Redefining Counterfeit Medicines and Updating the Legal Framework to Address Falsified Medicines: A Qualitative Policy Review

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ABSTRACT

Background. The existence of counterfeit medicines has been a long-standing global public health concern. In the Philippines, Republic Act No. 8203 Section 3 provides a definition of counterfeit medicines, outlines prohibited acts, and states liabilities and penalties of concerned parties. The Philippine legal definition of counterfeit medicine needs to be aligned to what is widely accepted by the international community and to update its scope to prevent varied interpretations due to a mix in the categories of "counterfeit medicines."

Objective. This qualitative narrative policy review aims to generate evidence on counterfeit and falsified medicines from grey literature and recent publications in order to propose recommendations for updating the legal framework to address specifically "falsified" medical products.

Methods. An online search was performed to identify relevant literature that discussed counterfeit medications. A review of narrative textual evidence from grey literature was conducted including extraction of data on the proliferation of fake, unregistered, and substandard medicines from published news articles and reports for the past six years. A review of published literature was also conducted to supplement findings from aforementioned reports and articles.

Results. Literature search revealed that the presence of counterfeit medicines remains prevalent in the country despite the enactment of RA 8203. Counterfeited products include over-the-counter medicines, prescription medicines, and vaccines. The classification of counterfeit medicines in grey literature, including news articles and FDA advisories, are aligned with the WHO definitions.

Conclusion. There is a clear need to update the regulatory framework on counterfeit medicines which would entail revisiting RA 8203 to amend the definition of counterfeit medicines and other related provisions in alignment with the WHO definitions.

Keywords: Philippines, drugs, medicine, counterfeit, falsified, fake, substandard, unlicensed, unregistered

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INTRODUCTION

The existence of counterfeit medicines has been a long-standing global public health concern. Historically, varied definitions of counterfeit medicines exist in the literature. The term "counterfeit" as used by the World Trade Organization (WTO) refers to "*unauthorized representation of a registered trademark carried on goods identical or similar to goods for which the trademark is registered, with a view to deceiving the purchaser into believing that he/she is buying the original goods.*"[1] This WTO definition of counterfeit, from an intellectual

property perspective, generally relates to trademark protection, which considers the rights of the owner as the main victim of counterfeiting. In contrast, counterfeiting of medicines, from a public health perspective, recognizes the patient as the main victim. As the proliferation of counterfeit medicines also poses an unacceptable risk to public health, these products should also be appraised from a public health perspective where the focus is on the protection of the health of the general population.

In 1992, the World Health Organization (WHO) Member States, the International Criminal Police Organization (INTERPOL), the Customs Cooperation Council (now the World Customs Organization), the International Narcotics Control Board, the International Federation of Pharmaceutical Manufacturers' Associations, the International Organization of Consumer Unions, and the International Pharmaceutical Federation operationally defined counterfeit medicine as "*one which is deliberately and fraudulently mislabeled with respect to identity and/or source.*" [2]

The International Medical Products Anti-Counterfeit Taskforce in 2008 elaborated that medical products with patent-related concerns, or without marketing authorization in the country (but are authorized in other countries), or those that are substandard or non-compliant with Good Manufacturing Practices and/or Good Distribution Practices, are not considered counterfeit.[2]

In 2017, the 70th World Health Assembly (WHA) endorsed the recommendation to replace the previously used term "substandard, spurious, falsely labeled, falsified and counterfeit (SSFFC) medical products" with "substandard and falsified medical products."[3] These products reported to the WHO global surveillance and monitoring system are classified into three groups which are separate and mutually exclusive. The classification are as follows:[3]

1. Substandard medical products are authorized medicines that do not meet their quality standards and/or specifications.
2. Unregistered/unlicensed medical products are medicines that have not yet been issued a marketing authorization by the national regulatory agency of the country in which they are being distributed.
3. Falsified medical products are medicines that intentionally make false claims concerning their identity, composition, and/or source.

In the Philippines, Republic Act (RA) No. 8203 (Special Law on Counterfeit Drugs), was enacted in 1996. It provides definitions, outlines prohibited acts, and states liabilities and penalties of concerned parties.[4] RA 8203 Section 3 defines counterfeit drug/medicine in the following manner:[4]

> *"Counterfeit drug/medicine refers to medicinal products with the correct ingredients but not in the amounts as provided hereunder, wrong ingredients, without active ingredients, with sufficient quantity of active ingredient, which results in the reduction of the drug's safety, efficacy, quality, strength or purity."*

Similarly, RA 8203 highlights that counterfeit medicines, whether branded or generic, involves deliberately and fraudulently mislabeling a drug's identity and/or source with or without fake packaging, which aligns with the 1992 WHO definition.[2,4] The law also considers counterfeit medicines as those that bear a registered trademark without authorization, those refilled in containers with legitimate labels by unauthorized personnel, unregistered drugs that are imported (except those for personal use as justified by verifiable medical records), and those whose active ingredients are either absent, substituted, or amounting to less than eighty percent (<80%), compared to an adulterated drug having reduced and lost efficacy upon drug expiry.[4]

The local definition of counterfeit medicine presents several concerns. First, the Philippine legal definition needs to be aligned to what is widely accepted by the international community, *i.e., substandard and falsified medical products*. To illustrate, a drug with less than eighty percent (<80%) of the active ingredient it purports to possess may not necessarily be an issue of counterfeiting, but a failure of a legitimate manufacturing company to follow current good manufacturing practices (CGMP). Second, RA 8203, Section 3 offers a definition that is prone to varied interpretations due to a mix in the categories of "counterfeit medicines". The complex definition puts the unregistered, falsified, and substandard products all under one category, and such presents challenges in the full implementation of the law. Current interventions are not appropriately addressing the problem due to the diversity of the issues being targeted. There are interventions and penalties that can only be applied to substandard products, while others are specific to unregistered products based on RA 9711 [Food and Drug Administration (FDA) Act of 2009].[5]

