Comprehending the Role of Physicians and Counterfeit Medicine in Bangladesh

Farzana Nazera^{1*}, Valliappan Raju²

¹PhD Aspirant, Limkokwing University of Creative Technology, Malaysia ²Professor, Limkokwing University of Creative Technology, Malaysia *Corresponding Author

Abstract: Counterfeit medicine is a dangerous problem in Bangladesh, making the country's healthcare system more challenging. For a developing nation like Bangladesh, finding a perfect solution to curb this problem is complex. According to the World Health Organization (2021), awareness is the key to preventing the innocent patient from taking counterfeit medicine. Due to the knowledge gap, it's hard for patients to detect the authenticity of medicine because it requires knowledge of medicinal formulation. Physicians of Bangladesh could play a vital role in preventing this counterfeit medicine problem by establishing guidance and cooperation relationships with the patients. The study reviewed the concept of counterfeit medicine, conducted a bibliometric analysis of counterfeit medicine on the Scopus database, and provided a relationship flow diagram of prospective guidance relationship between physicians and patients. The study concluded that the physicians should offer this consultation service to the patients, and the study expected that the patient willingly accepts it for getting the safeguard against counterfeit medicine.

Keywords: Bibliometric Analysis, Physicians, Patients, Counterfeit Medicine, Bangladesh

I. INTRODUCTION AND PROBLEM BACKGROUND

The world is now undergoing the steamroller of a devastating pandemic entitled "COVID19," which challenges every sector that is closely associated with the existence of mankind. Bangladesh is also severely affected, and its poor healthcare system worsens the situation. None can expect a better situation in a country with less than 1% G.D.P. spending on healthcare (Mohiuddin, 2020). Counterfeit medicine in Bangladesh pours oil on the flame of the poor healthcare system. As per the information provided by the drug market intelligence, an estimated Tk 600 crore of counterfeit medicines is traded in the Tk 18,000 crore medicine market in Bangladesh each year (*ibid*). Countless unregistered medicine shops sell those not properly monitored by the concerned authorities of Bangladesh (*ibid*).

Moreover, reputed medical hospitals are subject to selling counterfeited medicines in their treatment process (*ibid*). The same source argued that the steps taken by the concerned authorities linger for a time, subjecting to the willingness to take action against them. At this stage, awareness from the patient side is the key to preventing them from this mayhem of counterfeit medicines.

It's ironic that most patients have no idea which is counterfeited and which is not. Because medicines are highly

technical objects and can't be easily understood unless they have sufficient knowledge in medicine formulation, the paper would like to discuss how doctors can play an essential role in protecting general people from counterfeit medicine.

1.1 Problem Statement

Since ancient times, the relationship between doctor and patient has evolved. According to the previous study, there are three types of doctor-patient relationships, namely: (a) active passivity, (b) guidance-co-operation, and (c) mutual participation (Szasz & Hollender, 1956). The model of activity-passivity is entirely paternalistic, where the patients require the doctor's expert knowledge, and treatment is commenced "irrespective of the patient's contribution and regardless of the outcome" (Kaba & Sooriakumaran, 2007; MARMOR, 1953; Szasz & Hollender, 1956). The second type is guidance-co-operation, where the patient is ready and willing to "cooperate," and in doing so, places the doctor in a position of power; therefore, the doctor will speak of guidance and thus expect the patient to cooperate and obey without question (ibid). It was seen earlier that this relationship could be termed a "Parent-child" relationship (Goodyear-Smith & Buetow, 2001; Kaba & Sooriakumaran, 2007). The third type that is mutual participation, provides the patient with a greater degree of responsibility and is characterized by a high degree of empathy and has elements often associated with friendship and partnership with the doctor, as well as the imparting of expert medical advice (E. Balint, 1969; M. Balint, 1955; Kaba & Sooriakumaran, 2007; MARMOR, 1953; Szasz & Hollender, 1956). From these types, the research would like to focus on the guidance from the doctors towards their patients regarding the identification of counterfeit medicines. To fight against counterfeit medicine, a recommendation from the doctor is needed.

1.2 Objective of the Study

As per the relationship types provided by the researcher (Szasz & Hollender, 1956), all types of relationships are being observed in Bangladesh. However, the study would like to focus only on the "guidance cooperation" or "parent-child" relationship between doctor and patient, which is crucial for preventing counterfeit medicine use. The research would like to find out the objective of studying the relationship from the perspective of "guidance-cooperation" to prevent counterfeit medicine purchases by customers.

