Ind. J. Pharm. Edu. Res., 2026; 60(1):37-53.
https://www.ijper.org

Review Article

Compromised Medical Products: A Scoping review of Quality, Safety and Efficacy Concerns

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ABSTRACT

Background: In 2011, the World Health Organization (WHO) coined the term substandard/spurious/falsely labelled/falsified/counterfeit (SSFFC) to describe medical products that compromise quality, safety, and efficacy. Despite its broad usage, the term 'SSFFC' was not sufficient to differentiate between the various categories of illicit medicines, each of which requires distinct regulatory responses. In 2017, the WHO took a significant step by rationalizing the terminology, promoting transparency, and clearly distinguishing between substandard and counterfeit medicines. The rationality behind this study was to explore the various dimensions of SSFFC drug products from definitions to their global impact posed by these hazardous products. **Materials and Methods:** Databases like Scopus, Medline, PubMed, and Embase, were systematically searched for publications between October 2011 and January 2023. To ensure the results were appropriate, WHO alert data from 2019 to December 2024 was also reviewed. Using Covidence, descriptive analysis and narrative synthesis was performed. Out of 6424 of total articles, 4522 articles were assessed for eligibility after 1902 duplicates were eliminated out. For data extraction, 60 articles in total were selected. **Results:** The findings from this study provide a comprehensive compilation of definitions and characterizations of SSFFC medical products across different sources. The review also explored WHO global alerts, which provided the affected essential drugs in low- and middle-income countries, leading to significant health consequence in developing regions. **Conclusion:** The findings highlight the pressing need for stronger regulatory frameworks and international cooperation to combat the spread of SSFFC products. Additionally, the study's review of WHO global alerts emphasizes the urgency of addressing the health consequences posed by these products. It also provides recommendations for future research, emphasizing the need to explore regulatory actions for SSFFC medical products and to strengthen global efforts to protect public health.

Keywords: Substandard, Spurious, Falsified, Falsely labelled, Counterfeit.

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Received: 07-02-2025;

Revised: 24-04-2025;

Accepted: 18-06-2025.

INTRODUCTION

The World Health Organization (WHO) member nations adopted the new term "substandard/spurious/falsely labelled/falsified/counterfeit medical products" (SSFFC) to describe medical products of compromised quality, safety and efficacy in the year 2011. A recent report states these issues are very significant in low- and middle-income countries (LMICs).[1] These drugs range from lifestyle medications to life-saving ones and have a wide range without sparing any categories. They can lead to poor health outcomes, delays in treatment or failures, medication resistance, and a decline in trust in the healthcare sector that increases the burden of disease and, as a result, leads to higher rates of morbidity and mortality. Globally, substandard and counterfeit antimicrobial drugs, particularly beta-lactams, chloroquine, and artemisinin derivatives, are linked to higher mortality and morbidity rates. These drugs often contain reduced amounts of active ingredients, leading to ineffective treatment and increased risk of death.[2-4] Poor-quality medicines not only increase mortality but also impose a heavy economic challenge. In Uganda, the economic burden of substandard antimalarials includes significant productivity losses due to early death.[5] According to the WHO, poor medication is one that "fails to fulfil either its quality requirements or specifications, or both," whereas a falsified medicine is one that is "medical items that intentionally/fraudulently mislead their identity, composition, or source".[6]

Literature suggests that in developing nations, about 10 percent of pharmaceutical products are of inferior quality or even fraudulent. According to the WHO, 10% of medicines in

DOI: 10.5530/ijper.20261930

LMICs are Substandard or Falsified (SF). The most frequently reported SF medicines are antimalarials and antibiotics. These substandard medicines contribute majorly to the global burden of infectious diseases as well as Antimicrobial Resistance (AMR). Specifically, in Tuberculosis (TB), the low quality of anti-TB drugs contributes to the development of drug-resistant TB strains.[7] Among counterfeit drugs, antimalarials medications are the most prevalent, accounting for approximately twenty percent of all counterfeit products and drugs reported in 2017. These drugs can have a broad range of negative consequences, including treatment failure, toxicity, and the development of resistance to antimicrobials. They are marketed to mislead the end user about their origin, legitimacy, and efficacy. The WHO and other organizations have pushed for a greater public understanding of the hazards to public health posed by the lucrative illegal market in counterfeit medications. There is little information on knowledge and awareness of substandard and counterfeit medications.[6]

Several approaches have been suggested to address the issue of counterfeit drugs. These approaches include consumer education, working with law enforcement, legal proceedings and laws against illegal dealers, and technological countermeasures.[8] Confusion between the falsification of drugs and several other unwanted practices can also lead to disputes. These include the purposeful or negligent distribution of substandard or adulterated medicines, which in some cases may still be useful despite their flaws but in other cases may be so bad that their distribution may be viewed as a crime in and of itself. It can be complicated and unethical to produce and market products that violate intellectual property obligations.[9]Click or tap here to enter text. Developed nations with a highly advanced drug regulatory system are still finding to design and implement suitable solutions to fight this issue with latest technology and systems.

From the standpoint of the public health and safety, it is critical to distinguish between counterfeiting and other issues like infringement of intellectual property rights or the unintentional manufacturing of substandard medications in settings subject to regulatory regulation. The IMPACT (The International Medical Products Anti-Counterfeiting Taskforce program was introduced in 2006 by WHO, to focus and safeguard the health of the world's population. It produced some results that were pleasing, resulting in fruitful outcome. However, ambiguities in definition and concerns about potential conflicts of interest reduced its usefulness and made stronger inter-governmental agreements for combating pharmaceutical falsification necessary.[9] Research is ongoing in this prevention which has significant practical implications. Hence this scoping review aims to study the variations in the definitions of SSFFC medical products as reported in various literatures.

The causes of SSFFC medical products are complex and multifaceted. One major factor is the globalization of the pharmaceutical industry, which has led to an increasingly complex and fragmented supply chain. This has created opportunities for criminals to introduce fake counterfeit or substandard products into the market. In addition, weak regulatory frameworks in many countries, limited resources for regulatory agencies, and corruption can all contribute to the rise of SSFFC medical products. The rise of e-commerce and online pharmacies has also made it easier for criminals to distribute SF products to unsuspecting consumers.[10]

MATERIALS AND METHODS

The scoping review was selected because it addresses a wider topic rather than attempting to address very specialized research questions. It aims to map the current literature on SSFFC medical products identifying the range of evidence available and any gaps or inconsistencies in the literature. Additionally, it focuses on the alerts in the global scenario reported by the WHO. 'The Joanna Briggs Institute's guidelines and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses-Scoping Review Extension' (PRISMA) was used to comparatively evaluate the definitions of "SSFFC medical products" from publications.[11]

Stage 1: Identifying the research question

To establish research questions, the team held discussions while considering several key factors, including the study population, concept, and type of evidence. This study attempts to answer the research questions: What is the extent and variation in this definition of SSFFC medical products as reported in the literature, and what are the implications for addressing the ambiguity in the definition?