According to RA 8203, the FDA is the lead agency tasked to monitor and examine suspect counterfeit products, and submit results of examination for investigation and court proceedings. This task is currently being undertaken by the Center for Drug Regulation and Research despite not being formally delegated by the implementing regulations of the law. With limited human resource and available expertise handling a broad mix of 'counterfeit products', the government will have a difficult time addressing the counterfeiting problem effectively. Furthermore, with the reorganization of the FDA in 2009, many offices previously tasked to monitor counterfeit medicines have already been dissolved, and these responsibilities have been transferred to new offices which have not yet been officially designated by a new law or policy.[6]

For counterfeited dangerous drugs, functions similar to FDA roles are performed by PDEA. Investigations are being conducted by the Philippine National Police and the National Bureau of Investigation in coordination with the FDA. The Bureau of Customs protects entry points from imported counterfeit products, while the Intellectual Property Office handles resolution of intellectual property cases. It was not clear though among informants representing local

governments what their roles are, which can be considered a huge implementation gap.[6]

Accreditation of complaints desks established by a pharmaceutical organization is another function of FDA according to RA 8203. The responsibility of the complaint desk is to receive, verify, and refer complaints regarding counterfeit medicines from the organization's members. However, officers of different pharmaceutical organizations were not aware of the provision regarding complaint desks; the implementation of which could have enhanced the reporting of counterfeit medicines.[6]

The study of Robles et al. revealed that there has been an existing regulatory framework for counterfeit medicines (RA 8203) that is considered advantageous to the country. This law has implementing rules and regulations, as well as provisions supported from other laws such as the Criminal Code (1980), RA 6675 (Generics Act of 1988), RA 7394 (Consumer Act of 1996), RA 3792 (E-Commerce Law of 2000), RA 8293 (Intellectual Property Code of the Philippines of 2000), RA 3720 (Food, Drug and Cosmetics Act), RA 9502 (Cheaper Medicines Act of 2008), and RA 9711 (Food and Drug Administration Act of 2009).[6]

Health policies and reforms in the government can be achieved through legislation from the Congress and administrative orders from government agencies involved in health care, such as the DOH and the FDA. The Universal Health Care Act (RA 11223) embodies the overall healthcare framework of the Philippines, in which a whole-of-system, whole-of-government, and whole-of-society approach is being practiced in the development, implementation, and evaluation of health policies.[7] In alignment with the UHC Act, the Department of Health has developed the Philippine Medicines Policy 2022-2030, known as ACCESS, to ensure universal access to medicines and pandemic resiliency.[8] Its key pillars include assurance of safety, quality and efficacy of medicines, where one of the strategies is to combat substandard and falsified medicines, through adaptation of the WHO definitions and guidelines.[8] Since the Philippine healthcare system adapts a decentralized and devolved model, local government units are also key players in healthcare in their respective communities.

Despite efforts in the UHC, household out-of-pocket payment remains to have the highest share in total health expenditure for 2023, amounting to 44.4% of the total P1.44 trillion health expenditure.[9] Twenty-nine percent or a total of P360.05 billion were received by retailers and other providers of medical goods received from the total health expenditure.[9] In 2019, the Senate issued a resolution to investigate the proliferation of counterfeit medicines in the country to protect the welfare of Filipinos, citing that half of out-of-pocket health expenditures of Filipinos are spent to buy medicines from pharmacies.[10] This is in response to the UN Office on Drugs and Crime (UNODC) 2019 report, stating that the Philippines had the highest incidence of counterfeit medicines in the Southeast Asian region.[11]

Currently, the Philippine pharmaceutical industry is lucrative, which also makes it a target for crimes and corruption. In 2023, the industry was considered as the fastest growing market after generating a revenue of US$2.1 billion, making it the third largest pharmaceutical industry in the Southeast Asian region. However, the industry was plagued with corruption in the recent years, including the issue on the misuse of pandemic funds to procure substandard medical goods[12], and the alleged connivance between a pharmaceutical company and medical doctors[13].

Data from grey literature were gathered and utilized for this study. Grey literature includes a wide range of documents not controlled by commercial publishing and distribution channels, namely government reports, unpublished clinical trials, conference proceedings, graduate dissertations, and others.[14] The incorporation of grey literature, especially in public health research, helps mitigate the effects of publication bias as researches with null findings are less likely to be published in peer reviewed journals. This provides contextual information on how, why, and who benefits from specific public health interventions. Moreover, grey literature syntheses aid researchers and practitioners in properly comprehending existing interventions, the full extent of evaluations, and specific areas for further research.[15] Including grey literature also helps account for the significant time lag between research and publication, allowing researchers to utilize information in its earlier forms. Consequently, this helps simplify complex concepts for non-specialists and offers new information earlier than traditional publications, ultimately making it a critical resource for medical researchers.[16]

This qualitative narrative policy review aims to generate evidence on counterfeit and falsified medicines from grey literature and recent publications. The inclusion of grey literature was deemed beneficial to this paper as it can address evidence gaps brought about by the significant lag time due to the peer-review process required by the majority of journal publications before publication. Through the review of individual evidence from grey literature, an overall conclusion can be inductively drawn which can be used to compare the actual landscape of counterfeit medicines in the country based on evidence against the current legal framework. This will enable us to put forward recommendations to update the legal framework in the country in alignment with WHO definitions to address specifically "falsified" medical products, given that there are other existing laws regulating substandard products.

METHODS

Search Strategy

Evidence and literature search was conducted from June 2024 to July 2024. Information and reports on the presence of counterfeit medicines were derived from grey literature, specifically news articles and official advisories from the FDA from 2018 to 2024. A combination of the search

terms utilized were: *counterfeit, fake, falsified, substandard, contaminated, unregistered, unlicensed, and medicines*. Google Advanced Search was used as the search engine for retrieving news articles, utilizing the title and text preview or snippet of the search result to evaluate the relevance of the search result. Only the first five to ten pages of the Google search result was reviewed to ensure relevance.[17] FDA advisories on counterfeit medicines were retrieved from the FDA website. In addition, a literature search using PubMed and SCOPUS was conducted to identify published literature that classifies counterfeit, substandard, falsified, or unregistered medicines. Automated filters based on inclusion and exclusion criteria were used to refine the literature search. The studies covered in the search include those that provided detailed information, descriptions, or classifications of counterfeit, substandard, falsified, or unregistered medicines which may include, but not limited to, systematic reviews, randomized controlled trials, cohort, case control, economic evaluations, and descriptive studies.

