This suggests that pharmacists have a good level of knowledge regarding ADRs, which is essential for their role in pharmacovigilance.

Attitude towards ADR Reporting: The survey findings reveal that 17.46% of pharmacists have reported an ADR, while the remaining 82.54% have not reported any ADRs. It is worth noting that as the level of experience increased, the percentage of pharmacists who reported an ADR also increased. This suggests that more experienced pharmacists may be more proactive in reporting ADRs. Also, 84.13% of pharmacists believe ADR reporting should be mandatory for safety surveillance of drug product.

Patient Awareness of ADR Reporting: The survey results indicate that only 26.98% of pharmacists believe that Indian patients are aware of ADR reporting. This highlights the need for increased efforts to educate and raise awareness among patients about the importance of reporting ADRs for medication safety.

Awareness of ADR Reporting System: The analysis reveals that a majority of pharmacists (82.54%) are aware of the ADR reporting system of the PvPI. This indicates that pharmacists have knowledge of the dedicated system for reporting ADRs, which is a positive finding.

The awareness levels of community pharmacists regarding the PvPI and the ADR reporting system were compared with previous studies. Salim et al. (28) reported an awareness rate of 43.33% for PvPI, while Sah et al. (29) found an awareness rate of 60% for the ADR reporting system in India. In contrast, the present study shows a higher awareness rate of 82.54% among pharmacists for the ADR reporting system of PvPI.

Methods of ADR Reporting: The survey findings show that the highest number of pharmacists (58.73%) are aware of the ADR reporting form for healthcare professionals. Additionally, a significant number of pharmacists are aware of other methods such as patient reporting forms (15.87%), toll-free phone number (9.52%), and ADR PvPI mobile app (7.94%). This suggests that pharmacists have knowledge of various channels through which ADRs can be reported.

Reporting of ADRs: In the survey, 17.46% of pharmacists reported having reported an ADR, while 82.54% had not reported any ADR. Among pharmacists with over twenty years of experience, 75% had reported an ADR, indicating a higher likelihood of reporting with increased experience. In contrast, pharmacists with less than five years of experience had the lowest reporting rate, with only 10.53% reporting an ADR.

Comparing these findings with previous studies, Prakasham et al (30) reported an ADR reporting rate of 11.8% among community pharmacists in India, while the current study found a higher rate of 17.46%. Similarly, Nagraju et al. (31) found that only 1% of pharmacists surveyed had reported an observed ADR, whereas the current study's rate was 8%.

In summary, the survey results indicate that pharmacists have a good understanding of ADRs and are aware of the ADR reporting system in India. However, there is a need for increased patient awareness of ADR reporting. Efforts should be made to encourage and support pharmacists in actively reporting ADRs and to educate patients about the importance of reporting ADRs for medication safety.

d. Opinion on a Pharmacist's role in ADR reporting

This section aimed to collect community pharmacists' opinions on the convenience of the ADR reporting system and their perception of their role in ADR reporting. The objective was to assess their views on ease of reporting ADRs and their level of engagement in the process.

Table 4. Responses related to the opinion on pharmacist's role in ADR reporting.

Q. no.	Question	Respondent with a 'Yes' % (n)
11	How do you think a patient can achieve basic knowledge of ADR reporting?	76.19 (48)
12	Do you think that the current system of ADR reporting is effective?	47.62 (30)
13	Do you think a pharmacist plays a prominent role in ADR reporting?	90.48 (57)

The survey results revealed several key findings. First, a significant majority of pharmacists (76.19%) acknowledged their responsibility to educate patients about ADR reporting. They believed that patient counselling should include advising patients to inform their pharmacist or competent authority if they experience any adverse effects from the dispensed medication. Some pharmacists also noted that other healthcare professionals, such as physicians, should share in the responsibility of educating patients about ADR reporting.

In terms of the convenience of the ADR reporting system, nearly half of the pharmacists (47.62%) considered the PvPI system to be convenient. This indicates that a substantial portion of pharmacists find the system user-friendly and easy to navigate.

Moreover, an overwhelming majority of pharmacists (90.48%) expressed the opinion that they play an important role in ADR reporting, while a small portion of respondents disagreed. This highlights the widespread recognition among pharmacists of their significance in identifying and reporting ADRs, underscoring their active involvement in the process.

Overall, these survey findings demonstrate the willingness of pharmacists to educate patients about ADR reporting, their perception of the convenience of the reporting system, and their recognition of their crucial role in ADR reporting.

7.2 Falsified Medicines

This is the second part of the survey questionnaire and is divided into four sub-sections.

a. Knowledge of falsified medicine and its regulation

The objective of this section of the questionnaire is to evaluate the level of knowledge and understanding among community pharmacists regarding FMs. It aims to collect data on several key aspects related to FMs, including:

Understanding of FMs: The survey aims to evaluate the pharmacists' level of understanding regarding FMs. It intends to gather information about their knowledge of the definition of FMs, their awareness of the risks associated with these counterfeit products, and their familiarity with the regulations and legislation related to FMs. By assessing their understanding of FMs, the survey aims to gauge the pharmacists' preparedness in identifying and addressing this critical issue in the healthcare industry.