Stage 2: Identifying relevant studies

Two initial search rounds were conducted using specific search strategies in databases such as Scopus, Medline, PubMed and Embase and grey literature like Google Scholar. A detail about the search strategy is depicted in Table 1. The first strategy combined terms related to substandard, spurious, falsified, falsely labelled, and counterfeit medical items with other keywords. Additional Medical Sub Headings (MeSH) keywords were included in PubMed to broaden the search. No limitations on publication years were applied, and only titles and abstracts were reviewed. Each database had an extensive number of articles. To make sure the terms "SSFFC" and "medical products" were closely related in the text, the search strategy was further improved. Using revised parameters, a second preliminary search was carried out. With a focus on publications that used SSFFC medical items or related terms in their abstracts or titles, the inclusion criteria were created using the data acquired from the initial searches. *"The proximity criteria were adjusted for each database's search phrases so that the concepts "SSFFC" and "medical product" are next to each other.

Stage 3: Study selection

From the selected articles, two reviewers resolved the duplicates. The selection was based on the title and abstract. Studies included are: (1) Research articles on the human population (2). Studies that refer to the concept of substandard medical products and their derivatives like falsified, spurious, and counterfeit medicines (3) Review articles were excluded from the study. Furthermore, the eligibility criteria were applied accordingly through full-text reading to select the full articles that were included in the scoping review. The review was conducted using Covidence, a web-based application. The articles obtained from different databases like PubMed, Scopus, Embase and Google Scholar were imported into Covidence (in *.ris format). The disagreements between reviewers were resolved through discussion.

Stage 4: Charting the data

Two reviewers independently selected the data from the final articles. To ensure consistency in data collection and inter-reviewer reliability, data from each included article were extracted independently and in duplicate. Covidence was used for data charting. All the sentences in which the authors refer to the definition of SSFFC medical products or their derivatives were extracted as qualitative data. If a concept was mentioned several times, the sentence that provides the clearest definition of the concept was selected.

Stage 5: Highlighting the Global alerts of SSFFC Medicines

Two reviewers assessed the alerts as related to SSFFC medicines, and we conducted an analysis of available literature, focusing on global alerts as reported by the WHO. We segmented our analysis to evaluate regional trends and assess the outcomes to determine which areas are most affected and the categories of medicines involved. The selection was done from 2019 to December 2024 data.

RESULTS

Searches were preliminary conducted in November and December 2022. For the first search strategy, the terms substandard, spurious, falsified, falsely labelled, and counterfeit medical items were combined with several other keywords. The secondary review included studies published between October 2011 (when the WHO decided to establish a group on refining the definitions of SSFFC medical products) and January 31, 2023 (the date of the search). Eligible articles were those that had SSFFC medical products or similar terms in their titles or abstracts. Non-English language studies were excluded. Finally, a total of 1089, 2138, 2248, and 586 articles were imported from PubMed, Embase, Scopus, and Google Scholar, respectively. A few restrictions were added to Google Scholar searches to exclude irrelevant extra information. Covidence detected 1897 duplicates (5 duplicates manually detected) and was removed from further screening resulting in a total of 4522 articles. Inclusion and exclusion criteria were updated in the platform. In the second stage, title and abstract screening was conducted. Two independent reviewers evaluated 4522 articles to determine if they satisfied the inclusion and exclusion criteria for the selection of relevant articles.

In the next stage, data charting was performed where all the sentences in which the authors refer to the definition of SSFFC medical products or its derivatives were extracted as qualitative

Table 1: The search strategy of the study.

Database- Scopus, Medline, PubMed and Embase. Limits: in title/abstract (keywords); full text available; document type: article, review Publication date: October 2011 and January 2023	
#1	The search terms included concepts: “substandard” OR “spurious” OR “falsified” OR “falsely labelled” OR “counterfeit”*
#2	Drug *OR “drugs *” OR “medicine*” OR medical product*
#3	Pharmaceutical* OR “medication*” OR therapeutic product*
4#	#1AND #2 For instance, the search term was: (TITLE-ABS-KEY (“substandard” OR "”alsified” OR “spurious” OR “counterfeit” OR “falsely labelled”) AND TITLE-ABS-KEY “drug*” OR “drugs*” OR "medicine*" OR “medical product*”)
5#	#1AND #3 TITLE-ABS-KEY (“substandard” OR “falsified” OR “spurious” OR “counterfeit” OR “falsely labelled”) AND TITLE-ABS-KEY (“pharmaceutical*” OR "medication*”OR “therapeutic product*”)
6#	#1AND #2 1AND #3TITLE-ABS-KEY ("substandard" OR “falsified” OR “spurious” OR “counterfeit" OR “falsely labelled”) AND TITLE-ABS-KEY “drug*” OR “drugs*” OR "medicine*" OR “medical product*”) AND TITLE-ABS-KEY ("pharmaceutical*” OR “medication*” OR “therapeutic product*”)
7#	(“Drug Contamination” [MeSH] OR “Fraud” [MeSH] OR “Counterfeit Drugs” [MeSH] OR “Adulteration” [MeSH] OR “Substandard Drugs"[MeSH])AND(“Drugs” [MeSH] OR “Pharmaceutical Preparations” [MeSH] OR “Medicines” [MeSH] OR “Therapeutics” [MeSH])AND(“Pharmaceuticals” [MeSH] OR “Pharmaceutical Preparations” [MeSH] OR “Medications” [MeSH] OR “Drug Delivery Systems” [MeSH])

data. In case a concept is mentioned several times, the sentence that provides the clearest definition of the concept was selected. A total of 287 studies were excluded from the data extraction phase owing the reasons like full text not being available, and articles failing to give definitions of SSFFC medical products. Finally, 60 articles were included for extraction. Data extraction was done manually. A comprehensive table of different definitions used and their frequency of use in publications were presented. A detail about the final selected articles is depicted in Figure 1.