Due to the sensitivity of the topic on counterfeit medicines and urgency for action, not to mention, the confidentiality of information from both the regulatory body and industry perspectives, more recent or "current" evidences, including but not limited to alerts and advisories from the Philippine Food and Drug Administration (FDA), can be obtained from grey literature. This approach has been considered appropriate by the UP Manila Ethics Review Board (UPMREB), which issued a retrospective exemption from ethics review for this protocol.

Study Selection

Study selection was conducted independently by two authors, and disagreements were resolved by a third author. For news articles, these are included only if the source of the news or media outlet is recognized as a trusted source of information by the Reuters Institute.[18] These news outlets include local or regional news outlets, GMA Network, Philippine Daily Inquirer, Manila Bulletin, and The Philippine Star, among others. A published article is included in the study if it contains detailed information, descriptions, or classifications of counterfeit medicines according to WHO classifications or similar. A gray literature is included in the study using the similar criteria, and if the report is based in the Philippines, and the report classifies the nature of the counterfeit medicine. Excluded gray literature were blog websites, social media sites, non-textual webpages such as links to videos and ads, and other unrelated webpages. Literature not in English or Filipino were excluded. Duplicate news articles pertaining to a similar case were excluded.

Data Extraction and Quality Assessment

Analysis of the findings were done by looking at patterns on the reported evidence based on descriptions and alignment with the WHO's definition of counterfeit medicines. These were classified or clustered accordingly based on this framework. For news articles, the following data were extracted: category of the counterfeit medicine as reported in the article, category according to the WHO classification, news source and year of publication, and the medicines involved. For FDA advisories, the following data were extracted: category of the counterfeit medicine as reported in the advisory, category according to the WHO classification, FDA advisory number, and the medicines involved. For published journal articles, the following data were extracted: author and year of publication, countries included, WHO classification of the counterfeit medicine, and the category as reported in the article.

The data of included articles were analyzed through a narrative summary of evidence in text and tabular form. The summary includes the number of reports per year, the WHO classification of counterfeit medicine, and the drug classes of medicines involved. The quality of the grey literature included was assessed using the JBI Checklist for Narrative Textual Evidence.[19] The quality of the included literature was rated based on their score from the checklist, with scores 5 to 6 as "good", 3 to 5 as "fair", and 0 to 2 as "poor" quality. For published literature, the quality was assessed using the appropriate tools. AMSTAR-2 checklist (A MeaSurement Tool to Assess systematic Reviews) was used to assess systematic reviews.[20] For the SANRA checklist (Scale for the Assessment of Narrative Review Articles), a score of four or below indicates a very poor quality.[21] An author reviewed the quality of the evidence, while another author reviewed the quality assessment conducted. Disagreements between authors were resolved by a third author.

Ethical Considerations

The paper was submitted to the UP Manila Research Ethics Board (UPMREB) to ensure that ethical clearance is sought. All data collected from the study were publicly available from online resources including the FDA website and other research databases. The public may indirectly benefit from this research through the update of the regulatory framework on the definition of counterfeit medicines and provision of clearer descriptions of poor-quality medicines, ultimately helping in the detection and prevention of counterfeiting in the country. In line with this, the policy paper shall be published in a reputable journal for optimal dissemination.

RESULTS

Study selection

Initial literature search from Google, PubMed, and SCOPUS and handsearch resulted in 29,800,151. Filters (i.e., date of publication) and automation tools were used to further narrow down the number of records, in which 197 records remained. After screening, 95 records were assessed for eligibility. A total of 31 records were included in the review (Figure 1). To account for the Philippine setting, a total of 14 local news articles and 13 FDA advisories on counterfeit medicines were included in the study. Included in the study

as well are four published academic papers on counterfeit medicines in the international setting.

Descriptive Analysis

The following tables are a list of literature documenting the presence of counterfeit medicines in the local and international setting. Shown in Table 1 are examples of news reports on counterfeit medicines categorized as either falsified, unregistered or substandard, arranged from the most recent to the least recent news reports between 2018 and 2024.

Shown in Table 2 are examples of FDA advisories warning the public against counterfeit medicines, arranged from the most recent to the least recent advisories between 2018 and 2024.

Shown in Table 3 are examples of recent publications on counterfeit products around the globe, arranged from the most recent to the least recent publications between 2018 and 2024.

Among the 14 news articles, one report was made in 2024, two reports in 2023, one in 2022, three in 2021, one in 2020, one in 2019, and three in 2018. On the classification of counterfeit medicines, ten reports are on falsified medicines, three reports on unregistered medicines, and one report on substandard medicines. Six reports are on over-the-counter medicines, three reports on rabies vaccines, one report on traditional Chinese medicine, one report on COVID-19 vaccines, one report on monoclonal antibodies preparations, one report on antimicrobials, and one report on antiseptics.

