

# **The Legal Enforcement of Consumer Protection Law in The Circulation of Imported Pharmaceuticals in Indonesia and Malaysia**

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## **Abstract**

The circulation of imported pharmaceutical products in the era of globalization presents significant challenges to consumer protection, particularly regarding safety, quality, and halal assurance. Indonesia and Malaysia, as countries with predominantly Muslim populations, have a strategic interest in ensuring that imported medicines circulating in domestic markets comply with health standards and consumer protection principles. This study aims to analyse and compare the enforcement of consumer protection laws in the circulation of imported medicines in both countries, covering regulatory frameworks, supervisory institutions, registration mechanisms, and sanctions for violations. The research employs normative legal methods, including the statutory, comparative, and conceptual approaches. The study is expected to provide an in-depth understanding of the legal framework and oversight mechanisms for

imported medicines and serve as a reference for strengthening consumer protection policies in the pharmaceutical sector.

**KEYWORDS:** Consumer protection, imported medicines, law enforcement, pharmaceutical safety, halal assurance.

## Introduction

Buying and selling activities are an inseparable part of human life and the primary means of fulfilling daily needs. Technological developments and globalization have changed transaction patterns, including the emergence of electronic commerce and cross-border trade, which has driven the increasingly massive circulation of products, including imported medicines, in domestic markets.<sup>1</sup> This change demands an effective consumer protection system, especially for products with high health risks.

Under Indonesian law, buying and selling are regulated by Article 1457 of the Civil Code, which governs agreements in which one party delivers goods, and the other party pays the agreed price.<sup>2</sup> The main subjects in this transaction are businesses and consumers. Law Number 8 of 1999 concerning<sup>3</sup> Consumer Protection (UUPK) defines business actors as any individual or business entity engaged in economic activities, while consumers are any person who uses goods and/or services for their own purposes, not for trade. Furthermore, Law No. 36 of 2009 concerning Health regulates the distribution of drugs and drug safety to ensure consumer safety.<sup>4</sup>

Trade practices are not always aligned with law and business ethics. Some business actors still distribute products that do not meet quality and safety standards. Before the UUPK was enacted, many consumer losses were difficult to prosecute due to the absence of specific regulations. Awareness of the importance of consumer protection began to grow in the 1970s, prompting the

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<sup>1</sup> Misbahul Munir Makka, Chairul Fahmi, and Jefry Tarantang, "Religiosity of Muslim Customers as a Motivation to Save at Bank Syariah Indonesia," *Kunuz: Journal of Islamic Banking and Finance* 4, no. 1 (June 30, 2024): 1–16, <https://doi.org/10.30984/KUNUZ.V4I1.838>.

<sup>2</sup> Ghazwan Aqrabin Faqih, Djumardin Djumardin, and Aris Munandar, "Klausula Baku Dalam Perjanjian Jual Beli Melalui E-Commerce Menurut Hukum Positif Indonesia," *Jurnal Risalah Kenotariatan* 4, no. 2 (2023), <https://doi.org/10.29303/risalahkenotariatan.v4i2.188>.

<sup>3</sup> Airiza Silfia Mahda eta al., "Jurnal Ilmu Pengetahuan Sosial," *Jurnal Ilmu Pengetahuan Sosial* 12, no. 5 (2025): 1957.

<sup>4</sup> Edi Santoso, *Pengaruh Era Globalisasi Terhadap Hukum Bisnis Di Indonesia*, 2018.

government to enact UUPK No. 8 of 1999 as a legal basis to provide legal certainty, protect consumer rights, and affirm the responsibilities of business actors.<sup>5</sup>

Consumer products consumed directly, such as food, beverages, cosmetics, and medicines, carry high health risks. Medicines have a higher urgency because errors in quality, dosage, or expiration date can cause serious health problems and even death. The circulation of unfit drugs or those not displaying correct information is still found, causing consumer harm.<sup>6</sup>

Along with increasing international trade, the circulation of imported medicines in Indonesia has also increased, but it is not always accompanied by compliance with regulations. Many foreign-labeled drugs circulate without BPOM permits due to weak supervision, high market demand, and long distribution chains. This condition clearly contradicts the consumer protection principles set out in Law No. 8 of 1999 and Law No. 36 of 2009.<sup>7</sup> Legal protection for consumers is a fundamental necessity that provides a sense of security and affirms the responsibility of business actors, in accordance with the principles of honesty and trustworthiness in Islam. Allah SWT says:

