

Community Pharmacist' attitudes towards counterfeit medicines in Yogyakarta, Indonesia

Susi Ari Kristina^{1*}, Kadek Hendra Darmawan², Rizka Prita Yuliani¹, Fathul Mu'in¹, Vo Quang Trung³

¹Faculty of Pharmacy, Universitas Gadjah Mada, Yogyakarta, Indonesia.

²Ministry of Health, Jakarta, Indonesia

³Pham Ngoc Thach Unibersity of Medicine, Ho Chi Minh, Vietnam

Abstract. Counterfeit medicines (CFMs) is a catastrophic public health issue that encompasses all therapeutic classes in Indonesia. It is a consensus that community pharmacists in many countries could contribute to preventing the distribution of CFMs. Information on community pharmacists' attitudes regarding CFMs is lacking. This study explores the attitudes of community pharmacists in Yogyakarta, Indonesia, regards to CFMs. The specific aim was to identify the perceived reason, the method used to identify CFMs, and complemented with recommendations on what aspects are lacking today. A cross-sectional study involving 350 community pharmacists in Yogyakarta province was conducted. A semi-structured questionnaire assessed the components of their attitude toward CFMs. The Likert-scale statements were implemented to best describe pharmacists' attitudes in responding to specific questions. Most community pharmacists perceived a business profit induced by exceeded market demand and a medicine shortage as significant reasons for CFMs in Indonesia. They are confident in identifying CFMs through the medicine's appearance, packaging, and noticeable price difference. This study captures the need for enforcing regulators to take more responsibility for specific CFMs regulations and build a centralized system for reporting the potential cases of CFMs, allowing for continuous country CFMs surveillance. Community pharmacists could be a crucial supporting function in preventing CFMs from reaching patients. To enhance their role, a robust reporting system is urged to be adopted and socialized in a massive way.

Keyword. Pharmacist, Attitudes, CFMs, Perceived reasons, counterfeit medicines

1 Introduction

Imagine a patient being prescribed chemotherapy to treat a life-threatening tumor. A responsible pharmacist dispenses the prescribed medication and directs the patient without realizing the medicine does not contain an active ingredient. In this case, the patient is not successfully achieving the targeted therapy, and the physician and pharmacist are biased in evaluating the treatment outcomes based on the patient's response to a placebo instead of an active pharmaceutical ingredient. Counterfeit medicine (CFMs) is defined as illegal, generally lower priced, and often associated with lower qualities compared to its originator and poses a significant problem that is growing globally [1]. Contextually, CFMs are medical products that deliberately or fraudulently misrepresent their identity, composition, or source and are termed falsified [2].

CFMs encompass all therapeutic classes, from lifesaving to lifestyle products [3,4]. According to the World Health Organization (WHO) data, it is estimated that around 1% of prescribed medicines in developed nations and 10-50% in developing countries are counterfeit [5]. The European Commission predicts that 15% of the global medicine supply chain could be prone to counterfeit activity [6].

CFMs are a catastrophic issue that exposes significant risks to public health, taking the ineffectiveness and toxicity, and antibiotic resistance leading to an increased global morbidity and mortality rate, not to mention the economic consequences [7,8].

Indonesia, in 2016, experienced a widely publicized lawsuit against the counterfeited vaccine, which resulted in approximately 1500 children being injected with a fake vaccine [9]. This case got massive attention after a baby died later being vaccinated at one of the hospitals in Bekasi, West Java. This case revealed the distribution chain of counterfeit vaccines, which involved the falsifier, distributor, business owner, and healthcare professional (doctor and nurses) who were irresponsible and traded off the children's health with financial incentives from the counterfeit medicine. Police investigations later determined that counterfeiters had refilled used vaccine vials collected by an organized network of hospital cleaners [10].

The enforcement of regulations of CFMs differs among countries. In Indonesia, CFMs are not explicitly regulated in any government document to date. But the Ministry of Health's regulations number 284/2007[11] is mentioned as a facilitator of the high CFMs incidence; therefore, the newer MoH regulation (53/2016)[12] was enacted to prevent the circulation of CFMs in the drug store, known as *Apotek Rakyat* in local language [13].