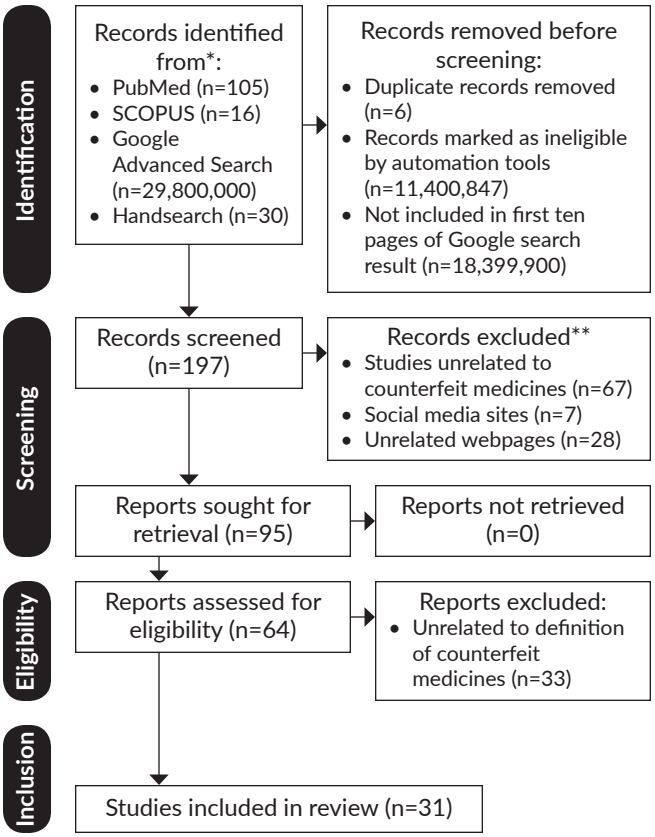

Figure 1. Flow diagram[22] for search process and study selection.

Table 1. News Reports of Counterfeit Medicines in the Philippines

Category (as reported)	Category (WHO classification)	News Source, Year	Medicine/s
Fake/counterfeit medicines	Falsified medical products	The Philippine Star, 2024[23]	• Medicol Advance • Bioflu • Tuseran Forte • Kremil-S • Alaxan FR • Biogesic
Unregistered antiseptic	Unregistered/ Unlicensed medical products	The Philippine Star, 2023[24]	• Agua Oxigenada F.E.U. XIV-10 Vols 120 mL
Fake/counterfeit medicines	Falsified medical products	Philippine Daily Inquirer, 2023[25]	• Alaxan • Neozep Forte • Bioflu • Tuseran Forte • Ponstan • Diatabs • Kremil-S • Medicol Advance • Lomotil
Contaminated/ substandard medicines	Substandard medical products	The Philippine Star, 2022[26]	• Promethazine Oral Solution BP • Pheniramine Maleate/ Ammonium Chloride Menthol (Kofex Malin Baby Cough Syrup) • Chlorpheniramine Maleate/ Phenylephrine HBr/ Dextromethorphan (MaKOFF Baby Cough Syrup) • Paracetamol/ Phenylephrine HCl/ Chlorpheniramine Maleate (MaGrip n Cold Syrup) **Contaminants: diethylene glycol and ethylene glycol*

Table 1. News Reports of Counterfeit Medicines in the Philippines *(continued)*

Category (as reported)	Category (WHO classification)	News Source, Year	Medicine/s
Fake/counterfeit medicines	Falsified medical products	Philippine News Agency, 2022[27]	• 31,700 capsules of Loperamide hydrochloride • 27,000 tablets of Losartan potassium • 31,500 capsules of Amoxicillin trihydrate • 13,100 capsules of Mefenamic acid • 12,200 tablets of Dicycloverine hydrochloride • 13,400 tablets of Carbocisteine
Fake/counterfeit medicines	Unregistered/ Unlicensed medical products	GMA News, 2021[28]	• Tocilizumab injection
Fake/ counterfeit medicines	Falsified medical products	The Philippine Star, 2022[29]	• 18,000 tablets of Bioflu and Neozep
Fake/counterfeit medicines	Falsified medical products	GMA news, 2021[30]	• COVID-19 vaccines
Unregistered medicines	Unregistered/ Unlicensed medical products	The Philippine Star, 2021[31]	• A Qi Mei Su Fen San Pian • OTC Anshenbunaoye • Erythromycin Estolate Tablets • OTC Huoxiang Zhengqi Shui • OTC [Label in foreign language] • OTC Guo Guang® Z50020601 [Label in foreign language] • OTC Z34020127 [Label in foreign language] • SPH H31020387 [Label in foreign language] • GB15979 12 g [Label in foreign language] • CISEN® H37021822 250 ml [Label in foreign language] • OTC Bei® Kangbingdukoufuye • Levofloxacin Hydrochloride Tablets 0.1 g • CISEN® Levofloxacin Lactate and Sodium Chloride Injection 100 ml: 0.2 g • SINE® Lincomycin Hydrochloride Injection 2 ml: 0.6 g • OTC Musk Hemorrhoids Ointment • CISEN® H37021756 5% 250 ml: 12.5 g [Label in foreign language] • CISEN® H37021825 5% 500 ml: 25 g[Label in foreign language] • Jinkui Shenqi Wan • Josamycin Tablets 0.2 g • OTC Z44022627 [Label in foreign language]
Fake/counterfeit medicines	Falsified medical products	World Health Organization, 2020[32]	• VERORAB, Rabies Vaccine for Human Use, Prepared on Cell Cultures (Inactivated) • SPEEDA, Purified Rabies Vaccines (Vero Cell) • RABIPUR, PCEC rabies vaccine for human use • EQUIRAB, Anti-Rabies Serum (Equine)
Fake/counterfeit medicines	Falsified medical products	World Health Organization, 2019[33]	• VERORAB, Rabies Vaccine for Human Use, Prepared on Cell Cultures (Inactivated)
Fake/counterfeit medicines	Falsified medical products	Manila Bulletin, 2018[34]	• 298 boxes of Bioflu (100 tablets per box) • 200 boxes of Biogesic (500 tablets per box) • 195 boxes of Alaxan FR (100 tablets per box) • 395 boxes of Medicol Advance (100 tablets per box) • 148 boxes of Neozep Forte (100 tablets per box) • 48 boxes of Solmux (100 tablets per box) • 18 boxes of Kremil-S (100 tablets per box) • 8 boxes of Dolfenal (100 tablets per box) • 8 boxes of Flanax Forte (250 tablets per box) • 5 boxes of Gardan (200 tablets per box) • 3 boxes of Imodium (200 tablets per box) • 4 pieces of Dermovate ointment
Fake/counterfeit medicines	Falsified medical products	Philippine News Agency, 2018[35]	• Purified Chick Embryo Cell Rabies Vaccine (Inactivated) (Rabipur) 2.5 I.U./mL Lyophilized Powder For Injection (ID/IM)
Fake/ counterfeit medicines	Falsified medical products	The Philippine Star, 2018[36]	• Paracetamol (Biogesic) 500 mg tablets

