

Legal Responsibilities of Telepharmacy In Sales of Prescription Drugs In Indonesia

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Abstract

The role of medication in healthcare services is crucial, but inappropriate use can endanger human health. Prescription drugs, including controlled substances, narcotics, and psychotropics, can only be dispensed by pharmacists based on a doctor's prescription at pharmaceutical service facilities in accordance with legal regulations to prevent misuse or abuse, which pose high health risks and can even be fatal. While the development of telepharmacy provides convenience for consumers in obtaining medications, it also introduces risks when prescription drugs are obtained without a doctor's prescription. This study aims to analyze the legal responsibilities of telepharmacy in the sale of prescription drugs and to understand the role of pharmacists in maintaining pharmaceutical standards within telepharmacy. Method: literature review sourced from Google Scholar. The Legal responsibility in Indonesian telepharmacy is governed by Government Regulations No. 71/2019 and No. 5/2021, Minister of Health Regulation No. 14/2021, Minister of Health Decree No. HK.01.07/MENKES/4829/2021, and BPOM Regulation No. 8/2020. Telepharmacy involves pharmacists, pharmacies, and electronic system operators, requiring adherence to service standards, data protection, and collaboration with conventional pharmacies. Therefore, regulations governing the pharmacy profession need to be updated to ensure telepharmacy services are safe and compliant with standards.

Keywords: Responsibility; Telepharmacy; Drugs; Prescription; Pharmacist

INTRODUCTION

Medicines have a very important role in the provision of health services. Inconsistencies in the use of medicines, both in terms of safety, effectiveness, and product quality, can potentially harm the human body. Health risks associated with over-the-counter medicines also arise, especially when there is a spread of counterfeit products that have the potential to cause allergic reactions, side effects, and other health problems. Consumers who do not follow the advice of doctors and pharmacists when purchasing medicines without a prescription also often put themselves at serious health risk (Ariestiana, 2020).

According to Article 1 of Law No. 17 of 2023, drugs are defined as materials, alloys of materials, including biological products, that affect or study the physiological system or state of human pathology to determine diagnosis, prevention, cure, recovery, health improvement, and contraception for humans (Republic of Indonesia, 2023). Article 320 Paragraph (1) explains that drugs can be divided into prescription drugs and non-prescription drugs. Furthermore, Article 320 Paragraph (2) of Law Number 17 of 2023 concerning Health states that prescription drugs include hard drugs, narcotics, and psychotropic drugs. Prescription drugs can only be dispensed by pharmacists at pharmaceutical service facilities in accordance with the provisions of laws and regulations and these drugs can only be dispensed by pharmacists on the basis of a doctor's prescription. This provision aims to prevent abuse and misuse given the high health risks of this class of drugs. Based on these risks, the law provides strict restrictions on the circulation of hard drugs, narcotics, and psychotropic drugs. This is to ensure the safe and proper use of drugs and prevent misuse (Ariestiana, 2020).

In line with Article 24 of Government Regulation No. 51 of 2009 concerning Pharmaceutical Work, it is stated that in performing pharmaceutical work at pharmaceutical

service facilities, pharmacists may deliver hard drugs, narcotics and psychotropic substances to the public on the basis of a prescription from a doctor in accordance with the provisions of laws and regulations. Based on this, the types that can only be delivered based on a doctor's prescription are hard drugs, narcotics and psychotropic substances. Only pharmacists with a license to practice can dispense these drugs and they must be sold at pharmacies with an operational license.

According to Decree of the Minister of Health of the Republic of Indonesia Number 02396/A/SK/VIII/1986 of 1986 on Special Marks for List G Drugs, prescription drugs are marked with a red round circle symbol with a black border with the letter K touching the border. Examples of drugs from this group are antibiotics, hormone drugs, and heart medications. Narcotic drugs can cause psychological and physical dependence if used by someone without careful supervision according to Article 1 of Law Number 35 of 2009 concerning Narcotics. Psychotropic drugs have psychoactive properties through selective effects on the central nervous system that cause characteristic changes in mental activity and behaviour (Republic of Indonesia, 1997). This class of drugs is marked with a white circle symbol with a red border and a red medal cross symbol. Inappropriate use of prescription drugs can carry high risks, such as worsening illness, poisoning the body, and even causing death (Bahrir, 2019). Deaths due to drug abuse are categorised as accidental deaths that arise from generally unforeseen events which usually involve some form of external factor (Handar, 2019).

The role of pharmacists in ensuring patient safety is crucial. Pharmacists, as graduates who have taken the oath of office, must continually improve their knowledge, skills, and behaviors to interact directly with patients. These interactions include providing drug information and counseling on correct usage, dosage, possible side effects, and interactions with food or other drugs. This information is essential to ensure patients understand how to use medications correctly for optimal therapeutic outcomes (Republic of Indonesia, 2016).

Technological advancements have had a huge impact on various sectors, including online health services. One innovation that has attracted great attention is telepharmacy services. In Indonesia, the use of telepharmacy services has increased rapidly since the COVID-19 pandemic. The most common services are the provision of various types of pharmaceutical products through mobile applications, both for prescription and over-the-counter drugs, as well as drug delivery services. However, the role of pharmacists in providing clinical pharmacy services through telepharmacy remains unclear, in contrast to practices in other countries (Unni *et al.*, 2022).