* Corresponding author: susiarik@ugm.ac.id

Providing an effective pharmaceutical service would not be adequate when the availability of CFMs may compromise the safety and efficacy of the medication. WHO good pharmacy practice guideline highlights the critical role of pharmacists in combating CFMs; ensure the dispensed medicines are effective and of quality [14,15].

The perception and attitudes of pharmacists about CFMs have been surveyed in several developing countries; its consensus that improvement in awareness through campaigns and pharmacy curriculum development, establishing strict control of medicine, building a CFMs reporting system, and enforcing the law will be needed to optimize pharmacists' contribution for preventing CFM reach patients [6,16,17]. Furthermore, community pharmacists are often the first point of access to affordable medicine in Indonesia [18]. However, there need to be more studies regarding CFMs in Indonesia, especially from the community pharmacy point of view. In addition, the current literature search did not reveal any studies related to community pharmacists and CFMs in Indonesia.

This study explores Indonesia's pharmacists' attitudes toward CFMs. We aimed to specifically outline the perceived reason for massively available CFMs in pharmacies, the method used to identify CFMs, and possible recommendations to address what aspects are lacking today.

2 Methods

2.1 Study design

This was a cross-sectional survey of 350 community pharmacists in five districts in Yogyakarta Province, and as concerned, this is the first study discussing the topic in Indonesia, conducted in March 2023. This study procedure was approved by Ethical Committee in Medical and Health Research, Gadjah Mada University no KE/FK/1035/EC/2023.

2.2 Study instrument

In order to collect the pertinent data, this study uses a questionnaire that was prepared after a prior literature review [6] and focus group discussion. In order to assess the content validity of the study, a consensus among professionals in the field of pharmacy practice was used. The current questionnaire was made up of Likert-scale statements and was divided into three main sections: (I) demographic information; (II) real-world experiences in identifying counterfeit medical products; and (III) professional attitudes of pharmacists toward CFMs. The questionnaire was pre-tested, refined and finally administered to the target sample through personal contact by the researcher. Informed consent information was attached to each questionnaire. A total of three hundred and fifty questionnaires were continuously administered.

2.3 Data collection

The study made use of convenience sampling. The main inclusion criteria were practicing pharmacists willing to participate and could speak and read *Bahasa*. Prior to data collection, the researchers verbally explained the purpose of the study and the approximate time needed to complete the questionnaire estimated at around 15 minutes and returned it up to 30 minutes after completion.

2.4 Data analysis

The collected data were analyzed using descriptive statistics, expressed as numbers and percentages. For this Likert-type statement, participants' responses were evaluated after dichotomizing them to strongly agree/agree and strongly disagree/disagree. In addition, content analysis was employed for structuring the open-ended questions.

3 Results

A total of 350 pharmacies participated in the survey; of these, the majority worked in independent pharmacies. Demographic characteristics are given in **Table 1**. The dominant age of participants was between 31 and 40 years; 73.43% were female, geographically spreading at five sub-regions of Yogyakarta with an average of years of practicing between 5-10 years.

Table 1. Demographic characteristics of community pharmacists

Characteristics	Category	n	%
Age	21-30	95	27.14
	31-40	132	37.71
	41-50	98	28.00
	>50	25	7.14
Gender	Female	257	73.43
	Male	93	26.57
Location of pharmacies	Sleman	94	26.86
	Yogyakarta	78	22.29
	Kulonprogo	67	19.14
	Bantul	59	16.86
	Gunung Kidul	52	14.86
Years of practicing	>5 years	97	27.71
	5-10 years	134	38.29
	>10 years	119	34.00
Number of patients per day	<20	175	50.00
	20-50	90	25.71
	>50	85	24.29
Type of pharmacies	Independent pharmacy	312	89.14
	Chain pharmacy	38	10.86

3.1 Perceived reasons for the availability of counterfeit medicine by pharmacist

A series of questions with multiple responses allowed; of the 350 pharmacists, as shown in **Figure 1** reported that 81,71% perceived that a business and profit-oriented resulted in the availability of CFMs in the community pharmacies. In contrast, about 73,71% and 69,73%, respectively, believed the market factors, including the medicine shortage and high community demand for medicine, drive the sales of CFMs. In addition, 54% of participants criticized the lack of control from medicine regulators on CFMs, which successfully perceived in facilitating the high availability of CFMs in the market.

