

# Prevalence and Trends of Adulterants Detected in Products Sampled by Sarawak Pharmacy Enforcement Branch

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## ABSTRACT

### Introduction:

Traditional medicines, health foods, supplements and over-the-counter products are generally perceived as safe by the general public. However, continuous surveillance has revealed otherwise, with adulterants commonly found in these products. This is worrying as the consumption of such products may bring serious harm. This study aimed to determine the prevalence and examine the trends of adulterants found in products sampled by the Sarawak Pharmacy Enforcement Branch.

### Methods:

This cross-sectional study utilised data from the Sarawak Pharmacy Enforcement Branch sampling database. All samples collected in Sarawak through intelligence activities, market surveillance, or complaints and submitted to the Department of Chemistry between January 2015 and December 2021 were included. The samples were qualitatively analysed for the presence of suspected adulterants.

### Results:

A total of 633 samples were analysed, with adulterants detected in approximately one-third of most product categories: traditional medicines (n=110; 32.0%), health foods (n=77; 38.7%), over-the-counter products (n=12; 25.0%), and supplements (n=11; 35.5%). A higher proportion of adulteration was observed in the "others" category (n=7; 63.6%). Overall, 282 adulterants were identified, with sex stimulants being the most common (n=84; 29.8%). Notably, more than half of the health food products (n=51; 66.2%) contained sex stimulants. Samples obtained through intelligence-led activities were significantly more likely to be adulterated compared to other sources (n=76; 85.4%,  $P<0.001$ ).

### Conclusion:

Adulteration remains a significant concern, with sex stimulants being the most prevalently detected in products sampled in Sarawak. Strict surveillance is important, and efforts to raise public awareness on this issue must be strengthened. The high detection rate in samples obtained through intelligence activities highlights the importance of targeted surveillance in products available in the market.

### Keywords:

Adulterants, traditional medicine products, health food products, supplement products, over-the-counter products

## INTRODUCTION

In recent years, public interest in commercial health products such as traditional medicines, dietary supplements, and over-the-counter products has increased, with many consumers using these products as primary healthcare measures. Globally, sales of herbal products have risen from over USD 100 billion and are projected to exceed USD 1 trillion within the next 20 years.<sup>1</sup> This growth is largely driven by the perception that natural-based medicines, supplements, and health food products are inherently safe and offer better health outcomes with fewer adverse effects.<sup>2,3</sup> Users of traditional medicines often trust the perceived "moderate nature" of herbal preparations and are generally reluctant to use Western medicines, which are commonly misconceived as being associated with more adverse reactions.<sup>4</sup> However, the potential risks associated with natural-based health products are frequently underestimated, with adulteration by synthetic drugs posing a significant concern.

Adulteration refers to the presence of undeclared chemical substances or active ingredients in a product, including prescription medicines that may cause serious adverse drug reactions.<sup>5</sup> Miller et al. define adulteration as "the addition of an impure or inferior component not ordinarily part of that substance, or the removal of a crucial entity, resulting in a debased product".<sup>6</sup> The adulteration of traditional medicines, dietary supplements, and health food products poses a significant threat to public health. Despite claims of natural composition, some manufacturers deliberately add prescription drugs to enhance product efficacy.<sup>7</sup> The inclusion of such drugs without medical supervision can lead to serious health hazards.<sup>5</sup> The presence of scheduled poisons such as mefenamic acid, diazepam, prednisolone, and indomethacin in adulterated traditional medicines were reported in two case series involving a total of 21 patients.<sup>8,9</sup> Furthermore, adulteration with sex stimulants, particularly sildenafil, has also been widely reported in traditional medicines and dietary supplements, with inappropriate use linked to fatal outcomes overseas.<sup>10,11</sup>