Table 2. Philippine FDA Advisory on Counterfeit Medicines

Category (as reported)	Category (WHO classification)	Philippine FDA Advisory No.	Medicine/s
Counterfeit drug products	Falsified medical products	FDA Advisory No. 2024-0801[37]	• Ibuprofen (Medicol® Advance) 200 mg Softgel Capsule • Phenylephrine Hydrochloride + Chlorphenamine Maleate + Paracetamol (Bioflu®) 10 mg/ 2 mg/ 500 mg Tablet • Dextromethorphan Hydrobromide + Phenylpropanolamine Hydrochloride + Paracetamol (Tuseran® Forte) (Reformulated) 15 mg/ 25 mg/ 325 mg Capsule
Counterfeit drug products	Falsified medical products	FDA Advisory No. 2024-0797[38]	• Aluminum Hydroxide + Magnesium Hydroxide + Simeticone (Kremil-S®) 178 mg/ 233 mg/ 30 mg Chewable Tablet • Ibuprofen + Paracetamol (Alaxan® FR) 200 mg/ 325 mg Capsule • Paracetamol (Biogesic®) 500 mg Tablet
Unregistered drug products	Unregistered/ Unlicensed medical products	FDA Advisory No. 2024-0746[39]	• OTC Topfond Luleitading Pian Loratadine Tablets • Lihua Bidouyan Pian [as translated] • MINSHENG Tobramycin and Dexamethasone Eye Drops 5 mL • TRT Pharma Pifubing Xuedu Wan • Dawnrays Levocetirizine Dihydrochloride Tablets 5 mg
Substandard (contaminated) drug products	Substandard medical products	FDA Advisory No. 2023-2595[40]	• Alergo Syrup • Emidone Suspension • Mucorid Syrup • Ulcofin Suspension • Zincell Syrup **Contaminants: diethylene glycol and ethylene glycol*
Substandard (contaminated) drug products	Substandard medical products	FDA Advisory No. 2023-0515[41]	• Ambroxol HCl Cough Syrup [Ambronol] • Paracetamol + Guaifenesin + Phenylephrine Hydrochloride Syrup **Contaminants: diethylene glycol and ethylene glycol*
Unregistered drug products	Unregistered/ Unlicensed medical products	FDA Advisory No. 2023-0162[42]	• Olarigen 50 (Olaparib) Capsule • Olarigen 150 (Olaparib) Tablet • Osmigen 80 (Osimertinib) Tablet
Unregistered drug products	Unregistered/ Unlicensed medical products	FDA Advisory No. 2022-1761[43]	• Progesterone Acetate Tablets, USP 10 mg 100's
Unregistered drug products	Unregistered/ Unlicensed medical products	FDA Advisory No. 2022-0942[44]	• Ivermectin Tablet USP Iverjohn-12 12 mg Tablet
Counterfeit drug products	Falsified medical products	FDA Advisory No. 2022-0611[45]	• Ibuprofen / Paracetamol (Alaxan FR) 200 mg / 325 mg capsule • Loperamide (Imodium) 2 mg capsule • Loperamide (Diatabs) 2 mg capsule • Mefenamic acid (Dolfenal) 500 mg film-coated tablet • Phenylephrine HCl / Chlorpheniramine maleate / Paracetamol (Bioflu) 10 mg / 2 mg / 500 mg film-coated tablet
Counterfeit drug products	Falsified medical products	FDA Advisory No. 2021-3535[46]	• Sildenafil Citrate (Viagra®) 100 mg Film-Coated Tablet
Counterfeit drug products	Falsified medical products	FDA Advisory No. 2020-348[47]	• Purified Rabies Vaccine (Vero Cell) Speeda 2.5 I.U. and 0.5 mL of Solvent Freeze-Dried Powder for Injection
Counterfeit drug products	Falsified medical products	FDA Advisory No. 2019-533[48]	• Cholecalciferol (Fern-D)
Unregistered drug products	Unregistered/ Unlicensed medical products	FDA Advisory No. 2018-153[49]	• Health and Natural Eye Drop

Table 3. Recent Publications on Counterfeit Products in other Countries

Author, Year	Countries included	Category (WHO classification)	Category (as reported)
Sharma et al., 2023[50]	Sri Lanka	Substandard medical products	Substandard medicines (SM) were subdivided into: • Contamination • Stability defect • Active pharmaceutical ingredient (API) defect • Packaging and labelling defects • Variation in physical properties such as weight and volume • Adverse events reported • Unclassified
Fincham, 2021[51]	United States, Canada	Substandard medical products; Falsified medical products	Addressed that consumers who shop online for medicines are likely to receive "unapproved, substandard, and counterfeit drugs." Counterfeit medications were defined as drugs that may include: • Incorrect or wrong ingredients • Insufficient or inactive ingredients • Fake packaging • Active ingredients that are different from those described on the package • Medicines that have expired or have no expiration date • Different quantity of impurities
Hodges & Garnett, 2020[52]	Global	Substandard medical products; Falsified medical products; Unregistered/ Unlicensed medical products	Recognized evidence gaps on the presence of different definitions of counterfeit medications. Terms used include: • Fakes • Counterfeit • Falsified • Spurious • Substandard • Unregistered
Grech et al., 2018[53]	Africa, America, Asia, Europe	Substandard medical products; Falsified medical products	Addressed the importance of characterizing results of antimalarial medicine based on agreed upon definitions. Generally, poor-quality medicines were classified as falsified or counterfeit, substandard or degraded, emphasizing the importance of the distinction between these categories for proper reporting. This study recorded outcomes as: • Falsified • Substandard • Degraded • Within quality specifications • No characterization; or, • Combination of these categories

For over-the-counter medicines, the reports include NSAIDs, cough and colds preparations, paracetamol, antacids and gastrointestinal medications, and topical corticosteroids. All, except for one, of the new articles have reported the classifications of counterfeit medicine consistent with the WHO definitions. One news article[28] has interchangeably classified the medicine as fake and unregistered.

