



Indonesia Facing Challenges of Pharmaceutical Care Implementation in Community Pharmacies: A Legal Perspective

I Gusti Ayu Rai Widowati¹, and Mohammad Zamroni^{2*}

1. Faculty of Health Sciences, Universitas Bali Internasional, Denpasar-Bali, Indonesia.

2. Faculty of Law, Universitas Hang Tuah, Surabaya-East Java, Indonesia.

*email: zamroni@hangtuah.ac.id

Published: 30/09/2023

How to cite (in APA style):

Widowati, I, G, A, R., Zamroni, M. (2023). Indonesia Facing Challenges of Pharmaceutical Care Implementation in Community Pharmacies: A Legal Perspective. *Jurnal Hukum Prasada*, 10(2), 69-79. doi: <https://doi.org/10.22225/jhp.10.2.2023.69-79>

Abstract

Pharmaceutical Care (PC) is a kind of interactive comprehensive service offered by the pharmacist to the patient, in which the pharmacist's physical presence is expected when providing pharmaceutical services to the patients at the pharmacy. However, pharmacists still prioritized internal management over interacting directly with patients. The objective of this research is to glance at the legal challenges of PC implementation in Indonesian community pharmacies. The normative juridical research method has been used, with a conceptual and legal approach. PC implementation in community pharmacies experiences major-level, mid-level, and minor-level challenges. PC standards in pharmacies are legally stated in Regulation of the Minister of Health of the Republic of Indonesia No. 73 of 2016, but there are still conflicts between pharmaceutical management and PC implementation. In the incident of a medication error, the pharmacist as the person responsible for PC in the pharmacy, is legally responsible. Pharmacists who do not meet PC standards in community pharmacies encounter administrative, civil, and criminal consequences.

Keywords: community pharmacy; health law; legal aspect; pharmaceutical care

I. INTRODUCTION

Since the concept of Pharmaceutical Care (PC) was introduced in the United States decades ago, it has evolved into the dominant form of practice for thousands of pharmacists worldwide. Because the pharmacist is also responsible for monitoring the patient's therapy, PC is currently known as the Pharmacist's compromise to provide optimal advantage to the patient's pharmacology. (Berenguer et al., 2004) As a consequence of the new paradigm from drug-oriented to patient-oriented, clinical training needs must be expanded. This paradigm shift is gradual but sure, commencing with a shift in the philosophical concept of pharmacy in community pharmacies from commodity-based to clinical service. (Hali Zerrin Toklu & Hussain, 2013)

There has been substantial discussion about the definition of PC since its outset. Pharmaceutical Care is the direct and responsible administration of pharmaceutical preparations to patients with the goal of achieving tangible results that improve the patient's quality of life. Pharmaceutical Care involves more than just administering medications; it also includes providing information to support appropriate and rational drug use, monitoring drug use, avoiding medication errors, and resolving drug-related problems caused by patient therapy. (Galt, 2000)

In Southeast Asia, there is a broad range of PC understanding and implementation, partly due to the distinctions in pharmaceutical policies and healthcare systems among countries. For historical reasons, the structure of Malaysian and Singaporean health systems is more similar to the British model of healthcare, whereas the structure of Indonesian health systems is more similar to the Dutch model. (Wen et al., 2019). This distinction is represented in the pharmacist's PC role. Pharmaceutical services in Malaysia have evolved from simply focusing on drug supply to focusing on quality drug use, with many community pharmacies now giving chronic disease management, medication review, quitting smoking services, and weight management initiatives. (Karuppanan et al., 2019; Lee & Mak, 2017) Over the last decade, Thailand has made significant progress in clinical pharmacy practice, community pharmacists in Thailand also provide innovative services such as health assessments, health promotion, drug use reviews, and developing strategies to create a corporate identity. Retail pharmacy owners in Thailand are also empowering community pharmacists to gain practical work experience to acquire wisdom, experience, and skills that will give customers trust in the dependability of their services. (Thavorn et al., 2021) Since 2005, private pharmacies in Cambodia have collaborated with the National Tuberculosis Program to refer indicative tuberculosis (TB) patients to public TB clinics for diagnosis and treatment. (Bell et al., 2016)

Even though clinical pharmacy and PC are indeed relatively new in Indonesia, awareness, and acceptance by healthcare providers are inconsistent. Pharmacists are now utilized by some hospitals to provide clinical services onwards, monitor medications, and provide counseling services. Since Indonesia is a highly populated and geographically multicultural country, it will presumably take years to implement the full spectrum of clinical pharmacy services. (Hermansyah & Kristina, 2020)

As stated in Article 1 paragraph (4), Government Regulation Number 51 of 2009 concerning Pharmaceutical Work is a reference point used as a guideline for pharmaceutical personnel in administering PCs in Indonesia: "Pharmaceutical Care is direct and responsible service to patients related to pharmaceutical preparations with the purpose of achieving tangible results to improve patients' quality of life."

