



Consumer Protection for Pharmaceutical Electronic System Operators (PSEF) based on the Principles of Consumer Safety and Security

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Abstract. This research intends to investigate consumer protection against the proliferation of Electronic Pharmacy System Operators in Indonesia in order to uphold the principles of consumer safety and security. It does this by using normative juridical research methodologies using legislative and comparative approaches. E-commerce is a method of conducting business using internet technology. In e-commerce, a website offers services or allows customers to select the products they want, after which the manufacturer sends the buyer's order right away. One area receiving a lot of attention is the expansion of online pharmacy services, which are becoming more and more popular among Indonesians. It is explained that consumers have the right to comfort, security, safety, and accurate information and services in relation to Law Number 8 of 1999 on Consumer Protection, particularly Article 4 numbers 1 and 3. The study's findings demonstrate that there is a solid foundation for the electronic pharmaceutical system's adoption in Indonesia if it is connected to the legal system, namely in relation to legal content, legal structure, and legal culture. However, by implementing the current methods in Germany and England, improvements are required, particularly with regard to oversight.

Keywords: Electronics, Pharmacy, Consumer.

1 Introduction

Advances in technology have an effect on many aspects of life, including using online health services. People are more inclined to use the internet to look up information due to the advancement of infrastructure and the falling cost of gadgets like laptops and cellphones, among other things. Every industry can use the internet, including public education, banking, government, and education. As information and technology have advanced, anyone can utilize the internet to grow their business locally and internationally. As a result, a large number of businesses and individuals use online media to sell or promote a variety of goods [1]. Customers and purchasers find it easier to research a product they want because to the internet's advancements, which also make information more accessible to all societal levels [2]. Aspects of people's lives that are supportive are also evolving quickly with the internet. Trade is one way to sustain people's lives.

One area receiving a lot of attention is the expansion of online pharmacy services, which are becoming more and more popular among Indonesians [3]. The rise of online pharmacies can be attributed to the huge volume of routine data processing that pharmacists perform, making manual data entry error-prone. Thus, fast, accurate, and effective hardware and software support for pharmaceutical services is required. In this online business sector, business players use an application to carry out their sales, which is an implementation of the topic under discussion [4]. Applications can also be thought of as computer programs that are specifically designed to aid or facilitate human activity on a certain machine. Internet-based health services have arisen as an innovation to promote public health, simplify operations, and reach a variety of customer types. This invention manifests as e-commerce, a type of business services delivered by internet technology that involves trading activities like online buying and selling [5].

E-commerce is a method of conducting business using internet technology. In e-commerce, a website offers services or allows customers to select the products they want, after which the manufacturer sends the buyer's order right away [6]. This system's goal is to boost product sales so that both parties profit from them, like in the case of the health industry [7].

Pharmacies, pharmacy stores, and private persons are using the growth of product sales through online media to sell medications. As a result, online pharmacies, online drugstores, or other websites that offer medications have emerged. These include:

1. <http://jualobatmurah.com/>
2. Medicastore Pharmacy (<http://apotik.medicastore.com>), is an official pharmacy that serves offline and online purchases;
3. K24 Pharmacy (<http://www.k24klik.com/>), is an online pharmacy that collaborates with partner pharmacies;
4. Site <https://www.klik-apotek.com>;
5. Site <https://www.goapotik.com/>, is a marketplace or forum for sellers or merchants (pharmacies) to sell health products online;
6. The Halodoc application is a software application that functions as a means of connecting third parties such as doctors, pharmacies, laboratories, couriers (service providers) and consumers

Online media sales of pharmaceuticals provide a larger consumer base, quicker transactions, lower costs, and the option for anonymous purchases. People can easily and quickly obtain medications by buying them online, particularly if those medications are thought to be beneficial for them [8]. Therefore, using the internet for transactions is appealing to people. Legal organizations that supply, oversee, and/or run pharmaceutical electronic systems for use by pharmaceutical service facilities may be considered Pharmaceutical Electronic System Operators (PSEF) in Indonesia. Before dispensing medications online, Pharmaceutical Electronic System Operators (PSEF) are required to possess a valid PSEF Registration Certificate [9].

The usage of online pharmaceutical services has grown significantly in Indonesia, particularly following the Covid-19 pandemic. The most popular services are drug delivery services and the availability of different kinds of pharmaceutical products via different mobile applications, including both prescription and over-the-counter

medications. In Indonesia, the function of pharmacists in offering clinical pharmaceutical services via internet pharmacy platforms is still rather obscure.

A sufficient digital system is needed by both traditional and online pharmacies (located in physical buildings) in order to gather, package, and process the input data provided and generate information that will help the pharmacy provide the best possible service. The website system is closely associated with online pharmacy. This is because, while making a purchase from an online pharmacy, customers are unable to view the product in person. Therefore, in order to ensure that they are eating the medication safely, they must first search up information about it on a specific website. In addition to their benefits, online pharmacies have drawbacks. For example, in web-based pharmacy services, pharmacies only provide medications based on prescriptions; customers and pharmacists are never in consultation.