Among the 13 FDA advisories, three reports were issued in 2024, three in 2023, and three in 2022. Additionally, one report was issued in each of the years 2021, 2020, 2019, and 2018. On the classification of counterfeit medicines, six reports were on falsified medicines, five reports on unregistered medicines, and two reports on substandard medicines. All of the 13 reports were consistent with the WHO classification of counterfeit medicines. On the medicine class being reported, five reports are on over-the-counter medicines, one report on traditional Chinese medicine, one report on anticancer drugs, one report on hormonal agents, one report on anti-helminthics, one report on erectile dysfunction drugs, one report on rabies vaccine, one report on vitamin supplement, and one report on ophthalmic preparations. Over-the-counter medicines reported include NSAIDs, cough and colds preparations, paracetamol, and antacids and gastrointestinal medications. All of the FDA advisories have reported the classifications of counterfeit medicine consistent with the WHO definitions.

Quality Assessment Results

All the news articles and FDA advisories were assessed as narrative reports, which the JBI Checklist for Narrative Textual Evidence[19] was used for. Out of the 14 news articles, four are of fair quality, while the remaining ten articles are of good quality. All 13 FDA advisories have scores of 3, indicating fair quality. Three of the published literature included in this study were assessed as narrative reviews, in which the SANRA checklist (Scale for the Assessment of Narrative Review Articles)[21] was used. All of the narrative reviews included in the study have satisfactory quality, with all having SANRA scores of above 4, thus of acceptable quality.

One published literature included in this study is a systematic review, thus AMSTAR-2 checklist (A MeaSurement Tool to Assess systematic Reviews)[20] was used, which was assessed to be a critically low quality review.

DISCUSSION

Since the enactment of RA 8203, accurate data on the prevalence of counterfeit medicines, cases resolved, number and effectiveness of public awareness campaigns, and the nature and value of counterfeit medicines seized remain unavailable. Records of these are often found at the Philippine FDA regional offices and PDA Compliance Division. However, there is an apparent lack of consolidation of these records. The primary mode of communication on reports of counterfeit medicines to the public include newspapers, television, radio, or the internet.[6] Healthcare professionals usually access reports from the website of the Philippine FDA through FDA advisories.

Over-the-counter medicines are the most common targets of counterfeiting and falsification due to their high demand in the market, majority of which are classified to be either substandard or falsified. As a result, the widespread prevalence of counterfeit OTC medicines remains to be a significant public health concern globally.[23,25,29,36] However, in recent years, the presence of counterfeit prescription maintenance medications and antimicrobials have become evident in the local market.[27,31] This can potentially lead to insufficient treatment and patient harm, as well as contribute to the development of drug-resistant strains of bacteria.[54,55] One study identified that counterfeited antibiotics account for 28% of global counterfeit drugs, with 78% coming from South-East Asia.[54] This is consistent with publications assessing the global status of counterfeit medications showing that the primary drug class of counterfeit medications was anti-infectives.[56,57] Other drug classes usually being counterfeited belong to genitourinary drugs and preparations for erectile dysfunction, cardiovascular, and central nervous system.[56,57] Manufacturers of counterfeit products are inclined towards medications meant to treat morbidity- and mortality-related diseases, especially in developing countries.[56-58]

The presence of counterfeit vaccines has also been documented, including falsified rabies vaccines[33,35] and falsified and unregistered COVID-19 vaccines[28,30]. This may result in decline in vaccination rates and coverage, resurgence of diseases, loss of control of epidemics, and mistrust in healthcare. Fake vaccine trafficking continues to be a growing phenomenon, especially in lower- and middle-income countries including India, Iran, Burma, Uganda, and China. In higher-income countries, vaccine quality is guaranteed through stringent and rigorous market authorizations and control processes, limiting the occurrence of counterfeiting.[59]

Unregistered drug products were also documented through the FDA advisories. Unregistered traditional Chinese herbal medicine continues to be rampant in the Philippines.[31] These herbal products may be of subpar quality, questionable efficacy, and contain hazardous chemicals, some of which include substances in the schedule listing of Dangerous Drugs Board, and may lead to clinical deterioration of patients.[60,61] Imported medications bearing foreign languages also comprise unregistered drug products. This is consistent with the current trend in the local pharmaceutical industry where imported drug products dominate the market. About two-thirds of registered medicines in 2018 were imported, while only one-third was manufactured in the country. These data, however, only reflect documented and registered drugs products, and similar numbers are estimated for unregistered drug products.[62]

Substandard drug products listed as examples above were those contaminated with diethylene glycol (DEG) and ethylene glycol (EG). DEG/EG are toxic yet cheap alternatives for glycerin as solvent, diluent, and ticketing agency used in cough and cold preparations for pediatric patients. Consuming even small quantities of DEG/EG can lead to fatality, especially in children. At least 300 children deaths have been documented around the globe due to ingestion of these substances from substandard medicines.[63] In Indonesia, DEG/EG were found to have contaminated at least 103 syrup products that led to 323 cases of acute kidney injury and 190 fatalities. These substances were used as solvents by at least six pharmaceutical companies, exceeding the safe threshold of 0.5 mg/kg body weight per day.[64] Since 2023, the WHO has released an urgent call to action to countries for the prevention and detection of substandard and contaminated medications with DEG/EG, and appropriate response towards their proliferation.[65]

