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Legal Feasibility of AI Implementation in Indonesian Pharmaceutical Services

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Abstract

The development of Artificial Intelligence (AI) offers significant potential to improve efficiency, accuracy, and personalization in pharmaceutical services. However, Indonesia lacks a specific legal framework to regulate its application, especially regarding patient protection and professional accountability. This study aims to analyze the compatibility of AI use in pharmaceutical services with principles of health law and consumer protection, and to identify legal gaps concerning liability for AI-induced harm. Using a normative juridical method, the study examines relevant laws and legal literature. The findings show that Indonesia's positive law does not yet regulate informed consent, algorithm validation, or legal responsibility in AI-based pharmaceutical services. This legal vacuum risks undermining patient rights. The study recommends sectoral regulations that address AI validation, independent audits, data protection, and liability frameworks tailored to AI characteristics, ensuring ethical and legally accountable implementation.

Kata Kunci

Artificial Intelligence;
Pelayanan Kefarmasian;
Hukum Kesehatan;
Perlindungan Konsumen;
Tanggung Jawab Hukum

Abstrak

Pengembangan Artificial Intelligence (AI) menawarkan potensi yang signifikan untuk meningkatkan efisiensi, akurasi, dan personalisasi dalam layanan farmasi. Namun, Indonesia tidak memiliki kerangka hukum khusus untuk mengatur penerapannya, terutama mengenai perlindungan pasien dan akuntabilitas profesional. Studi ini bertujuan untuk menganalisis kompatibilitas penggunaan AI dalam layanan farmasi dengan prinsip-prinsip hukum kesehatan dan perlindungan konsumen, dan untuk mengidentifikasi kesenjangan hukum mengenai tanggung jawab atas bahaya yang disebabkan oleh AI. Dengan menggunakan metode yuridis normatif, penelitian ini meneliti hukum dan literatur hukum yang relevan. Temuan tersebut menunjukkan bahwa hukum positif Indonesia belum mengatur *informed consent*, validasi algoritma, atau tanggung jawab hukum dalam layanan farmasi berbasis AI. Kekosongan hukum ini berisiko merusak hak-hak pasien. Studi ini merekomendasikan peraturan sektoral yang membahas validasi AI, audit independen, perlindungan data, dan kerangka kerja tanggung jawab yang disesuaikan dengan karakteristik AI, memastikan implementasi yang etis dan akuntabel secara hukum.

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INTRODUCTION

The use of Artificial Intelligence (AI) in pharmaceutical services in Indonesia has accelerated significantly in line with digital transformation in the health sector. AI is currently used for prescription analysis, therapy monitoring, drug safety, and medical consultation chatbots—a number of studies have shown an increase in the efficiency and accuracy of pharmaceutical services in hospitals and pharmacies[1]. For example, research by Anastasya & Khairinisa (2024) shows that AI is able to improve drug management, interaction prediction, and streamline pharmacy workflows[2]. er, the use of AI also poses legal risks such as patient data leakage, algorithm bias, and ambiguity of legal liability in the event of a service error[3,4]. This phenomenon creates a gap between the potential of technology and the actual legal framework in Indonesia.

The regulatory gap is crucial because although there are already regulations such as Law No. 17/2023 on Health, the ITE Law, and the PDP Law, there are no specific provisions governing AI in pharmaceutical practice. MOCI has issued an AI Code of Ethics Circular Letter (CL 9/2023), but it is still very general and has not touched on specific aspects of health services[5,6] Research in the field of telemedicine also reveals the need for legal certainty over patient data responsibility and technological oversight by stakeholders[7]. This emphasizes the urgency of normative research to answer the what, who, and how of legal responsibility in the application of AI in pharmaceuticals.

Previous studies have shown AI to make a real contribution in pharmacy services, especially improved prescription accuracy and reduced errors[8]. However, most use clinical evaluative or quantitative approaches without in-depth legal analysis. Studies such as Adaptive Behavioral AI by Fernández del Río et al. (2024) underscore the potential of the technology but have not examined the regulations and legal responsibilities that need to be prepared[9]. On the other hand, studies such as Irene & Andersen (2025) use a relevant normative approach, but are limited to the principle of strict liability and have not focused on the pharmaceutical sector[10]. General regulations such as in the JPH journal also show that there are still many shortcomings in the aspects of ethics, data protection, and legal accountability[11]. From a global perspective, MDPI emphasizes the importance of a risk-based approach in pharmaceutical AI, but Indonesia's local

[1] Ermita Ekalia Mita, Ariawan Gunadi, and Muhammad Abdurrohim, "Pengembangan Regulasi Penggunaan Artificial Intelligence Pada Bidang Kesehatan Di Indonesia Pada Aspek Hukum Dan Etika," *Jurnal Ilmu Hukum, Humaniora dan Politik* 5, no. 2 (2024): 1518–1533.