Table 2 presents a compilation of different definitions of "SSFFC medical products" used in various publications. It provides a summary of the definitions along with the number of articles following each definition and additional remarks.

Regarding "SSFFC medical products," the WHO defines them as medical products that are outside of specifications, including intentional, reckless, or negligent errors, false packaging, and those intended to deliberately deceive and imitate a genuine product. This comprehensive definition covers several types of errors, false packaging, and products intended to deceive and imitate genuine products.

Another definition specifically focuses on counterfeit medicines, describing them as deliberately and fraudulently mislabelled medicines concerning identity and/or source. This includes

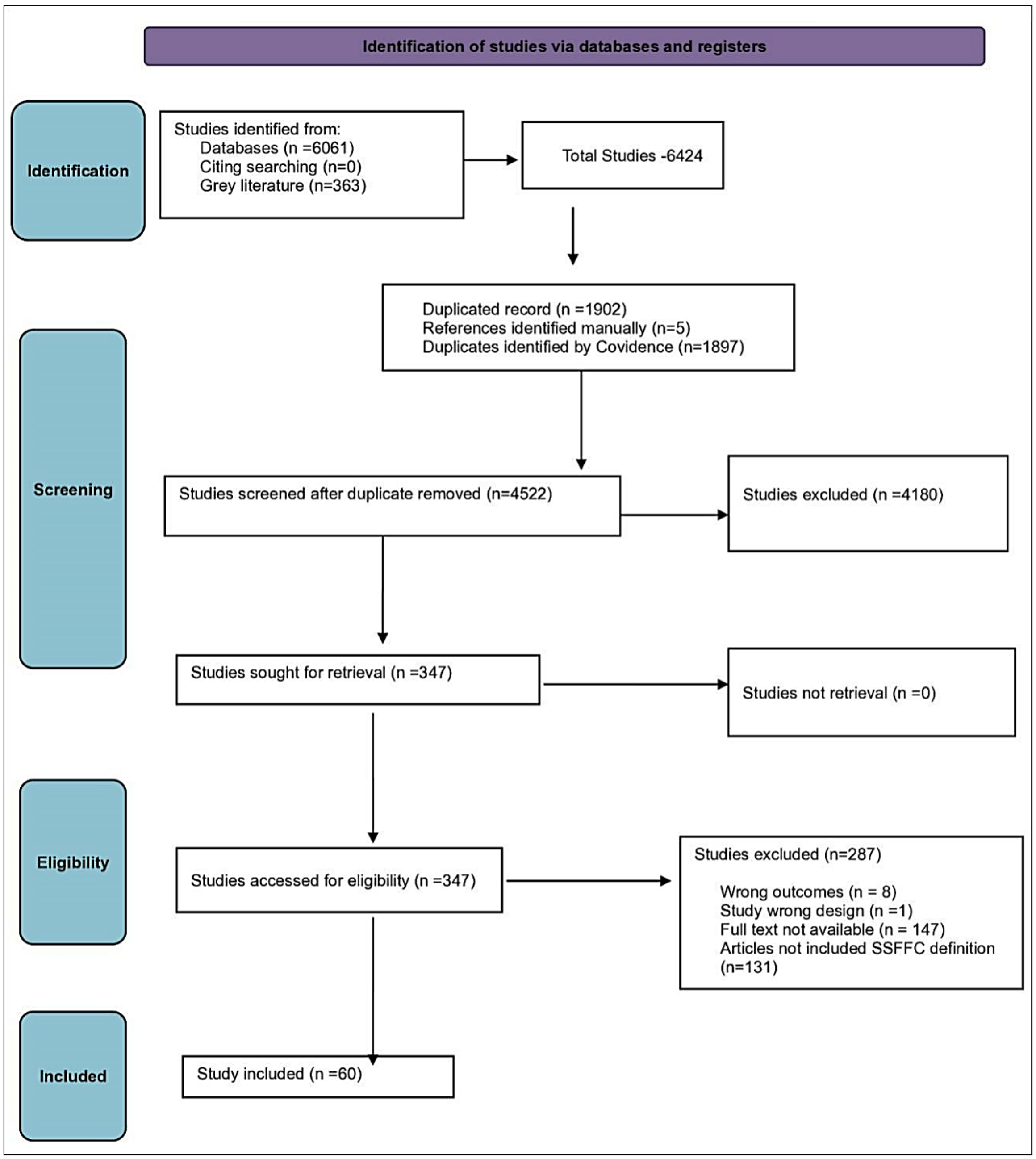

Figure 1: PRISMA flowchart for articles inclusion in scoping review.

products with correct or wrong ingredients, insufficient or excessive active ingredients, or fake packaging.

Table 2 also presents a summary of definitions for "Substandard medicinal products." The WHO defines substandard medicines as products that do not meet the required specifications in terms of content and ingredients. Other definitions highlight that substandard medicines may fail to meet international strength, purity, quality, or packaging criteria, and they may result from poor manufacturing practices, supply chain gaps, or inappropriate storage.

The total number of articles selected for this category was 31 which appropriately provides a thorough view on the issue while maintaining quality and ensuring balanced across various healthcare settings. The selection was chosen to understand a thorough analysis reflecting a global scope on various definitions of Substandard medicinal products without exceeding the scope of the review.

Furthermore, Table 2 provides a summary of definitions for "Spurious medicinal products." It includes definitions that describe spurious drugs as fake or not genuine but claimed or presented as genuine, possessing a potential risk of addiction to the patient. These drugs may have incorrect ingredients, insufficient active ingredients, or fake packaging.

Table 2: Summary of the individual definitions.