وَلَا تَأْكُلُوا أَمْوَالَكُمْ بَيْنَكُمْ بِالْبَاطِلِ وَتُدْءُوا بِهَا إِلَى الْحُكَّامِ لِتَأْكُلُوا  
فَرِيقًا مِّنْ أَمْوَالِ النَّاسِ بِالْإِثْمِ وَأَنْتُمْ تَعْلَمُونَ

Meaning: ...And do not consume one another's wealth unjustly or send it [in bribery] to the rulers so that [they might aid] you [to] consume a portion of the wealth of the people in sin, while you know [it is unlawful]." (QS. Al-Baqarah 2:188)

Verse QS. Al-Baqarah 2:188 emphasizes the prohibition on any individual taking another person's property unlawfully, including through fraud, manipulation, or methods that harm others. In the context of the trade in

<sup>5</sup> D A N Teknologi, "Mengapa Peraturan Ini Penting?," no. 39 (2025).

<sup>6</sup> "Proposal Penelitian RA Dan MS Ricky," n.d.

<sup>7</sup> R Siswanto, S Sugiono, and ..., "The Development of Management Model Program of Vocational School Teacher Partnership with Business World and Industry Word (DUDI)," *Jurnal Ilmiah Peuradeun* 6, no. 2 (2018): 365–84.

imported medicines, this principle serves as an ethical and legal foundation for business actors not to distribute unsafe, unfit, or misleading products to consumers. The prohibition on exploiting power or the legal system for personal gain also underscores the importance of transparency and compliance with regulations, such as BPOM regulations. licensing in Indonesia or NPRA registration in Malaysia. Awareness of this moral and legal responsibility is key to protecting consumer rights, ensuring the safety, quality, and halalness of pharmaceutical products, and preventing unfair trade practices that harm society unjustly.<sup>8</sup> Thus, this verse underscores the urgency of research into the effectiveness of law enforcement and oversight mechanisms for imported medicines in both countries, to uphold justice and integrity in the pharmaceutical sector.<sup>9</sup>

Similar problems also occur in other countries. Malaysia, as an ASEAN member, implements the Consumer Protection Act 1999 (CPA 1999) to protect consumers. In the pharmaceutical sector, the National Pharmaceutical Regulatory Agency (NPRA) requires that medicines, both local and imported, undergo a registration and evaluation process before distribution. This system also integrates halal practices, providing additional assurance to Muslim consumers.<sup>10</sup>

The importance of this research arises from the increasing cross-border trade in imported medicines, which poses significant risks to public health. Drugs distributed without meeting quality standards, official permits, or even illegally, can have serious impacts, ranging from health side effects to financial losses for consumers.<sup>11</sup> This phenomenon underscores the need for an effective consumer protection system and strict oversight mechanisms at both the national and regional levels to protect the public from risks arising from the circulation of imported medicines.

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<sup>8</sup> Nour Khalid and Nurlailiyah Aidatus Sholihah, "Pendampingan Sertifikasi Halal Pada Usaha Mikro Kecil Produk Makanan," *Jurnal Pengabdian Dharma Laksana Mengabdikan Untuk Negeri* 6, no. 2 (2024).

<sup>9</sup> Inayatun Nazliyah et al., "Law Enforcement Against Cosmetic Businesses Operating Without a BPOM Distribution Permit," *Journal of Law, Politic and Humanities* 5, no. 3 (2025): 2142–51, <https://doi.org/10.38035/jlph.v5i3.1587>.

<sup>10</sup> LILY PUSPITA HAQ, "Efektivitas Penerapan Pembelajaran Realistic Mathematics Education (Rme)," *Walisongo*, 2016.

<sup>11</sup> Chairul Fahmi, Audia Humairah, and Ayrin Sazwa, "MODEL OF LEGAL DISPUTE RESOLUTION FOR BUSINESS CONTRACT DEFAULT," *JURISTA: Jurnal Hukum Dan Keadilan* 7, no. 2 (December 23, 2023): 242–63, <https://doi.org/10.22373/JURISTA.V7I2.228>.