Telepharmacy provides convenience and benefits to the public, including the provision of various types of pharmaceutical products through mobile applications and drug delivery services. However, online drug sales also pose risks, especially when drugs that should be purchased with a doctor's prescription can be obtained without a prescription. Strict supervision is needed to ensure that hard drugs, narcotics, and psychotropic substances are only dispensed based on a valid doctor's prescription. Although the conventional buying and selling system still exists, many consumers are now turning to marketplaces as an alternative to conducting trade transactions. With the development of marketplaces, the sale of medicines through online platforms has increased, offering convenience to consumers. Nonetheless, consumers face risks due to this freedom, especially when buying drugs that should be purchased with a doctor's prescription (Acep, 2015).

An alarming example is the death of a resident of Karya Murni Village, Paguyaman Subdistrict, Boalemo District. The victim with the initials HA allegedly died after consuming hard drugs purchased without a doctor's prescription. The victim experienced side effects after taking the medicine and looked pale, then died. Upon investigation, the drugs consumed by the victim were obtained from a seller who falsified the distribution permit certificate and tricked consumers with the name of an online shop that appeared to be official. Cases like this show the

importance of strict supervision and effective legal protection in online drug sales (Wahyoo, 2020).

Effective legal protection for telepharmacy service users not only has legal implications, but also major social and health implications. This can impact on public safety in the use of medicines and trust in telepharmacy services. The involvement of unscrupulous health workers in the illegal distribution of hard drugs or List G drugs is also very worrying. The Directorate of Criminal Investigation of Polda Metro Jaya revealed a new mode of illegal drug distribution involving health workers. In this case, hard drugs such as Hexymer, Tramadol, and Alprazolam, which are class IV psychotropic drugs, were distributed by assistant doctors, assistant pharmacists, and nurses without a valid practice permit. Four suspects were arrested, with evidence in the form of hundreds of thousands of items of illegal drugs as well as cash and related equipment. The total value of confiscated goods from January to August 2023 reached IDR 45.7 billion (Lampung *Police* Public Relations, 2023).

In accordance with Article 436 of Law No. 17 of 2023 on Health, it is prohibited to perform pharmaceutical practices for people who do not have the expertise and authority regarding medicines. This means that the person who has the right to sell medicine online is a pharmacist. When someone who does not have the authority or certification sells prescription drugs online, it is illegal. The primary responsibility lies with the pharmacist who dispenses the prescription based on their expertise. The pharmacist's responsibility is to serve the prescription based on their professional responsibility and expertise, which also creates a responsibility to the consumer (Republic of Indonesia, 2017). Regulations require the purchase of hard drugs using a prescription to prevent misuse. If a consumer is harmed by the sale of hard drugs without a prescription, the pharmacist is liable, not the owner of the capital (Nur Alimah, 2020).

Thus, it is important to understand the complexity of the roles and challenges faced by telepharmacy services, especially in the distribution of prescription drugs as a form of consumer protection and compliance with strict pharmaceutical standards. It is necessary to review the legal and regulatory aspects relevant to telepharmacy services, as well as the obligations of pharmacists in ensuring that prescription drugs sold online comply with established safety and quality standards. This will also help understand how telepharmacy can serve as a trustworthy partner in a safe prescription drug delivery system.

Previously, a study titled "Perlindungan Hukum Terhadap Konsumen Atas Penjualan Obat-Obatan Ilegal Secara Online" by Anisa Utami and Herwastoeti analyzed illegal online drug sales through marketplaces and the legal protection for consumers. This research, however, focuses on the legal responsibilities of prescription drug sales through telepharmacy services in collaboration with PSEF, and discusses the role of pharmacists in telepharmacy services, in addition to BPOM's supervisory role. Second, a study titled "Perlindungan Hukum Terhadap Konsumen dan Pelaku Usaha Dalam Jual Beli Obat Secara Online" by Hilda Maulana explored online sales of over-the-counter drugs on certain platforms concerning legal protection for consumers and businesses. In contrast, this research analyzes legal responsibilities in telepharmacy services collaborating with PSEF concerning prescription drug sales.

Research on "*Legal Responsibility of Telepharmacy Services in Prescription Drug Sales in Indonesia*" is crucial for providing comprehensive insights into the legal responsibilities of telepharmacy services in the context of prescription drug sales in Indonesia and how pharmacists uphold pharmaceutical practices according to service standards to maintain the integrity and safety of public health services.

RESEARCH METHODS

The main focus of this research is normative legal research using secondary data. Secondary data is obtained through desk research along with information from field observations. In the process of preparing this research, a statue approach was used, which emphasizes the analysis of laws and regulations as the basis (Soerjono and Sri, 2012). This legal method uses the Law of the Republic of Indonesia Number 8 of 1999 concerning Consumer Protection as the basis of research to examine consumer protection in the context of online pharmacies. In addition, this analysis refers to Government Regulation Number 51 concerning Pharmaceutical Work and Regulation of the Minister of Health of the Republic of Indonesia Number 73 of 2016 concerning Pharmaceutical Service Standards in Pharmacies. Conceptual approach, refers to an approach that adopts theoretical concepts to understand facts directly related to the object of research material that pharmacies must be patient-oriented (pharmaceutical care) and in accordance with pharmaceutical standard regulations.