1.3 Aim and Research Questions

The research aims to consult existing literature on counterfeit medicine, its problem in the world, and the Bangladesh perspective by doing a systematic literature review. After conducting the literature review, the study proposed a model of the guidance cooperation relationship between doctor and patient in the light of preventing counterfeit medicine in Bangladesh. Research questions were as follows:

- RQ₁ What is counterfeit medicine according to the existing literature of Scopus?
- RQ₂ How does counterfeit medicine create problems in the healthcare system of Bangladesh?
- RQ₃ How guidance cooperation relationship would prevent counterfeit medicine?

1.4 Originality and Value

The study conducted a bibliometric analysis of the Scopus database on counterfeit medicine. This bibliometric analysis would pave the way for further research on counterfeit medicine. Also, the paper made a literature review on counterfeit medicine and the role of physicians in Bangladesh, which attracted a new dimension of research in healthcare and behavioral disciplines.

II. RESEARCH METHODOLOGY

In this study, I discussed existing literature to develop the concept of counterfeit medicine. For the literature review, the study considered the peer review publications on google scholar and Scopus. According to Joshi et al. (Joshi et al. 2021), both Scopus and Web of Science are equally good for doing bibliometric analysis as a part of a systematic literature review. However, they preferred Scopus over Web of Science because Scopus updates daily, whereas Web of Science updates weekly. I used "counterfeit medicine" and "doctorpatient relationship" on the search button of Scopus to do my bibliometric analysis. After developing networks based on different parameters, I found the related keywords that played a role in this area of research and helped develop my conceptual model of the doctor-patient relationship for preventing counterfeit medicine in Bangladesh.

2.1 Ethical Consideration and Quality Assurance

I only considered the peer review publications available in google scholar and the Scopus databases. I didn't consider any newspaper write-ups to avoid bias. For doing bibliometric analysis, I considered Scopus, which was deemed authentic to doing bibliometric research (Joshi et al., 2021).

2.2 Delimitation of the study

This bibliometric analysis only to the Scopus database. I did not conduct interviews with physicians and patients and relied only on the existing literature to develop my conceptual model.

III. LITERATURE REVIEW

3.1 Concept of Counterfeit Medicine

According to World Health Organization (Dégardin et al., 2014; Mukhopadhyay, 2007), counterfeit drugs as medicines that are manufactured below established standards of safety, quality, and efficacy and are deliberately and fraudulently mislabeled to hide their true identity and source. Their (WHO) definition of counterfeit medicines includes products with the wrong drug, without any active compound, with insufficient quantities of the active ingredient, or with the correct ingredients in the proper amounts but in fake packaging (*ibid*). A recent modification of their definition includes the term "spurious/falsely labeled/falsified/counterfeit (SFFC) medicines" as synonymous (WHO, 2021). They publish a guideline for finding out Counterfeit medicines, which are given below:

- The stakeholders (e.g., patients, doctors, sellers) should examine the packaging condition, spelling mistakes, or grammatical errors of medicine name and ingredient(s) name;
- They should check the manufacture and expiry dates and ensure any details on the outer packaging match the dates shown on the inner packaging;
- Sellers should ensure the medicine looks correct, is not discolored, degraded, or has an unusual smell;
- Patients should discuss with the pharmacist, doctor, or other healthcare professional as soon as possible if they suspect the product is not working properly or they suffer an adverse reaction; and
- Patients and their families should report suspicious medical products to the National Medicines Regulatory Authority.

It's difficult to say the amount of counterfeit medicine being produced and sold by unscrupulous traders, but WHO warned that it is the tip of the Iceberg and that more than 10% of the global medicine market consists of fakes. Still, the estimate can't be equally applicable to all countries (Mukhopadhyay, 2007). Medicine counterfeiting has turned into a new branch of organized crime, and its links with other illegal traffic were established as its role in funding terrorist activities (OECD, 2008).