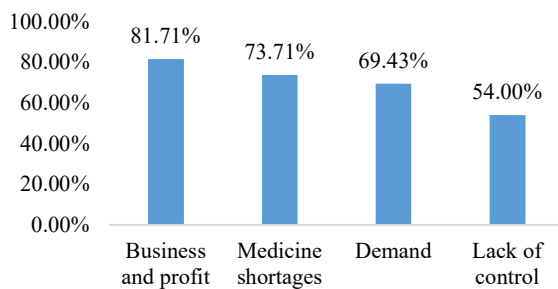


Fig. 1. The reason for the availability of CFMs, according to pharmacists (n=350)

3.2 Pharmacists' practice to identifying counterfeit medicines

A significant percentage of the 350 pharmacists (93,71%) identified CFMs through the medicine's physical appearance and 54% of them through their packaging, as reported in **Figure 2**. While cost is reported as one of the explicit determinants of CFMs that are recognizable, that could trigger the pharmacist's attention to the possibility of CFMs in their practice. In addition, the supplier, whether they are reputable is considered as the way to recognize the CFMs.

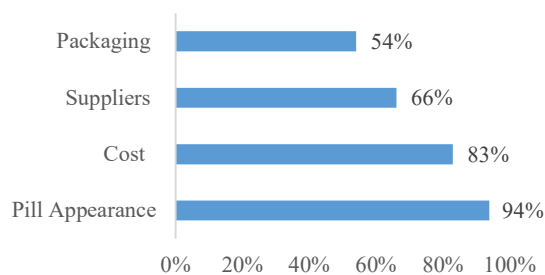


Fig. 2. Practice in identifying CFMs among community pharmacist (n=350)

3.3 Pharmacists' attitude regarding counterfeit medicines

Figure 3 shows the respondents' attitudes regarding counterfeit medicines. Most pharmacists consider the Indonesian Ministry of Health (MoH) responsible for guaranteeing the safety and efficacy of medicine before it is distributed to the national drug market. About 70% of pharmacies perceive that CFMs are primarily sold through online platforms. The urgency of specific

regulations to combat CFMs is raised by 89,14% of participants, including the law for selling medicine in e-commerce. In contrast, a significant number of pharmacists are still confused about how to report the CFMs even though they are confident enough in identifying the CFMs.

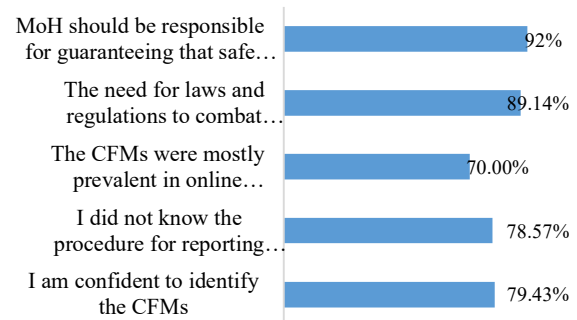


Fig. 3. Attitude regarding counterfeit medicines (n=350)

3.4 Recommendation for preventing counterfeit medicines

According to **Table 2**, most community pharmacists strongly agree on an action to report suspicious medicine to the CFMs reporting system if applicable, legalizing online pharmacies, and adopting continuous surveillance activities by regulators. Meanwhile, intrinsically, community pharmacists agree upon the consensus on avoiding purchasing medicine from non-reputable suppliers.

Table 2. Recommendation to prevent the CFMs from community pharmacists (n=350)

Recommendations from community pharmacists	Strongly agree/agree	
	(n)	(%)
Report suspicious medicines to the CFM reporting system	312	89.14
Adopt a Code of Ethics for pharmacists	280	80.00
Approved online pharmacies	256	73.14
Avoid purchasing drugs from unapproved suppliers	236	67.43
Continuous surveillance	213	60.86

4 Discussion

Community pharmacists' attitudes toward counterfeit medicine (CFMs) revealed deficiencies in knowledge of reporting procedures and the CFMs incidence, yet the respondents feel confident in identifying the potential cases of CFMs during their regular practice. It is an elsewhere consensus that community pharmacists hold a crucial role in preventing the distribution of CFMs, hence their function needs to be leveraged for better public health [19].