Evidence from regional surveillance further highlights the scale of the problem. A landmark analysis of 1,437 samples collected from seven South East Asian countries found that 35% failed chemical analysis, 46% failed packaging analysis, and 36% were classified as falsified products.<sup>12</sup> The study demonstrated widespread circulation of substandard and counterfeit antimalarial medicines,

particularly along the Thailand–Cambodia border, contributing to drug resistance and posing serious public health risks.<sup>12</sup>

In Malaysia, all pharmaceutical products are required to be registered with the Drug Control Authority (DCA) under the Ministry of Health (MOH) Malaysia, in accordance with Regulation 7(1)(a) of the Control of Drugs and Cosmetics Regulations 1984. Adulteration is legally defined under Section 15 of the Sale of Drugs Act 1952 as the condition in which a product contains or is mixed or diluted with any substance that diminishes its beneficial properties as compared with such article in a pure and normal state, and in an undeteriorated and sound condition or which in any other matter operates or may operate to the prejudice or disadvantage of the purchaser or consumer. It also includes cases where any substance or ingredient has been extracted or omitted, resulting in the beneficial properties of the article as sold being less than those of the article in its pure and normal state, thereby potentially prejudicing the purchaser or consumer. Additionally, a product is considered adulterated if it contains or is mixed or diluted with a substance of lower commercial value than such article in a pure and normal state and in an undeteriorated and sound condition. The presence of any substance which renders the drug injurious to health also constitutes adulteration. Lastly, a product that does not comply with the standard prescribed by any regulations made under this Act is also deemed adulterated.<sup>13</sup>

In recent years, Malaysia has strengthened regulatory enforcement against adulterated health products. Notably, during Operation Pangea XVI in 2023, the Pharmaceutical Enforcement Division, in collaboration with the Malaysian Communications and Multimedia Commission and the Royal Malaysian Customs Department, blocked 1,675 websites and seized illegal pharmaceuticals valued at over RM500,000.<sup>14</sup> In 2024, Ops Legacy 2.0 conducted across Penang, Kedah, and Johor resulted in the seizure of sex stimulants and controlled drugs worth RM4.4 million from illegal manufacturing sites and warehouses.<sup>15</sup> Concurrently, the National Pharmaceutical Regulatory Agency (NPRA) implemented digital traceability tools, including FarmaTag and FarmaChecker, to enable consumer verification of product authenticity.<sup>16</sup> Collectively, these initiatives indicate a shift towards risk-based, inter-agency, and technology-enabled enforcement approaches.

Despite these efforts, adulteration remains prevalent. A Malaysian study analysing 59,440 traditional herbal products seized between 2008 and 2014 found that 6,452 (11%) were adulterated, with most originating from outside Malaysia, particularly Indonesia.<sup>17</sup> These products were commonly marketed for pain and fever relief, with steroids being the most prevalently detected adulterants.<sup>17</sup> A MOH Malaysia press release in 2010 further highlighted a concerning trend of products adulterated with scheduled poisons, especially male sex stimulants, appetite suppressants, anti-

inflammatory agents, and whitening agents.<sup>18</sup> Additionally, NPRA reported an increasing trend of adverse drug reactions related to adulterated products between 2000 and 2012.<sup>19</sup>

Enforcement efforts continue to face challenges, including fragmented regulatory frameworks, weak border and online marketplace oversight, and high costs associated with laboratory analyses. The rapid expansion of e-commerce has further complicated detection and control, while offenders often adapt their strategies to evade predictable enforcement measures. Limited coordination among regulatory and enforcement agencies also constrains effective action. Despite the magnitude of the issue, there are limited studies reporting the types and trends of adulterants based on actual samples obtained through enforcement activities or complaints. Therefore, this study aimed to determine the prevalence and trends of adulterants detected in products submitted for analysis by the Sarawak Pharmacy Enforcement Branch between 2015 and 2021.