Sl. No.	Definitions	No. of articles following the definition given below	Remarks
	Substandard medicinal products		
1	Substandard medicines, also referred to as out-of-specification products, are defined by the WHO as "products that do not meet the required specification in terms of content and ingredients."[14-16]	8	The various definitions of substandard medicines share a common theme of not meeting required quality standards, but there are some differences. The WHO's definition describes substandard medicines as not meeting required specifications in terms of content and ingredients, while the US Pharmacopoeia's definition emphasizes that substandard products do not meet international strength, purity, quality, or packaging criteria. Another definition specifies that substandard medicines are legal pharmaceutical products that fail to meet quality standards due to poor manufacturing practices, supply chain gaps, or inappropriate storage. Some definitions use the term "out of specification" to refer to substandard medicines, and others describe them as genuine medicines that have not achieved quality standards for several reasons, such as unintentional errors or inadequate regulatory oversight.
2	Substandard medicines (or out-of-specification products) are defined as "a genuine medicine produced by manufacturers authorized by the national medical regulatory authority which does not meet the quality specifications set for them by national standards."[17-24]	3	
3	"A substandard product, according to the United States Pharmacopoeia, is one that is legally branded or generic but does not meet international strength, purity, quality, or packaging criteria."[18]	1	
4	"Substandard medicines are legal pharmaceutical products manufactured by registered companies that fail to meet quality standards or specifications and originate from poor manufacturing practices, supply chain gaps or inappropriate storage that led to degradation of the active ingredients."[25]	1	
5	"Substandard medical products: Also called 'out of specification'; these are authorized medical products that fail to meet either their quality standards or their specifications, or both." (WHO 2017).[26-40]	15	
6	'Substandard medicines' are genuine products which unachieved quality standards.[41,42]	2	
7	"Substandard medicines are those that for unintentional reasons do not meet the legally required quality specifications of a country's regulators (usually a specialized medicine regulatory authority)."[43]	1	

Spurious medicinal products			
1	"A drug shall be deemed to be spurious: (a) if it is imported under a name which belongs to another drug; or (b) if it is an imitation of, or a substitute for, another drug or resembles another drug in a manner likely to deceive or bears upon it or upon its label or container the name of another drug unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug; or (c) if the label or the container bears the name of an individual or company purporting to be the manufacturer of the drug, which individual or company is fictitious or does not exist; or (d) if it has been substituted wholly or in part by another drug or substance; or (e) if it purports to be the product of a manufacturer of whom it is not truly a product." (Section 9B of India's Drug and Cosmetics Act 1940).[43]	1	The first definition is specific to India's Drug and Cosmetics Act 1940, which states that a drug is spurious if it is imported under a name belonging to another drug, is an imitation of another drug, or if its label or container bears the name of a fictitious or non-existent manufacturer. The second definition is more general and defines spurious drugs as fake or not genuine but presented as such, with a potential risk of addiction to the patient. The third definition is more comprehensive and includes intentional mislabelling and misrepresentation of drugs, with incorrect or insufficient ingredients and fake packaging.
2	"Spurious defines those which are fake or not genuine but claimed or presented to be genuine. A spurious drug possesses an addictive danger to the patient."[44]	1	The fourth definition is like the third but emphasizes intentional illegal manufacturing and mislabelling to deceive and hide the drug's identity. The fifth definition, according to the Black Law Dictionary, defines spurious drugs as those replicated or reproduced without permission by someone other than the original manufacturer, which may contain inappropriate amounts of the principal component, unlevelled ingredients, or duplicate labelling or wrapping.
3	"Spurious or counterfeit drugs are those where the identity and source of the manufacturer are intentionally and duplicitously mislabeled. These false drugs represented with an incorrect ingredient or correct ingredient with wrong proportion or without principal ingredient with fake packaging."[44]	1	
4	"Spurious drugs are those which are intentionally and illegally mislabeled and manufactured to misinform and misrepresent the consumers (patients) by hiding their identity."[44]	1	
5	Black Law Dictionary' says "a drug which is manufactured by someone other than original manufacturer by replicating or reproducing the genuine product without taking prior permission with a view to defraud. A spurious drug may compose of an inappropriate amount of principle component or may contain an unlevelled ingredient or may be marketed with duplicate labelling or wrapping."[44]	1	
Falsified medicinal products			
1	"Falsified medicines are medical products that deliberately or fraudulently misrepresent their identity, composition, or source."[15,16,19,23,26-33,35-42,45-51]	29	The first statement defines falsified medicines as those that intentionally or fraudulently misrepresent their identity, composition, or source. The second statement states that if an authorized manufacturer fails to meet quality standards or specifications due to misrepresentation of identity, composition, or source, the medical product can be considered falsified.
2	"When the authorized manufacturer deliberately fails to meet these quality standards or specifications due to misrepresentation of identity, composition, or source, then the medical product should be considered falsified."[27]	1	

	Counterfeit medicinal products		
1	"A counterfeit medicine is one which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredient or with fake packaging." (1992 WHO).[14,17-18,21-22,43,48,51-58]	15	These definitions all refer to counterfeit medicines, which are intentionally misrepresented in some way. According to the World Health Organization, counterfeit medicines are those that are labelled fraudulently with respect to their identity and/or source. This definition can apply to both branded and generic products, and the counterfeit product may include incorrect ingredients or insufficient active ingredients or be packaged deceptively. The Philippine Food and Drug Administration define counterfeit products as medicines with correct or incorrect ingredients in wrong amounts, or without active ingredients. The European Medicines Agency adds that counterfeit medicines can refer to medicines that do not comply with European Union laws on intellectual and industrial property rights. Black's Law Dictionary states that counterfeit drugs are those made by copying or imitating an original product without authority or right, with the intention to deceive or defraud. Finally, the USFDA defines counterfeit medicines as those that bear a trademark or identifying mark of a drug manufacturer, processor, packer, or distributor other than the person who made, processed, packed or distributed it.
2	"A counterfeit product as a medicine with correct ingredients in wrong amounts, wrong ingredients, without active ingredients, or with sufficient quantity of active ingredient that results in the reduction of the drug's safety, efficacy, quality, strength or purity." (Philippine Food and Drug Administration).[12]	1	
3	In accordance with Black's law dictionary, the term "counterfeit drug may be used to describe a drug made by someone other than the genuine manufacturer, by copying or imitating an original product without authority or right, with a view to deceive or defraud, and then marketing the copied or forged drug as the original."[59]	1	
4	According to the European Commission, "counterfeit medicines refer to medicines that do not comply with European Union law on intellectual and industrial property rights, for example, unregistered medicines sourced from parallel import." (European Medicines Agency).[60]	1	
5	"A counterfeit medicine is a product packaged and improperly labelled, in a deliberate and fraudulent manner, in which it does not respect its source or identity and may contain alterations and adulterations in its original formula."[61]	1	
6	"A drug which, or the containers or labelling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint or device or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed or distributed such drug and which thereby falsely purports or is represented to be product of or to have been packed or distributed by such other drug manufacturer, processor, packer, or distributor." (USFDA).[52,62]	2	
7	"A counterfeit drug is a fake medicine which may contain inappropriate ingredients or products with correct ingredients but without active ingredients or with incorrect packing."[63]	1	
8	Counterfeit medications have been defined as "products deliberately and fraudulently produced and/or mislabelled with respect to identity and/or source to make it appear to be a genuine product."[64]	1	