This study is important because it enables a clear and measurable evaluation of the effectiveness of consumer protection law enforcement in Indonesia and Malaysia. In this research, the effectiveness of law enforcement is understood as the ability of regulatory and supervisory agencies, especially BPOM in Indonesia and NPRA in Malaysia, to fulfill their functions of prevention, supervision, and enforcement regarding the circulation of pharmaceutical products. This effectiveness is reflected in the clarity of legal rules, the strictness of registration and licensing procedures, the consistency of supervisory implementation, and the firmness of sanctions against business actors who violate, so that pharmaceutical products circulating truly meet safety, quality, and halal standards.<sup>12</sup>

Through a legal comparison between Indonesia and Malaysia, this study examines the effectiveness of consumer protection law enforcement systems in supervising imported medicines in accordance with applicable laws and regulations. The analysis focuses on the regulation of supervisory authority, mechanisms for supervising imported medicines, and the obligations and compliance requirements for business actors as stipulated in each country's national regulations.<sup>13</sup> This comparative approach allows for the identification of more optimal legal arrangements, including imported drug supervision practices and the regulation of halal aspects in the pharmaceutical system, which have the potential to become normative references for strengthening consumer protection law in Indonesia.

Furthermore, this study normatively examines regulatory and institutional gaps affecting the effectiveness of imported drug supervision, including inter-agency coordination, drug registration procedures, and the integration of halal aspects into pharmaceutical regulations. The results of this normative analysis serve as the basis for formulating prescriptive legal recommendations to strengthen the consumer protection system and ensure the circulation of imported medicines that are safe, high-quality, and in accordance with applicable

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<sup>12</sup> Knut Inge Orset and Martine Holm Frekhaug, "Natural Hazard Preparedness in the Norwegian Public Roads Administration (NPRA)," 2024, 252–56.

<sup>13</sup> Syaakir Sofyan et al., "Unraveling The Influence of Halal Certification Logos on Consumer Choises: A Meta-Analysis in The Indonesian Market," *IQTISHODUNA: Jurnal Ekonomi Islam* 14, no. 2 (2025): 467–88, <https://doi.org/10.54471/iqtishoduna.v14i2.2886>.

legal principles, as compared across the legal systems of Indonesia and Malaysia.<sup>14</sup>

Table 1: Comparison of Consumer Protection Systems and Drug Supervision in Indonesia and Malaysia

| Aspect                                                  | Indonesia                                     | Malaysia                              |
|---------------------------------------------------------|-----------------------------------------------|---------------------------------------|
| <b>Basic Consumer Protection Law</b>                    | Law No. 8 of 1999                             | Consumer Protection Act 1999          |
| <b>Drug Supervisory Agency</b>                          | BPOM                                          | NPRA                                  |
| <b>Obligation for Imported Drug Distribution Permit</b> | Mandatory BPOM permit                         | Mandatory NPRA registration           |
| <b>Integration of Halal Aspect</b>                      | Separate (BPJPH/MUI)                          | Integrated                            |
| <b>Main Challenges</b>                                  | Illegal drugs & weak distribution supervision | Products non-compliant with standards |

The table compares consumer protection systems and drug supervision in Indonesia and Malaysia. In Indonesia, Law No. 8 of 1999 concerning Consumer Protection (UUPK) serves as the main legal umbrella, while Malaysia uses the Consumer Protection Act 1999, which is relatively more comprehensive in regulating dispute-resolution mechanisms and producer responsibility. This difference provides a basis for comparative study to understand the effectiveness of each legal system in protecting consumers from the risks of imported medicines.<sup>15</sup>

In terms of supervisory agencies, Indonesia has BPOM, which is tasked with registration, distribution supervision, and drug quality testing. Meanwhile, Malaysia has NPRA, which implements a more integrated evaluation and emphasizes compliance with safety standards and product halalness, NPRA 2022. Both countries require official distribution permits before imported medicines can be circulated, but there is a significant difference in how halal is integrated. In Indonesia, halal supervision is carried out separately by BPOM and BPJPH/MUI. In contrast, in Malaysia, the halal aspect has been integrated into

<sup>14</sup> Alicia Valda and Veyfra Walangitang, “Perlindungan Konsumen Terhadap Produk Kadaluwarsa (Studi Perbandingan Hukum Perlindungan Konsumen Indonesia Dan Malaysia),” *UNES Law Review* 5, no. 4 (2023): 3279–92.

