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COUNTERFEIT MEDICINE: SHOULD PARALLEL IMPORT OF MEDICINE BE BANNED IN MALAYSIA?

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ABSTRACT

Parallel import is the activity of importing and reselling products without the patent holder's permission. Parallel importation is legal on the principle of flexibility found in the TRIPS Agreement under the provisions of Article 6 (exhaustion of intellectual property) and Article 8 (scope of public health interest) to guarantee access to medicinal products. However, whether parallel imports are regulated or otherwise by countries is provided for under Paragraph 5(d) of the Doha Declaration on TRIPS and Public Health 2001 which states that member countries are given the freedom to determine their exhaustion regime. This explains why there are countries that allow parallel trade in medicines whereas some do not. The main reason for some countries (including Malaysia) not allowing parallel imports is the belief that parallel importation is associated with the penetration of counterfeit medicines into the market. Therefore, this paper aims to determine the relationship between parallel imports and incidents of counterfeit medicinal products in the country. The discussions include measures that can be implemented to ensure the quality, safety, and efficacy of parallel import drug products are not compromised. In conclusion, findings from this study suggest that the parallel import of medicine is not related to the increase in cases of counterfeit medicine, hence should not be banned in Malaysia.

Keywords: Parallel import; Counterfeit; DOHA Declaration; Drug registration; Parallel import of pharmaceutical products

INTRODUCTION

Counterfeit medicine is defined as one that is deliberately and fraudulently mislabelled with respect to identity or source. Counterfeiting can happen to both branded and generic products, which may include products with correct ingredients or with the wrong ingredients, without ingredients, with insufficient active ingredients, or with fake packaging (WHO, 1999). Counterfeit medicine not only has a negative impact on the economy but is also harmful to consumers' health and, at worst, can lead to death.

Medicinal products in Malaysia are categorized as pharmaceutical products that are governed by the Ministry of Health Malaysia, specifically the Pharmaceutical Services Division (PSD). The PSD oversees the implementation of laws related to medicinal products to ensure medicinal products in the Malaysian market are of good quality, effective, and safe to use. As such, issues regarding counterfeit and parallel imports of medicine are under PSD's assessment.

Parallel imports in pharmaceuticals consist of the trading of genuine pharmaceutical products that have been placed on the market in another country by,

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or with the consent of, Intellectual Property Right (IPR) owner into parallel authorized distribution channels in another country (Nguyen Nhu Quynh, 2011). Previous studies have shown that parallel imports are beneficial in offering cheaper prices for medicines. This is because parallel imports create competition in the market and are able to prevent monopolies (Rodziah Ahmad, 2002). The effect of parallel imports on reducing patent-sourced medicines and lowering healthcare costs has been evident in the European Union (Aguiar & Ernest, 2020). The cessation of parallel import prohibition in Israel had led to the opening of the market, which improved the bargaining power of players in the pharmaceutical market and reduced drug prices there (Marcowitz-Bitton, Nahmias, & Rozencwaig-Feldman, 2022). This is not limited to developed countries. In large developing countries like China, there has been a shift towards permitting parallel imports as income levels rose and dependence on supply from developed countries declined, while emphasis was being placed on consumer surplus so that firms moved from price discrimination to uniform pricing (Zeng & Zhang, 2020). However, parallel imports of medicine in Malaysia are currently prevented by its national legislation on drug registration regulation. Pharmaceutical companies that hold patent protections are the group that vehemently opposes the authorization of parallel imports, claiming that parallel imports would lead to the dumping of counterfeit medicinal products in the market. If parallel imports come from unauthorized resellers, it is argued that those could be fake or low quality drugs, especially if they come from developing countries that are not strict against or even benefit from the circulation of harmful counterfeit drugs (Pederson, 2023). This paper carries out a study to determine the association between parallel imports and the incidence of counterfeit products in the country.

For the purpose of writing this paper, several countries are listed, and the practice of parallel imports of medicine in those countries has been identified. The number of counterfeit medicine cases in countries where parallel imports are legalized was observed in comparison with the number of counterfeit medicine cases in countries where parallel imports are prohibited or restricted to relate to the association between counterfeit and parallel imports. A literature review was done to support the research findings. This research conducts content analysis. Content analysis can be defined as "a research technique for making replicable and valid inferences from texts (or other meaningful matter) to the contexts of their use" (Bengtsson 2016; Krippendorff 2004). The use of content analysis is not limited to primary data and can be extended to secondary data (Harris, 2001).