Unregistered/ Unlicensed” and “Unregistered generics			
1	“Unregistered or unlicensed medical products that have not undergone evaluation or approval by the National or Regional Regulatory Authority (NRRA) for the market in which they are marketed or distributed are subject to permitted conditions under national or regional regulations and legislation.”15,19,26,30,37-39,46,47	9	The first definition describes unregistered or unlicensed medical products that have not undergone evaluation or approval by the National or Regional Regulatory Authority. The second definition refers to unregistered medicines that lack legally required marketing authorization of the country's regulators. The third definition mentions unregistered generics as safe and effective medication produced without proper IP law authorization.
2	“Unregistered medicines are those that do not have the legally required marketing authorization of the country’s regulators to be imported or sold there-for example, internationally diverted or stolen medicines.”58	1	
3	“Unregistered generic” refers to safe and effective medication manufactured without proper IP law authorization.43	1	

The Table 2 also covers definitions for "Falsified medicinal products" and "Counterfeit medicinal products." Falsified medicines are those that deliberately or fraudulently misrepresent their identity, composition, or source. Counterfeit medicines, according to the WHO, are fraudulently mislabelled with respect to identity and/or source and can include incorrect ingredients, insufficient active ingredients, or fake packaging.

Lastly, Table 2 summarizes the definitions for "Unregistered/ Unlicensed" and "Unregistered generics." Unregistered or unlicensed medical products refer to those that have not undergone evaluation or approval by the National or Regional Regulatory Authority (NRRA) and are subject to permitted conditions under national or regional regulations and legislation. Unregistered medicines lack the legally required marketing authorization of the country's regulators, which includes internationally diverted or stolen medicines. Unregistered generics, on the other hand, are safe and effective medications produced without proper intellectual property law authorization.

The summary table depicted in Table 3 provides a comprehensive overview of different definitions associated with "SSFFC medical products," "Substandard medical products," "Spurious medical products," "Falsified medical products," and "Counterfeit medical products." These definitions help in understanding the various aspects and implications of each category.

Table 4 summarizes the WHO alerts on substandard and falsified medicines over the past five years of global report.[65] The level of existence of SSFFC drugs can be understood with the representation of this table.

Mostly the cases are reported from LMICs and the suppliers are from all over the world. The most vulnerable population are children who have experienced several EG and DEG poisoning due to the consumption of substandard and counterfeit cough and cold syrups.[66] Many deaths were reported from Indonesia due to EG and DEG poisoning and the cause was kidney failure of the infants.[67] Following instances of substandard and counterfeit pharmaceuticals around the world, regulatory bodies have acted proactively to improve drug safety and stop similar accidents in the future. Through cooperation between the US, Japanese, and European Pharmacopoeias, the Pharmacopoeial Discussion Group has progressed the harmonisation of general chapters and compendial monographs for excipients.[68] On the other side, anti-malarial medications seem to be of poor and compromised quality which poses a serious risk to public health in malaria-endemic nations, harming both individuals and their communities.[69] Several analytical methods are approached for testing including Global Pharma Health Fund (GPHF) Minilab which is an accessible test kit based on semi-quantitative thin-layer chromatography (TLC) that is frequently used in medication quality surveillance worldwide.[70] Various other life saving drugs as well are included in the SSFFC categories.

DISCUSSION

The aim of this review is to provide a comprehensive understanding of the many definitions and interpretations of SSFFC medications. Through a thorough screening procedure and extensive search, a significant number of relevant articles were reviewed in order to ascertain the definitions and features of these objects. The results shed light on the many categories of medical products that pose health risks to the general population and offer valuable insights into the details of SSFFC-related terminology. The WHO's definition of SSFFC medical items is extensive and covers a wide range of issues, such as errors, false packaging, and products that imitate or confuse genuine pharmaceuticals. As per the description, SSFFC products are complicated, involving substandard goods that fall below the quality standards in addition to misleading labelling and misrepresentation. The WHO’s comprehensive approach is important that might occur within the global pharmaceutical

Table 3: Summary of the definition of "SSFFC medicinal products.

Sl. No.	Definitions	No. of articles following the definition given below	Remarks
1	The WHO defines "Substandard/ Spurious/ Falsely labelled/ Falsified/Counterfeit (SSFFC) medical products are medical products that are outside of specifications, which includes intentional, reckless, or negligent errors, false packaging, and those intended to deliberately deceive and imitate a genuine product.[12]	1	The first definition is a comprehensive one given by the WHO for SSFFC medical products, covering several types of errors, false packaging, and products intended to deceive and imitate genuine products. The second definition is more specific and focuses solely on counterfeit medicines, defining them as fraudulently mislabelled medicines with respect to identity and/or source, including products with correct or wrong ingredients, insufficient or too much active ingredients, or fake packaging, but it does not cover other types of substandard or spurious medicines.
2	"Medicines which are deliberately and fraudulently mislabelled with respect to identity and/or source, and also which may include products with correct ingredients or with the wrong ingredients, without active ingredients, with insufficient or too much active ingredient, or with fake packaging."[13]	1	

Table 4: Summary of WHO reports on substandard and falsified medicines over the past five years.[65]

WHO alert no	Region identified	Category	API	Issues
Nº1/2019 (WHO, 2020)	Philippines	Rabies Vaccines	Falsified Verorab vaccines.	Not manufactured by the original manufacturer.
Nº2/2019 (WHO, 2020)	America	ICLUSIG 15 mg and ICLUSIG 45 mg.	Falsified Ponatinib Hydrochloride.	The batch numbers do not correspond to genuine manufacturing records.
Nº3/2019 (WHO, 2020)	Malaysia	ICLUSIG 45 mg.	Falsified Ponatinib Hydrochloride.	The label found both in English and German language.
Nº4/2019 (WHO, 2020)	South East Asia	Oral cholera vaccine.	Falsified DUKORAL	The displayed batch number does not correspond to genuine manufacturing records, and the combination of the manufacturers Valneva Canada Inc. and Crucell not exist on any packaging in any market.
Nº5/2019 (WHO, 2020)	Africa	Meningitis vaccines	Falsified Mencevax ACWY vaccines	The batch number and expiry date combinations displayed do not correspond to genuine manufacturing records.
Nº6/2019 (WHO, 2020)	Africa	Antihypertensive and diuretic medicine.	Falsified hydrochlorothiazide 50 mg.	Contain glibenclamide instead of hydrochlorothiazide.
Nº7/2019 (WHO, 2020)	Iran and Pakistan	Treatment of leishmaniosis.	Falsified meglumine antimoniate.	The packing is in English and French languages but displays spelling mistakes in both languages.