Customers are entitled to comfort, security, safety, and accurate information and services, as well as Law Number 8 of 1999 concerning Consumer Protection, namely Article 4 numbers 1 and 3. The rights of consumers to accurate, understandable, and truthful information are not upheld by online pharmacy operations or procedures. This is as a result of the lack of direct pharmaceutical services. In actuality, medication is something that should be purchased fully informed, and a pharmacist or other qualified healthcare professional should take great care when using it.

When it comes to laws governing the sale of drugs over the internet, Malaysia is ahead of other nations according to the Malaysian Ministry of Health's Guidelines for E-Pharmacy Services in Online Healthcare Services. The American Council enacted legislation in America that particularly governs internet pharmacies. Germany, which has unique laws governing online pharmacies and the distribution of pharmaceuticals acquired through the internet. In this instance, independent regulators and government agencies in England are tasked with keeping an eye on websites that sell drugs online. Pharmaceutical Electronic System Operators are the regulations and guidelines for delivering healthcare services in Indonesia (PSEF). As a Pharmaceutical Electronic System Operator (PSEF) engaged in telemedicine, you are subject to the regulations set forth by the Ministry of Health, which is the appropriate authority on health-related topics. The Food and Drug Supervisory Agency Number 8 of 2020 on Supervision of Drugs and Food, which is distributed online, the Government Regulation of the Republic of Indonesia Number 5 of 2021 on Implementation of Risk-Based Business Licensing, the Regulation of the Minister of Health of the Republic of Indonesia Number 14 of 2021 on Business Activity and Product Standards for Implementing Risk-Based Business Licensing in the Health Sector, and the Official and Licensed Pharmaceutical Electronic System Operators (PSEF) issued by the Ministry of Health for Pharmacy Electronic System Operators domiciled in Indonesia are required to abide by the applicable provisions.

Only 13 electronic pharmacy service providers were registered as telemedicine service providers from 2021 to 2022, but only 9 of them also offered electronic pharmacy services, according to data given by the Republic of Indonesia's Ministry of Health. As a result, more research is required to determine how to implement operational registration regulations and ensure consumer safety and security for pharmaceutical

electronic service providers in Indonesia, in compliance with the Consumer Protection Law's mandate.

2. Method

With a statutory and comparative approach, this research employs a normative juridical approach. The data used is secondary data in the form of primary legal material, derived from a number of regulations, including the Food and Drug Supervisory Agency's Number 8 of 2020 regulation on the supervision of food and drugs that is distributed online, the Government Regulation of the Republic of Indonesia Number 5 of 2021 on the implementation of risk-based business licensing, and the Minister of Health's Regulation of the Republic of Indonesia Number 14 of 2021 on Business Activity and Product Standards for Implementing Risk-Based Business Licensing in the Health Sector. Scientific publications pertaining to research titles are examples of secondary legal documents. Tertiary legal materials also take this shape. In order to gather the information and theoretical framework required for the discussion, a documentary study pertinent to the research issue was conducted as part of the data collection process. Qualitative data analysis was done, and descriptive explanations were provided. Legal research is conducted through literature reviews, which involve gathering data and analysis based on legal experts' theories and other scientific sources.

3. Result and Discussion

In the modern global economy, the pharmaceutical business is a crucial sector. The pharmaceutical industry has drawn interest from investors due to the rising demand for personal care and health products. It is common for individuals to be unable to distinguish between Pharmaceutical Electronic System Operators and Pharmaceutical Wholesalers, notwithstanding the fact that there are two distinct licensing schemes for pharmaceutical industry participants. When engaging in business activities using a business to business (B2B) model, pharmaceutical wholesalers are required to get an electronic license or permit known as E-Licensing for Pharmaceutical Wholesale Trade (E-PBF). The term "business-to-business" (B2B) describes the kind of trade or economic exchange that occurs between two enterprises [10]. Furthermore, the B2B model places more emphasis on offering goods and services to other businesses than it does on direct customer interaction. Because of this, it is categorized as having a high level of business risk in the context of the pharmaceutical industry and is targeted at business actors with considerable trade between enterprises. The business to consumer (B2C) paradigm is the focus of Pharmaceutical Electronic System Operators (PSEF), in the meantime. A business that sells goods or services directly to customers is known as a business-to-consumer (B2C) model. Consequently, retailers are referred to in this B2C pharmaceutical business.