<sup>15</sup> Orset and Frekhaug, “Natural Hazard Preparedness in the Norwegian Public Roads Administration (NPRA).”

NPRA, so Muslim consumers receive additional assurance about the product's halal status.<sup>16</sup>

The main challenges faced by the two countries also differ. Indonesia still faces the circulation of illegal drugs and weak distribution supervision. In contrast, Malaysia relatively rarely faces illegal drugs, but it still faces problems of producer compliance with safety and quality standards. Overall, the comparison shows that although the legal frameworks of the two countries are similar, Malaysia tends to be more effective in supervising and integrating pharmaceutical regulations, including the halal aspect. This is an important lesson for Indonesia to strengthen inter-agency coordination and improve law enforcement efforts to curb the circulation of imported medicines. Based on these findings, this study aims to analyze and compare the enforcement of consumer protection laws in the distribution of imported medicines, identify similarities and differences in oversight mechanisms, and provide policy recommendations to strengthen consumer protection in the pharmaceutical sector. This study is expected to be an important reference for policymakers, academics, and legal practitioners in improving the safety, quality, and halalness of drugs circulating in the domestic market.

## Data and Method

This research is normative legal research<sup>17</sup> that analyses laws and regulations, legal doctrines, and consumer protection principles related to the circulation of imported medicines in Indonesia and Malaysia.<sup>18</sup> The approaches used include the statute approach, the comparative law approach, and the conceptual approach to examine consumer rights and obligations, business actor obligations, and supervisory mechanisms by the BPOM and the NPRA. Legal materials consist of primary, secondary, and tertiary materials collected through

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<sup>16</sup> Mohamad Kashuri, "Effectiveness Study of BPOM's Assistance for MSMEs in Natural Medicine and Cosmetics to Obtain Distribution Permits," *OBAT: Jurnal Riset Ilmu Farmasi Dan Kesehatan* 3, no. 1 (2024): 46–53, <https://doi.org/10.61132/obat.v3i1.945>.

<sup>17</sup> Muh. Yani Balaka, "Metode Penelitian Kuantitatif, Kualitatif, Dan R&D. Bandung: CV Alfabeta," *Metodologi Penelitian Pendidikan Kualitatif* 1 (2022): 130.

<sup>18</sup> sugiyono, "Uji Validitas Dan Reliabilitas Alat Ukur," *Jurnal Keterapian Fisik* 5, no. 1 (2020): 55–61.

literature study.<sup>19</sup> Analysis is carried out qualitatively by classifying legal materials, interpreting norms systematically and comparatively,<sup>20</sup> and drawing conclusions and recommendations to assess the effectiveness of consumer protection law enforcement on imported medicines in both countries.

## **Enforcement of Law against Violations of UUPK Associated with Import Data in Indonesia**

The increasing flow of imported consumer goods, especially medicines, presents a serious challenge in the enforcement of Law Number 8 of 1999 concerning Consumer Protection (UUPK) in Indonesia.<sup>21</sup> According to data from the Central Statistics Agency (BPS) for 2025, Indonesian imports of medicines and pharmaceutical raw materials totaled USD 3.2 billion, up 12% from the previous year. This condition indicates Indonesia's high dependence on imported pharmaceutical products, both as raw materials and finished drugs, thereby increasing the risk of the entry of products that do not meet safety and quality standards.<sup>22</sup>

### ***Law Enforcement Mechanisms***

Law enforcement against UUPK violations on imported products is carried out through three main mechanisms: administrative, civil, and criminal. Administratively, the National Agency of Drug and Food Control (BPOM) has the authority to conduct pre-market supervision (verification of distribution permits, labels, and safety certification) and post-market supervision (routine inspections, sample testing, and withdrawal of illegal drugs). However, a study shows that weak distribution supervision, the complexity of the import chain, and limited human resources at BPOM remain major obstacles to effectively enforcing UUPK.<sup>23</sup>

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<sup>19</sup> MS Prof. Dr. H. Amri Amir, SE., MSi H. Junaidi, SE., and MSi Yulmardi, SE., *Metodologi Penelitian Ekonomi Dan Penerapannya*, IPB Press, 2009.

