

## Illegal Medical Product and Deferred Prosecution Agreement in Malaysia

Zeti Zuryani Mohd Zakuan<sup>1\*</sup>, Siti Asishah Hassan<sup>2</sup>, Anida Mahmood<sup>3</sup>

<sup>1</sup>Department of Law, Universiti Teknologi MARA, Cawangan Perlis, Kampus Arau, 02600, Arau, Perlis, Malaysia.

Email: zeti@uitm.edu.my

<sup>2</sup>Department of Law, Universiti Teknologi MARA, Cawangan Perlis, Kampus Arau, 02600, Arau, Perlis, Malaysia.

Email: asishah879@uitm.edu.my

<sup>3</sup>Faculty of Law, Universiti Teknologi MARA, 40450 Shah Alam, Selangor, Malaysia.

Email: anida131@uitm.edu.my

### ABSTRACT

The recent covid-19 pandemic has seen a demand for medical products. The problem identified is that unscrupulous traders are seen to be taking advantage of the situation by selling illegal products. The Ministry of Health seized 23 278 illegal pharmaceutical products worth more than RM 600 000 during Operation Pangea XIII, which was conducted in 2020. One of the factors identified for such illegal activity is the prosecution and penalty imposed on the traders is ineffective in acting as a deterrent as the profits gained from selling the products are much higher than the fine imposed. Adopting a doctrinal approach, this article analyses the provisions for combatting illegal medical products in Malaysia. The article aims to assess whether the provisions successfully overcame the problems of illegal medical products on the market. It is submitted the present law is outdated. It was found that Malaysia should consider implementing DPA. This is because based on the experience of other jurisdictions, DPA is able to deter traders from selling illegal medical products by imposing hefty penalties. Thus, DPA will create healthy environments for the consumption of medical products for Malaysia consumers.

### CORRESPONDING AUTHOR (\*):

Zeti Zuryani Mohd Zakuan  
(zeti@uitm.edu.my)

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**Contribution/Originality:** This study contributes to the existing literature on illegal medical product and deferred prosecution agreement. Deferred prosecution agreement is a new method of resolution which is quite alien to Malaysian Legal System. Thus, reference to other jurisdictions is needed to understand the method well.

## 1. Introduction

In Malaysia, every consumer is granted with eight basic rights. The rights are the right to a basic need, right to safety, right to consumer education, right to redress, right to be informed, and right to healthcare. These rights are taken care of by particular institutions.

Nevertheless, in Malaysia, these rights are neither explicitly codified in the Consumer Protection Act 1999 nor in any other statutes (Ismail et al., 2018).

Recognizing the importance of consumer protection, the Malaysian government established eight Ministries with consumer orientation. The Ministries are the Ministry of Domestic Trade, Cooperatives and Consumerism; Ministry of Health; Ministry of Agriculture and Agro-Based; Ministry of Housing and Local Government; Ministry of Transportation; Ministry of Science, Technology, and Environment; Ministry of Human Resources; and Ministry of Finance (Zakuan et al., 2013). With regard to these consumer rights, consumers have a right to healthcare, which means, if the products purchased and consumed by the consumers are detrimental to their health, the consumers are said to be deprived of this right.

The recent covid-19 pandemic has seen an increase in the sale of illegal products in Malaysia. Operation Pangea XIII, an international operation coordinated by Interpol, was conducted in Malaysia to combat the sale of illegal drugs and medical products. Within a week of the operation, illegal products worth US \$14 million worldwide has been seized (Ong et al., 2020).

In Malaysia, the Ministry of Health (MOH) seized more than one million units of unregistered medicines worth RM 2.55 million and 23 278 units of illegal pharmaceutical products worth more than RM 600 000 during raids conducted on 50 unlicensed premises (Khairulrijal, 2020). The statistics show the seriousness of illegal products in Malaysia.