This research is descriptive analytical in nature which reveals the legislation relating to legal theories and how it should be in the future (*ius constituendum*). Secondary legal data is the data source of this research. Secondary legal data can consist of primary legal materials, secondary legal materials, and tertiary legal materials. In this case, the data used in this research comes from the category of secondary legal data.

In normative legal research, the data collection method involves a literature study of various legal materials, including those that are primary, secondary, and tertiary, as well as non-legal materials that are relevant to the research focus. The data analysis method used is qualitative data analysis method, which analyzes secondary data without using statistics to answer the problems in this study. In this case, the research will describe the facts, problems, and provisions regarding telepharmacy services which are then tested with reference to existing theory.

RESULT AND DISCUSSION

Legal Compliance in the Implementation of Telepharmacy Services

According to the Decree of the Minister of Health Number HK.01.07/Menkes/4829/2021 concerning Guidelines for Health Services Through Telemedicine during the 2019 Corona Virus Disease (Covid-19) Pandemic, telepharmacy is part of telehealth or telemedicine. Public services in the health sector are government functions aimed at ensuring fundamental rights, such as the right to a dignified life, recognized by laws. The state must provide these services professionally and based on good governance principles. Ensuring access to public services is crucial for realizing human rights. This access must align with development, as meeting basic needs is essential for fostering participation based on independence and equality (Maif *et al.*, 2021).

According to the Minister of Health Regulation Number 14 of 2021, telepharmacy is a pharmaceutical service by pharmacists using telecommunications technology and information systems to assist patients. It is a telemedicine practice focused on pharmaceutical aspects, with the pharmacist fully responsible (Ameri *et al.*, 2020).

Telepharmacy uses technology to provide remote pharmaceutical services through a Pharmacy Electronic System Operator (PSEF), which ensures services meet government standards for security and reliability. Legal compliance in e-pharmacy involves adhering to laws and regulations. Providers must meet these obligations, with sanctions for non-compliance. Jurist Hans Kelsen states that sanctions apply to those violating the rule of law in their operations (Raisul, 2018).

As of May 2023 there are thirteen pharmacy e-service providers registered with the Ministry of Health of the Republic of Indonesia, but only eight of them also provide telemedicine services. This shows the importance of reviewing the implementation of legal compliance in web-based telemedicine service providers. The list of electronic pharmacy system providers that have registered with the Ministry of Health as Pharmaceutical Electronic System Providers (PSEF) are not all telemedicine service providers (only telepharmacy). The list can be seen in Table 1.

Table 1 List of Pharmacy Electronic System (PSEF) Providers

Service Provider Site	Telepharmacy Service Availability	Telemedicine Service Availability
https://kimiafarmaapotek.co.id/kimia-farma-mobile/	Available	Available
www.goapotik.com	Available	Available
www.prixa.ai	Available	Not Available
https://century-pharma.com/marketplace	Available	Not Available
https://lifepack.id	Available	Not Available
https://www.gooddoctor.co.id/health-mall/	Available	Not Available
www.klikdokter.com	Available	Available
mandjur.co.id	Available	Not Available
https://www.alodokter.com/	Available	Available
k24klik.com	Available	Available
www.sehatq.com	Available	Available
https://shop.vivahealth.co.id	Available	Available
www.halodoc.com	Available	Available

The Pharmaceutical Electronic System Operator (PSEF), as a legal entity managing the pharmaceutical electronic system, is responsible for providing services such as drug prescription, consultation, information education, and therapeutic monitoring. PSEF must comply with Government Regulation No. 71/2019 on Electronic System Operators, ensuring a secure and reliable electronic system. PSEF must ensure operational security, reliability, and service sustainability, following guidelines to meet legal and operational standards set by the government, as follows:

a. Government Regulation No. 71/2019 on Electronic System Providers

The Pharmacy Electronic System Operator (PSEF) must ensure clear agreements with users about the services provided and guarantee the security and internal safeguards of managed information. As a private electronic system provider, PSEF is responsible for managing, processing, and storing electronic data in Indonesia, ensuring effective supervision by the ministry or law enforcement agencies. PSEF must include complete information on the service provider's identity, transaction details, proof of service eligibility and security, application usage instructions, contract terms and conditions, and agreement processes. Additionally, users must have their personal data and privacy secured and be provided with consumer services, including a complaint phone number.

b. Government Regulation Number 5 of 2021 concerning the Implementation of Risk-Based Business Licensing

The government regulates risk-based business licensing, which includes rules on business licenses categorized based on the level of business risk, namely high and low risk. This regulation has an impact on entrepreneurs who want to carry out their business activities. According to Article 119 of Government Regulation No. 5/2021 on the Implementation of Risk-Based Business Licensing, business licenses in the health sector include pharmaceutical business

activities and the provision of medical devices. Business licenses in the health sector must comply with laws and regulations related to the practice of health workers.