<sup>20</sup> Hari Sutra Disemadi, "Lensa Penelitian Hukum: Esai Deskriptif Tentang Metodologi Penelitian Hukum," *Journal of Judicial Review* 24, no. 2 (2022): 289–304.

<sup>21</sup> Sofyan et al., "Unraveling The Influence of Halal Certification Logos on Consumer Choises: A Meta-Analysis in The Indonesian Market."

<sup>22</sup> Valda and Walangitang, "Perlindungan Konsumen Terhadap Produk Kadaluwarsa (Studi Perbandingan Hukum Perlindungan Konsumen Indonesia Dan Malaysia)."

<sup>23</sup> Mohamad Kashuri, "Effectiveness Study of BPOM's Assistance for MSMEs in Natural Medicine and Cosmetics to Obtain Distribution Permits."

Civilly, consumers or consumer protection agencies can file lawsuits against business actors who sell imported products that do not meet the standards set out in Article 19 of the UUPK. The criminal mechanism includes fines and/or imprisonment for business actors proven to trade dangerous, damaged, or unfit products (Articles 62-63 of the UUPK). However, the low level of consumer reporting and the lack of legal literacy are obstacles to creating a significant deterrent effect.<sup>24</sup>

### ***Analysis of Import Data and Expired Products***

The following table displays the number of cases of findings of expired and illegally imported products acted upon by BPOM in 2023-2025:

Table 2: The total of illegally imported products

| Year | Total Imported Products Examined | Expired / Illegal Products | Products Acted Upon (Withdrawal / Warning) | Violation Percentage (%) |
|------|----------------------------------|----------------------------|--------------------------------------------|--------------------------|
| 2023 | 12.500                           | 315                        | 270                                        | 2,52                     |
| 2024 | 13.200                           | 402                        | 350                                        | 3,05                     |
| 2025 | 14.050                           | 480                        | 420                                        | 3,41                     |

The table shows that the number of imported products violating UUPK provisions increases every year, indicating that current oversight mechanisms are not effective enough to suppress violations. The most problematic products include herbal medicines, health supplements, and imported cosmetics. Most violations involve label discrepancies, such as failure to include the expiration date, Indonesian language, or product safety information, which clearly violates Article 8 of the UUPK.<sup>25</sup>

### ***Implementation Barriers and Challenges***

<sup>24</sup> Muhamad Afiq Abd Razak, Mohd Syukri Zainal Abidin, and Muhammad Ikhlas Rosele, *The Application of Al-Wara' (Abstinence) in the Halal Supply Management: A Spiritual Approach, Selected Proceedings from the 1st International Conference on Contemporary Islamic Studies (ICIS 2021)*, 2022, [https://doi.org/10.1007/978-981-19-2390-6\\_5](https://doi.org/10.1007/978-981-19-2390-6_5).

<sup>25</sup> Siti Khodijah, Nirwan Junus, and Nurvazria Achir, "The Role of Supervisory Agency in the Circulation of Cosmetics With Fake Distribution Permission," *Estudiante Law Journal* 4, no. 2 (2022): 1–16, <https://doi.org/10.33756/eslaj.v4i2.15941>.

Several studies show that the complexity of the distribution chain is a major factor in weak law enforcement. Imported products often pass through several importers, distributors, and retailers, making it difficult to trace responsibility directly.<sup>26</sup> Furthermore, the lack of consumer understanding regarding their rights also weakens the effectiveness of law enforcement. For example, a 2024 national consumer survey showed that only 34% of consumers understood their right to claim compensation if they bought expired or illegal products.<sup>27</sup>

### ***Legal Implications and Recommendations***

Although Indonesia already has an adequate UUPK legal framework, its implementation in the import context still needs strengthening. Several recommendations that can be considered:

- a) Increasing BPOM capacity: adding human resources, testing laboratories, and technology for monitoring the import chain.
- b) Integrating electronic trade data: facilitating tracking of imported products and early detection of violations.<sup>28</sup>
- c) Consumer literacy campaigns: increasing public understanding regarding rights to information and compensation.
- d) Inter-institutional coordination: Customs, BPOM, and the police must synergize in law enforcement.