The problem with illegal medical products on the market is that the products can pose a serious health risk to the consumer if they contain toxic ingredients. Consumption of these products will affect the health of the consumers. Thus, it is advised that these kinds of products should be removed from the market. The question, then, arises as to whether consumers are protected if the illegal medical product consumed is defective. Under Malaysian law, if the product consumed is defective, the consumer will be protected under product liability law. In order to rely on product liability, the consumer must prove that the consumer suffers injury due to the defect.

## 2. Literature Review

The literature review revolves around three main keywords of this research, i.e., medical product, illegal medical product, and deferred prosecution agreement.

The literature on medical product is mostly on the definition. Fairgrieve et al. (2020) opined that medical product include test kits, personal protective equipment, chemical-based products, ventilators, medicines, blood products, and vaccines. Ong et al. (2020) stated that medical product includes hand sanitizers, face mask, and gloves. Nortajuddin (2020) divided the medical product into three categories which are medicines (antivirals, herbal medicines, and malaria treatment), medical equipment (facemask, disinfectants, fake coronavirus test kits, gloves, and ventilators), and sanitizers (hand sanitizers, soaps, and cleaning wipes). Medical device is also considered as medical product according to Mokhtar et al. (2016). Medical product has been clearly identified by scholars, however medical product is not defined by any law in Malaysia. According to Zulkifli et al. (2016), medical product is covered under the definition of drug under the Control of Drugs and Cosmetics Regulation 1984. However, in the UK, medical product is clearly defined Article 1 of Directive 2001/83/EC. Medicines & Healthcare products Regulatory Agency (MHRA)

(2020) stated that a product is considered as a medical product if it is presented for preventing disease and the function of the product is for restoring health.

Illegal medical product has been widely used in scholarly literature in the wake of pandemic covid-19. The increase in the production of availability of medical product on the market contributes towards the sale of illegal medical product in Malaysia (Abdul-Rahman, 2012). Khairulrijal (2020) and Ong et al. (2020) opined that these illegal products can be toxic and pose a serious health risk to consumers, as they may include the wrong ingredients, ineffective ingredients, or no active ingredients, thus should be combatted. Ong et al. (2020) agreed with the government's action to participate in Operation Pange XIII to seize illegal medical product in Malaysia. Khairulrijal (2020) agreed with this idea and reported that raids on unlicensed premises could combat the sale of illegal medical product.

Seizure and raids of illegal medical product conducted will lead to the prosecution of the traders. Abdul-Rahman (2012) has found that prosecution is ineffective as the fine imposed on traders is relatively low. Loo et al. (2019) agreed with the finding. He further stated that the profits gained from selling illegal medical product are much higher than the fine imposed. Previously, Bidin (2009) and Zulkifli et al. (2016) opined that the sale of illegal medical product generates profits to the criminals and at the same time threatens the pharmaceutical industries as it leads to substantial financial losses to the industries.

The ineffectiveness of traders' prosecution for illegal medical product is due to the lack of legal provisions relating to illegal medical product in Malaysia. Zulkifli et al. (2016) and Ismail (2013) submitted that there is no specific definition of an illegal medical product under Malaysian law. They further opined that under The Sale of Drug Act 1952, there are specific provision under regulation 7(1)(a) and 7(1A) (a-g) of Control of Drugs and Cosmetics Regulation which requires all products to be registered with the National Pharmaceutical Regulatory Agency before entering the market. Hence, by applying the provision, products that fail to comply with the requirement may be considered an unregistered drug in which illegal medical product could be among them. From the discussion, it is clear that there is no provision which provides for illegal medical product in Malaysia.

For the purpose of consumer protection, illegal medical product falls under Part X of Consumer Protection Act 1999 (CPA 1999) which adopts European Product Liability Directives (85/374/EEC). In order to succeed in suing traders for illegal medical product, the consumer must prove a defect based on consumer expectations of safety. Zakuan et al. (2019) and Fairgrieve et al. (2020) argued that it is unfair to put the burden on the consumer because the consumer is vulnerable and they are not aware of the production process, especially when it involves a technically complex product. Mokhtar et al. (2016) opined that CPA 1999 fails to respond to patients' need to obtain compensation against the manufacturer. Fairgrieve et al. (2020) later stated that the EU Product Liability Directive is also unable to solve the issue of medical product. The authors suggested that alternatives to the law need to be introduced. Based on the arguments, since CPA 1999 is based on EU Directive, it is submitted that CPA 1999 is not able to protect the consumer in issues relating to illegal medical product.