Telemedicine platforms, including doctor consultation services, must adhere to medical practice rules. Similarly, pharmacists providing pharmaceutical services must follow statutory provisions governing their practice.

c. Minister of Health Regulation Number 14 of 2021 concerning Business Activity and Product Standards for Health Sector Risk-Based Business Licensing Implementation

PSEFs must comply with the legal guidelines that govern the requirements that must be met. These include the application for the PSEF register mark and any special or technical requirements. At the stage of applying for the PSEF registration mark, service providers must obtain a business license from the Ministry of Industry, a PSE registration mark from the Ministry of Communication and Information Technology, and ensure that the responsible pharmacy has an Identity Card (KTP) and Pharmacist Registration Certificate (STRA). In addition, service providers must make non-tax state revenue (PNBP) payments.

d. Decree of the Minister of Health Number HK.01.07/MENKES/4829/2021

Telepharmacy services at pharmaceutical service facilities according to the provisions:

- 1) Electronic prescription services by pharmacists must be in accordance with the pharmaceutical service standards stipulated in laws and regulations.
- 2) Pharmacists communicate with the doctor who wrote the prescription to confirm or provide advice that may result in changes to the electronic prescription.
- 3) Pharmaceutical preparations, medical devices, BMHP, and/or health supplements prepared on the basis of electronic prescriptions can be given to patients or their families at pharmaceutical service facilities, or delivered through delivery services.

e. NA-DFC Regulation No. 8/2020 on the Supervision of Drugs and Foods Circulated Online

The pharmaceutical industry selling drugs and food online must ensure product safety, efficacy, and quality by providing detailed reports. These reports should include information on pharmaceutical business entities, wholesalers, branch traders, and pharmacies, as well as the start date of online sales, the pharmacy e-service provider's name, the website address, and the types of drugs sold. Pharmacy Electronic System Operators (PSEFs) must include user terms and conditions, facilitate product-related complaints, and educate about prohibited products. They are also required to conduct regular monitoring and evaluation of online drug sales, including data on the PSEF's profile, collaborating pharmacies, and the procurement and delivery of drugs.

Based on the Minister of Health Regulation Number 14 of 2021 concerning Business Activity and Product Standards at the Health Sector Risk-Based Business Licensing Provider, in conducting telepharmacy services on a network basis, pharmacies must partner with Pharmacy Electronic System Providers (PSEF) in the use of electronic systems in the form of online retail or marketplaces on special pharmaceutical features in accordance with the provisions of laws and regulations for Pharmaceutical Supplies, Medical Devices and BMHP except narcotics and psychotropic drugs, injection preparations (other than insulin) and birth control implants (Republic of Indonesia, 2021).

PSEF itself is a legal entity that provides, manages, and/or operates Electronic Systems for its own needs and/or the needs of other parties, for example in telepharmacy services. The telepharmacy policy in Indonesia is in accordance with the Circular Letter of the Minister of Health Number HK.02.01/MENKES/303/2020 of 2020 concerning telepharmacy in the context of telemedicine and contained in the Minister of Health Regulation Number 14 of 2021 concerning Organizers of Risk-Based Business Licensing in the Health Sector, and the Food and Drug Supervisory Agency (BPOM) Regulation Number 8 of 2020 concerning the Supervision of Drugs and Food Circulated Online.

Based on Regulation of the Minister of Health Number 14 of 2021, the Pharmacy Electronic System is used to support pharmaceutical service facilities in terms of telepharmacy, including information on drug availability, electronic prescription services, self-medication services, drug delivery and/or other electronic pharmaceutical services in accordance with pharmaceutical service standards. In addition, based on BPOM Regulation Number 8 of 2020, pharmacies and PSEF (Pharmacy Electronic System Operator) provide a communication function between patients and pharmacists.

PSEF is prohibited from using social media, daily deals, and classified ads for pharmaceutical electronic systems; conducting their own drug sales; partnering with non-pharmaceutical facilities; and sharing information about certain drug preparations, as per Article 30 of BPOM Regulation Number 8 of 2020 on Online Drug and Food Supervision. In some countries, support for telepharmacy is limited. For example, South Korea, despite its advanced digital industry, has not yet authorized telepharmacy. Although telemedicine has been legally recognized since 2003, its use is restricted, and drug sales through telepharmacy and online consultations are prohibited. Full authorization of telemedicine and telepharmacy in South Korea's hospitals and clinics is expected by February 2024 (Hyonhee, 2024).

In the United States, telepharmacy is seen as a way to cut operational costs and save money for hospital pharmacies. It can reduce medication approval times to 14-20 minutes and lower medication errors during off-hours or when staff is limited. Telepharmacy allows for 24/7 prescription filling, enabling pharmacists to focus on patient care, enhance clinical quality, and improve patient satisfaction. It expands services to underserved areas, including rural locations, and supports post-hospital care with medication reconciliation and follow-up calls. Compliance with HIPAA regulations and oversight by the American Society of Hospital Pharmacists (ASHP) contribute to better health outcomes, fewer hospital re-visits, reduced care costs, and higher patient satisfaction (Poudel and Nissen, 2024).