Counterfeiting can also be a violation of intellectual property (I.P.) detained by owners of copyrights, patents, and trademarks (Dégardin et al., 2014). Counterfeit trademark goods, according to the Agreement On Trade-Related Aspects Of Intellectual Property Rights (TRIPS), are "any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the co-owner" (W.T.O., 2012). An illegal (Newton et al., 2008; Seiter, 2009), as per the definition of TRIPS, contains the same active pharmaceutical ingredients (APIs) as genuine products,

sometimes even in the same proportion. In contrast, other counterfeits contain no APIs, the wrong amount of active pharmaceutical ingredients, or even other APIs. Wrong APIs are randomly selected or chosen with a chemical structure similar to the genuine ones. Counterfeit medicines provoke adverse events and mask the clinical signs and a wrong API in a medicine that makes the patient think they are curing the disease but are not, e.g., the counterfeits that reduce the fever caused by malaria but fail to cure the disease itself (Fernandez et al., 2008; Harris et al., 2009; Newton et al., 2008). The medicine, packaging, and documentation are also often targeted for counterfeited (Isles, 2020). The main targets of counterfeiters in developing countries (for example, life-saving medicines for malaria, Bangladesh) are tuberculosis, and human immunodeficiency virus/acquired immune deficiency syndrome. (Fernandez et al., 2008; Newton et al., 2008).

Each continent has been suffering from counterfeit medicine for a long time. Considering the estimated sales volume, Counterfeit sales are massive in Africa and Asia but also high in Latin America (Dégardin et al., 2014; Newton et al., 2008; Sh Ph M Sh Ph.D. Marv Shepherd et al., 2011). Counterfeit medicines may lead to avoidable morbidity, mortality, drug resistance, early death or treatment failure, and loss of faith in health systems, especially in low-income and middle-income countries. Besides countries, counterfeit medicine practice has been found to be a significant difference between urban and rural areas (ibid). Many counterfeits are sold in street markets, especially in Africa (ibid). Counterfeiters are increasingly willing to enter the legal supply chain, resulting in pharmacies and hospitals not always being safe (ibid). Nor are developed countries immune. Counterfeits are increasingly being seized in Europe, especially in the United Kingdom (U.K.) and the United States (ibid). Many are sold on the Internet to patients in industrialized countries as it has become harder for counterfeiters to sell their products in local pharmacies (ibid). Counterfeit drugs kill more than 250,000 children a year worldwide (Mohiuddin, 2020).

We are now in the Internet era, and many technological revolutions make our life depend on the Internet. Counterfeit medicine problem irks too much due to trading through the Internet. The WHO estimated that over half of the Internet medicines sold in 2008 were counterfeit, and Buying medicines online is quicker, more confidential, and more convenient, especially for the elderly or disabled (Dégardin et al., 2015; Feudtner, 2007; Orizio et al., 2009; Przyswa & Guarnieri, 2011). Also, Consumers are attracted by buying over the counter at low prices (ibid). In most cases, these websites originate from other countries, and websites selling counterfeit goods are mostly based in North America. In contrast, temporary websites, which change daily and send spam, tend to be managed from China or Eastern Europe (ibid).

3.2 Bibliometric Analysis of Counterfeit Medicine

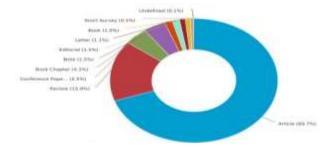
For conducting the bibliometric analysis of counterfeit medicine, I wrote "counterfeit medicine" on the search bar of the Scopus database. Scopus database showed 392 documents (See Appendix 1.2). The year-wise publication from 2016-2021 (up to April 01) showed a downward trend, which is provided below:

Table 1: 5-year publication trend on counterfeit medicine in Scopus Database

Year	Number of Publication
2016	34
2017	25
2018	22
2019	21
2020	16
2021 (up to April 01, 2021)	09

Regarding document types, most documents were Articles (69.7%), and the number of articles was 1968. The next three were Review (448), Conference Paper (127), and Book Chapter (121). Below is the pie chart shown in details

Figure 1: Percentage of documents publications by type in the Scopus database



Counterfeit medicine publications are dominated by medicine in the subject area consisting of 177 documents, followed by Pharmacology, Toxicology, Pharmaceutics (141), and Chemistry (89). The pie chart showed the share based on the subject area:

Figure 2: Publication documents based on the subject area in the Scopus database

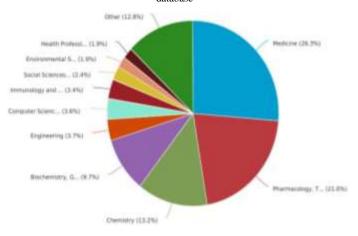
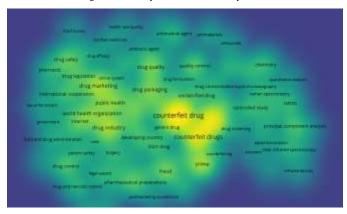
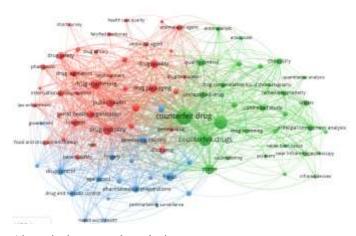


Figure 3: Density visualization of keywords



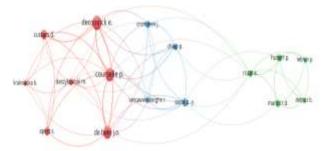
For analyzing keywords that were connected with counterfeit medicine found, 2852 keywords. I considered the keywords which occurred at least ten times. I found the highest occurrence was counterfeit drugs (171), counterfeit medicines (123), and counterfeit drugs (108). The density visualization was given above.

Figure 4: A network analysis of relevant keywords of Counterfeit medicine



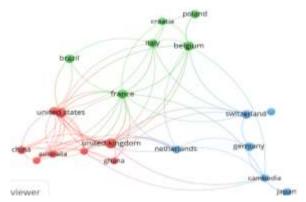
Above is the network analysis

Figure 5: Network analysis of authors and their co-authorship with others



For analyzing the authors, I found 1038 author names. I set the filter of at least three documents and five citations to consider for bibliometric analysis, and based on that; I found 60 authors who met the threshold. The highest documents and citations were attracted by Deconincke, whose number of papers was 18 and whose citations were 497. The network analysis of the authors provided above.

Figure 6: Country names based on publications and citations



The bibliometric analysis found 93 country names on the Scopus database related to counterfeit medicine research. I considered 20 countries that had at least five publications and five citations. Most documents were from the United Kingdom, with 70 and 111 citations. In terms of inter-country publications, the U.K. also leads the race. The network analysis provided above

The highest cited paper was "Poor quality drugs: Grand challenges in high throughput detection, countrywide sampling, and forensics in developing countries," written by Newton *et al.* in 2008, which attracted 150 citations. The top five papers provided below;

Table 2: Most Cited Papers in Counterfeit Medicine

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Paper Title	Contributor	Year
A collaborative epidemiological investigation into the criminal fake artesunate trade in South East Asia (Newton et al., 2008)	Newton P.N., Fernandez F.M., Plancon A., Mildenhal D.C., Green M.D., Ziyong L., Christophel E.M., Phanouvong S., Howells S., McIntosh E., Laurin P., Blum N., Hampton C.Y., Faure K., Nyadong L., Soong C.W.R., Santoso B., Zhiguang W., Newton J., Palmer K.	2008
Substandard and counterfeit medicines: A systematic review of the literature (Almuzaini et al., 2013)	Almuzaini T., Choonara I., Sammons H.	2013
Comparison and combination of spectroscopic techniques for the detection of counterfeit medicines (Sacré et al., 2010)	Sacre PY., Deconinck E., De Beer T., Courselle P., Vancauwenberghe R., Chiap P., Crommen J., De Beer J.O.	2010
Characterization of genuine and fake artesunate anti-malarial tablets using Fourier transform infrared imaging and spatially offset Raman spectroscopy through blister packs (Ricci et al., 2007)	Ricci C., Eliasson C., MacLeod N.A., Newton P.N., Matousek P., Kazarian S.G.	2007
A review of existing and emerging digital technologies to combat the global trade in fake medicines (Mackey & Nayyar, 2017)	Mackey T.K., Nayyar G.	2017

In the Scopus database, the Journal Of Pharmaceutical And Biomedical Analysis has published 26 documents on counterfeit medicine so far, followed by the pharmaceutical journal (10), Talanta (8), and Forensic Science International (7).