The literature on deferred prosecution agreement (DPA) emerged in 1992 when DPA was first introduced in the US. Delaney (2009) stated that a deferred prosecution agreement (DPA) is an agreement reached between a prosecutor and an organization that could be

prosecuted under a judge's supervision. The Agreement allows a prosecution to be suspended for a defined period provided the organization meets certain specific conditions. According to [Brez et al. \(2018\)](#), DPA enables corporate to reach an agreement with the public prosecutor for deferred prosecution in exchange for the imposition of certain requirements. In the US, prosecutors have increasingly used DPA against corporate in enforcing white-collar crime such as fraud, bribery, and other economic crime ([Delaney, 2009](#)). [Hickey \(2021\)](#) suggested that the adoption of DPA in the US should be extended to cases that involve bribery committed by foreign corporate actors. It was proposed that money gained from foreign bribery should go to the victim of the corruption, which is the government. [Bu \(2021\)](#) identified the adoption of DPA in the UK is to combat bribery. Same goes with Singapore, whereby DPA was introduced to deal with corruption cases ([Brez et al., 2018](#)).

The purpose of introducing DPA is to enable a corporate body to make full reparation for criminal behavior without the collateral damage of a conviction ([Bakerdonelson, 2013](#)). DPAs are a way of holding companies to account without punishing innocent employees and are an essential tool in changing the corporate culture for the better ([Hawley et al., 2020](#)). [Delaney \(2009\)](#) opined that DPA had enabled the company to avoid the costs and consequences associated with a lengthy criminal investigation and trial. It also provided the government with a move-efficient means to hold corporate wrongdoers accountable and influence corporate compliance culture changes. According to [Bu \(2021\)](#), DPA allows prosecutors and the courts to address bribery effectively and build confidence in the justice system. According to [Sinaga \(2021\)](#), the primary purpose of introducing DPA is to recover losses faced by the government due to corruption. [Sinaga \(2021\)](#) further argued that by implementing DPA, the running of the corporation would not be affected, and it will not lose its reputation compared to the process of prosecution. The newly introduced DPA regime gives the Singapore authorities greater flexibility in sanctioning corporates ([Brez et al., 2018](#)).

In the US, [Bakerdonelson \(2013\)](#) identified that, apart from white-collar crime cases, DPA has also been used in medical product and services cases. The cases involved Wright Medical Group in 2010 and WakeMed Health and Hospitals in 2012. Both cases involved fraud committed toward the patients. In the UK, [Bu, 2021](#) stated that DPA had been introduced in the United Kingdom's Crime and Courts Act 2013, which received royal assent in April 2013 and became effective on 24 February 2014. DPA framework in Singapore was introduced under its Criminal Procedure Code after successfully enacted the Criminal Justice Reform Act for that purpose ([Brez et al., 2018](#)). Singapore is the first country in the ASEAN region to introduce DPA in its legal system. According to [Chua et al. \(2019\)](#) the Singapore model of DPA draws heavily from the UK, and both require proof to a court that DPA are in the "interest of justice" and that their terms are "fair, reasonable and proportionate." Indonesia has not introduced DPA in its legal system. However, [Sinaga \(2021\)](#) proposed that DPA should be introduced to combat corruption cases in Indonesia. The author suggested that if DPA is to be introduced in Indonesia, the law relating to DPA needs to be introduced in its criminal procedure code which is called KUHAP. This is to ensure that the prosecutor will have a specific law to refer to pertaining to DPA. In Malaysia, the government has not considered adopting DPA for any cases, even for corruption cases. According to [Idzam & Mohammed. \(2020\)](#), the reason given for not adopting DPA in corruption cases is due to the absence of DPA in the Malaysian Anti-Corruption Commission arsenal of tools. She further argued that it would be prudent for Malaysia to consider adopting DPA in corporate criminal liability cases, given that global trend.