Awareness of the FM Threat: The survey seeks to assess the pharmacists' familiarity with the risks associated with FMs. This could involve their understanding of the potential dangers posed by counterfeit medicines and their impact on public health.

Knowledge of FM Legislation: The questionnaire aims to determine the pharmacists' awareness of the legislation and regulatory measures in place to address FMs. This could include their knowledge of specific laws or regulations related to the detection, prevention, and reporting of FMs.

Table 5. Responses related to the knowledge of falsified medicines and its regulations amongst the pharmacists.

Q. no.	Question	Respondent with a 'Yes' % (n)
14	Do you know what a falsified medicine is?	74.6 (47)
15	Do you know that a falsified medicine can cause a serious threat to the health of the consumer?	74.6 (47)
16	Are you aware of section 17, 17A and 17B of Drug and Cosmetic Act, 1940 of India governing the regulations of poor-quality drug comprises of misbranded, spurious and adulterated drugs?	73.02 (46)

The analysis of the survey results highlights several key findings regarding the pharmacists' understanding and awareness of FMs:

Understanding of FMs: A significant majority of pharmacists (74.6%) demonstrated a fundamental understanding of the term "falsified medicine." This indicates that they possess a basic knowledge of what constitutes a falsified medicine and can differentiate it from genuine, authorized medications.

Awareness of the Threat: All surveyed pharmacists showed awareness of the threat posed by FMs. This suggests that they recognize the potential risks and dangers associated with counterfeit medications and the importance of addressing this issue.

Knowledge of Legislation: The results indicate that 73.02% of the pharmacists surveyed were familiar with sections 17, 17A, and 17B of the Drug and Cosmetic Act, 1940, which govern the regulations pertaining to poor-quality drugs, including misbranded, spurious, and adulterated drugs. This suggests that a significant portion of the pharmacists possess knowledge of the legal framework surrounding FMs in India.

b. Experience with falsified medicines

The objective of this section of the questionnaire is to assess the knowledge and experiences of community pharmacists regarding FMs. The survey aims to collect information about their familiarity with the risks and threats posed by FMs, their understanding of the legislation and regulations pertaining to FMs, their personal encounters with FMs, and whether they have reported any incidents related to FMs. By gathering this information, the survey seeks to gain insights into the practical experiences and actions of community pharmacists in dealing with the issue of FMs.

Table 6. Responses related to experience of pharmacists with falsified medicines.

Q. no.	Question	Respondent with a 'Yes' % (n)
17	Have you come across a falsified medicine?	20.64 (13)
18	Have you reported a suspected distribution of falsified medicines?	20.64 (13)

The analysis of the survey results indicates that a small percentage, specifically 20.64% of the surveyed pharmacists, reported encountering FMs in their practice. Among the pharmacists who encountered FMs, the same percentage, 20.64%, reported these incidents to the competent authority. This suggests that a relatively small proportion of pharmacists who encountered FMs took the step of reporting them to the appropriate regulatory body.

Overall, these findings reveal a relatively low incidence of pharmacists encountering FMs in their practice, and a similarly low proportion of those pharmacists reporting these incidents. This information highlights the need for further investigation and intervention to address the issue of FMs in the pharmaceutical supply chain. It indicates the importance of raising awareness and enhancing reporting mechanisms to ensure the identification and prevention of FMs.

c. Reporting of falsified medicines

The objective of this section of the questionnaire is to gather the opinions of community pharmacists regarding their perspectives on the potential points of distribution of FMs and the adequacy of the legislation covering FMs. The aim is to collect information on their views regarding where FMs may enter the pharmaceutical supply chain and their assessment of the effectiveness of existing legislation in addressing the issue of FMs. By capturing the opinions of community pharmacists, this section seeks to gain insights into their perspectives on the distribution of FMs and the regulatory measures in place to combat them.

Table 7. Responses related to the reporting of falsified medicines by pharmacists.

Q. no.	Question	Respondent with a 'Yes' % (n)
19	It is evident that some of the branded and generic medicines including life-style medicines are sold as falsified products (32, 33) What according to you is the major point of distribution of these falsified medicines?	
	➢ Online Pharmacy	58.73 (37)
	➢ Street Hawkers	15.87 (10)
	➢ Black market vendors	9.52 (6)
	➢ Pharmacy store	7.94 (5)
	➢ Others	3.17 (2)
	➢ Unanswered	4.77 (3)

Upon evaluating the results, it was observed that among the pharmacists surveyed, 58.73% believed that the major point of distribution of FMs in India is online pharmacies. Furthermore, 15.87% of pharmacists believed that street hawkers are responsible for the distribution of FMs, while 9.52% believed that black market vendors, such as smugglers, play a significant role. In addition, 7.94% of pharmacists believed that pharmacy stores are a major point of distribution for FMs in India. A small percentage, 3.17%, expressed that there are other sources acting as points of distribution for FMs in the Indian market.