## METHODS

### *Study Design*

This was a cross-sectional study utilising data from the sampling database of the Sarawak Pharmacy Enforcement Branch. All samples submitted to the Department of Chemistry between January 2015 and December 2021 for qualitative analysis of suspected adulterants were included. Samples were obtained through intelligence-led activities (field intelligence gathering and strategic information collection), market surveillance (routine inspections and entry-point surveillance), and complaints lodged by the public, medical practitioners, or pharmacists from hospitals and health clinics.

Suspected adulterants were identified based on reported complaints, adverse reactions experienced by users, and observable visual or sensory cues. Enforcement officers requested qualitative laboratory analyses to detect the presence of suspected adulterants in the samples. Analyses were performed using high-performance liquid chromatography (HPLC) with photodiode array detection.

Sampling records with incomplete data and samples submitted solely for active ingredient identification at the request of medical practitioners were excluded. Products that could not be identified due to loose packaging or absence of labelling were also excluded, as these conditions were not classified as adulteration.

### *Data Extraction*

Data were extracted from the sampling database and tabulated using a data collection form validated by three senior pharmacy enforcement officers. The form captured key variables, including product category, product name, type of adulterant detected, and source of sampling. Data collectors were briefed prior to extraction to ensure accuracy and consistency.

**Statistical Analysis**

Descriptive statistics were used to present the product category, prevalence and trend of adulterants detected in the samples, name and type of adulterants detected. Pearson's Chi-square test was also employed to determine the association between the source of the samples and the adulteration rate.

**RESULTS**

A total of 592 sampling records were screened, with no missing data found in the sampling records and two samples were excluded from the study as they were not considered adulterants. Overall, a total of 633 products were sampled from the year 2015 to

2021 (Table 1). Traditional medicines products (n=344; 54.3%) and health food products (n=199; 31.4%) were the most commonly sampled product categories.

Among the traditional medicines product sampled, 110 (32.0%) were found to be adulterated. Meanwhile, adulterants were detected in 77 (38.7%) of the health food products sampled and a quarter (n=12, 25%) of the over-the-counter products sampled. (Table 2)

Figure 1 demonstrates the rate of adulterants detected in the samples based on the product category from 2015 to 2021.

**Table 1. Products sampled by Sarawak Pharmacy Enforcement Branch from 2015 to 2021 (n=633)**

Product Category	Samples submitted for analysis, n (%)							Total
	2015	2016	2017	2018	2019	2020	2021	
Traditional Medicine Products	62 (57.9)	110 (49.6)	71 (64.6)	33 (63.5)	32 (50.8)	15 (39.5)	21 (51.2)	344 (54.3)
Health Food Products	24 (22.4)	84 (37.8)	29 (26.4)	16 (30.8)	20 (31.7)	15 (39.5)	11 (26.8)	199 (31.4)
Over-the-counter Products	18 (16.8)	13 (5.9)	3 (2.7)	3 (5.8)	6 (9.5)	0 (0.0)	5 (12.2)	48 (7.6)
Supplement Products	3 (2.8)	15 (6.8)	7 (6.4)	0 (0.0)	5 (7.9)	0 (0.0)	1 (2.4)	31 (4.9)
Cosmetic Products	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (7.9)	1 (2.4)	4 (0.6)
Others	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (13.2)	2 (4.9)	7 (1.1)
<b>Total</b>	<b>107 (100.0)</b>	<b>222 (100.0)</b>	<b>110 (100.0)</b>	<b>52 (100.0)</b>	<b>63 (100.0)</b>	<b>38 (100.0)</b>	<b>41 (100.0)</b>	<b>633 (100.0)</b>