From the discussion above, prosecution of traders for illegal medical product in Malaysia is ineffective as the fine imposed on the traders is relatively low. Other countries have considered implementing a DPA regime in economic crime cases. Malaysia may need to learn lessons from other jurisdictions and consider implementing the DPA framework to combat illegal medical product as it affects the country's tax revenue. By adopting this mechanism, payment of penalty to the government can cover the tax revenue losses suffered due to the sale of illegal medical product. Besides, the penalty imposed on the trader will act as a deterrent to the crime committed by the traders. Adopting DPA will prevent the company from going out of business and directly affect employment loss. Thus, it is proposed that Malaysia reforms its relevant legislation to introduce the DPA framework in its legal system. Owing to this, the research aims to develop a DPA model to act as a deterrent for illegal medical product in Malaysia.

The literature reviewed above clearly indicates that there is yet a DPA model for illegal medical product. All this while, there is no agreement between prosecutor and traders. The existing prosecution theory is piecemeal, fragmented and non-uniform in nature. This is the first time, offences related to illegal medical product addressing private agreement which is embedded in DPA. The DPA is derived from the concept of freedom of contract. The concept of freedom of contract equates consensus, willingness, efficiency, autonomous and more satisfactory result. The DPA theory which perceived freedom of contract as a strategy to increase efficiency in addressing problem of illegal medical product is to be used as a means to gain optimal solution for deterrence. It is positioned that this theory could provide a better alternative to the existing prosecution model.

### **3. Methodology**

This paper aims to review the situation of illegal medical products in Malaysia and how deferred prosecution (DPA) is important to cater to this issue. This is doctrinal qualitative research. It deals with the law on a particular issue where the legal doctrine is analysed as to its development and applications (Abdullah, 2020). This type of research is selected because the basic aims of this research is to discover, explain, examine, analyse and present in a systematic form, facts, principles, provisions, concepts, theories, or the working of certain laws or legal institution (Yaqin, 2007). The paper adopts the doctrinal analysis by examining the existing primary and secondary materials, mainly statutory provisions and case law.

### **4. Illegal Medical Products in Malaysia**

In Malaysia, there is no specific definition of an illegal medical product under Malaysian law. Still, there are specific provisions under regulations 7(1)(a), 7(1A)(a-g) Control of Drugs and Cosmetics Regulation 1984, which provides for registration requirements for all medical products with the National Pharmaceutical Regulatory Agency before entering the market. It also needs to follow a process that requires stringent evaluation and final approval by the Drug Control Authorities (DCA). After the medicinal products go through all the requirements, it is known as registered drugs or registered products (Zulkifli et al., 2016). Thus, illegal medical product which does not fulfill the requirements under the regulations above falls under the definition of unregistered drugs.

In the UK, medical product is defined under EU Directive. EU Directive, which is being implemented by the UK and EU countries, defines medicinal products under Article 1 of Directive 2001/83/EC. Under the first limb, the medicinal product is "Any substance or

combination of substances presented as having properties for preventing disease in a human being." Under the second limb, the medicinal product is defined as "Any substance or combination of substances which may be used in, or administered to, human beings, either with a view to restoring, correcting or modifying psychological functions by exerting pharmacological, immunological or metabolic action or to making a medical diagnosis" (the second limb: function) (MHRA, 2020). According to the definition, a medical product that contains medicinal substances and the substances act in a manner that is more than ancillary, the product is likely to be regulated as a medicinal product. It is submitted that medical product is clearly defined in the UK.