The demographic characteristics of respondents identified that female pharmacists were over-represented, which is aligned with data on the ratio of male to female pharmacists in Indonesia being 1:3. In

contrast, the relevant study in Lebanon reported the opposite respondent's characteristics where male pharmacists were more interested and willing to share their practical experiences regarding CFMs [6]. Additionally, it is recognized that accumulated years of practicing impacted community pharmacists' attitudes toward CFMs [9].

Responses in the first section of the questionnaire showed various perceptions from Indonesian community pharmacists on how CFMs could circulate through a pharmacy chain. There is a market incentive when a high demand for medicine is not matched by the limited supply capacity from a legitimate supplier, which causes a medicine shortage. A massive counterfeit resulting from a medicine shortage was documented in the USA when Tamiflu (Oseltamivir) was prescribed during the Influenza season. Counterfeiters break into the medicine supply chain as a consequence of pharmacists' search for alternative medicine vendors due to unmet demand, resulting in sporadicities of fraudulent distributors [19].

Besides the market incentives, a more significant profit margin is another perceived reason for the availability of CFMs at pharmacies. The same circumstances were found in relevant studies involving community pharmacists in Egypt [20], Lebanon [6], and Ethiopia [21]; the pharmacy professional decided to carry out CFM transactions from uncertified sources for a significant profit. In the Indonesian context, this perceived activity has been pronounced since many pharmacies are not owned by the pharmacist but by the profit-oriented businessman; hence, a larger profit seems to be an option compared to the availability of safe products at the outlet.

Consistent with a study in Jordan [22], adequate legislation and lack of control from regulators were primary reasons perceived by community pharmacies that successfully incentivizes the pharmacist to make CFMs available at the pharmacy store. Even though the regulation is in place, the lack of in-house control made the pharmacist normalize counterfeiting activities, thus facilitating the spreading of CFMs in the community pharmacy.

Indonesian pharmacists' way of detecting CFMs was limited to standard practice. Firstly, through pill appearance and packaging. In Nigeria [23], pharmacists outlined the packaging checked, and included the product registration number and manufacturer code manually. Meanwhile, In Indonesia, the National Food and Drug Authority holds a website for everyone to check the originality components of drugs, herbal products, food, and cosmetics (batch number, manufacturer information, recall history, etc.). But the website does not fully recognize the counterfeiting aspect of medicine since the identity could be correct for CFMs. Other studies in Lebanon [6] reported the challenges of distinguishing CFMs from originators through visual examination, even for a pharmacist with more than ten years of service.

Along with drug appearance and packaging, in the U.S., advanced medicine labeling technologies were initiated that could primarily be utilized for product authentication since they are complex and/or expensive

to copy. Pharmaceutical manufacturers currently use holograms, colour-shifting inks, embedded codes, images, and dyes on packaging to create an additional layer of protection. More recently, barcodes carrying medication products' identification for track-and-trace purposes were employed for advancing the medicine packaging complementing the anticounterfeiting technologies which can assist the community pharmacists in authenticating the products better [19].

The legitimate medicine supplier where counterfeiting incidence rarely occurs is another way perceived by the respondents to characterize the CFMs. Pharmacists were recommended to be selective when purchasing medicine only from authorized wholesalers or other reliable sources. Indonesian pharmacists are aware of the importance of choosing a trusted wholesaler to purchase medicine stock. Meanwhile, there is a rising concern in Nigeria since the pharmacists claimed that they sourced their medicine personally from wholesalers, which can be at high risk for counterfeiting medicine [23,24].