Different countries have adopted telepharmacy services with different models. For example, Denmark uses an online pharmacy platform that provides medicine purchase and consultation services. In Japan, telepharmacy is limited to over-the-counter medicines that can be purchased without a prescription. In Scotland, there is a Telepharmacy Robotic Supply Service (TPRSS) that includes prescription screening, over-the-counter drug sales, and virtual consultations. In Canada, the GeriMedRisk platform is used for geriatric pharmacology consultations. In Indonesia, several registered PSEFs such as Goapotik, Prixai.ai, Century Pharma, Lifepack.id, Good Doctor, Klikdokter, Alodokter, SehatQ, and VivaHealth have been providing telepharmacy services that include drug delivery by working with third parties to ensure the drugs reach the patients safely.

Table 2: Telepharmacy services in Denmark, Japan, Scotland, and Canada

No	Country	Form of Service	Refference
1	Denmark	Through the platform http://www.apoteket.dk For counseling conducted via phone, video, or text message (counseling is conducted not only during the purchase but can also be done through the front page of the website)	Ho <i>et al</i> , 2015
2	Japan	Telepharmacy for over-the-counter drugs that can be purchased without a prescription. The steps in ordering over-the-counter drugs online (via e-mail), namely:	Nakai and Tanaka, 2015

		Confirmation of the patient's condition (gender, age, conditions/diseases, adverse side effects that have experienced, current medical treatment, pregnant/not pregnant current medical treatment, pregnant/not pregnant, comments or other questions) or other questions). Information from the pharmacist (dosage and administration, cautions, etc.) Answers from the patient (ensuring the patient understands) Delivery	
3	Scotland	Using tele-technology (Telepharmacy Robotic Supply Service (TPRSS), including: Prescription screening Sales of over-the-counter drugs Virtual face-to-face advice from community pharmacist using a video link Minor ailment service Sale of medicines to individual patients Health promotion campaign	Inch <i>et al</i> , 2017
4	Kanada	Using the GeriMedRisk platform which is a geriatric pharmacology consultation service that aims to optimize patient treatment to improve cognition, mobility, function, and mental health, the consultation method uses telephone and video.	Elbeddini and Yeats, 2020

Telepharmacy services also include drug delivery to patients, which is practiced in countries like Japan, China, Spain, the Netherlands, the UAE, Egypt, and Zimbabwe. In Indonesia, according to the Food and Drug Supervisory Agency Regulation Number 8 of 2020, online drug delivery can be made directly to patients or through a legal third party. The delivering pharmacy or third party must ensure the quality, safety, and confidentiality of the medicine, provide product information, and ensure accurate delivery. Article 9 of the regulation specifies that drug delivery can be done by pharmacies independently or in collaboration with legal entities, with a focus on maintaining drug safety and confidentiality, as follows:

- a. Able to ensure drug safety and quality;
- b. Include product information, labeling, and/or instructions for use;
- c. Keep the contents of the shipment confidential;
- d. Send the medicine in a sealed container;
- e. Ensure the medicine reaches its destination;
- f. Document drug handover, including from third parties to patients.

If a third party is used, a delivery document must be provided with additional third party information including the name, address, and telephone number of the sending pharmacy or third party and the person making the delivery. The third party must not provide information about the medicine. All online drug deliveries must follow the regulations applicable to electronic commerce. From several telepharmacy service concepts from various countries, several things can be adapted and applied in Indonesia to improve telepharmacy services that are more efficient, safe, and in accordance with the needs of the community, namely:

- a. Develop a unified and flexible online platform for medicine purchase and pharmacy consultation, which can be accessed at any time;
- b. Introducing more advanced *telepharmacy* technologies such as TPRS (Telepharmacy Robotic Supply Service) to improve services and efficiency;
- c. Create specialized services for certain patient groups (elderly) and strengthen the drug delivery system to ensure safety and reliability;
- d. Tighten safety and confidentiality standards in drug delivery and telepharmacy consultations;
- e. Adopt international standards for licensing and certification of pharmacists engaged in telepharmacy services. Any pharmacist providing telepharmacy services must have a special license recognized by the Ministry of Health;
- f. Develop an integrated national platform for online pharmacy services, as done in Denmark. This platform should allow drug purchase, direct consultation, and patient health monitoring and a secure data backup system and easy access by supervisors for auditing and monitoring;
- g. Encourage collaboration between pharmacists and other healthcare professionals to ensure good coordination in patient care, as is done in Canada with GeriMedRisk.

Although telepharmacy offers many benefits, its implementation still faces pros and cons. Some of the advantages and limitations in the implementation of telepharmacy can be seen in Table 3.