Consumers who suffer injury due to the consumption of illegal medical product is protected under product liability provided under Part X of the Consumer Protection Act 1999 (CPA 1999). Product liability in Malaysia is based on the same law under the English Consumer Protection Act 1987. The English Act adopts European Product Liability Directives (85/374/EEC). Under Malaysian product liability, Part X introduces the concept of strict liability. Liability is imposed on the producer if the consumer suffers damage due to a defect in the product. It is not required for a consumer to prove a breach of duty or contract in order to sue the producer (Zakuan et al., 2015).

Strict liability regime has been introduced under Part X in matters relating to injury, loss of personal property, or death due to a defective product. Thus, if an illegal medical product injures the consumer, the consumer can rely on Part X of CPA 1999. To date, the effectiveness of the law is not certain since the law has not been challenged.

Under Part X, the burden of proof is vested upon the consumers to prove the defect based on the consumer expectation test. However, the burden of proof imposed on the consumer is unfair since the majority of the consumer are vulnerable consumers. These vulnerable consumers have no information and knowledge on mass production and also when it involves technically complex products. Thus CPA 1999 seem unable to protect the consumer when involving illegal medical product (Zakuan et al., 2019).

To date, there is no decided case in Malaysia challenging Consumer Protection Act 1999, thus, decided cases in the UK need to be followed. Thus, according to Mokhtar et al. (2016), CPA 1999 fails to respond to patients' need to obtain compensation from the manufacturer. Owing to this, it is submitted that the government needs to intervene and consider having a specific law for medical products and services in Malaysia.

It is clear that the existing legal framework is not able to protect the consumers who suffer injury due to the consumption of the illegal medical product. Hence, something needs to be done to prevent illegal medical products from entering the market. The best way would be to prevent traders from selling illegal products.

The problem of illegal medical products in Malaysia is expanding day by day. This is due to the huge consumption of medical products by consumers. The issue is under the jurisdiction of the Ministry of Health (MoH). In order to protect consumers in Malaysia, the Ministry has enacted a few laws, namely the Food Act 1983, the Disease Prevention and Control Act 1988, The Medicines (Advertisement and Sale) Act 1956 (Revised 1983), the Sale of Drugs Act 1952, Poisons Act 1952 (Revised 1989) and Pharmacists Registration Act 1951.

The MoH is well aware of this problem and has taken various steps to overcome the problem. For this purpose, MoH has established special divisions for the handling of pharmaceutical products and services. The divisions are National Pharmaceutical Regulatory Agency, Pharmacy Enforcement Division, and Pharmacy Practice and Development Division.

National Pharmaceutical Regulatory Agency (NPRA) is an agency introduced to impose quality control on the pharmaceutical product in Malaysia. It was set up in October 1978. All pharmaceutical and cosmetics products in Malaysia must be registered and approved by National Pharmaceutical Regulatory Agency (NPRA) (Loo et al., 2019). The Agency plays a vital role in combating illegal medical products in Malaysia. NPRA is equipped with the infrastructure and facilities which meet the requirement for testing and quality control activities. One of the functions of NPRA is to implement the registration and licensing of medical products. Registration and licensing of the product are important to ensure safety, efficacy, and quality (Zakuan et al., 2014). This is one of the actions taken by NPRA to overcome the problem of illegal medical products. The registered product might increase the confidence of the consumer in making purchases.

Pharmacy Enforcement Division plays a vital role in ensuring that pharmaceuticals, traditional and cosmetics available in the market are genuine in terms of registration and notification. The Division ensures that the supply and marketing, advertisement, and usage of the products comply with the existing legislation. The Pharmacy Enforcement Division's objective is to ensure all pharmaceutical and medical products in the market are of quality and safety. Its function includes ensuring pharmaceuticals and health products, medical products, and medical services advertisements comply with the rules and legislations. Pharmacy Enforcement Division is given the authority to seize illegal products on the market. Items seized by the Division include unregistered and adulterated products. The Division is responsible for ensuring that pharmacy service strategic plans and policies are implemented accordingly. It will ensure the effective distribution of human resources, relevant and continuous training is carried out, the practice of a quality system, and administrative and financial matters are carried out according to rules and guidelines (Zakuan et al., 2014). The unregistered drug is like a silent killer in the pharmaceutical industry; it damages the pharmaceutical economy and the consumer's health (Zulkifli et al., 2016).