Community pharmacists are effortlessly accessible to the general public because they provide prescription drugs and sell drugs without a prescription in compliance with legal regulations. Community pharmacists' areas of expertise include counseling patients about the use of prescription and non-prescription drugs, providing drug information to other health workers, patients, and the general public, and participating in health promotion. In line with global trends, the role of the community pharmacist in primary care has evolved into a clinical and patient-centered service. A community pharmacist service for vulnerable patients has been developed. This service necessarily requires more knowledge and clinical skills on the part of community pharmacists, including drug reviews that aim to enhance medication adherence and rational drug use by patients. (Hermansyah et al., 2016; Widowati et al., 2022)

Community pharmacist involvement is raising in both developed and developing countries. Improvements to PC drug therapy management services compensate for cognitive services rather than just drug products. This makes it possible for pharmacists to put more emphasis on direct interactions with patients. (Hermansyah et al., 2016) However, it has been reported that some workflow barriers include a lack of time to engage with patients have affected the completion of this service. (Hermansyah et al., 2012) This research focused more on the current challenges of implementing PCs and their future solutions.

II. METHOD

This research is discussed and analyzed using normative legal research methods. This research applies a conceptual and statutory approach, along with primary, secondary, and tertiary materials. Primary materials include authoritative legal materials such as laws and regulations. Secondary materials are extracted from literature studies that are relevant to the problem and are sourced from books, literature, articles, and papers in legal circles. Tertiary material is intended to supplement this paper. This study also captures empirical

data by interviewing policymakers in the pharmaceutical industry. The findings of this research are described in a descriptive analysis of legal research.

III. DISCUSSION

Challenges of Pharmaceutical Care Implementation in Community Pharmacy

Several concerns that inhibit PC sustainability in Indonesia should be acknowledged in the future. The authors classify these challenges as macro-level, mid-level, and micro-level.

Macro-level challenges

Several macro-level issues are dictated by legal, regulatory, and economic barriers to PCs as part of the healthcare system. In Indonesia, health system constraints include a lack of recognition and strong support from health authorities, a lack of funds to support the continuity of pharmacies, and a lack of investment in the pharmaceutical sector, which has resulted in several cases of shortage of pharmacists, as well as the need for transformation of pharmaceutical staff as the start of PC reform. (Anggriani et al., 2020; Meilianti et al., 2021)

The pharmacist job, like many others, is getting more complex and intricate. The Indonesian Pharmacist Association wished pharmacists to be more engaged in patient care. Pharmacists are trained in the education program to evaluate drug interactions, side effects, and adverse reactions. Moreover, computer technology can be introduced and used as an assistance in retail practice, with programs having direct access to records of all medications used by patients. Potential side effects of therapy and drug interactions, emphasizing the existence of legal responsibilities following the pharmacist profession's responsibilities.

The Ministry of Health (MoH) regulates community pharmacy practice in Indonesia at the national level, with District Health Offices acting as an extension of the MoH at the provincial level. Based on MoH Regulation No. 73 of 2016 concerning Pharmaceutical Service Standards in Pharmacies, pharmacists must acknowledge and be aware of the risks of medication errors during the service process, as well as identify, prevent, and overcome drug, pharmaco-economic, and socio-pharmaco-economic problems. Pharmacists must comply with service standards to avoid this. Pharmacists must be able to communicate with other health professionals when determining therapy to support rational drug use. Pharmacists must also monitor the use of ships and evaluate and document all of their findings.

Previous study has revealed that there is a legitimate policy framework for regulating and enforcing the practice of community pharmacists, particularly through pharmaceutical practice laws and regulations, that defines a core domain of pharmacy practice that is specific and unique to pharmacists. Other regulations reinforce a set of competencies that community pharmacists must master, as underlined in the Indonesian Pharmacist Competency Standards. (Hermansyah et al., 2018)

Mid-level challenges

Mid-level challenges include PC cultural and organizational barriers, as well as determining not only the level but also the quality of community pharmacy services. The community pharmacy performs in a fast-paced setting. To remain competitive, they must be able to adapt to service implementation. However, the community pharmacy's traditional culture, which primarily focuses on drug delivery, has left community pharmacies unprepared and unable to, for example, adopt and adapt to new technologies.