As seen in the news reports (Table 1) and FDA advisories (Table 2), the current WHO classification is already in use. The term "counterfeit" is often interchanged with the terms "fake" and "falsified", while contaminated drug products are subsumed under the "substandard" category. Even though the WHO updated the definitions for substandard and falsified medical products and created new categories for such, not everyone adheres to these changes, and there are still differing interpretations in use.[66] This is substantiated by various journal publications demonstrating the contrasting terminologies used by different countries, as listed in Table 3. In a retrospective study in Sri Lanka, although adhering to the WHO definitions, poor-quality medicines were framed as either 'substandard medicines' and 'falsified' or counterfeit medicines. Categories were also created to further expound on the defects of encountered poor-quality medicines, with the most frequently reported type being contamination (36.2%). Findings were similar to FDA's analysis of drug recalls in the USA noting that contamination was the most common reason for recall (50.1%), highlighting the challenges in manufacturing.[67]

The study of Hodges and Garnett has highlighted the persistent problem of inconsistencies in the definitions of counterfeit medications.[52] This issue has impeded multiple

international efforts in battling counterfeit medications as no single legal definition has been consolidated among countries.[68] Despite the recognition that better terminologies shall be crafted, it will only be possible through collection of actual data from worldwide surveillance, monitoring, and alert systems that will help inform international organizations such as the WHO on which terminologies are the most fitted and effective to use.[52] In congruence, it was noted that there is no clear agreement on the definition describing substandard and falsified medicines, to which creating a structured definition has only led to disagreement and opposition.[53] The competing interests of pharmaceutical companies and public health organizations are partly to blame for the inconsistencies in this situation.[69] Nonetheless, the lack of clear distinctions between categories of poor-quality medicines has led to confusion, resulting in poor reporting in medicine quality and problems with international trade of quality generic medicines.[53,70] Findings of the study notes that delineation of the categories of medicines help provide an accurate characterization and analysis of their quality. The accurate characterization of medicine quality initiates a concerted effort to address this public health concern, mainly through: (1) implementation of stringent pre-qualification processes, ensuring procurement and distribution of high-quality medicines; (2) initiation of awareness and education campaigns on poor-quality medicines helping the public identify counterfeit medicines and prevent safety issues; and (3) the development of tailored countermeasures such as strengthening supply chains and implementing technological innovations like SMS-based verification systems, to prevent infiltration of counterfeit medicines into regulated markets.[53]

In the Philippine context, based on the provisions of RA 8203, all falsified, unregistered, and substandard medicines are grouped together under only one definition as counterfeit medicines. This definition of counterfeit medicines is much broader when compared to definitions currently used by the international community. Furthermore, the law does not distinguish the prohibited acts and violations of the law, and penalties are similar regardless of the intent or motive in selling the products identified in the definition. This may lead to actual and potential problems and has opened doors for various interpretations that may hinder implementation of strategic interventions.

The importation of drug products that are not yet registered to the Philippine FDA is a point of contention and may be subject to varied interpretations based on which law is being cited. According to the RA 8203 definition, imported drugs that have not yet been registered are considered as counterfeit medicines, and constitutes a criminal offense. However, RA 9502 or Cheaper Medicines Act, as interpreted by a Supreme Court ruling, allows for parallel importation of unregistered medicines. This inconsistency is demonstrated by a 2009 Supreme Court case of Roma Drug v. RTC of Guagua, Pampanga.[71] In August 2000, the National Bureau of Investigation (NBI) conducted a raid on Roma Drug, upon the request of then SmithKline Beecham Research Limited, and seized several imported medicines. The NBI then filed a complaint against the owner of Roma Drug for violation of Section 4 (prohibition of the sale of counterfeit medicines) of RA 8203. The Supreme Court ruled that with inconsistencies on the provisions of RA 8203 and RA 9502 on the importation of unregistered medicines, the provisions of the more recent RA 9502 nullifies the provisions of RA 8203. Thus, the Court ruled that the ban on the importation of unregistered drugs is no longer valid. Since the provisions of RA 8203 on importation of unregistered drugs are no longer applicable, the FDA now invokes the provisions from RA 3720 as amended by RA 9711 (FDA Act of 2009) in dealing with cases of unregistered imported drugs.[6]

Substandard medicines are loosely defined under the scope of counterfeit medicines in RA 8203, without consideration of when the deterioration of quality of the product has occurred. Degradation leading to substandard quality may occur after a pharmaceutical product with acceptable quality leaves the manufacturer. Exposure to inappropriate storage conditions in the supply chain may result in degradation of its quality as demonstrated by nonconformance to specifications, hence becoming substandard. Studies have shown that improper storage, such as exposure to temperature or humidity conditions beyond the labeled storage requirements, results in unintentional degradation of the potency of the drug product. In a study conducted in India on the effects of temperature to the pharmacological action of insulin, it was observed that storage at 32 and 37 degrees Celsius for 28 days showed 14% to 18% decrease in the potency of both regular and biphasic formulations of insulin.[72] Consequently, the insulin products did not show a significant decrease in blood sugar levels of the rabbits when compared to those receiving insulin stored at 5 degrees Celsius. Similarly, vaccines and labile drugs also show decrease in potency if not stored under controlled temperature.[72] In another study conducted on Cambodian samples of amoxicillin-clavulanic acid, it was found that improper packaging and storage conditions may reduce the quality of these products at community pharmacies in this tropical country.[73]

In the Philippines, while there are no published studies on possible effects of storage on quality and efficacy, inappropriate storage conditions do exist. In a study conducted by Loquias et al. on the effects of typhoon Haiyan on medicine management system in health care facilities, improper storage conditions are evident, such as, inappropriate temperature and humidity, and lack of storage facilities for pharmaceutical products which were exacerbated with the typhoon Haiyan as a result of indiscriminate acceptance of donations.[74,75] The proper handling of medicines from suppliers until it reaches the primary health care facilities is also not ensured. It is therefore likely that unintentional degradation of the potency of these pharmaceutical products happens. Such instances therefore warrant interventions that would target the supply chain process.