Loo et al. (2019) conducted a study to evaluate the function of PED in dealing with parties involved in illegal medical products. The study looked at the prosecution rate and fine imposed for the offence committed. The offence is provided under the Poison Act 1952 and Control of Drug and Cosmetic Regulation 1984. The maximum penalty imposed under the Act is RM 2000 for an individual and RM 50 000 for a company. Based on the study conducted for the year 2014 to 2016, it was found that the median fine imposed for such offences ranged between RM 850 to RM 3000. The fine imposed is considered low, which does not clearly address the impact of illegal medical products on public health.

The study serves as an indicator of the effectiveness of prosecution and penalty imposed on the traders. According to Loo et al. (2019), the result suggested that the current penalty fails to act as a deterrent as the profits gained from selling products and cosmetics are much higher than the fine imposed and consequently compromising public health. He opined that there is a necessity to review or redraft relevant acts and their regulations to address the low intensity of the punishment, which will deter the offences committed.

The ineffectiveness of the prosecution and the fine imposed can be seen in the cases below, which involve individuals. In *PP v Dr. Mazlan Mohd* [2001] 2 CLJ, The respondent was a medical practitioner charged for an offence under reg. 7 of the Control of Drugs and Cosmetics Regulations 1984 for selling and supplying an unregistered drug. The court acquitted and discharged the case on the basis that the prosecution failed to prove the sale of the drug. In another case, *Zulkufli Muhd Gade v PP* [2017] 1 LNS 1783, the appellant was charged in Session Court under Control of Drug and Cosmetics Regulations 1984. Regulations 7(1)(a) read together with section 30(1) of the same Regulation for 48 charges. He was charged with possession of unregistered products and drinks suspected to contain drugs. The appellant was convicted and sentenced to a fine of RM 10000 in default six months imprisonment for each charge. The total amount of fine that the appellant needs to pay is RM 480 000. The appellant appealed to the High Court. The court reduced the fine to RM 5000 for each offence in default five months imprisonment. The High Court found that the total fines of RM 480000 was excessive.

It is clear that the existing legal and institutional frameworks are ineffective in protecting consumers in relation to illegal medical products. Hence, it is essential to look at another mechanism to protect the consumers. This research suggested that the government should consider the Deferred Prosecution Agreement (DPA) to combat the issue of illegal medical products on the market. This mechanism does not provide redress to consumers, but payment of penalty to the government can cover the tax revenue losses suffered due to the sale of illegal medical products on the market. In addition, the penalty imposed on the trader will act as a deterrent to the crime committed by the traders.

#### **4.1. Deferred Prosecution Agreement**

A deferred Prosecution Agreement (DPA) is an agreement reached between a prosecutor and an organization that could be prosecuted under the supervision of a judge. The Agreement allows a prosecution to be suspended for a defined period provided the organization meets certain specific conditions. DPA can be used for fraud, bribery, and other economic crime. They apply to organizations, never to individuals. Key features of DPA are to enable a corporate body to make full reparation for criminal behavior without the collateral damage of a conviction; they are concluded under the supervision of a judge, who must be convinced that DPA is in the interest of justice and that the terms are 'fair, reasonable and proportionate.'; they avoid a lengthy and costly trial; and they are transparent, public events.

#### **4.2. Deferred Prosecution Agreement in other Jurisdictions**

DPA was first introduced in the US back in 1992. In the US, prosecutors have increasingly used DPA against corporate in enforcing white-collar crime. DPA has enabled the company to avoid the costs and consequences associated with a lengthy criminal investigation and trial. It also provided the government with a more efficient means to hold corporate wrongdoers accountable and influence changes in corporate compliance culture ([Delaney, 2009](#)).