Table 3. Advantages and Limitations of Telepharmacy

No	Reference	Advantages	Limitations
1	Ho <i>et al</i> , 2015	High level of patient satisfaction with telepharmacy services	Emphasize the need for professional text message operators such as pharmacists or pharmacists with theory and practical experience to ensure that the questions asked by customers can be answered sufficiently.
2	McFarland <i>et al</i> , 2017	Help improve access to pharmaceutical services	Difficulties in technology.
3	Inch <i>et al</i> , 2017	Addressing health service inequalities in remote underserved areas	Most of the local users are elderly and therefore not familiar with technology.
4	Le <i>et al</i> , 2018	<ul style="list-style-type: none"> . Virtual consultations allow patients to access medications. . medication with a comfortable feeling in home that leads to drug regimen adherence . Improve ease of access to pharmaceutical services for patient 	<ul style="list-style-type: none"> . Security issues leading to patient health information . Large initial investment, telepharmacy may not be relevant with facilities
5	Ilma <i>et al</i> , 2021	Improving the relationship between patient with the pharmacist	<ul style="list-style-type: none"> . Limitations in the process services that require observation . Shortcomings in terms of legality recipe

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- . Exploring complete patient information
 - . Overcoming time constraints in digging up information
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Effective telepharmacy services require a standardized healthcare delivery model that is governed by clear regulations. In some countries such as the United States and some European countries, laws governing telepharmacy are already in place (Švarcaitė, 2022). However, in many other countries, telepharmacy-related regulations and policies still need to be implemented and developed. Therefore, it is important to review the latest policies and regulations before implementing telepharmacy services.

Legal Liability of Prescription Drug Sales

The use of information and communication technology in the health sector, such as telepharmacy, can enhance health service delivery. Telepharmacy, defined as pharmaceutical services provided by registered pharmacists via telecommunications to remote patients, offers an alternative to expand pharmacy reach (Koster et al., 2021). Electronic health information systems, like electronic health records, facilitate pharmacists' access to examination and drug therapy information. However, more research on remote services, including smartphone apps, software, and online drug purchases, is needed to ensure safe, effective, and accessible pharmaceutical care.

Article 320 Paragraph (2) of Law No. 17 of 2023 Concerning Health states that prescription drugs include hard drugs, narcotics, and psychotropic drugs, which can only be dispensed by pharmacists based on a doctor's prescription to prevent misuse. The law restricts the circulation of these drugs due to their high health risks.

Similarly, Government Regulation No. 51 of 2009 concerning Pharmaceutical Work states that in performing pharmaceutical work at pharmaceutical service facilities, pharmacists may deliver hard drugs, narcotics, and psychotropic substances to the public on prescription from a doctor in accordance with the provisions of laws and regulations. This means that prescription drugs cannot be purchased without a doctor's prescription.

Deviations in the circulation of hard drugs, narcotics and psychotropic substances in the community are increasingly prevalent. Pharmacies, which are supposed to be legal facilities for hard drugs, are allegedly selling these drugs illegally without a doctor's prescription, both in conventional and online pharmacies. In fact, pharmacy staff should provide correct information about hard drugs according to what is stated on the packaging. Pharmaceutical workers certainly have a certificate for their profession which is the basis that the health worker is competent, because they have passed the competency test from the government and have also been sworn in to carry out their profession as health workers (Enina, et al., 2023). This emphasizes the need for stricter enforcement of regulations and better education among pharmacies and the public.

Law enforcement is essentially an effort to enforce legal norms, both in the form of orders and prohibitions. The purpose of law enforcement against criminal acts of narcotics and psychotropic abuse is to improve the health status and human resources of Indonesia. Therefore, in order to realize people's welfare, efforts should be made to improve the field of medicine and health services, among others by seeking the availability of certain types of narcotics which are urgently needed as medicines and preventing and eradicating the danger of abuse and illicit trafficking of narcotics and narcotics precursors (Muhammad Yunus et al., 2021).

Regulations on the sale of prescription drugs, which can only be dispensed by pharmacists, are set out in the following regulations:

- a. Article 25 of Government Regulation No. 51 of 2009 concerning Pharmaceutical Work states that pharmaceutical work must still be carried out entirely by the pharmacist concerned. This is intended to avoid pharmaceutical work being performed by those who do not have the competence and authority.
- b. Article 51 Paragraph (1) of Government Regulation No. 51 of 2009 Concerning Pharmaceutical Work states that pharmaceutical services at pharmacies, health centers or hospital pharmaceutical installations may only be performed by pharmacists.
- c. Article 6 Paragraph (2) of BPOM Regulation Number 8 of 2020 concerning the Supervision of Drugs and Foods Circulated Online which states that
- d. Article 10 Paragraph (1) of BPOM Regulation Number 8 of 2020 concerning the Supervision of Drugs and Food Circulated Online which states that pharmacies must ensure that patients submit the original prescription for hard drugs to the pharmacy which is carried out at the same time as the delivery of hard drugs by pharmacies and / or third parties to patients.