Lastly, the definition includes medicines which have been intentionally altered, such as, fake, adulterated and those fraudulently or deliberately mislabeled for reasons of profit at the expense of public safety. While there are currently no published studies or reports in the Philippines on the effects of these medicines to public safety, literature documents its tremendous impact on patient's health such as development of drug resistance to serious harm and death.[54,76] It also has serious economic implications such as waste of consumer income, higher health expenditures, and reduction in incentives to engage in research development and innovation on the part of the pharmaceutical sector.[77]

The presence of counterfeit medicines in the country remains to be prevalent despite the efforts of various governing bodies to address this problem, which reflects the gaps and flaws in the country's regulations and implementation. There is a clear need to update the regulatory framework on counterfeit medicines which would entail revisiting RA 8203 to update the definitions and other provisions, as well as other local regulations in relation to substandard and falsified medicines.

In order to update the regulatory framework on counterfeit medicines, it is imperative to update first its definition in RA 8203. It is recommended to amend the RA 8203 definition of counterfeit medicines in alignment with the 2017 WHO recommendations on the definition of substandard and falsified medical products. Thus, counterfeit medicines may be redefined as "deliberately or fraudulently misrepresenting their identity, composition or source as specified by the Philippine FDA." Additionally, substandard medicines and unregistered medicines may be categorically defined. Substandard medicines may be defined as "registered medical products that fail to meet the quality standards or specifications required by the Philippine FDA." Unregistered medicines may have their own definition as those products "that have not undergone evaluation and/or approval by the Philippine FDA for the market in which they are marketed/distributed or used, subject to permitted conditions under national or regional regulation and legislation."

The important distinction between counterfeit and substandard medicines is the deliberate intention to misrepresent the product under the guise of a legitimate one. On unregistered medicines, the definition is broad enough to include locally-produced and imported medicines. Additionally, this definition also accounts for other laws in the country that govern the importation of medicines, i.e., the parallel importation provisions of RA 9502.

The delineation and distinction of substandard and falsified medicines is important since related laws and regulations on counterfeit medicines are anchored on the definitions provided by RA 8203. Aside from RA 8203, it is also recommended that the other laws included in the regulatory framework on counterfeit medicines, including but not limited to FDA Act of 2009 (RA 9711), Philippine Pharmacy Act of 2016 (RA 10918), Comprehensive Dangerous Drugs Act of 2002 (RA 9165), Cheaper Medicines Act (RA 9502), Cybercrime Prevention Act (RA 10175), and the Consumer Act (RA 7394) may also be amended to reflect the updated definitions and classifications of counterfeit medicines in RA 8203. Specifically, these laws may be amended to specify and delineate the prohibited acts in relation to the three classifications of substandard and falsified medicines in relation to the subject of each law. Considering the different nature and gravity of falsified, unregistered, and substandard medicines, it is important to impose sanctions that recognize the distinction among these three classifications. The updated regulatory framework may focus more on falsified products since existing policies are in place to address the regulation of unregistered and substandard products.

The redefinition of counterfeit medicines, and subsequent addition of definitions for substandard and unregistered medicines, imposes an indispensable role to the Philippine FDA. The proposed amendments in the law will only provide a general definition of what constitutes a counterfeit, substandard, and unregistered medicine. The FDA will be tasked in providing the technical definitions based on guidelines and specifications. The updating of the regulatory framework is also an opportunity to further strengthen the implementation of other existing policies and guidelines related to quality assurance and product integrity. In making a clear distinction between falsified medicines from unauthorized sources and substandard products from licensed manufacturers, regulatory agencies like FDA can effectively advocate to pharmaceutical establishments the implementation of Good x Practices (e.g., Good Manufacturing/Storage/Distribution Practices). As ascertaining product quality along the supply chain and proving the intent to harm among licensed pharmaceutical establishments is difficult, it may prove more effective to engage them in ensuring they comply with standards rather than considering them as criminals in the same way as those who intentionally falsified medical products. An updated regulatory framework must mean appropriate sanctions and interventions. Offenses must be penalized accordingly, such that falsification of medical products is more serious and deserves a heavier penalty.

It is also recommended that the updated regulatory framework addresses the gaps in terms of identifying appropriately offices with clear mandate and functions that will enforce the provisions, from national level down to local governments, including the private sector. With these in place, there will be clearer communication strategies to inform all stakeholders and the general public, and improved multi-sectoral collaboration among government entities and the private sector. Currently, the FDA has launched a Technical Working Group called "Oplan Katharos" focused on the detection, seizure, storage, and responsible disposal of counterfeit, unregistered, and non-compliant health products.[78] Activities conducted under this program may be coordinated with related and involved government agencies for its effective implementation.

Additionally, standardizing the terminologies used in reporting cases of counterfeit medicines is beneficial for improving documentation and public dissemination. Better documentation of cases would allow for more effective monitoring and evaluation, and assess whether there is a need to update policies or improve implementation. Effective dissemination will lead to increased awareness among all stakeholders thereby encouraging unified action to tackle this public health issue.

Limitations

This qualitative policy review only included grey and published literature gathered through online search. The review conducted may not be comprehensive and is only limited on the evidence available from Internet sources. Furthermore, the quality of grey literature may not be thoroughly appraised as compared to published literature. The inclusion of quantitative evidence is recommended to provide empirical support to the results of this policy review. It is recommended to conduct a stakeholder analysis on the results of this policy review to generate a comprehensive and holistic approach in addressing the gaps in the regulatory framework on counterfeit medicines.

CONCLUSION

Issues of counterfeit medicines remain to be prevalent even with existing regulations, such as RA 8203, in place to combat them. Classifications of counterfeit medicines in reports are aligned with the WHO definition. The current situation where the ambiguous framework of the law is implemented by resource-constrained agencies with limited participation of other key stakeholders must be improved through a series of reforms starting with making the regulatory framework more responsive. There is a clear need to update the regulatory framework on counterfeit medicines which would entail revisiting RA 8203 to amend the definition of counterfeit medicines and other related provisions

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