Previous study has highlighted the high level of patient expectation provides an opportunity for pharmacists at both primary and secondary care health facilities to continue developing pharmaceutical care services. Improving drug information services, patient counseling, and reducing patient wait times can all help to increase patient satisfaction in pharmaceutical care services. (Larasanty et al., 2019)

Given the accessibility of community pharmacy settings and the readiness of the profession to provide care that is more inclusive of chronic disease patients, Indonesian community pharmacists may be advised to adopt a PC model for chronic diseases. Patients' unique sociocultural health beliefs, preferences for alternative medicine, and family/social peer involvement, as well as stronger collaboration between pharmacists and physicians, should all be considered in such a PC model. (Setiawan et al., 2019)

Pharmaceutical Care Standards in community pharmacies have been set by the MoH No. 73 of 2016. This standard is intended to act as a basic guideline in the administration of pharmaceutical services; it outlines the minimum level of service that pharmacists must consistently offer in each setting. In this standard, pharmacists are encouraged to provide two types of services: (1) pharmaceutical supply and management, and (2) clinical pharmacy services. Even though application varies by location, these standards have established the basis for any pharmacist-related activity.

Micro level challenges

The micro-level challenges include pharmacists' capacity. Community pharmacists tend to work in storage facilities within the pharmacies. Problems arise when interprofessional collaboration, requires communication and teamwork. In addition to a lack of transdisciplinary skills, pharmacists lack sufficient knowledge in specific topics as well as self-confidence, limiting the range of services available to patients. As a result, in the pharmaceutical field, a competency-based approach is required, with a competency framework to assess performance, define knowledge gaps, and adjust learning activities to facilitate pharmacist performance improvement. (Udoh et al., 2021) The uneven distribution of pharmacists, as well as both intrinsic and extrinsic barriers such as negative perceptions from other health workers and limited trust among pharmacists to provide new services, are also all barriers to further implementation. (Wen et al., 2019)

Competence is a physical or intellectual ability, skill, or both; it is the performance capacity to do as well as known; it is carried out under standard conditions; it is rated as "adequate", "appropriate", "decent", "suitable" or "qualified" by some level or performance standard; it can be upgraded; it refers to the underlying complex capabilities; and it must be observed in real-life situations. (Saseen et al., 2017)

Under the Health Act No. 36 of 2009 (Article 108 point 1): "Pharmaceutical practice includes the manufacture, including quality control, of pharmaceutical preparations, assurance, logistics, storage, and distribution of drugs, drug utilities on a doctor's prescription, drug information services, and improvement medicines, medicinal ingredients, and traditional medicines."

Pharmacists are health care workers with expertise and authority, according to Government Regulation Number 51 of 2009 (Article 1 point 3). Pharmacists must be capable of carrying out work based on their knowledge, skills, and work attitude. As stated in MoH Regulation No. 889/Menkes/Per/V/2011 concerning Registration, Practice Permits and Work Permits for Pharmaceutical Workers (Article 1 point 5), pharmacists must possess a certificate of professional competence, which is a letter acknowledging a pharmacist's competency to carry out work/professional practice throughout Indonesia after passing the competency test.

Pharmacist competencies are described as follows.

Ensure that pharmacists have all the required qualifications to perform their duties and can provide pharmaceutical services in accordance with the guidelines of pharmaceutical practice.

Contribute to the advancement of pharmaceutical education by determining learning outcomes, developing curricula, and evaluating learning outcomes (on-the-job training);

Continuously improve self-competence.

There has been a paradigm shift in patient-centered pharmacy practice over the last decade. Pharmacists must be competent and committed to providing a full range of pharmaceutical services as well as meeting the challenges of global health and patient care

to fulfill their expanded scope. The Indonesian Pharmacist Competency Standards established by the Indonesian Pharmacist Association are prerequisites for entering the workforce and engaging in professional practice. The Indonesian Pharmacist Competency Standards is made up of 10 (ten) competency standards, which are as follows:

- Professional and ethical pharmaceutical practice;
- Optimizing the use of pharmaceutical preparations;
- Issuance of pharmaceutical preparations and medical devices;
- Provision of information on pharmaceutical preparations and medical devices;
- Formulation and production of pharmaceutical preparations;
- Public health preventive and awareness-raising efforts;
- Management of pharmaceutical preparations and medical devices;
- Effective communication
- Improve organizational skills and interpersonal relationships; and
- Increase self-competence.

Risk Management Challenge

Understand the risks of medication errors

Risk management is a crucial facet of the pharmacist's job. Traditional pharmaceutical practices have succeeded in reducing drug costs to control risks, but have not resolved problems associated with medication use. The rapid development of pharmaceutical technology that produces new drugs requires attention to the risks that patients may encounter. Better involvement of community pharmacists in medication risk management necessitates convincing and a clear mandate to resolve therapeutic risks. (Kallio et al., 2020)

Based on the 1999 IOM (Institute of Medicine) report, at least 44,000, if not 98,000, patients died in hospitals in one year as a result of medication errors that could have been avoided. This number outnumbers deaths from traffic accidents, breast cancer, and AIDS combined. According to Bates' research (Bates et al., 1995), the ordering stage has the highest rating for medication errors (49%), followed by administration management (26%), pharmacy management (14%), and transcribing (11%).