Telepharmacy businesses, both through online pharmacies and marketplaces, must be liable to consumers if consumers can buy hard drugs but there is no pharmacist in the online pharmacy or marketplace. In addition, online pharmacies and marketplaces can also be held liable if consumers can buy hard drugs without a doctor's prescription even though there is a pharmacist. Telepharmacy business actors can be held liable if there is harm to consumers due to buying hard drugs online where there is no pharmacist because it is like giving permission to sellers to sell hard drugs, narcotics, and psychotropic substances freely. Consumers can take legal action against online pharmacies and marketplaces. Legal action can be taken if an online pharmacy operates without a pharmacist and provides hard drugs without a doctor's prescription. Consumers can also file legal actions against marketplaces that allow such online pharmacies to sell hard drugs, narcotics, and psychotropic substances freely, which suggests complicity in illegal sales for profit.

This violates Article 7(b) of Law Number 8 Year 1999 on Consumer Protection, which requires business actors to provide correct, clear, and honest information about goods and services, including usage instructions. Failure to inform consumers that hard drugs must be purchased with a prescription due to potential harmful side effects constitutes a violation of this law.

Violation of Article 7 Letter (b) obliges business actors to be responsible to consumers who are harmed, in accordance with the provisions of Article 19 of Law Number 8 Year 1999 on Consumer Protection. The article states that business actors must provide compensation for damage, pollution, or losses suffered by consumers due to consumption of goods or services traded, in this case losses due to consuming hard drugs, narcotics, and psychotropic drugs without the supervision of a doctor and/or pharmacist because they are obtained freely without a doctor's prescription. Regarding the burden of proof, Article 22 of the Consumer Protection Law stipulates that the business actor is responsible for proving the presence or absence of elements of fault in the related criminal case, without closing the possibility for the prosecutor to also carry out the proof.

Consumers can take legal remedies, namely through the court based on Article 45 of Law Number 8 Year 1999 on Consumer Protection and outside the court based on Article 47 of Law Number 8 Year 1999 on Consumer Protection. There are three ways to resolve disputes outside the court through the Consumer Dispute Resolution Agency (BPSK), namely conciliation, mediation, and arbitration.

Meanwhile, the activities of producing or distributing pharmaceutical preparations that do not meet the standards and / or requirements for safety, efficacy or benefits, and quality will be followed up according to Article 435 Jo. Article 138 Paragraph (2) and Paragraph (3) of Law Number 17 of 2023 concerning Health with a maximum imprisonment of 12 (twelve) years or a maximum fine of IDR 5 billion.

In addition, business actors who trade goods and/or services that do not meet or do not comply with the required standards and provisions of laws and regulations will be followed up as stipulated in Article 62 paragraph (1) Jo. Article 8 paragraph (1) letter (a) of Law Number 8 of 1999 concerning Consumer Protection with a maximum imprisonment of 5 (five) years or a maximum fine of Rp2 billion.

Pharmacies selling hard drugs online are liable for consumer losses from non-prescription sales, whether or not they offer pharmacist counseling. Consumers can seek legal remedies under Law No. 8/1999 on Consumer Protection through courts or the Consumer Dispute Resolution Agency (BPSK). The legal relationship between the consumer, online pharmacy, and marketplace is governed by an electronic agreement detailing service terms. Marketplaces require that hard drug purchases include a doctor's prescription uploaded by the consumer. Online pharmacies, regardless of counseling services, must adhere to these regulations.

According to Article 1457 of the Civil Code states that buying and selling is an agreement, by which one party binds himself to deliver an object, and the other party to pay the promised price. The valid conditions of an agreement stipulated in Article 1320 of the Civil Code (KUHPperdata), namely:

- a. The agreement of those who bind themselves;
- b. The existence of capacity to enter into an agreement;
- c. About a certain object;
- d. Regarding lawful causa/cause.

Pharmacists are also professional service business actors who also provide information, communication and education services to consumers. The relationship between consumers and pharmacists is a direct service relationship because consumers utilize the services of pharmacists. In transactions through telepharmacy between consumers and *online* pharmacies as drug providers, there is a legal relationship that occurs through electronic buying and selling which creates contractual ties. Consumers also have a legal relationship with the *marketplace* as a provider of *online* buying and selling platforms. This relationship begins when consumers and *online pharmacies* agree to the terms and conditions set by the *marketplace*, which are outlined in the form of an electronic agreement (Nur Alimah, 2020).

If consumers are harmed by the actions of pharmacists, *online* pharmacies, or *marketplaces*, they can pursue legal remedies under Law Number 8 Year 1999 on Consumer Protection. In the context of consumer protection law, there are two types of remedies: pre-purchase and post-purchase. Pre-purchase remedies include legislation and self-regulation, while post-purchase remedies include judicial and out-of-court settlements. Out-of-court dispute resolution can be done through the Consumer Dispute Settlement Body (BPSK) (Fedora, 2018).

The Role of the Food and Drug Administration (BPOM) Regarding Telepharmaceuticals

Article 436 of Law No. 17 of 2023 Concerning Health prohibits individuals without the necessary expertise and authority from performing pharmaceutical practices, meaning only certified pharmacists can legally sell drugs online. When uncertified individuals sell prescription drugs online, it is illegal. The primary responsibility lies with the pharmacist to dispense prescriptions based on their professional expertise, ensuring they meet consumer safety standards.