Nº8/2019 (WHO, 2020)	Philippines	Rabies vaccines	Falsified Verorab, Speeda, and Rabipur Equirab.	Verorab and speeda of 4 different combinations of batch numbers, rabipur of 2 different combinations and equirab 3 different combinations have been discovered.
Nº9/2019 (WHO, 2020)	Uganda and Kenya	Antibacterials	Falsified Augmentin (Amoxicillin trihydrate - Potassium clavulanate).	Labelling and packaging inconsistencies.
Nº10/2019 (WHO, 2020)	Central African Republic, Chad and Uganda.	Antimalarials	Falsifiedquinine sulphate 300 mg and 800 mg and quinine bisulphate 300 mg.	There are labelling and packaging inconsistencies, including spelling errors and did not identify the expected active ingredient.
Nº11/2019 (WHO, 2020)	Haiti	Antibacterials	Falsified amoxicillin+clavulanic acid products.	The packaging is in French language but displays numerous inconsistencies, including spelling errors.
Nº1/2020 (WHO, 2020)	Chad, Cameroon, Nigeria	Antimalarials	Falsified Quinine Sulphate	Under dose of expected API.
Nº2/2020 (WHO, 2020)	Americas, Guyana and Kenya	Medical device (delayed diagnosis of HIV status).	NA	delayed diagnosis of HIV status.
Nº3/2020 (WHO, 2020)	Australia, Brazil, Canada, PR China, Russian Federation, Singapore, Republic of Korea, United States of America.	Falsified medical products, including *in vitro* diagnostics, that claim to prevent, detect, treat or cure COVID-19.	NA	At this stage, there is no vaccine to prevent COVID-19
Nº4/2020 (WHO, 2020)	Burkina, Faso, Cameroon, Democratic Republic of Congo, France, and Nigeria.	Antimalarials.	Falsified Chloroquine.	Required amount of API not found.
Nº5/2020 (WHO, 2020)	Argentina, Australia, Latvia, Malaysia and Saudi Arabia.	Concentrate for solution for infusion.	Falsified and contaminated Defibrotide 200 mg vials.	Misrepresentation of their identity, composition, and source.
Nº6/2020 (WHO, 2020)	Mexico	Influenza Vaccine	Falsified Fluzone, Quadrivalent Influenza Vaccine.	Misrepresent their identity, composition and source.
Nº7/2020 (WHO, 2020)	Brazil and Turkey	Treatment of Hepatitis C	Falsified Harvoni (Ledipasvir/ sofosbuvir).	Misrepresent their identity, composition and source.
Nº1/2021 (WHO, 2021)	Chad	Retinol	Falsified Vitamin A	Falsified drug with low API.
Nº2/2021 (WHO, 2021)	Mexico	COVID-19	Falsified Vaccine	The batch number and expiry dates are falsified. The glass vials and label are different from genuine COVID-19 Vaccine BNT162b2 vials.

Nº3/2021 (WHO, 2021)	Cameroon, the Democratic Republic of Congo, Ghana and Nigeria.	Treatment of duodenal and gastric ulcers	Falsified Misoprostol 200 mg.	Does not contain any active ingredient.
Nº4/2021 (WHO, 2021)	Mexico	Broad-spectrum antiviral	Falsified Remdesivir injection 100 mg/20 mL (5 mg/mL).	The batch number and the expiry date do not correspond to any remdesivir manufactured by GILEAD.
Nº5/2021 (WHO, 2021)	Uganda, India and Myanmar.	COVID-19	Falsified COVISHIELD vaccine.	COVISHIELD 2 mL -the genuine manufacturer does not produce COVISHIELD in 2 mL (4 doses) COVISHELD is not the correct spelling.
Nº6/2021 (WHO, 2021)	Islamic Republic of Iran.	COVID-19	Falsified COVID-19 Vaccine	The product label and artwork are inconsistent with genuine COVID-19 Vaccines The expiry date on the labels is falsified.
Nº7/2021 (WHO, 2021)	Islamic Republic of Iran.	COVID-19	Falsified COVID-19 Vaccine	The falsified products are illicitly refilled vials of used and discarded genuine COVID-19 VACCINE AstraZeneca (ChAdOx1-S).
Nº8/2021 (WHO, 2021)	Chad,Coted'Ivoire, and Mali(Africa)	Antimalarials	Falsified Combiart (combination of artemether and lumefantrine)	Two expected active ingredients (artemether and lumefantrine) were not detected
Nº9/2021 (WHO, 2021)	Argentina, Estonia, India and Uruguay	Treatment of paroxysmal nocturnal hemoglobinuria (PNH), atypical hemolyticuremic syndrome (aHUS), generalized Myasthenia Gravis (gMG) in adults, and neuromyelitis optica spectrum disorder (NMOSD).	Falsified eculizumab	Misrepresent their identity, composition or source.
Nº2/2022 (WHO, 2022)	Guatemala and India	Broad-spectrum antiviral.	Falsified DESREM (Remdesivir) 100 mg/mL.	The labels have multiple spelling errors and use the wrong font styles and colours.
Nº3/2022 (WHO, 2022)	Brazil, India, Bolivia, Egypt.	Human normal immunoglobulin.	Falsified (Intratect) Immunoglobulina G EndovenosaBiotes.	Misrepresent their identity and source.
Nº4/2022 (WHO, 2022)	Jordan,Türkey, Kuwait, United Kingdom, and Poland	Treat symptoms of cervical dystonia, glabellar lines (wrinkles), and spasticity.	Falsified DYSPORT (*Clostridium botulinum* type A toxin-haemagglutinin complex).	The safety, sterility, and quality of the products referenced in this alert are unknown.