According to an analysis of risk events in the pharmaceutical services process, adverse drug events, medication errors, and adverse drug reactions are the first order of groups in patient safety that require a systems approach to manage, given the complexity of the relationship between "errors are humane" (to err is human). and a highly complex pharmacotherapeutic procedure. Complex multifactor and multi professions; types of medical services, the number of types and quantities of drugs per patient, environmental factors, workload, employee competence, leadership, and so on are all factors that influence the risk of these drugs. There is currently a lack of publicly available information on how community pharmacies manage medication errors and what strategies are implemented to reduce medication errors, which is due in part to community pharmacy corporate policy. Community pharmacies may be able to take a more significant role in reducing medication errors if they improve transparency in their quality assurance strategies and commit to engaging patients in their efforts to improve patient safety. (Hong et al., 2019)

Drug safety practices in Indonesia face a variety of pharmacovigilance challenges, including adverse drug reactions and their reporting, medication errors, self-medication, and other security concerns. Improving the drug safety system and covering all drug safety activities; education in terms of continuing professional development and programs; drug safety research; awareness programs for health care professionals and the general public; regulations and guidelines; and international cooperation are all highly recommended to improve drug safety practices in Indonesia.

Drug dispensing can be done at pharmacies in pharmaceutical services. Pharmacists

sell over-the-counter (OTC) medications and dispense prescription medications. According to Regulation of the MoH No. 73 of 2016 (Article 1 point 4): "A prescription is a written request from a doctor or dentist, both in paper and electronic form, to a pharmacist to provide and deliver drugs to patients by applicable regulations."

Drug dispensing is shifting from a product-oriented to a patient-oriented model. Pharmacists used to rush out OTC medications or prescriptions to patients in an unstructured delivery of information. However, since the introduction of clinical pharmacy and the PC concept, pharmacists have been required to provide good pharmaceutical care services to patients when dispensing drugs. In Indonesia, dispensing practices are still product-oriented rather than patient-centered, which has an impact on the outcome of patient treatment. The patient must receive appropriate drug counseling for the benefits of the treatment to be fully utilized. Previous research has found that pharmacists have not developed their skills in the proper use of drugs, raising the possibility of dispensing drugs without or with inaccurate counseling. This is also correct not only in Indonesia but in most drug dispensing in developing countries, where it is inconsistent with pharmacists' new role. As a result, medication errors are conceivable.

Patient safety

Article 1 of the MoH Regulation No. 11 of 2017 concerning Patient Safety states: "Patient safety is a system that makes patient care safer, including risk assessment, identification and management of patient risks, incident reporting and analysis, the ability to learn from incidents and follow-up, and the ability to implement solutions to minimize risks and prevent injuries caused by errors."

Understanding patient safety allows pharmacists to identify areas of strength in their work unit as well as areas that need improvement. Improvement efforts that target flaws, such as staff shortages or high work pressure, will benefit pharmacists and their patients. This has significant implications for pharmacists' professional practice in carrying out their responsibilities in treating patients with complex drug regimens (polypharmacy) with chronic conditions, where medication errors are common. And this, as mentioned in paragraph (4) letter d, necessitates patient safety education for pharmacy staff, as well as letter g, where communication is critical for officers to achieve patient safety.

This is endorsed by the Consumer Protection Act No. 8 of 1999 (Article 2), which states that efforts to protect consumers are carried out by several relevant consumer protection principles. The five principles mentioned are the principles of benefit, fairness, balance, consumer security and safety, and legal certainty. Based on the Consumer Protection Act (Article 4), the patient's right as a consumer is a right to comfort, security, and safety when consuming goods and/or services, in this case, safety in pharmacies' PCs.

Strategies to Face Current Challenges

Implementing Good Pharmacy Practice

Good Pharmacy Practice (GPP) is a standard that ensures pharmacists provide PCs to increase job satisfaction. Based on MoH Regulation No. 73 of 2016 (Article 4 point 1), the implementation of PC standards in pharmacies must be accompanied by the availability of patient safety-oriented pharmaceutical resources. Human resources and facilities/infrastructure are essential pharmaceutical resources.

The pharmacy profession is rapidly expanding, with new roles being created in collaboration with other healthcare professionals, national and international organizations, and institutions. The GPP Guidelines are forward-thinking and adaptable, and they should continue to be relevant as new roles emerge. Standardizing various aspects of the pharmacy is one of the most important ways to ensure the quality of drugs and pharmaceutical services for the general public. GPP guidelines are a critical step toward improving pharmacy services.

The World Health Organization (WHO) and the Federation of International Pharmacists (FIP) emphasize that the GPP guidelines are intended for use by national professional pharmaceutical associations, as well as national authorities and other relevant

bodies in charge of drafting relevant documents, laws, and regulations in their respective countries. It is not a national standard in and of itself, but rather guides the specific roles, functions, and activities that can be accomplished while carrying out the mission of practicing pharmacy in the current century.