FINDINGS

PARALLEL IMPORT OF MEDICINE IN RELATION TO COUNTERFEIT INCIDENCE.

FIGURE1. Parallel importation of medicine products practices by countries

Country	Parallel import	
	Allow	Prohibited
Germany	/	
UK	/	
France	/	
Switzerland	/	
United States		/
Japan		/
Singapore		/
Malaysia		/
Indonesia		/

Source: Author / figure1

Figure 1 lists several countries and their parallel import trade practices for

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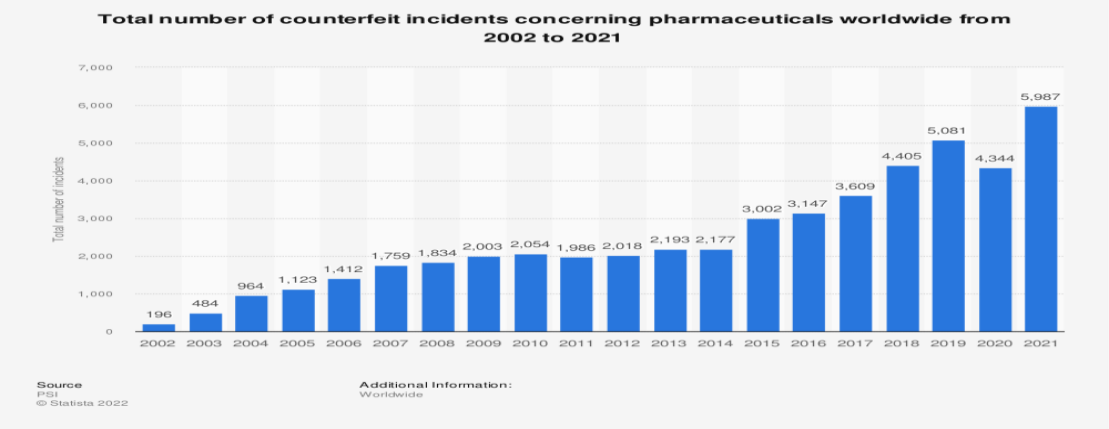
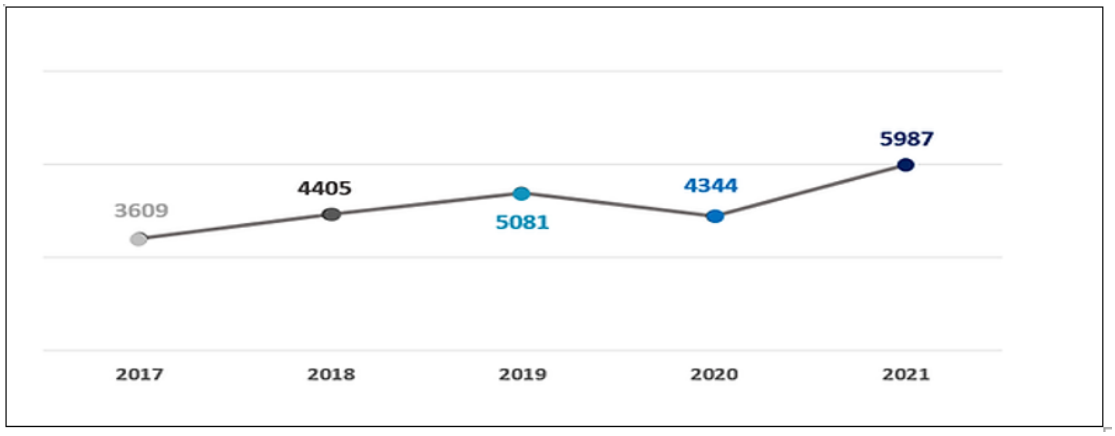
pharmaceutical products. The table shows that countries such as Germany, France, the United Kingdom, and Switzerland allow or permit parallel import trade of medicine products in their countries. On the other hand, countries such as the United States, Japan, Singapore, and Malaysia prohibit the parallel import of medicine. In relation to the study, the question on whether the authorization of parallel import trade for pharmaceutical products will lead to the dumping of counterfeit pharmaceutical products in the market, can be answered by looking at the relations between counterfeit cases (as shown in the statistic below) in those countries and their practices on parallel import activities. If parallel importation of medicine will be the cause of the dumping of counterfeit products in the market, it should not occur or increase significantly in countries where parallel import is prohibited.