Pharmaceutical Electronic System Operators works with a variety of companies to provide its services. In this instance, in order to perform delivery and pick-up to customers, the electronic pharmacy system organizer must first work with the service provider—telemedicine in this case—the pharmacy as a partner in terms of selling

medications and food online, customers as service users, and third parties in terms of delivery services. Electronic pharmacy service providers have specific duties when it comes to offering telemedicine-related electronic pharmacy services.

Three (three) aspects of legal system theory can be used to study how to safeguard drug consumers while adhering to the principles of consumer safety and security: substance, structure, and legal culture.

There are multiple regulations that regulate electronic pharmacy system operators in Indonesia, beginning with the substantive aspects of those regulations. These restrictions include:

1. Government Regulation Number 71 of 2019 concerning Electronic System Operators states that telemedicine, as an electronic system service provider, must guarantee the services in the form of user agreements by having internal security for the information managed service provider and providing security for the information used. To provide effective oversight carried out by ministries or law enforcement agencies, telemedicine, as a private electronic system provider, can handle, process, and store data on electronic systems and electronic data located in Indonesian territory. Information about the identity of the electronic system service provider, an explanation of the objects used for transactions, evidence of the suitability and security of the services rendered, instructions on how to use electronic system applications, terms and conditions of the contract, and the procedure by which the parties came to an agreement are all required to be included by electronic system operators. Pharmaceutical electronic service users must also be assured of the protection and security of their personal information, as well as the availability of customer support through the provision of a complaint service phone number.
2. Government Regulation Number 5 of 2021 Concerning the Implementation of Risk-Based Business Licensing: In order to influence entrepreneurs who will conduct business activities, the government provides regulations regarding risk-based business licensing. These regulations include rules regarding business permits that are grouped based on the business's level of risk, whether the business implementation has a high level of risk or low risk. This is in accordance with Government Regulation Number 5 of 2021 on the Implementation of Risk-Based Business Licensing, which grants business permits in the health subsector. Article 119 of this regulation lists pharmaceutical business activities, medical equipment provision, household health needs support, and animal and virus control. Laws and regulations in the health sector govern business licensing, which is connected to the practice of health workers. The pharmacist is the party performing the pharmaceutical service function in compliance with the provisions of the pharmacist practice legislation if the telemedicine platform includes a consultation service provided by a physician. This is because of the regulations pertaining to medical practice and pharmaceutical services.
3. The Health Minister's Regulation Number 14 of 2021 Concerning Product and Activity Standards for Risk-Based Business Licensing in the Health Sector Guidelines pertaining to legal regulations that service providers must follow by

meeting the requirements Pharmacy Electronic System Operators must meet in order to submit a PSEF registration certificate, also known as the Special/Technical Requirements. When applying for a PSEF registration certificate, you need to have a pharmacy that is in charge of PSEF, possess a Resident Identity Card and STRA, and have paid non-tax state revenues. You also need to obtain a business operation permit from the Ministry of Industry and a PSE registration certificate from the Ministry of Communication and Information Technology. The service provider must collaborate with a pharmacy to sell the products included in the service, which include medications and medical equipment sold through the telemedicine platform. Electronic Pharmacy System Operators are required to meet certain standards, including ease of use and high-quality medication with pharmaceutical services. needs to obtain a distribution permit in order to buy illegal substances on the telemedicine platform. These illegal substances include opioids, psychotropics, birth control implants, and injection preparations (apart from insulin). Second, data from the Ministry of Health's information system must be connected to information and technology facilities. Product availability data is accessible at all times, and service documents are kept in the Pharmacy Electronic System for a maximum of five years. Thirdly, customers who purchase medications through electronic pharmacy services with or without a prescription benefit from real-time, direct communication between the pharmacist and the patient for future obligations, as well as a prescription verification service. These services are offered by electronic pharmacy system providers. It is necessary for relevant parties—in this situation, pharmacists—to offer advice or drug-related education.

4. The Food and Drug Supervisory Agency Number 8 of 2020 Regulation about Supervision of Drugs and Food Distributed Online mandates that the pharmaceutical industry, which sells drugs and food through an online system, ensure the efficacy, safety, and quality of the products sold. It also requires the pharmaceutical industry to provide reports on the products sold, which include information about the start of online drug sales, the names and addresses of pharmaceutical business entities, pharmaceutical wholesalers, branch pharmaceutical traders, and pharmacies, as well as information about pharmaceutical electronic service providers and pharmacy websites that collaborate with PSEF in online drug sales. Mention the brands and kinds of medications that are sold online.