Nº5/2022 (WHO, 2022)	Venezuela (Bolivarian Republic of), Colombia, Dominican Rep, and Ecuador.	Used as a short-acting intravenous general anaesthetic.	Falsified DIPRIVAN (Propofol).	Venezuela (Bolivarian Republic of), Colombia, Dominican Rep, and Ecuador.
Nº6/2022 (WHO, 2022)	Gambia	Substandard baby Cough and Cold Syrup.	Falsified Paracetamol phenylephrine HCl and chlorphenamine maleate.	Diethylene glycol and ethylene glycol, more than specified limit.
Nº7/2022 (WHO, 2022)	Indonesia	Substandard baby drops, baby Cough and Cold Syrup	Falsified Paracetamol phenylephrine HCl and chlorphenamine maleate.	These products contain unacceptable amounts of ethylene glycol and/or diethylene glycol as contaminants.
Nº8/2022 (WHO, 2022)	Yemen and Lebanon	Treatment of cancer and autoimmune diseases.	Falsified Substandard (contaminated) METHOTREX 50 mg.	Fail to meet either their quality standards or specifications.
Nº1/2023 (WHO, 2023)	Uzbekistan and Cambodia	Substandard analegesic and anitpyretic syrup and drops.	Substandard Paracetamol BP, guaifenesin BP, and phenylephrine hydrochloride B.	Unacceptable amounts of diethylene glycol and ethylene glycol.
Nº2/2022 (WHO, 2022)	India	Bacterial blepharitis (red, swollen, irritated, and itchy eyelids), bacterial conjunctivitis (eye discharge, redness, and itching), bacterial keratitis (inflammation of the cornea), and trachoma.	Falsified Tetracycline hydrochloride ophthalmic ointment.	The product is available under various labelling.
Nº3/2022 (WHO, 2022)	United Arab Emirates, Kyrgyzstan, UK/ Ireland and US.	An antithrombotic agent used to treat severe veno-occlusive disease (VOD) in adult and paediatric patients undergoing haematopoietic (blood) stem cell transplantation.	Falsified DEFITELIO (defibrotide sodium).	Does not contain any active ingredient.
Nº4/2022 (WHO, 2022)	Marshall Islands and Micronesia	An expectorant used to relieve chest congestion and the symptoms of cough.	Substandard (contaminated) GUAIFENESIN SYRUP TG SYRUP.	The analysis found that the product contained unacceptable amounts of diethylene glycol and ethylene glycol as contaminants.
Nº5/2022 (WHO, 2022)	Cameroon	Analegesic and anitpyretic Syrup and drops.	Substandard (contaminated) syrup Paracetamol, phenylephrine hydrochloride and chlorpheniramine maleate.	The analysis found that the product contained unacceptable amounts of diethylene glycol and ethylene glycol as contaminants.

Nº6/2023 (WHO, 2023)	Republic of Iraq	Analegesic and anitpyretic Syrup and drops.	Substandard Paracetamol, and chlorphenamine maleate.	Unacceptable amounts of diethylene glycol and ethylene glycol.
Nº7/2023 (WHO, 2023)	India and Turkiye	An antithrombotic agent used to treat severe Veno-Occlusive Disease (VOD) in adult and paediatric patients undergoing haematopoietic (blood) stem cell transplantation.	Falsified DEFITELIO (defibrotide)	Genuine DEFITELIO with Lot 20G20A was packaged in German/ Austrian packaging. The falsified products instead are in UK/Ireland packaging. DEFITELIO does not have marketing authorization in India and Türkiye.
Nº8/2023 (WHO, 2023)	Maldives and Pakistan, Belize, Fiji and Lao People's Democratic Republic.	Analegesic and Antipyretic Syrup and drops suspensions.	Substandard (contaminated) syrup and suspension medicines.	Unacceptable amounts of diethylene glycol and ethylene glycol.
Nº1/2024 (WHO, 2024)	Pakistan	Falsified DOW USP/EP propylene glycol.	Substandard Propylene Glycol.	Under dose
Nº2/2024 (WHO, 2024)	Brazil the United Kingdom of Great Britain and Northern Ireland, and the United States of America.	Treatment of hyperglycemia in type 2 diabetes mellitus in adults, adolescents, and children over 12 years of age.	Falsified batches of OZEMPIC (semaglutide).	Batch number and serial number does not match with the guinine manufacturer.
Nº3/2024 (WHO, 2024)	Finland	Treatment for moderate to severe pain.	Falsified Oxymorphone Hydrochloride 40 mg.	The tablets contained metonitazene instead Oxymorphone Hydrochloride 40 mg as labelled but contain only 5 to 10 mg.
Nº4/2024 (WHO, 2024)	Pakistan	Raw material (excipient) utilized in pharmaceutical and other manufacturing processes.	Falsified DOW USP/EP Propylene Glycol.	PROPYLENE GLYCOL had been found to be contaminated with ethylene glycol.
Nº5/2024 (WHO, 2024)	Armenia, Lebanon and Turkiye	Treatment of Non-Small Cell Lung Cancer (NSCLC) in adults.	Falsified IMFINZI (durvalumab) injection 500 mg/10 mL.	Dates or lot number considered suspicious. Packing is not real and it is misprinted.

supply chain.[6] Other definitions emphasise on features of SSFFC products, including fraudulent or counterfeit medications. For example, counterfeit medications are sometimes described as intentionally mislabelling their identity and source, which may involve using the wrong ingredients, insufficient active substances, or false packaging.[8] This description highlights a serious public health and safety issue, particularly in LMICs where regulatory control is inadequate, and gap exists in the knowledge sharing between all the stakeholders and the patients. In the same way, the definitions of substandard drug products highlight issues in meeting required specifications regarding the content, strength, and purity. Usually, inadequate supply chain management, poor production techniques, or inappropriate storage led to these products. Substandard products are not always counterfeit but can be extremely harmful to patient's health. It is important to distinguish between counterfeit and substandard medications.[14] The review's inclusion of unlicensed and unregistered medicinal items provides their discussion of SSFFC products with an essential perspective. Unregistered medications, which have not received regulatory agency approval, offer significant risks since they might be marketed without sufficient quality and efficacy testing.[47] Further, as reported the term of SF medicines are low-quality or counterfeit medications that are the consequence of fraud, illicit marketing, unapproved imports, and insufficient manufacturing monitoring.[71] The wide range of definitions gathered through the various sources highlights the terminology used to identify SSFFC products.