FIGURE2. Total number of counterfeit incidents concerning pharmaceuticals worldwide 2002-2021



Source: Mikulic, M. (2022) / figure2

FIGURE3. Pharmaceutical crime (counterfeiting, illegal diversion, and theft incidents) for last five (5) years worldwide



Source: Pharmaceutical Science Institute Portal, 2023/ figure3

Figure 2 shows the latest statistics worldwide on the total number of counterfeit incidents concerning pharmaceutical products from 2002 to 2021. The statistics have shown a significant increase in the number of cases over time (Mikulic, 2022). This data indicates that counterfeiting incidents continue to occur regardless of whether the country allows or prohibits parallel importation of medicine products. This data is consistent with the Intellectual Property Crime Threat Assessment 2022,

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produced jointly by the European Union Intellectual Property Office (EUIPO) and the European Union Agency for Law Enforcement Cooperation (Europol), where this report states that trade in counterfeit pharmaceutical products in the EU seized by EU customs authorities has been increasing over the years (European Union Intellectual Property Office and European Union Agency for Law Enforcement Cooperation, 2022). Meanwhile, the assessment by the US Food and Drug Administration (FDA) Office of Criminal Investigation Database from 2016 through 2021 reports that the US Drug Enforcement Administration confiscated 9.5 million counterfeit pills from April 2020 to April 2021, where this number is more than the previous two years combined, despite few actions conducted in the US to combat counterfeit (White, 2022).

The Pharmaceutical Security Institute (PSI), a non-profit organization based in Vienna that is dedicated to sharing information on the counterfeiting of pharmaceutical products, has also reported that the counterfeiting of pharmaceutical products in 2021 has increased by 38% from 2020 in the worldwide incident total (Figure 3). The PSI Counterfeiting Incident System (CIS) records incidents of pharmaceutical crimes, which consist of activities of faking and counterfeiting of medical products, their packaging, and associated documentation, as well as theft and illegal diversion from various sources, including open media reports, PSI member company submissions, and public-private sector partnerships. The Institute found that regions with high numbers of incidents are not necessarily weak in their enforcement and inspection programs. In fact, this pharmaceutical crime was identified by their law enforcement and inspection activities. Likewise, those regions with a low number of counterfeit incidents do not mean they have weak enforcement and inspection programs. Incidents are seemingly under or undetected due to a lack of funding or inadequate legal and regulatory structures (Pharmaceutical Science Institute, 2023).

EXISTING INTERNATIONAL AND NATIONAL CONTROL FOR COUNTERFEIT AND PARALLEL IMPORT DRUG PRODUCTS IN MALAYSIA

Internationally, several instruments have been developed to combat counterfeit pharmaceutical products, such as the Council of Europe Convention on the Counterfeiting of Medical Products (MEDICRIME Convention), Supply Chain Security, and Online Pharmacy Authentication (Organisation for Economic Co-operation and Development/EUIPO, 2020). The MEDICRIME Convention was developed by the Council of Europe and provides countries with a model legal framework that allows international coordination in the investigation and prosecution of pharmaceutical criminals. The supply chain of pharmaceutical products has been closely monitored from the manufacturer to the final user by establishing the Falsified Medicines Directive (FMD) in Europe, the Drug Supply Chain Security Act in the US, and the pharmaceutical track and trace system (ITS) in Turkey. A similar initiative has been taken in the online chain, where online pharmacy authentication was introduced and a logo was used for legally operating online pharmacies and retailers (OECD/EUIPO, 2020).

EU for example, has regulated counterfeit and parallel imports of their medicinal products accordingly. EU measures to control counterfeit medicinal products by strengthening the product authenticity identification system (PTTS), reporting obligations of falsified or counterfeit medicine to the EU authority system (EMA's website to be used by pharmaceutical companies when notifying EMA of any suspected falsification of their centrally authorized medicines), tougher rules on the import of active substances, strengthening the supply chain and requirements for wholesale distributors, and implementing a common, EU-wide logo to identify legal online pharmacies. On the other hand, specific laws and regulations

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were provided to control the parallel import of products in EU countries.