To assess the research affiliation in counterfeit medicine, Scientific Institute of Public Health, Brussels led the research showing 18 affiliations. Universite de Liege followed the lead of 13 affiliations. Universidade Federal do Rio Grande do Sul, Universiteit Antwerpen and University of Oxford, all had 10 affiliations.

3.3 Counterfeit Medicine Problem in Bangladesh

Bangladesh is making a reputation as an exporter of cheap genuine drugs to more than 80 countries, and its pharmaceutical industry contributes nearly 1% of the total Gross Domestic Product (G.D.P.). It is paying the second largest revenue to the country (Sultana and Sobhan, 2013). Bangladesh manufactures about 450 generic drugs for 5,300 registered brands which have 8,300 different forms of dosages and strengths. These include antibiotics, anti-ulcerants, flouroquinolones, anti-rheumatics, non-steroid drugs, nonnarcotic analgesics, antihistamines, and oral diabetes medications (Safwan, 2012). But this glory seems to fade when it comes to the counterfeit medicine problem in the country. Bangladesh has a high counterfeit medicine burden, produced in numerous drug factories along the Bangladeshi, Indian, Pakistani, Chinese, and Thai borders. And the main channels for distributing substandard and counterfeited drugs are the country's vast network of nearly 80,000 unlicensed pharmacies (Sultana and Sobhan, 2013).

As per The World Bank classification, WHO stated that more than 1 in 10 medical products in low- and middle-income countries are counterfeited (WHO, 2021). According to The World Bank (2021), Bangladesh aspired to become a middleincome country, so Bangladesh falls under this danger range. However, the real situation is quite adverse; as I mentioned previously, the market size of Counterfeit Medicine is more than Tk 600 crore per year (Mohiuddin, 2020). In 2016, the government revoked the licenses of 20 pharmaceutical companies for producing adulterated and low-quality medicine (ibid). Aside from that, the parliamentary panel recommended that 14 companies' licenses to manufacture antibiotics (penicillin, nonpenicillin, and cephalosporin groups) be revoked, 22 companies' permission to produce medicine of the penicillin and cephalosporin groups be suspended, and the government be ordered to immediately stop these companies from producing medicines. But the government is yet to act on it (ibid). Three hundred seventy cases of fake medicines had been filed in the first six months of 2019, according to the DGDA (ibid). Posh hospitals of Bangladesh, Apollo, and United were accused of keeping and selling substandard reagents and drugs (ibid). More than 100,000 unlicensed drug stores, which are largely unregulated and unaccountable, worsen the situation. And run by salespeople who are mostly trained informally through a process of 'apprenticeship, where most medicines are dispensed irrationally without any prescription (*ibid*).

From the discussion, it can be said that the counterfeit medicine problem is a deep-rooted problem in Bangladesh

that can't be easily removed soon. So, awareness should come from the patient, which is the key to preventing the problem.

IV. ROLE OF PHYSICIANS IN PREVENTING COUNTERFEIT MEDICINE

According to Dégardin, Roggo, and Margot (2014), raising awareness is the key to preventing counterfeit medicine. However, patients, who don't have pharmaceutical knowledge, won't understand whether the medicine has been counterfeited or not. Moreover, according to Mohiuddin (2020), many medicine shops are unregistered, and sales staffs have little to no knowledge about counterfeiting. So, in this case, only the physicians can extend their hand in support of preventing counterfeit medicine. Based on the existing literature, to develop the guidance cooperation doctor-patient relationship to prevent counterfeit medicine, the underlined strategies should be taken:

4.1 Developing Interpersonal Communication

Communication is the key to understanding and resolving any sort of health-related problem. Communication skills include attentive listening, showing and practicing empathy, and using examples open-ended questions, some of communication. Improved doctor-patient communication tends to increase patient involvement and adherence to recommended therapy, influence patient satisfaction. adherence, and health care utilization, and improve quality of care and health outcomes (Almuzaini et al., 2013; Diette & Rand, 2007; Roter et al., 2002). These communication skills are important for both parties in getting and receiving guidance in preventing counterfeit medicine. Patients often regard their doctors as one of their most important sources of psychological support, so physicians' empathy in this aspect could help them a lot.