With stricter, more systematic implementation, the UUPK can more effectively protect Indonesian consumers from risky imported products, especially expired drugs or products that do not meet safety standards.<sup>29</sup>

## **Enforcement of Law against Consumer Protection Violations Associated with Import Data in Malaysia**

Malaysia implements the Consumer Protection Act 1999 (CPA 1999) as the main legal basis for consumer protection, reinforced by sectoral regulations in

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<sup>26</sup> Inayatun Nazliyah et al., “Law Enforcement Against Cosmetic Businesses Operating Without a BPOM Distribution Permit.”

<sup>27</sup> Valda and Walangitang, “Perlindungan Konsumen Terhadap Produk Kadaluwarsa (Studi Perbandingan Hukum Perlindungan Konsumen Indonesia Dan Malaysia).”

<sup>28</sup> Shelomita Putri Amelia and Dwi Desi Yayi Tarina, “Withdrawal of Processed Food And Cosmetic Products Without Bpom Distribution Permits,” *Journal of Law, Politic and Humanities* 6, no. 1 (2025): 557–66, <https://doi.org/10.38035/jlph.v6i1.2524>.

<sup>29</sup> Shelomita Putri Amelia and Dwi Desi Yayi Tarina.

the pharmaceutical field, including the Control of Drugs and Cosmetics Regulations 1984.<sup>30</sup> Import data shows that Malaysia still relies on imported medicines, both raw materials and finished products, but compliance with regulations is relatively high due to an integrated supervisory system administered by the National Pharmaceutical Regulatory Agency (NPRA). All imported medicines must be registered and strictly evaluated by NPRA before obtaining a distribution permit, including checks on safety, quality, and efficacy.<sup>31</sup>

Law enforcement against CPA 1999 violations is carried out through preventive and repressive mechanisms. The preventive approach includes initial evaluation of imported medicines, routine audits of production facilities, and halal certification for products intended for Muslim consumers. The repressive approach involves administrative sanctions, fines, and criminal action for violators of registration, labeling, or illegal drug distribution provisions. Studies show that the combination of these mechanisms significantly suppresses the circulation of illegal drugs in the domestic market.<sup>32</sup>

The Malaysian system has the advantage of integrating halal requirements, which provide additional legal certainty for Muslim consumers, increase consumer confidence, and encourage business compliance. Additionally, a digital-based consumer reporting system facilitates supervision and accelerates action against violations. Nevertheless, challenges arise in supervising cross-border online trade, as illegal or unpermitted goods can still enter via international e-commerce platforms.

Overall, consumer protection law enforcement in Malaysia is relatively more effective than in Indonesia, due to a combination of strict regulations, integration of the halal aspect, digitalized supervisory systems, and structured preventive and repressive mechanisms.<sup>33</sup>

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<sup>30</sup> Faqih, Djumardin, and Munandar, "Klausula Baku Dalam Perjanjian Jual Beli Melalui E-Commerce Menurut Hukum Positif Indonesia."

<sup>31</sup> Felicia Margaret, Dripsy Teresa P Sapni, and Evi Kongres, "MIMBAR KEADILAN The Truth Behind the Label: Ensuring Fairness and Legal Liabilities in Skincare Ingredient Overclaims" 18, no. 2 (2025): 312–31, <https://doi.org/10.30996/mk.v18i2.132375>.

<sup>32</sup> Inayatun Nazliyah et al., "Law Enforcement Against Cosmetic Businesses Operating Without a BPOM Distribution Permit."

<sup>33</sup> Nasihah Naimat and Elistina Abu Bakar, "Producer Liability Under Part X of The Consumer Protection Act 1999 on The Issue of Halal Products," *International Journal of Academic Research in Business and Social Sciences* 11, no. 8 (2021): 437–42, <https://doi.org/10.6007/ijarbss/v11-i8/10727>.