At the national level, in Malaysia, the control of pharmaceutical products is under the administration of the Pharmaceutical Services Division (PSD) of the Ministry of Health. Specifically, the Pharmaceutical Enforcement Division (PED) is the law enforcement unit under the PSD that enforces the laws related to pharmaceutical products, mainly the Pharmacists Registration Act 1951, the Poisons Act 1952, the Dangerous Drugs Act 1952, the Sale of Drugs Act 1952, and the Medicines (Advertisement and Sale) Act 1956. However, the making of counterfeit conduct an offense has not been spelled out in those laws. Section 15 of the Sale of Drug Act 1952 treats counterfeited medicine as an adulterated product, and a person convicted under this provision shall be liable to a fine not exceeding twenty-five thousand ringgit or to imprisonment for a term not exceeding three years or to both, and for a second or subsequent offense, he shall be liable on conviction to a fine not exceeding fifty thousand ringgit or to imprisonment for a term not exceeding five years or to both. Meanwhile, a body corporate that commits this offense for which no penalty is expressly provided shall be liable on conviction to a fine not exceeding fifty thousand ringgit, and for a second or subsequent offense, it shall be liable on conviction to a fine not exceeding one hundred thousand ringgit (Sale of Drug Act 1952, Section 12).

Currently, there is no law enforcement provision for parallel importation of medicine products under laws governed by the PSD. That makes no parallel import medicine products available in the Malaysian market. The conviction of importing parallel medicine products shall be treated as importing unregistered products, which amounts to punishment similar to an adulterated offense. Hence, there is no specific provision for both. It is obviously the lack of severe punishment provided by the laws that may be the main cause of the occurrence of counterfeit medicine in the country. Malaysia does not authorize the practice of parallel import in medicine products. However, according to a February 2013 analysis by the Emerging Markets Network (EMHN), about 5% of medicines in Malaysia are counterfeited and the cases spike up by years (Zulkifli et al., 2016). This proves that counterfeit incidents will continue to happen no matter how strictly the country restricts parallel importation or not. This, by the way, proves that counterfeit medicine is not associated with parallel import.

Many literatures have supported that main reasons that lead to counterfeit incidents are (a) high demand for less expensive drugs, (b) low availability of medical products, (c) social tolerance for counterfeit products, (d) globalization and consumer access to the internet (e-commerce), (e) complex and fragile supply chains, (f) limited technical capacity to monitor products throughout the supply chain, (g) complex import-export mechanisms, (h) the use of free and special economic and trade zones, (i) lack of law enforcement, (g) weak national regulatory policies on the manufacturing and marketing of medications, and (k) lack of adequate financial and political commitments (Bottoni & Caroli 2019; Sweileh 2021; OECD/EUIPO, 2020; Bakker-t Hart, Ohana, & Venhuis 2021; Bolla, Patel, & Priefer 2020; Odiase 2021; (Tesfaye et al 2020; Karunamoorthi 2014; Pisani et al 2019). The COVID-19 pandemic drives more challenges to combat counterfeiting as the pandemic created a public health emergency, economic distress, and misinformation-driven panic that made the access and supply of high-quality essential medicines and health products problematic and pushed consumers and vendors more towards counterfeit pharmaceuticals (Ziavrou, Noguera, & Boumba, 2022), and increasing access to the internet creates broader networking that worsens the counterfeit scenario.

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DISCUSSION

The findings above have shown that counterfeiting and parallel imports are two different issues that need to be addressed separately. Therefore, it is recommended that measures should be taken to avoid possibility occurrence of counterfeit medicines in relation to parallel import practices by regulating laws to control and monitor parallel importation of medicine practices through the following mechanisms: mandatory registration of parallel import drug products, developing mechanism to differentiate between parallel import and counterfeit products, establishing specific provision for counterfeit and parallel importation of medicine to enable clear penalty for conviction or infringement, and enhancing the collaboration with other agencies domestically and internationally to combat counterfeit medicine concerning parallel import practice.