**Table 2. Samples detected with adulterants based on the product categories from 2015 to 2021 (n=633)**

Product Category	Adulterants detected in the products sampled, n (%)							Overall Adulteration Percentage (%)
	2015 (n=107)	2016 (n=222)	2017 (n=110)	2018 (n=52)	2019 (n=63)	2020 (n=38)	2021 (n=41)	
Traditional Medicine Products	19 (30.6)	52 (47.3)	22 (31.0)	1 (3.0)	8 (25.0)	3 (20.0)	5 (23.8)	32.0
Health Food Products	9 (37.5)	33 (39.3)	11 (37.9)	7 (43.8)	9 (45.0)	4 (26.7)	4 (36.4)	38.7
Over-the-counter Products	2 (11.1)	4 (30.8)	0 (0.0)	0 (0.0)	4 (66.7)	0 (0.0)	2 (40.0)	25.0
Supplement Products	0 (0.0)	6 (40.0)	5 (71.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	35.5
Cosmetic Products	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (33.3)	1 (100.0)	50.0
Others	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (100.0)	0 (0.0)	71.4
<b>Total</b>	<b>30</b>	<b>95</b>	<b>38</b>	<b>8</b>	<b>21</b>	<b>13</b>	<b>12</b>	<b>34.3</b>

Note: Percentage values represent the adulteration percentage for each product category by year, calculated as: (number of adulterated samples in each category/number of samples analysed in each category) × 100%

The overall adulteration percentage was calculated as: (total number of adulterated samples/total number of samples analysed) × 100%

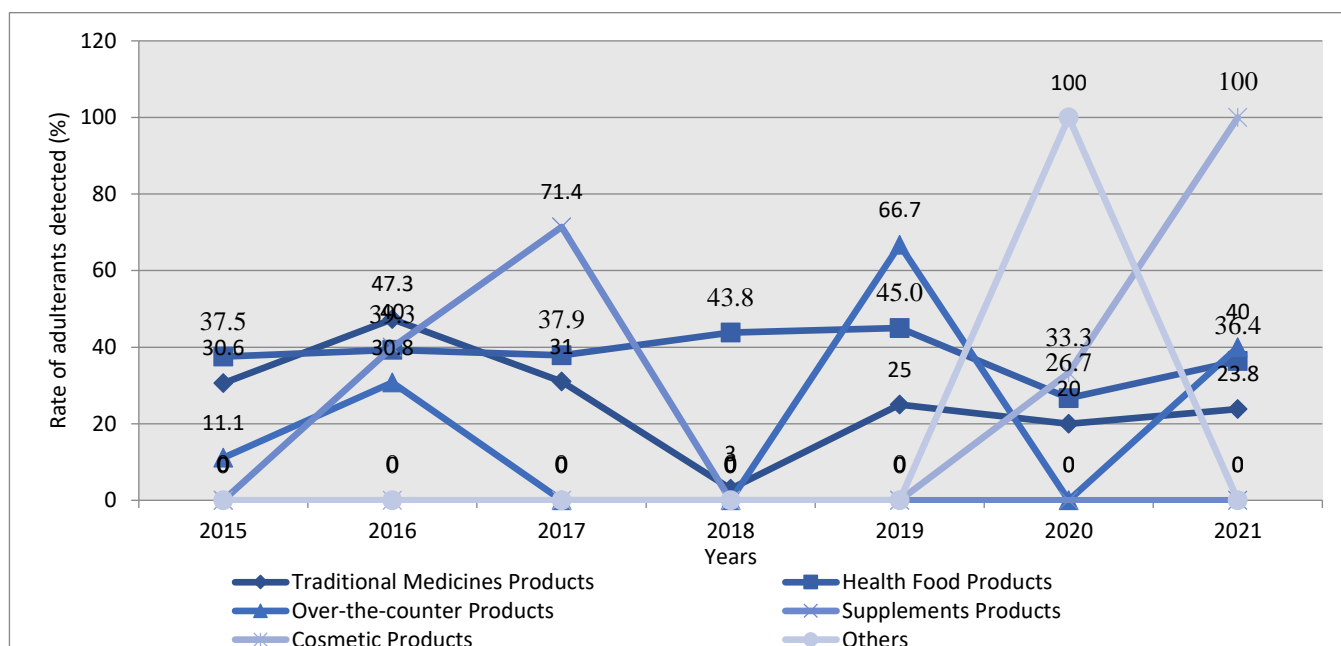


Figure 1: Rate of adulterants detected in the samples by product categories from 2015 to 2021