The utilization of GPP is a method of implementing the pharmacist's professional practice philosophy, which aims to protect the public from unprofessional pharmaceutical services. GPP in Indonesia has been updated several times to reflect changes in legal requirements in the community pharmacy setting. The MoH Regulation No. 73 of 2017 on GPP in community pharmacies is divided into two parts: pharmacy management standards and clinical services. This regulation is a government policy designed to help Indonesia implement GPP.

Not all pharmacists are practiced by the GPP. According to research, pharmacists are already aware of and have GPP documents in their pharmacies, but this is not being implemented. This is due to a lack of ability in clinical service science and management, necessitating the use of training materials. GPP necessitates a pharmacist who is both time and ability dominant. Continuing education and training are also required, including through seminars, socialization, and pharmacy practice supervision, which may involve collaboration with professional organizations and pharmaceutical colleges.

Pharmacists must refer to MoH Regulation No. 73 of 2016 when performing PC in pharmacies, which lists various activities such as managing pharmaceutical preparations, medical devices, consumable medical materials, and clinical pharmacy services that must be performed and are the responsibility of a pharmacist. However, several aspects of pharmaceutical services that have not been addressed in the pharmaceutical service standards still require clarification. Furthermore, MoH Regulation No. 73 of 2016 mandates the compilation of Technical Guidelines for Pharmacy Service Standards in Pharmacies, which are expected to become guidelines for pharmacists in pharmacies in carrying out pharmaceutical services by standards.

This technical guideline discusses pharmaceutical services such as drug management and clinical pharmacy services, as well as their objectives, benefits, parties involved, required facilities and infrastructure, stages of implementation, and evaluation. These technical instructions are also used as guidelines and references in pharmacies to implement pharmaceutical services by standard operating procedures (SOP). The technical instructions state that the scope includes a series of managerial management of pharmaceutical preparations beginning with requirement planning, procurement, receiving, storage, distribution, destruction and withdrawal, control, and administration. Similarly, the technical instructions include several clinical pharmacy services such as assessment and prescribing, dispensing, drug information, home pharmacy care, drug therapy problems, and monitoring of drug side effects.

With the publication of this technical guideline as a guideline for the implementation of MoH Regulation No. 73 of 2016, pharmacists have 2 (two) main roles, namely as the manager of the pharmacy and as a clinical service provider in their professional service. Given the complexity of managerial management performance, pharmacists will find it difficult to interact directly with patients. The Chairperson of the Supervisory Board of the Indonesian Pharmacists Association for the Bali Regional Management also stated that with the condition of pharmacies with high performance (such as pharmacies in primary/middle/primary clinics, pharmacies with doctor practices, pharmacies open 24 hours, and pharmacies with a high turnover), should be accompanied by a pharmacist when performing clinical services. Government Regulations No. 51 of 2009 Article 20, states that pharmacists can be assisted by companion pharmacists when performing pharmaceutical work at pharmaceutical service facilities.

Clinical responsibilities of pharmacists

Clinical pharmacy services are direct services provided by pharmacists to patients to improve therapeutic outcomes and minimize the risk of side effects due to drugs, for patient safety (patient safety), so that quality patient's quality of life is assured, based on the

Technical Guidelines for Pharmaceutical Service Standards in Pharmacies issued by the MoH. Assessment and prescription services, dispensing, drug information services, counseling, home pharmacy care, monitoring of drug therapy, and monitoring of drug side effects.

Pharmacists must establish a network with pharmacies and other healthcare facilities in their community to facilitate communication and collaboration in the delivery of prescription services. To provide clinical pharmacy services to patients effectively, efficiently, and on time, it is necessary to prioritize patients for clinical pharmacy services, particularly counseling, PIO, home pharmacy care, or PTO activities. Pediatric patients, geriatric patients, polypharmacy patients, patients receiving drugs with a narrow therapeutic index, chronic disease patients, and chemotherapy patients must be prioritized for clinical pharmacy services.

The presence of pharmacists in clinical services is important in serving patients through education and achieving adherence to therapy. However, due to work conflicts between managerial and clinical services, this role is frequently overlooked or even ignored. Several studies have found that clinical services delivered by pharmacists can improve medication adherence. Pharmacists practice their profession by the mandate of MoH Regulation No. 73 of 2016. As a result, pharmacists are expected to provide drug services to patients, particularly prescription services.

Pharmacists are in a strategic position to reduce medication errors, both in their interactions with other health professionals and during the treatment process. Increasing reporting, providing drug information to patients and other health workers, increasing the continuity of patient treatment regimens, and improving the quality and safety of patient treatment at home are all possible contributions.