There are a few cases involving medical products and services which involved DPA in the US. In 2012, WakeMed Health and Hospitals (WakeMed) was charged for a crime for falsely classifying patients for inpatient hospital stays and fraudulently billed Medicare for associated services. WakeMed and the US Department of Justice (DOJ) entered into a two-year DPA and a five-year Corporate Integrity Agreement (CIA). WakeMed agreed to

pay \$8 million, a figure representing a multiple of the underlying overpayment amount plus damages, and submit to an independent monitor's review. In this case, the judge accepted DPA to protect WakeMed's healthcare providers, employees, and patients (Bakerdonelson, 2013).

Another medical product case involving Wright Medical Group which is in 2010. A medical device manufacturer entered into a one-year DPA with govt to resolve the criminal complaint of its subsidiary, Wright Medical Technology Inc. (WMT). WMT was charged for entering into a financial arrangement with orthopedic surgeons that involved the offer and solicitation of payment from Wright in exchange for the surgeon's use of Wright's hip and knee joint products. Both parties agreed to a five-year Corporate Integrity Agreement (CIA) and to pay \$7.9 million in civil and administrative claims (Bakerdonelson, 2013).

In the UK, DPA was introduced in the United Kingdom's Crime and Courts Act 2013, which received royal assent in April 2013. The underlying principle behind the application of DPA in England and Wales are retribution, restoration, and rehabilitation. The UK government introduced Deferred Prosecution Agreements (DPAs) for England and Wales as a way to tackle economic crime and build confidence in the justice system. DPA is a way of holding companies to be accountable without punishing innocent employees and is an important tool in changing the corporate culture for the better (Hawley et al., 2020). The government hopes that DPA will provide proportionate penalties for wrongdoing, restitution, and compliance. Apart from that, DPA is hoped to produce certainty and speed of enforcement action.

Singapore introduced the DPA framework under its Criminal Procedure Code after successfully enacted the Criminal Justice Reform Act for that purpose. DPA was introduced in Singapore to deal with corruption cases. DPA enables corporate to reach an agreement with the public prosecutor for deferred prosecution in exchange for the imposition of certain requirements (Brez et al., 2018). The Singapore model for approval of DPA draws heavily from the UK, and both require proof to a court that DPA are in the "interest of justice" and that their terms are "fair, reasonable and proportionate" before DPA can be approved (Chua et al., 2019). Under the new regime, the example of requirements that may be imposed in a DPA includes payment of a financial penalty, victim compensation, charitable donation, disgorgement of profits, implementation of or improvement to a compliance program, the appointment of a monitor, and cooperation in the investigation. This newly introduced DPA regime will give the Singapore authorities greater flexibility in sanctioning corporates (Brez et al., 2018).

In Malaysian government has not considering adopting DPA for any cases, even for corruption cases. According to Idzam & Mohammed (2020), the reason given for not adopting DPA in corruption cases is due to the absence of DPA in the Malaysian Anti-Corruption Commission arsenal of tools. She further argued that it would be prudent for Malaysia to consider adopting DPA in corporate criminal liability cases, given that global trend.

## 5. Conclusion

From the above discussion, it is clear that an increasing number of countries have considered implementing a DPA regime. Malaysia may need to learn lessons from other jurisdictions and consider implementing the DPA framework to combat illegal medical products as it affects the country's tax revenue. By adopting this mechanism, payment of

penalty to the government can cover the tax revenue losses suffered due to the sale of illegal medical products. In addition, the penalty imposed on the trader will act as a deterrent to the crime committed by the traders. Adoption of DPA will prevent the company from going out of business and directly affect the loss of employment. Thus, it is proposed that Malaysia reforms its relevant legislation to introduce the DPA framework in its legal system. Owing to this, the research aims to develop a DPA model to act as a deterrent for illegal medical products in Malaysia.

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### Conflict of Interest

The authors reported no conflicts of interest for this work and declare that there is no potential conflict of interest with respect to the research, authorship, or publication of this article.

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