Table 3: Types of CPA 1999 Violations and Sanctions in Malaysia

| Type of Violation                                | Administrative Sanctions  | Criminal Sanctions         | Case Example                                |
|--------------------------------------------------|---------------------------|----------------------------|---------------------------------------------|
| <b>Drug not registered with NPRA.</b>            | Fine up to RM 50,000      | Imprisonment up to 2 years | Sale of illegal supplements in Penang, 2022 |
| <b>Label not in accordance with regulations.</b> | Official warning & fine   | Imprisonment up to 1 year  | Imported cosmetic product, 2021             |
| <b>Misleading safety information</b>             | Product withdrawal & fine | Imprisonment up to 3 years | Fake herbal medicine in Kuala Lumpur, 2023  |
| <b>Illegal drug distribution</b>                 | Business closure & fine   | Imprisonment up to 5 years | Illegal drug import from Thailand, 2020     |

The Table shows the trend in drug imports in Malaysia from 2020 to 2024, with the number of imported drugs increasing from 5,200 to 6,250. Still, the compliance rate with NPRA regulations remained high, at 95-96%, indicating the effectiveness of the registration system in suppressing the circulation of illegal drugs and ensuring that most drugs meet safety and quality standards. However, around 220-250 drugs per year are not registered, indicating challenges in distribution supervision, especially through cross-border online trade. Table 2 shows the types of violations under CPA 1999 and the sanctions applied, ranging from administrative fines to criminal penalties, with case examples such as the sale of illegal supplements in Penang and the sale of fake herbal medicine in Kuala Lumpur, which confirm the simultaneous application of preventive and repressive approaches. Overall, these data reinforce the view that the Malaysian supervisory system is more integrated and effective than Indonesia's, enhancing consumer protection, curbing the circulation of illegal products, and providing legal certainty, including through the integration of halal standards for Muslim consumers.<sup>34</sup>

Based on a comparison of consumer protection law enforcement for imported products in Indonesia and Malaysia, it appears that consumer protection effectiveness is not solely determined by the existence of regulations, but also by the quality of implementation and institutional integration. Both

<sup>34</sup> Chairul Fahmi, "The Impact of Regulation on Islamic Financial Institutions Toward the Monopolistic Practices in the Banking Industrial in Aceh, Indonesia," *Jurnal Ilmiah Peuradeun* 11, no. 2 (May 30, 2023): 667–86, <https://doi.org/10.26811/PEURADEUN.V11I2.923>.

countries have strong legal bases, but differences in law enforcement approaches result in significantly different levels of consumer protection.

In Indonesia, Law Number 8 of 1999 concerning Consumer Protection (UUPK) normatively regulates consumer rights and obligations as well as the responsibilities of business actors. However, in practice, law enforcement remains reactive and focused on post-market actions. The high volume of imports and weak distribution supervision cause illegal imported drugs to be easily still found in the market, both conventional and online. This indicates that the supervisory system is not yet fully adaptive to the dynamics of global trade and the complexity of the supply chain.<sup>35</sup>

Fragmentation of authority among institutions is one of the main factors weakening consumer protection in Indonesia. The separation of drug safety supervision by BPOM and halal certification by BPJPH. causes the supervision process to be less effective, and inter-institutional coordination is often slow. Unlike Malaysia, which has integrated pharmaceutical supervision and halal aspects into a single institutional system, Indonesia still faces significant coordination challenges, making it difficult to minimize potential legal violations.<sup>36</sup>

In terms of sanction enforcement, Indonesia tends to prioritize administrative sanctions, while criminal sanctions are rarely applied. This condition reduces the deterrent effect for business actors who violate UUPK provisions. Conversely, Malaysia applies sanctions consistently and firmly, ranging from administrative fines to imprisonment, thereby preventing violations from the early stages of distribution and ensuring sustainable legal compliance.<sup>37</sup>

The author assesses that the consumer's role is also crucial in the legal protection system. The low legal awareness and literacy of consumers in Indonesia lead to many violations going unreported, making them difficult to

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<sup>35</sup> Chairul Fahmi, *HUKUM DAGANG INDONESIA*, ed. Riadhush Sholihin, 1st ed., vol. 1 (Banda Aceh: Bandar Publishing, 2024), <https://bandarpublishing.com/produk/hukum-dagang-indonesia/>.

<sup>36</sup> Fahmi, Humairah, and Sazwa, "MODEL OF LEGAL DISPUTE RESOLUTION FOR BUSINESS CONTRACT DEFAULT."