Subsequently, it has to do with the legal framework or organizations that serve as oversight bodies and authorized parties. Pharmaceutical products supplied in Indonesia, including over-the-counter drugs, restricted over-the-counter drugs, traditional medicines, herbal medicines, and health supplements, can be monitored for drug distribution online in a number of ways. Article 98 of Law Number 36 of 2009 on Health regulates drug distribution permits, drug classifications, standards, and requirements for pharmaceutical products. These requirements state that pharmaceutical preparations must be safe, effective/beneficial, high-quality, and reasonably priced. The Food and Drug Monitoring Agency (BPOM) is in charge of

oversight in this situation. It can work with law enforcement to address legal infractions pertaining to pharmaceutical products sold that do not meet safety, benefit, and quality standards and requirements. (2) Drug sales sites also require oversight in the course of their operations. Together with the Ministry of Communication and Information, the Food and Drug Supervisory Agency and the Ministry of Health may accomplish this. In this sense, if a website is not registered with the Ministry of Health, the Ministry of Communication and Information may design a system that will allow it to be blocked immediately from any website that contains content related to drug sales. This is a significant issue since, given that medicines are products with usage and delivery guidelines and that the entity selling them requires government approval, it is difficult for someone to sell them without restriction.

Last but not least, given the technologically savvy culture of Indonesian society and the growing public interest in conducting drug purchases and sales through online media, the Ministry of Health, the Food and Drug Supervisory Agency, and the Health Service can educate the public as consumers about making online medicine purchases so that they are not easily duped by freely circulated products.

The author provides Malaysian, English, and German laws and oversight of drug sales through the media as a point of comparison.

The Guidelines for E-Pharmacy Services in Online Healthcare Services, published by the Malaysian Ministry of Health, aim to guide licensed pharmacists in providing e-pharmacy services in compliance with statutory requirements and other requirements established by the Ministry of Health. They also offer guidance to platform providers in creating a system that will enable licensed pharmacists to provide e-pharmacy services through the system in compliance with stipulated laws and other regulations. Finally, the guidelines clarify the responsibilities of both pharmacists and platform providers involved in regulating e-pharmacy services. These recommendations are meant for platform providers and licensed pharmacists that offer e-pharmacy services for the supply or sale of prescription drugs.

Three government agencies and independent regulators oversee websites run by online pharmaceutical businesses in England. The first is the Medicines and Healthcare Products Regulatory Agency (MHRA), a body established by the British government that is specifically responsible for monitoring and controlling pharmaceuticals, medical supplies, and blood components used in transfusions within the country. Regarding information on websites registered as online vendors, the MHRA offers a dedicated webpage. In addition to pharmacies registering on this website, members of the public can report infractions against their online pharmacy; (2) The Independent Regulator of Health and Social Care in England is a separate entity whose mission is to guarantee that social and health services offer high-quality, safe, and effective care while also contributing to the improvement of those services. Each online pharmacy needs to be integrated with its official website, which is thereafter given a badge or logo to be shown there. The online pharmacy registration information will show up when clicked; (3) Upholding standards and the public's trust in pharmacies is the General Pharmaceutical Council's (GPhC) responsibility to protect, promote, and safeguard the health, safety, and welfare of the public. The GPC is an independent body that oversees pharmacists, pharmacy technicians, and pharmacy premises in the United Kingdom.

For Indonesian pharmacists, GPhC is comparable to the Indonesian Pharmacists Association (IAI), a professional association. Additionally, GPhC offers a logo and registration code that the online seller's website needs to show.

The government and the leading German pharmacist association, ABDA (Bundesvereinigung Deutscher Apothekerverbände), control the sale of pharmaceutical items in the country. In order to support licensed pharmacists and complete pharmaceutical services in Germany, the ABDA represents the interests of pharmacy as a health profession in society. Prescription and over-the-counter (OTC) drugs are only available through pharmacies; they are not sold openly, with the exception of food supplement stores that have been approved by the federal government. It is also possible to say that a pharmacist oversees the sales of drugs. Since all pharmacies in Germany are run by pharmacists, those with online pharmacy programs are either government-designated food supplement stores or pharmacists. This makes Germany a unique pharmacy market.

4. Conclusion

The idea of consumer safety and security is one of the tenets of consumer protection in Indonesia. This is meant to ensure that every customer who uses goods from commercial entities has a guarantee of security and safety. There are various ways to assess the extent to which consumer protection has been implemented, such as examining the legislative framework, legal content, and legal culture. Legally speaking, Indonesia has the authority to implement licensing for operators of pharmaceutical electronic systems; thus, in order to obtain legality in the form of a registration certificate, each operator of a pharmaceutical electronic system is required to register its commercial activities. Regarding legal framework, Indonesia has a number of government agencies whose job it is to monitor and advise the populace in order to establish a sound legal culture around the dealing of medicinal products online. The Food and Drug Supervisory Agency, the Ministry of Health, and the Ministry of Communication and Information are the pertinent organizations. The comparison between Indonesia and Malaysia, England, and Germany yielded results that point to a number of regulations and supervision systems that could be adopted and put into place to improve online pharmaceutical product trading activities in Indonesia. Of particular note were the regulations pertaining to the categories of drugs that could be traded online

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