53 samples were detected with multiple adulterations; with 42 samples detected with 2 adulterants, 10 samples with 3 adulterants, and 1 sample with 4 adulterant. Overall, 282 adulterants with sex stimulants (n=84, 29.8%) were the most frequently detected. This was followed by corticosteroids (n=64; 22.7%), analgesic/ antipyretic agents (n=41; 14.5%), appetite suppressants (n=26; 9.2%), antihistamines (n=20; 7.1%) and lastly the other adulterants that did not fall into any of the above categories, including antibiotics, diuretics,

antidiabetics, dermatological agents and nicotine (n=47; 16.7%). (Table 3)

Lastly, the results indicated a significant association between the source of the sample and the likelihood of adulteration ( $\chi^2=127.57$ ,  $P<0.001$ ). Samples obtained through intelligence activities had the highest adulteration rate, with 85.4% found to be adulterated. In contrast, only 23.6% of samples obtained from complaints and 28.6% from routine market surveillance were adulterated. (Table 4)

Table 3. Classification of adulterants detected in the samples (n=282)

Classification of Adulterants	n (%)	Adulterants	n (%)
Sex stimulant	84 (29.8)	Sildenafil and its analogs (Acetildenafil; Aminotadalafil; Hydroxyhomosildenafil; Thiodimethylsildenafil)	50 (17.7)
		Tadalafil	25 (8.9)
		Udenafil	2 (0.7)
		Vardenafil	7 (2.5)
Corticosteroids	64 (22.7)	Betamethasone	10 (3.5)
		Dexamethasone	52 (18.4)
		Prednisolone	2 (0.7)
Antihistamine	20 (7.1)	Chlorpheniramine	20 (7.1)
Analgesic/Antipyretic	41 (14.5)	Diclofenac	11 (3.9)
		Ibuprofen	4 (1.4)
		Mefenamic Acid	1 (0.4)
		Paracetamol	7 (2.5)
		Phenylbutazone	4 (1.4)
		Piroxicam	14 (5.0)
Appetite suppressant	26 (9.2)	Sibutramine	26 (9.2)
Other Adulterants	47 (16.7)	Other Adulterants	47 (16.7)

Table 4. Source of the products sampled (n=633)

Detection of adulterants	Intelligence activities (n=89)	Complaints (n=296)	Market surveillance (n=248)	$\chi^2$ -statistics	P-value <sup>a</sup>
Adulterants detected	76 (85.4)	70 (23.6)	71 (28.6)	127.57	<0.001
No adulterants detected	13 (14.6)	226 (76.4)	177 (71.4)		

<sup>a</sup>Chi-square test for independence

## DISCUSSION

Nearly one-third of the sampled products contained adulterants, a prevalence markedly higher than that reported in a previous Sarawak study (0.45%), the national estimate for Malaysia (3–5%), and the World Health Organization estimate for low- and middle-income countries (10%).<sup>20–22</sup> This discrepancy is primarily attributable to the targeted nature of the sampling strategy employed in this study. Unlike routine surveillance, a substantial proportion of samples were obtained through intelligence-led activities and complaint-driven investigations, which are specifically designed to detect adulterated products. Consequently, higher detection rates are expected. This targeted approach highlights the complementary role of enforcement-based studies in elucidating adulteration patterns beyond population-level prevalence estimates. In addition, this study screened for adulterants irrespective of registration status, whereas the previous Sarawak study focused on unregistered products, and national estimates encompass a broader category of substandard and falsified medicines.