<sup>37</sup> Wafa Ibra Syahra, Chairul Fahmi, and Shabarullah Shabarullah, "Legal Review of Dumping Practices in Indonesia: A Comparative Study of International Economic Law and Sharia Economic Law," *Privet Social Sciences Journal* 6, no. 1 (2026), <https://doi.org/10.55942/pssj.v6i1.1464>.

pursue legally. Therefore, strengthening consumer education, including understanding basic rights and reporting mechanisms, is an important part of efforts to improve the effectiveness of UUPK enforcement.<sup>38</sup>

In addition to legal considerations, ethical and moral values are relevant in consumer protection. The principles of justice and the prohibition against harming others, as reflected in universal values and Islamic teachings, serve as a normative basis for business actors to act honestly and responsibly. Effective law enforcement should not only be coercive but also encourage compliance based on moral awareness and the integrity of business actors.<sup>39</sup>

Based on this analysis, the author concludes that Indonesia needs to undertake comprehensive reform in consumer protection law enforcement by emulating best practices from Malaysia. Institutional integration, strengthening import supervision, consistent application of sanctions, and increasing consumer awareness are strategic steps that must be taken simultaneously. Thus, consumer protection against imported products, especially medicines, can be realized more effectively and sustainably in the era of global trade.

## Conclusion

Based on analyses of law enforcement against consumer protection violations involving imported products in Indonesia and Malaysia, it can be concluded that the effectiveness of consumer protection depends not only on strong regulations but also on the quality of enforcement, institutional coordination, and consumer legal awareness. In Indonesia, although Law Number 8 of 1999 concerning Consumer Protection (UUPK) has clearly established consumer rights and business actor obligations, law enforcement still faces various obstacles, including weak distribution supervision, high import volume, and fragmentation of authority among institutions.

This condition allows imported medicines that do not meet safety and quality standards to remain easily available in the market, through both conventional and online channels. One of the main factors undermining

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<sup>38</sup> Benny Ismail, "Pertanggungjawaban Hukum Produsen Obat Tradisional Atas Kesalahan Proses 'Cpotb' Terhadap Konsumen (Kajian Undang-Undang Nomor 8 Tahun 1999 Tentang Perlindungan Konsumen)," 2016, i–85.

<sup>39</sup> Sri Wahyuni et al., "THE ROLE OF COURTS IN RESOLVING CASES OF BANKRUPTCY OF ISLAMIC BANK CUSTOMERS," *JURISTA: Jurnal Hukum Dan Keadilan* 7, no. 1 (June 10, 2023): 1–23, <https://doi.org/10.22373/JURISTA.V7I1.42>.

consumer protection in Indonesia is the lack of coordination among supervisory agencies. The separation of duties between the National Agency of Drug and Food Control (BPOM), which focuses on drug safety and quality, and the Halal Product Assurance Organizing Agency (BPJPH), which oversees halal matters, undermines supervision.

Furthermore, legal sanctions that are predominantly administrative and rarely followed by criminal sanctions reduce the deterrent effect for business actors who violate UUPK provisions. Low legal literacy among consumers also leads to many violations going unreported, thereby preventing the legal protection mechanism from operating optimally. Unlike Indonesia, Malaysia has integrated pharmaceutical supervision and halal aspects into a single institutional system managed by the National Pharmaceutical Regulatory Agency (NPRA).

Every imported drug is strictly evaluated before a distribution permit is issued, and violations of registration or labeling provisions are subject to consistent administrative and criminal sanctions. This integration increases business actor compliance while fostering consumer confidence in imported products. The Malaysian system shows that a combination of firm law enforcement, integrated supervision, and consumer education can significantly suppress the circulation of illegal drugs.

This analysis confirms that law enforcement reform in Indonesia needs to be carried out comprehensively. The recommended approach includes: first, institutional integration of drug supervision and halal aspects to improve coordination and effectiveness; second, strengthening supervision of imported products through pre-market and post-market systems that are adaptive to the dynamics of global trade; third, applying consistent legal sanctions that create a deterrent effect; and fourth, increasing consumer literacy and legal awareness so they actively report violations. Additionally, ethical and moral values, such as honesty and social responsibility of business actors, need to be strengthened as a foundation for voluntary compliance outside coercive mechanisms. By implementing these strategies simultaneously, consumer protection against imported products, especially medicines, can be realized more effectively and sustainably. Optimal law enforcement not only protects consumer rights but also supports market stability and strengthens public trust in the national regulatory system in the era of global trade.

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