Pharmacist's legal relationship with patients

According to Article 1 of MoH Regulation No. 11 of 2017: "Patient safety is an approach that makes patient care safer, including risk assessment, identification and management of patient risks, incident reporting and analysis, the ability to learn from incidents and their follow-up, as well as implementing solutions to minimize risks and prevent injuries caused by incorrectly performing ad hoc procedures." Therefore, any unintended incidents and conditions that resulted in or have the potential to cause harm to the patient must be preventable.

Risk management is an important aspect of the pharmacist's job. Traditional pharmaceutical practices have succeeded in lowering drug costs to control risks, but have not resolved problems associated with drug use. Medicines are critical to public health. However, as the population ages, medication use has increased significantly, as have medication errors, which are emerging as a growing risk for global health care. The rapid development of pharmaceutical technology, which produces new drugs, necessitates consideration of potential patient risks. (Kallio et al., 2020)

If a medication error occurs, such as a dispensing error caused by negligence, the pharmacist is said to have violated Article 9 of the Pharmacist Code of Ethics, which can harm the patient. Medication errors caused by dispensing that occur in cases of medication errors that are not by the prescription violate the provisions of Article 8 paragraph (1) letters b, c, d, and e of Consumer Protection Act No. 8 of 1999. Then, as a result of medication errors caused by the administration, particularly when a patient is not informed about other effects or side effects of the drug being consumed, a pharmacist is said to have violated the prohibitions stipulated in Article 8 paragraph (1) letter that business actors are prohibited from trading goods and/or services that do not meet or comply with the standards required and the provisions of laws and regulations. In general, if a medication error occurs, the pharmacist at their service has failed to meet the requirements outlined in MoH Regulation No. 73 of 2016.

According to Article 58, paragraph (1) of The Health Act, "Everyone has the right to seek compensation from a person, health worker, or health provider who causes harm as a result of errors or negligence in the health services they receive."

Possible solutions include:

Negotiated settlement of problems, such as changing medications and returning cash spent on medications. Face-to-face meetings between the pharmacist and the patient can help to resolve disputes sooner. Negotiation takes place when the pharmacist meets with the patient and comes to an agreement.

Errors in administrative matters when drugs are administered to patients. Patients can contact the pharmacist to get the correct information about the medications they are taking.

Sanctions for PC standards infractions in pharmacies

Pharmacists must follow professional standards, professional discipline regulations, and the pharmacist code of ethics when performing their duties. Before serving, a pharmacist must take an oath and obtain a work permit based on the regulations in force in Indonesia.

Administrative Sanctions

If the pharmacist commits negligence and allows the responsibility for pharmaceutical services to be carried out unprofessionally, causing dissatisfaction or loss to the consumer, then the first thing to do is mediation.

Based on MoH Regulation No.73 of 2016 Article 12 paragraph (1) states that infractions of the provisions may be subject to administrative sanctions, in the form of written warnings, temporary suspension of activities, and/or revocation of permits.

Civil Sanctions

Based on Article 1365 of the Civil Code, both intentional culpability and negligence have the same legal consequences, namely that the perpetrator remains responsible for compensating for all losses resulting from the unlawful act he committed.

Criminal sanctions

Criminal liability (*toereken-baarheid*) is the obligation of individuals or corporations to bear the consequences for their actions because they have committed a detrimental crime. In the case of a violation of the medical service contract, the offended party may file a default action in court. If it is proven that the patient committed default and caused harm to the doctor, for example, by neglecting to compensate the doctor for the service offered, the patient can be sued by the court for compensation. Similarly, if a doctor breaches the contract, causing harm to the patient (for example, by failing to provide medical services to the patient's medical needs), the doctor may be sued in court for damages. Naturally, the plaintiff must establish the existence of the defendant's default. (Zamroni, 2021)

The same applies to pharmacists and patients in correlation with the lawsuit for medication errors and negligence perpetrated by the pharmacist, the patient must submit proof to back up his claim. Errors and omissions from the aspect of criminal law only arise if the health services performed result in or cause the patient to die or suffer from a disability. If this happens, the sanction is not only compensation in the form of material but can be in the form of body confinement as stipulated in the provisions of Article 359 and Article 360 of the Criminal Code, which can be punished with imprisonment for a maximum of 5 (five) years or light imprisonment for a maximum of 1 (one) year.

IV. CONCLUSION

In terms of legal aspects, Pharmaceutical Care in Indonesia was stated in MoH Regulation No. 73 of 2016, but there are still conflicts between the implementation of pharmacy managerial and clinical pharmacy services, so their implementation has not been optimal. As the person in charge of pharmaceutical services at the pharmacy, the pharmacist is legally responsible and can encounter administrative sanctions if PC standards are not met due to ignorance, negligence, or a lack of attention. Administrative, civil, and criminal sanctions are all conceivable.