Aligned with other studies in other countries [17,20,25], pharmacists in Indonesia perceived that it is an urgent need for specific laws and regulations to combat CFMs. Even though some respondents may be aware of the existence of a chapter in Indonesia Health Law (36/2009) [26] about the penalty for medicine counterfeiters, it needs to regulate the CFMs comprehensively. Another center of discussion of implementing a medicine counterfeiter chapter in health law is the deviation of the penalty and the actual court ruling [27]. A court case in Medan, Indonesia, only ruled an antibiotic counterfeiter with one year of prison without any financial penalty. At the same time, it should be a maximum of five years of prison with financial consequences of IDR 2 billion [28]. In Ethiopia, weak regulation infringement is a driving factor for the high prevalence of medicine counterfeit cases [21].

Uniquely, responders in this study rely on the regulators to guarantee the distribution of safe and effective medicine through pharmacy circumstances. This is aligned with the perception of Lebanese pharmacists [6]. Meanwhile, in other countries like the U.S., collaborative activity between cross-function stakeholders is already initiated. The system calls MedWatch, a national system that involves pharma companies, Food and Drug Authority (regulators), community pharmacists, and business owners to ensure that only safe medicines circulate through the U.S. pharmacy channels [19].

A contradictive condition was revealed in this study; even though most responders feel confident in identifying the CFMs, almost 78% do not know the procedures for reporting the CFMs nor know the existing reporting mechanisms used by regulators. Currently, the National Food and Drug Authority in Indonesia operates a generic reporting or complaint system that the general Indonesian population could utilize to report any suspicious medicine, food, or cosmetics, which means not explicitly designated for clinicians or community pharmacists to report the potential counterfeit medicine. In other words, the

current system does not specify supporting the continuous surveillance system for CFMs in the community.

To add to the attitude of community pharmacists in Indonesia toward CFMs, most of them believe that CFMs are prevalent in e-commerce (online commercial platforms). It is synergized with the data that approximately 60% of medicines that purchased online could be counterfeited or substandard [29]. In the U.S., thousands of online vendors sell unapproved and/or counterfeit medicines, including the sale of prosection regiment therapy without requiring a prescription [30].

This study seeks recommendations from the community pharmacy point of view regarding the CFMs. Since there is no reporting system to report suspicious medicine from health professionals, including pharmacists, this organized system needs to be prioritized by the medicine regulator in Indonesia. A relevant study in Lebanon [17] supports this recommendation; in the same circumstances where no CFMs reporting system exists in the country, establishing the integrated system would allow pharmacists to report any suspected CFMs in a more systematic order efficiently. In short, the centralized reporting system of CFMs will contribute to building a continuous country surveillance system for better response and track-and-trace for CFMs incidents.

Indonesian community pharmacists urged to strengthen the Code of Pharmacists implementation. A case study in Jordan [22] and Iran [16] reported several conditions where pharmacists could possibly name other pharmacists that deal with CFMs yet are still reluctant to inform authorities. As informing peers is highlighted in the current Code of Pharmacists, pharmacists are ideally able to remind peers not to deal with CFMs when considering the effect and consequences for themselves and the community.

Lastly, it is highly recommended that community pharmacists avoid purchasing from unapproved medicine suppliers. The same suggestion has campaigned in the U.S., where pharmacists urge to procure medications from known, reliable sources. This campaign is supported by wholesale distributors accreditation program called 'the Verified-Accredited Wholesale Distributor' by the National Association of Boards of Pharmacy (NABP) [19]. The same distributor system could be adopted in Indonesia to systematically help the pharmacist choose legitimate distributors, increasing trust and reliability of sources of safe medications.

This study potentially overlooked the representation of opinion and practice by Indonesian pharmacists as a whole nation since respondents were selected conveniently rather than by random sampling and it's limited to specific geographic areas; hence generalization is hard to achieve. However, since this is the first CFMs study using a pharmacist point of view in Indonesia, the result could serve as a preliminary overview of the attitude of community pharmacists regarding CFMs. Further study is needed to explore other aspects of CFMs, including a case study of Indonesian pharmacists on actual practice to identify CFMs and their consequences to the health system.

5 Conclusion

Community pharmacists hold a critical role as gatekeepers to prevent the distribution of CFMs in Indonesia before reaching the population. By understanding their attitude toward CFMs, a better recommendation could be formulated to strengthen medicine safety and prevent the public from the harmful consequences of CFMs' circulation throughout the legal supply chain.

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