Some pharmacists provided additional insights into the sources of FM distribution. One pharmacist mentioned that consumers often purchase false medicines through television advertisements that make unauthorized claims, such as offering weight-loss remedies or medicines for treating alopecia. Another pharmacist attributed the distribution of FMs to unethical pharmacy practices.

These findings indicate that the sale of FMs through online pharmacies, street hawkers, and smuggling is a significant issue in India. The insights provided by the pharmacists highlight the need for stringent measures and effective regulation to address the distribution of FMs through these channels and prevent their harmful impact on public health.

d. Opinion on a Pharmacist on the issue of falsified medicines

In this section of the questionnaire, the opinions of community pharmacists were sought to assess their views on the adequacy of legislation concerning FMs and their perception of their own role in addressing this issue. The objective was to gain insights into their perspectives on the effectiveness of current FM legislation and their responsibilities and contributions in combating the distribution and use of FMs. By capturing the opinions of community pharmacists, this section aimed to evaluate their outlook on the existing

legislative framework and their role in tackling the challenges associated with FMs.

Table 8. Responses related to the opinion of pharmacists on the issue of falsified medicines.

Q. no.	Question	Respondent with a 'Yes' % (n)
20	Do you think the present legislation is adequate for combating the issue of falsified medicines?	47.62 (30)
21	Do you think a pharmacist plays a prominent role in addressing the issue of falsified medicines?	55.56 (35)

The analysis of the results reveals that there is a divided opinion among the surveyed pharmacists regarding the effectiveness of the current legislation related to FMs in India. While 47.62% of the pharmacists believed that section 17, 17A, and 17B of the Drugs and Cosmetics Act of India are effective in combating falsification, the majority, 52.38%, did not share this view.

Regarding the role of pharmacists in addressing the issue of FMs, 55.56% of the surveyed pharmacists believed that they play an important role, while 44.44% disagreed.

Some pharmacists also provided their views on how community pharmacists can work to resolve the issue of FMs. Suggestions included ensuring the purchase of medicines from reputable distributors and emphasizing the ethical nature of the profession, with a commitment to dispensing only original drugs due to concerns for patient health.

These insights shed light on the varying perspectives of pharmacists regarding the effectiveness of FM legislation and their role in addressing the challenges posed by FMs.

8. Conclusion

In conclusion, this research provides valuable insights into the knowledge, attitudes, and perspectives of community pharmacists in India regarding Pharmacovigilance, ADR reporting, and FMs. The findings indicate that overall, pharmacists in India demonstrate a good understanding of Pharmacovigilance and ADR reporting. However, there is a need to improve their knowledge of Indian legislation related to these areas.

The study reveals that pharmacists primarily acquire their pharmacovigilance education through college or university. They have a positive attitude towards ADR reporting and consider it an essential aspect of their professional role. Encouragingly, when pharmacists encounter ADRs, they promptly report them to the competent authorities, using methods such as manual form filling. This indicates their active engagement in pharmacovigilance practices.

However, the study also reveals areas for improvement. Pharmacists observed a low level of patient knowledge about ADR reporting, indicating the need for interventions to enhance patient education in this regard. Additionally, some pharmacists expressed their concerns about the convenience of the reporting system, suggesting the need for streamlining and simplifying the process.

Although encounters with FMs were relatively low among the surveyed pharmacists, those who did encounter FMs reported them promptly to the appropriate authorities. This highlights the vigilance of pharmacists in identifying and addressing the issue of FMs in India.

Furthermore, the study highlights that a significant proportion of pharmacists hold the perception that Indian FM legislation is inadequate. This indicates the importance of revisiting and strengthening the existing legislation to effectively combat the distribution of FMs.

The findings also shed light on the major sources of FM distribution in India, namely online pharmacies, and street hawkers. Addressing these sources of distribution is crucial in ensuring patient safety and protecting public health.

Overall, this research provides important insights into the knowledge, attitudes, and perspectives of community pharmacists in India regarding Pharmacovigilance, ADR reporting, and FMs. The study calls for interventions to enhance patient education, improve the convenience of the reporting system, and strengthen Indian FM legislation. These findings can inform policymakers, regulatory bodies, and healthcare professionals in developing strategies to strengthen pharmacovigilance practices and combat the distribution of FMs, ultimately contributing to patient safety and the overall quality of healthcare in India.

Acknowledgements

I am grateful to all those with whom I have had the pleasure to work during this and other related review projects.

Financial Disclosure statement: The author received no specific funding for this work.

Conflict of Interest

The author declares that there is no conflict of interest regarding the publication of this article.

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