As per the study report, a higher percentage of low-quality medications in Asia (23.4%) than in Africa (11.4%) were reported to include 50% API. Furthermore, the therapeutic classes most likely to have low API of 50% were antibiotics and antimalarials (18.0% and 16.7% of all poor-quality samples, respectively). This might indicate additional medication counterfeiting, which would necessitate additional investigation and verification by the concerned authority.[72] The penetration of SF medications into supply chains remains a challenge for nations classified as LIC (Low-income countries) and LMIC. It has already been determined that because of the increased demand for life-saving therapies for infectious diseases in LICs and LMICs, SF medications provide an even bigger hazard in these regions.[73] Genuine manufacturers’ and drug regulators' reputations have been harmed by recent SSFFC events worldwide. It is imperative to respond quickly to address quality concerns with these medications and stop such instances in the future. Standardised laws across national borders, cooperation between governmental and regulatory organisations, and rigorous adherence to good manufacturing standards guarantee that the situation gets better on a national, regional, and international level.[74]

STRENGTHS AND LIMITATIONS

A key strength of this study lies in its comprehensive definition of SSFFC drug products, established over an extended period. It also highlights the health hazards and safety concerns by addressing the global health issues reported by the WHO that are associated with SSFFC drug products. However, this scoping review has overlooked some relevant sources of information which was not previously captured indepth. Additionally, the review's findings rely on the scope of the review question and the chosen search strategy.

FUTURE RESEARCH

A systematic review can be conducted using this information as a precursor to it. The global nature of the SSFFC medical product trade, future research should emphasize the importance of collaboration and international cooperation. Analysing the effects of cross-border cooperation between regulatory bodies, law enforcement organisations, and pharmaceutical companies, as well as looking into the efficacy of global frameworks like the WHO's Global Surveillance and Monitoring System, can offer important insights into improving coordination and information sharing to combat SSFFC medical products. Future studies and research should examine areas for development and assess the way the current regulatory systems are working to prevent SSFFC medicinal products. This includes evaluating the way regulatory agencies monitor and enforce quality standards, determining whether policies and penalties prohibit the counterfeiter and identifying regulatory gaps that enable SSFFC medical product to reach the market.

CONCLUSION

This scoping review insight into detail ambiguity and inconsistency in the definition of SSFFC medical items as demonstrated by the distinct definitions from various data sources and the grey literature. This study has a wide collection of varied definitions that emphasise a lack of agreement and consistency in describing the term SSFFC. Further, the findings highlight the urgent need for a uniform and widely recognised definition of SSFFC medicinal items for the public to avoid any kind of confusion and provide clarity. To combat SSFFC medical products it is essential to have a common vocabulary and knowledge for properly identify and report the issues faced on a regular basis. The implementation of a standard and uniform definition could make it easier to gather, examine, and contrast data from different regions or locations and agencies. This will make it possible to evaluate the scope and effects of SSFFC medical goods on public health and patient safety with greater accuracy and precision. Additionally, it would facilitate to the quality treatments and the assessment of their efficacy without wasting much time and reduce the hazards associated with SSFFC medical items.

The regulatory organisations collaborate significantly to improve the efficacy, safety, and quality of medications intended for both domestic and regulatory markets. Raising stakeholder awareness, encouraging improvements in pharmaceutical technologies and procedures, and supporting harmonised pharmacopoeial standards are crucial steps in ensuring improved product compliance and safety, which will make safe medications more widely available.

ACKNOWLEDGEMENT

We would like to thank Manipal College of Pharmaceutical Sciences, Manipal Academy of Higher Education for library access and support provided for this literature search. We would also like to acknowledge "covidence.org" for providing the access for data extraction of this work.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

AUTHOR CONTRIBUTIONS

The following authors participated in the article's development or revising it; SD: Writing-Review and Editing. NN: Conceptualization, Data Curation, Formal Analysis, Investigation, Methodology, Software, Validation, Visualization, Writing - Original Draft Preparation. PA: Software, Validation, Visualization, Formal Analysis, Writing-Review. MJ: Methodology, Writing-Review and Editing. PM: Conceptualization, Data Curation, Funding Acquisition, Project Administration, Resource, Visualization, Final Review.

ABBREVIATIONS

SSFFC: Substandard spurious falsely labelled falsified counterfeit; **WHO:** World health organisation; **LMIC:** Low and middle-income countries; **LIC:** Low-income countries; **EG:** Ethylene glycol; **DEG:** Di- Ethylene glycol; **SF:** Substandard or falsified; **AMR:** Antimicrobial resistance; **TB:** Tuberculosis; **IMPACT:** The International Medical Products Anti-Counterfeiting Taskforce program; **PRISMA:** Preferred Reporting Items for Systematic Reviews and Meta-Analyses-Scoping Review Extension; **MeSH:** Medical Sub Headings; **API:** Active Pharmaceutical Ingredients; **NRRA:** National or Regional Regulatory Authority; **GPHF:** Global Pharma Health Fund; **TLC:** Thin-layer chromatography.

SUMMARY

The worldwide issue of substandard, Spurious, Falsely labelled, Falsified, and Counterfeit (SSFFC) medical products that threaten quality, safety, and efficacy is discussed in this article. In order to classify these dangerous items, the World Health Organization (WHO) coined the term "SSFFC" in 2011. SSFFC drugs, including lifestyle and life-saving prescriptions, provide serious health concerns, including increased morbidity and mortality, drug resistance, and treatment failure, especially in Low- and Middle-Income Countries (LMICs).

Higher mortality rates are associated with these substandard medications, especially in patients suffering from infectious diseases like malaria, TB, and Antimicrobial Resistance (AMR). Additionally, the productivity implications of premature deaths from counterfeit or sub standards drugs result in financial losses. The manuscript emphasizes that treatment failures and resistance get worse by antimalarials drug counterfeiting that are common in global online platforms.

While the problem is still complex, efforts to counteract SSFFC drugs include consumer education, legal proceedings, and technological measures. There is confusion between counterfeiting and other problems, such as inadvertently distributing inferior medications or violating intellectual property. Although the WHO's International Medical Products Anti-Counterfeiting Taskforce (IMPACT) program has made advancements, it still faces obstacles because of definitional inconsistencies and regulatory conflicts. The issue is made worse by the growth of internet pharmacies and inadequate laws in many nations. The purpose of this review is to investigate the differences in definitions of SSFFC goods and focuses on the global alerts reported by the WHO highlighting the most affected category of medicines in different regions.

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Cite this article: Dewan S, Naik NN, Artham P, Janodia MD, Muragundi PM. Compromised Medical Products: A Scoping review of Quality, Safety and Efficacy Concerns. Indian J of Pharmaceutical Education and Research. 2026;60(1):37-53.