REFERENCES

- Anggriani, Y., Ramadaniati, H. U., Sarnianto, P., & Pontoan, J. (2020). The impact of pharmaceutical policies on medicine procurement pricing in Indonesia under the implementation of Indonesia's Social Health Insurance System. *Value in Health Regional Issues*, 21, 1–8. <https://doi.org/10.1016/j.vhri.2019.05.005>
- Bates, D. W., Cullen, D. J., Laird, N., Petersen, L. A., Small, S. D., Servi, D., Laffel, G., Sweitzer, B. J., Shea, B. F., Hallisey, R., Vliet, M. Vander, Nameskal, R., & Lepae, L. L. (1995). Incidence of adverse drug events and potential adverse drug events. *JAMA*, 274(1), 29–34.
- Bell, C. A., Pichenda, K., Ilomaki, J., Duncan, G. J., Eang, M. T., & Saini, B. (2016). Responding to cough presentations: an interview study with Cambodian pharmacies participating in a National Tuberculosis Referral Program. *Journal of Evaluation in Clinical Practice*, 22(2), 261–266. <https://doi.org/10.1111/jep.12467>
- Berenguer, B., C, L. C., M.J., de la M., & M.J., M.-C. (2004). Pharmaceutical Care: Past , Present and Future. *Current Pharmaceutical Design*, 10, 3931–3946.
- Galt, K. A. (2000). *The need to define “Care” in Pharmaceutical Care: An Examination Across Research, Practice and Education*. 64, 223–233.
- Hali Zerrin Toklu, & Hussain, A. (2013). The changing face of pharmacy practice and the need for a new model of pharmacy education. *Journal of Young Pharmacists*, 5(2), 38–40. <https://doi.org/10.1016/j.jyp.2012.09.001>
- Hermansyah, A., & Kristina, S. A. (2020). Primary health care policy and vision for community pharmacy and pharmacists in Indonesia. *Pgharmacy Practice*, 18(3), 1–12.
- Hermansyah, A., Sainsbury, E., & Krass, I. (2016). Community pharmacy and emerging public health initiatives in developing Southeast Asian countries: a systematic review. *Health Soc Care Community*, 24(5), e11–e22. <https://doi.org/10.1111/hsc.12289>
- Hermansyah, A., Sainsbury, E., & Krass, I. (2018). Multiple policy approaches in improving community pharmacy practice: the case in Indonesia. *BMC Health Services Research*, 18(449), 1–14.
- Hermansyah, A., Sukorini, A. I., Setiawan, C. D., & Priyandani, Y. (2012). The conflicts between professional and non-professional work of community pharmacists in Indonesia. *Pharma Pract (Granada)*, 10(1), 33–39. <https://doi.org/10.4321/s1886-36552012000100006>
- Hong, K., Hong, Y. D., & Cooke, C. E. (2019). Medication errors in community pharmacies: The need for commitment, transparency, and research. *Research in Social & Administrative Pharmacy*, 15(7), 823–826. <https://doi.org/10.1016/j.sapharm.2018.11.014>
- Kallio, S., Eskola, T., Pohjanoksa-mäntylä, M., & Airaksinen, M. (2020). Medication risk management in routine dispensing in community pharmacies. *International Journal of Environment Research and Public Health*, 17(21), p.8186.
- Karuppannan, M., Thana, L. S. M. S., & Gnanasan, S. (2019). Malaysian pharmacists ' involvement in Pharmaceutical Care: A narrative review. *Archives of Pharmacy & Pharmacology Research*, 2(1), 1–9. <https://doi.org/10.33552/APPR.2019.01.000528>
- Larasanty, L. P. F., Cahyadi, M. F., Sudarni, N. M. R., & Wirasuta, I. M. A. G. (2019). Patient satisfaction with pharmaceutical care services provided at primary-level and secondary-level health facilities in Indonesia's health coverage system. *Journal of Health Reserach*, 33(1), 80–88. <https://doi.org/10.1108/JHR-06-2018-0033>
- Lee, S. W. H., & Mak, V. S. L. (2017). Train- the- trainer program on cardiovascular health for community pharmacists in Malaysia. *International Journal of Clinical Pharmacy*, 39(6), 1166–1170. <https://doi.org/10.1007/s11096-017-0540-5>
- Meilianti, S., Smith, F., Ketut, D., Naya, R., & Bates, I. (2021). A country-level national needs assessment of the Indonesian pharmacy workforce. *Research in Social and Administrative Pharmacy*, 17(11), 1989–1996. <https://doi.org/10.1016/j.sapharm.2021.03.003>
- Saseen, J. J., Ripley, T. L., Bondi, D., Burke, J. M., Cohen, L. J., Mcbane, S., Mcconnell, K. J., Sackey, B., Sanoski, C., Simonyan, A., Taylor, J., & Griend, J. P. Vande. (2017). ACCP clinical pharmacist competencies. *Pharmacotherapy*, 37(5), 630–636. <https://doi.org/10.1002/phar.1923>
- Setiawan, C. H., Widayati, A., Virginia, D. M., Armour, C., & Saini, B. (2019). The role of pharmacists in the pharmaceutical care of asthma patients in Yogyakarta , Indonesia: the patients' views. *Journal of Asthma*, 57(9), 1017–1028. <https://doi.org/10.1080/02770903.2019.1622715>
- Thavorn, J., Klongthong, W., Watcharadamrongkun, S., & Chittipa Ngamkroekjoti. (2021). The impact of wisdom and Pharmaceutical Care on the corporate identity of Thai Pharmacy Retail Stores *. *Economics and Business*, 8(1), 317–326. <https://doi.org/10.13106/jafeb.2021.vol8.no1.317>