To protect the public from dangerous or illegal pharmaceutical products, the Indonesian Minister of Health collaborates with the Food and Drug Administration (BPOM). Established by

Presidential Decree No. 166/2000, BPOM operates the Food and Drug Monitoring System (SISPOM) to detect, anticipate, and monitor pharmaceutical products, ensuring consumer safety. SISPOM includes producer, consumer, and government surveillance, emphasizing good manufacturing practices, consumer education, and effective supervision. BPOM, alongside the Ministry of Health and Health Office, also educates the public on purchasing pharmaceutical products online to enhance awareness and compliance with prescription drug regulations.

Update of Pharmaceutical Professional Law on Telepharmacy

Telepharmacy represents a significant advancement in pharmaceutical services by using information and communication technology to provide remote pharmaceutical care. Existing regulations, such as Government Regulation No. 51/2009 on Pharmaceutical Work, primarily focus on conventional, in-person services. Technological advancements necessitate an update to these regulations to encompass telepharmacy practices.

Government Regulation No. 51/2009 governs the procurement, production, distribution, and service of pharmaceutical preparations. Its objectives include patient protection, service quality, and legal certainty. The regulation also addresses implementation, personnel discipline, and supervision of pharmaceutical work, including mechanisms for enforcing discipline through warnings, administrative sanctions, and revocation of licenses.

Pharmacists are responsible for dispensing prescriptions and are liable for losses resulting from the sale of hard drugs without a prescription. Article 24 mandates that hard drugs, narcotics, and psychotropic substances be dispensed only with a doctor's prescription. Consumers have the right to seek legal action against online pharmacies or marketplaces for losses due to non-compliance with these requirements. To maintain uniformity in pharmaceutical practices, various Ministry of Health regulations outline service standards across different health facilities. These regulations emphasize a balance between product-oriented and patient-oriented services, requiring pharmacists to prioritize rational treatment and prevent medication errors to ensure patient safety. The rapid development of technology has increased the need for efficient, accessible pharmaceutical services. However, the current regulations under Government Regulation No. 51 Year 2009 do not address telepharmacy adequately. An update is necessary to cover the technological aspects of pharmaceutical services.

Telepharmacy services require pharmacists to play a crucial role in remote consultations and drug orders. The evolution of telepharmacy highlights the need for pharmacists to adapt to new technology and provide quality remote services. Existing regulations do not yet specify standards or qualifications for telepharmacy, which is crucial for ensuring service quality. The update of regulations should include specific qualifications and training requirements for pharmacists involved in telepharmacy, addressing the risks of medication errors and inadequate consultations. Standards should ensure that telepharmacy services meet safety and effectiveness criteria, including proper prescription verification and patient education.

Data protection is vital in telepharmacy, given the increased risk of data breaches with technology use. Service standards must include strict regulations on protecting personal and medical data, including encryption, restricted access, and secure storage procedures. These measures will enhance service quality and patient trust in telepharmacy. Regulations should incorporate mechanisms for ongoing evaluation and monitoring to ensure that telepharmacy services meet established standards. Regular reporting, auditing, and adherence to service standards will build public confidence in telepharmacy and enhance the reputation of compliant service providers.

Lastly, updating Government Regulation No. 51/2009 and related regulations to explicitly include telepharmacy will provide a clear framework for its practice. This should involve defining telepharmacy, setting service standards, and establishing an integrated national

platform for secure and efficient telepharmacy services, including comprehensive data protection and continuous monitoring.

CONCLUSION

Legal responsibility in telepharmacy in Indonesia, according to Government Regulation Number 71 of 2019 concerning Electronic System Operators; Government Regulation Number 5 of 2021 concerning the Implementation of Risk-Based Business Licensing; Minister of Health Regulation Number 14 of 2021 concerning Business Activity and Product Standards for Risk-Based Business Licensing in the Health Sector; Minister of Health Decree Number HK.01.07/MENKES/4829/2021 on Guidelines for Health Services Through Telemedicine During the 2019 Corona Virus Disease (COVID-19) Pandemic; and BPOM Regulation Number 8 of 2020 on the Supervision of Drugs and Food Circulated Online. Telepharmacy involves various parties including pharmacists, pharmacies, and pharmaceutical electronic system operators (PSEF). Telepharmacy must meet pharmaceutical service standards, ensure data security and confidentiality, and collaborate with conventional pharmacies for drug provision. Compliance with strict regulations from the Ministry of Health, BPOM, and other regulations ensures that all parties involved, including service providers, pharmacies, consumers, and third parties, understand and fulfill their legal responsibilities. Violations of these provisions may result in sanctions stipulated by law, highlighting the importance of understanding and fulfilling legal responsibilities to maintain the integrity and security of telepharmacy services.

Regulations on the pharmaceutical profession need to be updated to accommodate technological developments and the needs of the community. Currently, the regulation still focuses on conventional direct services. Updates should include specialised service standards, electronic reporting systems, data protection, pharmacist training, continuous monitoring, and integration with the national health information system. Appropriate regulations will ensure telepharmacy improves access and quality of pharmaceutical services in Indonesia while maintaining quality and safety.

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