[2] Gracia Anastasya and Miski A. Khairinisa, "The Rise of Artificial Intelligence in Pharmacy: Transforming Medication Management and Patient Care," *Pharmacology and Clinical Pharmacy Research* 9, no. 2 (2024): 142–155.

[3] Farah Bidara and Nadya Putri Auliya Serawaidi, "Literature Review: Peluang Dan Tantangan Penggunaan Keceerdasan Buatan Dalam Meningkatkan Pelayanan Farmasi Klinis," *Jurnal Kesehatan Mahardika* 12, no. 1 (2025): 158–171.

[4] biplawfirm.id, "Artificial Intelligence Dalam Perspektif Hukum: Perkembangan, Regulasi, Dan Aspek Kesehatandi Indonesia," https://biplawfirm.id/artificial-intelligence-dalam-perspektif-hukum-perkembangan-regulasi-dan-aspek-kesehatandi-indonesia/?utm_source=chatgpt.com.

[5] Masinton Pasaribu, "The Application of Artificial Intelligence in the Legislative Process and Judicial System in Indonesia," *Journal of Law and Business (Selisik)* 10, no. 2 (2024): 163–181.

[6] SSEK Law Firm, "Regulation of Artificial Intelligence in Indonesia," *SSEK Law Firm*, last modified February 29, 2024, accessed July 24, 2025, https://ssek.com/blog/indonesia-law-update-regulation-of-artificial-intelligence/?utm_source.

[7] Aulia Anugrah Intani and Fauza Annisa, "Legal Analysis of Artificial Intelligence Technology Development in Healthcare Industry in Indonesia," *South-East Asian Journal of Advanced Law and Governance (SEAJ ALGOV)* 1, no. 1 (2024): 1–19.

[8] Ana Fernández del Río et al., "Adaptive Behavioral AI: Reinforcement Learning to Enhance Pharmacy Services" (2024).

[9] Ibid.

[10] Liana Salwa Irene, Christian Andersen, and Universitas Kristen Maranatha, "The Implementation of the Strict Liability Principle in Legal Liability of Artificial Intelligence in Indonesia ' s Healthcare Sector" 5, no. 6 (2025): 5171–5180.

[11] Ardian Dwi et al., "Legal Arrangement of Artificial Intelligence in Indonesia : Challenges and Opportunities," *Jurnal Peradaban Hukum* 1, no. 2 (2023): 14–29.

regulations are still far from strict[12]. In summary, there are several main research gaps**,** namely, 1). The lack of normative research that focuses on AI in pharmaceutical services. 2). The regulatory gap of the pharmaceutical AI sector in Indonesia's positive law. 3). There has been no in-depth analysis of the legal accountability mechanism from the legal perspective of health legislation, ITE Law and Personal Data Protection Law.

This article is here to fill this gap with: 1). Positive legal analysis (statute approach) on AI-related regulations in the pharmaceutical sector; 2). Comprehensive review of legal liability (civil, criminal, ethical) in the event of AI malpractice; 3). Constructive recommendations for policy makers, regulators, and digital pharma actors. The contribution of this article is significant in several dimensions. Academically, it adds to the legal literature of digital health and opens up a new normative discourse on pharmaceutical AI. Practically, it is a pragmatic regulatory guide for BPOM, the Ministry of Health, and pharmacist associations, as well as legal risk mitigation for health technology service providers. At the community level, this research is expected to increase user trust in AI-based pharmaceutical services, while ensuring that the protection of patients' rights is maintained.