4.2 Participate in Professional Training Programs Related to Patient Management

Concerned authorities of Bangladesh, public and private, should arrange patient management training programs for self-awareness, self-monitoring, and training. That professional development program would allow them to understand the theory of good doctor-patient communication, learn and practice these skills, and be capable of modifying their communication style if there is sufficient motivation and incentive (Almuzaini et al., 2013; Bensing & Sluijs, 1985; Feudtner, 2007; Lee et al., 2002; Roter et al., 2002; Stewart et al., 2000). It is important to practice new skills with regular feedback on the acquired behavior from the training (*ibid*). It is to be noted that medical education should go beyond skills training to encourage physicians' responsiveness to the patient's unique experience (*ibid*).

4.3 Establishing Collaborative Environment

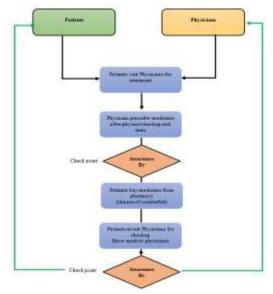
Albeit it is quite challenging in a country where public health is in a challenging position (Mohiuddin, 2020), a Collaborative environment could be the key to developing physician-patient relationships to a great extent. It is a reciprocal and dynamic relationship involving the 2-way

exchange of information where doctors should collaborate with their patients to provide the best care because doctors tend to make decisions based on quick assessments, which may be biased (Almuzaini et al., 2013; Feudtner, 2007; Lee et al., 2002; Minhas, 2007; Roter et al., 2002). This environment requires the doctors to take the time or set up opportunities to offer and discuss treatment choices with patients and share the responsibility and control with them (*ibid*). This collaborative chamber should be established in both the medical center and the private chamber. However, it would be a bit more convenient for the physicians to establish such a collaborative environment in their private chamber, because they have much influence in their domain.

4.4 Conflict Management Skill

Patients often go nervous while visiting the hospital and the private chamber in front of the physicians. This unspoken and thus unclear or unknown to one or both parties generated feelings of discord, i.e., possible causes of conflict (Feudtner, 2007). For physicians, conflict is often challenging as it can evoke feelings of helplessness, frustration, confusion, anger, uncertainty, failure, or sadness (Feudtner, 2007; Lee et al., 2002). They should recognize these feelings and develop skills to identify problematic responses in the patient or themselves to de-escalate the situation and enable the relationship problems to be turned into a clinical success of minimizing avoidance behavior (ibid). In addition to minimizing avoidance behavior, which prevents patients from expressing opinions, effective doctor-patient communication should involve productive conversation, which involves understanding of both parties' perspectives, by shifting from a perspective that is rigidly certain of one's belief to a more exploratory approach that strives to understand the situation from another perspective (ibid). The communication process between doctor and patient would be like an interactive flowchart which I provide below

Figure 7: Doctor-Patient Relationship in preventing counterfeit medicine



(Source: Author)

This interactive and mutually dependent relationship flow would provide a safety measure for innocent patients, who are often victims of counterfeit medicine due to the knowledge gap. Physician's consultation and verification would play a safe and secure role in preventing the mayhem of counterfeit medicine. This framework gives a glimpse of a possible solution to the counterfeit medicine problem that physicians can easily implement. The medical authority should introduce this consultation service in the physicians' private chambers to offer patients to take this service. However, depending on the medical center and physician's willingness, it can be either paid or voluntary.

V. LIMITATIONS, FUTURE STUDY, AND CONCLUSION

The study discussed the existing literature on counterfeit medicine, its adverse impact on people's health, the adverse situation in Bangladesh, and the possible solution of interacting with physicians in the light of cooperation. There was no interview taken by either physicians or patients regarding this matter. Future studies would focus on taking interviews of both ends to test the significance of this relationship. For doing the bibliometric analysis, the study considered the Scopus database. The study believes it should be more rigorous if it considers more than one database. Future studies would focus on other reputed databases like Web of Science and compare bibliometric analysis.

The study concluded that the interactive relationship flow designed by the researcher should be highly dependent on the physicians' willingness, so the researcher put emphasis on arranging training on developing interpersonal communication. Patients of Bangladesh have no such position to bargain this issue, and enlightening a large population is quite impossible. This model should be a key theme in motivating physicians to offer consultative services for identifying counterfeit medicines.

Contribution of Co-author

Dr. Valliappan Raju: Overall Review of the manuscript, including academic guidance, proofreading, and conceptual framework of the study.

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