DRUG REGISTRATION AS A REGULATORY MEASURE TO CONTROL THE QUALITY, SAFETY, AND EFFICACY OF PRODUCT

To ensure that parallel imported drug products also have the quality, safety, and effectiveness of their use, it is important to make registration for parallel imported drug products mandatory. Pharmaceutical quality assurance, according to the WHO definition, is the sum of all activities and responsibilities that are organized with the objective that the medicinal product that reaches the user is safe, quality, and achieves the effect desired by the user. Hence, in a drug production and supply chain, quality control will be able to ensure the quality of the product from raw materials, manufacturing, marketing, and up to the post-marketing activities of the product, where all these aspects are outlined in the drug registration requirements.

Like the European Medicines Agency (EMA) in the European Union and the USFDA in the United States, the National Pharmaceutical Regulatory Agency (NPRA) is a Malaysian drug regulatory authority that plays a role in carrying out quality control for drug products. NPRA ensures the quality, safety, and efficacy of drug products through document assessments and laboratory testing before the products are approved for marketing, based on the laws that control drug products in Malaysia, namely the Poison Act 1952, the Dangerous Drug Act 1952, the Sale of Drug Act 1952, and the Medicines (Advertisement and Sale) Act 1956. Thus, NPRA is responsible for accepting, approving, rejecting, or canceling applications for registration and issuing licenses regulated by the laws. The NPRA also plays a role in conducting post-registration surveillance activities such as conducting product sample analysis, monitoring Good Manufacturing Practice (GMP) compliance for pharmaceutical manufacturers through licensing and inspection, and monitoring adverse drug reaction effects. Administrative punishment, such as product recalls and cancellations, will be imposed for any incompliance with the required standards stipulated in the laws. To conclude, only products that have gone through the MOH registration process can be guaranteed quality, safety, and efficacy. So, prejudices against local and imported drugs, including parallel imported drugs, should not be an issue, as all products that enter the Malaysian market will go through the equal registration assessment process.

REGISTRATION NUMBER AND SERIALISATION AS A TOOL TO DISTINGUISH REGISTERED AND COUNTERFEIT PRODUCTS

The main concern, if Malaysia allows imported parallel products to be on the market, is related to the issue of how to distinguish imported parallel products from other drug products to avoid user confusion. Therefore, as suggested in the paragraph above, the country must be able to develop a mechanism to differentiate between parallel imports and counterfeit products. In this context, Malaysia's drug registration system

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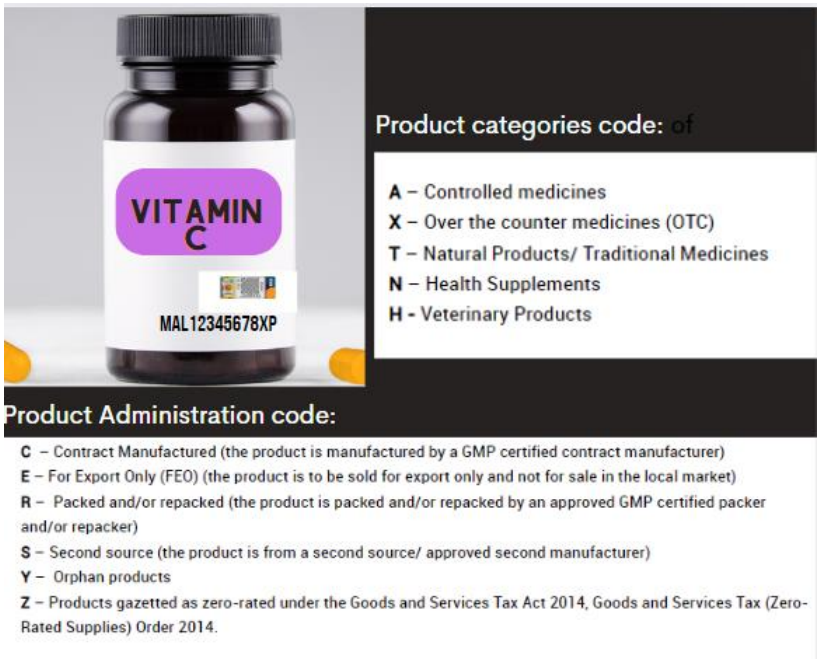
already provides identity or features for its registered products.