Traditional medicine and health food products constituted the majority of samples analysed and adulterated products detected. This likely reflects strong consumer demand driven by the perception that these products are natural and safer than conventional medicines.<sup>23</sup> Traditional medicines have a long history of use in disease prevention and treatment, although factors influencing their use remain inconsistently reported.<sup>24–25</sup> The high prevalence of adulteration in health food products, particularly those marketed as sex stimulants, is of concern, as these products are subject to less stringent premarket testing and regulatory approval in Malaysia compared to pharmaceutical medicines. This regulatory gap mirrors trends observed in the European Union and the United States, where food supplements are often exempt from rigorous premarket evaluation.<sup>23</sup> The absence of stringent controls, limited pharmacological data on adulterants (including scheduled poison analogues), and analytical challenges posed by complex food matrices create opportunities for deliberate adulteration to enhance perceived efficacy and profitability.<sup>23,26</sup>

A total of 282 adulterants were detected between 2015 and 2021, with sex stimulants, corticosteroids, analgesics or antipyretics, and appetite suppressants being the most prevalent. These findings are consistent with previous reports on phosphodiesterase type 5 inhibitor adulteration in male sexual performance products.<sup>27–30</sup> Corticosteroids, predominantly dexamethasone, were also frequently identified, in line with data from the Malaysian Centre for Adverse Drug Reaction Monitoring and studies from Hong Kong.<sup>26,31,32</sup> Analgesics, mainly non-steroidal anti-inflammatory drugs such as piroxicam and diclofenac, accounted for a notable proportion of adulterants, consistent with findings from Singapore and South Korea.<sup>33,34</sup>

Samples obtained through intelligence-led activities were significantly more likely to be adulterated than those obtained through complaints or routine market surveillance. This underscores the critical role of pharmacy enforcement officers in proactively identifying high-risk products and emerging market trends. The findings also support continued investment in intelligence-based enforcement strategies to optimise resource utilisation and public health impact.

The observed decline in the number of samples submitted for analysis over time likely reflects a strategic shift towards more selective and targeted enforcement, prioritising cases with higher evidential value and public health significance. This approach aligns with contemporary enforcement models that emphasise focused surveillance and coordinated action against high-risk products and operators.

Nevertheless, fragmented regulatory frameworks and limited inter-agency coordination continue to present challenges, creating enforcement gaps that may be exploited by irresponsible manufacturers and distributors.<sup>35</sup> Strengthening risk-based regulatory frameworks and establishing formalised, multi-agency coordination mechanisms are therefore essential.<sup>36</sup> In parallel, public health awareness campaigns should be intensified to educate consumers on the risks associated with unregistered or mislabelled products.<sup>37</sup> Emerging technologies, including artificial intelligence and machine learning, offer promising tools for monitoring e-commerce platforms, analysing consumer complaints, and integrating laboratory data in real time.<sup>38</sup> Digital traceability systems, such as QR-code verification platforms successfully implemented in China and India, could further enhance detection and prevention efforts if integrated with the NPRA database in Malaysia.<sup>39</sup>

## Limitations

This study provides baseline data on the prevalence and trends of adulterants detected in products submitted for analysis in Sarawak. Although the findings may not be fully generalisable to the whole country, they are likely indicative of the national trends.

As all samples submitted to the Department of Chemistry were purposively selected, variability in product selection was limited. Furthermore, the identification of suspected adulterants relied on the professional judgement of enforcement officers, which may have resulted in the non-detection of unanticipated adulterants.

## CONCLUSION

Traditional medicine and health food products constituted the majority of samples submitted for analysis, compared with over-the-counter products. Sex stimulants and corticosteroids were the most prevalent adulterants detected, while analgesics, appetite suppressants, and antihistamines were identified less frequently. These findings underscore the persistent public health risk posed by adulteration with scheduled poisons, particularly in



products marketed for natural health benefits. Stronger enforcement and risk-based regulatory strategies are therefore essential to address this ongoing issue effectively.

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#### CONFLICT OF INTEREST

All authors declare that they have no conflicts of interest.

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#### ETHICAL APPROVAL

This study was registered with the National Medical Research Register (NMRR-17-1603-35165) and was approved by the Medical Research & Ethics Committee (MREC).

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