- Udoh, A. A., Bruno-tomé, A., Ernawati, D. K., & Galbraith, K. (2021). The effectiveness and impact on Performance of pharmacy-related competency development frameworks: A systematic review and meta-analysis. *Research in Social and Administrative Pharmacy*, 17(10), 1685-1696.
- Wen, S., Lee, H., & Bell, J. S. (2019). Pharmaceutical Care in Asia. In *The Pharmacist Guide to Implementing Pharmaceutical Care* (pp. 191–197). Springer International Publishing. <https://doi.org/10.1007/978-3-319-92576-9>
- Widowati, I. G. A. R., Duarsa, D. P., Nyoman, N., Budayanti, S., Diantini, A., & Januraga, P. P. (2022). Modified pharmacy counseling improves outpatient short-term antibiotic compliance in Bali Province. *International Journal of Public Health Sciences*, 11(3), 1102–1111. <https://doi.org/10.11591/ijphs.v11i3.21537>
- Zamroni, M. (2021). Proof of default in medical service contract dispute. *Croatian International Rleation Review*, 27(88), 192–204. <https://doi.org/10.2478/CIRR-2021-0001>
- Undang-Undang Republik Indonesia Nomor 8 Tahun 1999 Tentang Perlindungan Konsumen. Lembaran Negara Republik Indonesia Tahun 1999 Nomor 42. Tambahan Lembaran Negara Republik Indonesia Nomor 3821.
- Undang-Undang Republik Indonesia Nomor 36 Tahun 2009 Tentang Kesehatan. Lembaran Negara Republik Indonesia Tahun 2009 Nomor 144. Tambahan Lembaran Negara Republik Indonesia Nomor 5063.
- Undang-Undang Republik Indonesia Nomor 36 Tahun 2014 Tentang Tenaga Kesehatan. Lembaran Negara Republik Indonesia Tahun 2014 Nomor 298. Tambahan Lembaran Negara Republik Indonesia Nomor 5607.
- Peraturan Pemerintah Republik Indonesia Nomor 72 Tahun 1998 tentang Pengamanan Sediaan Farmasi dan Alat Kesehatan. Lembaran Negara Republik Indonesia Tahun 1998 Nomor 138. Tambahan Lembaran Negara Republik Indonesia Nomor 3781.
- Peraturan Pemerintah Republik Indonesia Nomor 51 Tahun 2009 Tentang Pekerjaan Kefarmasian. Lembaran Negara Republik Indonesia Tahun 2009 Nomor 124. Tambahan Lembaran Negara Republik Indonesia Nomor 5044.
- Peraturan Menteri Kesehatan Republik Indonesia Nomor 919/MENKES/PER/X/1993 Tahun 1993 tentang Kriteria Obat Yang Dapat Diserahkan Tanpa Resep.
- Peraturan Menteri Kesehatan Republik Indonesia Nomor 889/MENKES/PER/V/2011 Tentang Registrasi. Izin Praktik, dan Izin Kerja Tenaga Kefarmasian. Berita Negara Republik Indonesia Tahun 2011 Nomor 322.
- Peraturan Menteri Kesehatan Republik Indonesia Nomor 31 Tahun 2016 Tentang Perubahan Atas Peraturan Menteri Kesehatan Nomor 889/MENKES/PER/V/2011 Tentang Registrasi, Izin Praktik, Dan Izin Kerja Tenaga Kefarmasian. Berita Negara Republik Indonesia Tahun 2016 Nomor 1137.
- Peraturan Menteri Kesehatan Republik Indonesia Nomor 73 Tahun 2016 Tentang Standar Pelayanan Kefarmasian di Apotek. Berita Negara Republik Indonesia Tahun 2017 Nomor 50.
- Peraturan Menteri Kesehatan Republik Indonesia Nomor 11 Tahun 2017 Tentang Keselamatan Pasien. Berita Negara Republik Indonesia Tahun 2017 Nomor 308.