Products that have been registered with the Malaysian Ministry of Health will have two main features, namely a unique registration number (MAL) and a Hologram PharmaTag^{TM} sticker label. These two features are outlined in the Drug Registration Guidance Document to be displayed on the drug product box as an identification measure to distinguish the authenticity and registration status of the product.

1. MAL Registration Number

FIGURE 4. Malaysian Pharmaceutical Product Registration Number



Source: Author's Illustration, 2024/ figure4

The MAL number is a drug registration number in Malaysia that starts with MAL followed by an 8-digit number and ends with a product category code. For example, the A category code is for controlled drugs, e.g., antibiotics and diabetes drugs; X for drugs without prescription, e.g., fever medicine; T for traditional medicine, e.g., herbal pills; N for health supplements, e.g., vitamins; and H for animal products. The product status can easily be checked through the NPRA website and is also available at the Google Play Store to be downloaded at no cost to the public.

Noticing that the MAL numbers or digits have the potential to be falsely printed and used by irresponsible individuals or companies, the authority has strengthened product safety controls by requiring the use of hologram stickers on every pharmaceutical product registered with the MOH.

2. FarmaTag^{TM} hologram

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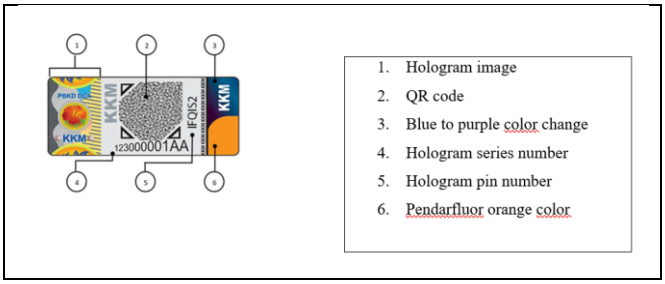
FIGURE5. FarmaTag^{TM} Hologram Security Label



Source: The Pharmacy Services Programme, Ministry of Health Official Portal, 2021/ figure4

Hologram FarmaTagTM is a high-tech, locally made label that is equipped with high-security features as a protection for all registered pharmaceutical products in Malaysia. It was started in 2005 under the provisions of Rule 29(1) of the Drug and Cosmetic Control Regulations of 1984. This sticker is used to help users identify between genuine and counterfeit drug products. The FarmaTagTM hologram is equipped with various advanced safety features that can be used not only by the public but also widely by enforcement officers. A decoder or hologram scanner is used to determine the authenticity of the hologram stickers. The device can be found in all licensed pharmacy premises and pharmaceutical regulatory authority offices in each state in the country. To make it more friendly for the public, the authenticity of the FarmaTagTM hologram can also be checked online using the FarmaChecker app, which can be downloaded for free from a mobile phone (Pharmaceutical Services Programme Official Portal, 2021).

Hologram is one of the latest advancement to optimise drug serialisation. Serialisation is a process to ensure drug traceability by assigning a unique registration number for each unit of drug (Pascu, Hancu, & Rusu, 2020) . This thechnology allows the checking of medicines even for those under prescription. With the most advanced technology, its use allows the unique number to be identified even if there is 40 percent damage to the code, and coordination between countries can translate into globally linked drug authentication and even emergency alert systems (Pascu et al, 2020).

In meeting current needs and situations, Malaysia is moving towards a competitive serialisation system by introducing the use of the international standard Pharmaceutical Track and Trace System (PTTS). This PTTS has been used in other developing countries, such as the United States, Europe, Turkey, Argentina, and Brazil (Kootstra & Kleinhout-Vliek, 2021). The specific regulations provided by the government mandate the implementation of PTTS. For example, PTTS requirements in the EU are governed by the Falsified Medicines Directive (FMD) 2011 and its Delegated Regulation (EU) 2016/161, while in the United States, PTTS requirements are governed by the Drug Supply Chain Security Act (DSCSA) 2013. PTTS is applicable in the majority of the EU Member States since 2019, while in the US is in November 2023 (European Medicines Agency Website 2019; ECA Academy 2022).

Malaysia has announced its plan to develop a PTTS that will cover the entire supply chain in July 2022. The PTTS pilot project was launched from January 2023 to June 2023, involving a number of imported and locally made products. The results from this pilot project will be used to improve the system and the development of Malaysian Pharmaceutical Track and Trace Implementation Guidelines (Director of

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Pharmaceutical Services Programme Directive, 2022).

PTTS has two main components: (i) a unique identification number for each major drug package to allow users to authenticate, and (ii) a 2D barcode that integrates all product information along the supply chain. PTTS is able to track all pharmaceutical product chains from the factory to the final user (Shaikh et al., 2019). As a result of this enhanced safety and security system, PTTS is able to prevent the penetration of counterfeit products into pharmaceutical supply chains and, hence, ensure that patients or consumers receive genuine, safe, and effective medicinal products.

STRENGTHENED INTERNATIONAL COLLABORATION TO COMBAT COUNTERFEIT MEDICINE

In today's technological era, crime is more transnational. In this context, a platform of cooperation between the authorities in the country must be well established to combat international pharmaceutical crime.

At present, INTERPOL is a global organization that provides a cooperation platform. Interpol enables police to work directly with their counterparts, even between countries that do not have diplomatic relations. The Illicit Goods and Global Health Programme (IGGH) is a program that enhances global cooperation and enforcement capabilities in the area of pharmaceutical crime. Counterfeit product crime is listed under the field target of INTERPOL operations.

Interpol works with law enforcement agencies, international organizations, businesses, and INTERPOL member nations to develop a modern approach to combating pharmaceutical crime. The activities carried out by INTERPOL include gathering information and sharing intelligence (such as threat assessments and analytical reports); coordinating international law enforcement operations; supporting multi-agency task forces to enhance coordination between law enforcement, customs, regulatory agencies, and the private sector; and raising public awareness of pharmaceutical crime and helping consumers to make informed choices. Interpol has coordinated reactive strategies such as Operation Pangea, and Operation Afya and Heera to combat counterfeit pharmaceutical products.

Operation Pangea has been fighting the international trafficking of fake medications that are marketed and sold online since 2008. Pangea also seeks to increase public knowledge of the dangers of purchasing medications via unofficial websites. Operation Pangea XIV in 2021 seized about USD 23,414,483 of illegal pharmaceuticals and took down 113,020 websites. Meanwhile, Operation Afya and Heera target criminal groups involved in the manufacturing, distribution, and trafficking of illegal medicines across the southern and western African regions. Operation Afya 2021 resulted in the seizure of counterfeit products with an estimated value of USD 3,532,489, triggering over 300 criminal and administrative cases with 179 offenders apprehended.

CONCLUSION

Counterfeit is a global problem. The increasing number of counterfeit cases happened due to modernization, no matter whether the country practices parallel importation of medicine or restricts the practices. Currently, the parallel importation of medicine authorization has not been implemented in Malaysia. However, Malaysia is not exempt from being a country with an increasing number of counterfeit cases by the years. This proves that counterfeiting is not associated with parallel imports.

Parallel importation of medicine is permitted under the provisions of Article 6

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and Article 8 of the flexibility TRIPS. Countries that prohibit parallel imports of medicine associate parallel imports of medicines with an increase in the incidence of counterfeit products in the market. However, this paper explains that parallel imports and counterfeiting of medicine products are two different issues in terms of the legal treatment provided.

Therefore, this paper suggests parallel importation of medicine should not be banned in Malaysia, as counterfeit events are not associated with parallel import practices. This paper also suggests that the parallel importation of drug products should be regulated through the drug registration process without compromising quality, safety, or efficacy. This paper, in other words, suggests Malaysia not hesitate to allow parallel import of drug products as an approach to utilizing the exhaustion of intellectual property protection for the benefit of public health provided by Article 6 and Article 8 of TRIPS Agreements to enhance access to medicine for public health in terms of availability and affordability of medicine.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

AUTHORS' CONTRIBUTION

The conceptualization and design of this study were undertaken by Hairanie Sa'ban (HS) and Haniff Ahamat (HA). The search was conducted by HS. The data were extracted by HS, subsequently verified by HA, and subjected to a thorough review. The initial draft of the manuscript was prepared by HS, and HA conducted an extensive assessment of the manuscript with regards to its significant intellectual content. The draft of the manuscript underwent critical revisions by HA. The final manuscript for publication was read and approved by all authors.

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