In the context of the rapid development of artificial intelligence (AI) technology in the health sector, including in pharmaceutical services, various legal issues have emerged that have not been explicitly and comprehensively regulated within a positive legal framework in Indonesia. In the midst of the great potential of AI in improving the effectiveness of pharmaceutical services, there are serious challenges related to legal certainty, professional authority, legal responsibility, and consumer/patient protection. The absence of specific legal norms governing the use of AI in pharmaceutical services causes a legal vacuum, regulatory ambiguity, and the risk of maladministration or malpractice that has not been addressed judicially. Therefore, this study is designed to examine and formulate the following main problems:

1. How does the current positive legal arrangement in Indonesia regulate the implementation of artificial intelligence technology in pharmaceutical services?
2. Has the application of AI in pharmaceutical services met the principles of health law and consumer protection in Indonesia?
3. What is the form of legal liability that can be imposed in the event of errors or losses due to the use of AI in pharmaceutical services?
4. What is the urgency of establishing specific regulations regarding the use of AI in pharmaceutical services, and what direction can normative recommendations be offered?

RESEARCH METHODS

This research uses a normative juridical approach, which is a legal research approach that relies on the study of applicable positive legal norms. This approach was chosen because the main focus of the research is to examine the feasibility of implementing artificial intelligence technology in pharmaceutical services based on the legal system in Indonesia, especially to see the extent to which positive law is able to accommodate, regulate, and provide legal certainty for the use of this technology.

The data studied in this study are secondary data, consisting of: Primary legal materials, namely laws and regulations that regulate the fields of health, information technology, and consumer/patient protection, such as: Law Number 17 of 2023 concerning Health, Law Number 11 of 2008 jo. Law No. 19 of 2016 concerning Information and Electronic Transactions (ITE), Law Number 27 of 2022 concerning Personal Data Protection, Law Number 8 of 1999 concerning Consumer Protection, Regulation of the Minister of Health, BPOM, or the relevant Code of Ethics for the Pharmacist Profession. Secondary legal materials, namely legal literature, scientific journals, previous research results, expert opinions, and government

[12] Mita, Ariawan Gunadi, and Muhammad Abdurrohim, "Development of Regulations on the Use of Artificial Intelligence in the Health Sector in Indonesia in Legal and Ethical Aspects."

policy documents or professional organizations that provide an understanding of the concepts of health law, pharmaceuticals, and AI regulations and ethics in public services. Tertiary legal materials, such as legal dictionaries, legal encyclopedias, and other supporting documents to strengthen the interpretation and normative analysis of primary and secondary legal materials[13].

This research was carried out through the stages of legal inventory, legal interpretation, and systematic legal analysis. The data analysis technique is carried out qualitatively, by interpreting relevant laws and regulations and analyzing their coherence with the practice and urgency of applying AI in pharmaceutical services. This study also uses statute approach, conceptual approach, and comparative approach (on a limited basis), to review the legal systems that apply in other countries (e.g. the European Union or Singapore) in regulating AI in the health sector as a reflective and comparative material.

The output of this method is expected to be able to answer legal issues raised in problem formulation, provide constructive juridical recommendations, and contribute to the development of a legal framework that is adaptive to technological innovation in the pharmaceutical service sector.

RESULTS AND DISCUSSION

Positive legal arrangements in Indonesia related to the implementation of AI in pharmaceutical services

An analysis of positive legal arrangements in Indonesia shows that until now there is no sectoral regulation that specifically regulates the implementation of artificial intelligence (AI) technology in pharmaceutical services. Indeed, there are a number of laws that generally touch on technology and information aspects, such as Law Number 17 of 2023 concerning Health which in Article 334 paragraph (2) states that "health technology includes hardware and software," which can implicitly include AI. However, these norms are not enough to provide legal certainty for the practice of using AI that has unique characteristics, such as system autonomy, machine learning algorithms, and potential systemic risks to patient safety[14]. Meanwhile, Law Number 11 of 2008 concerning Electronic Information and Transactions (ITE) and its derivative regulations such as Government Regulation No. 71 of 2019 and Permenkominfo No. 5 of 2020 have regulated the Implementation of Electronic Systems (PSE), which includes aspects of the accountability of technology providers. However, these provisions are too general and do not provide for specific supervision and evaluation of AI used in the pharmaceutical sector, including the need to validate algorithms before they are used in services. The absence of these sectoral norms creates a legal vacuum that can be an obstacle to the safe, ethical, and responsible application of AI in pharmaceutical services. Indonesia's legal system is still reactive and has not been able to anticipate the presence of disruptive technologies such as AI in the pharmaceutical sphere that directly touch public health rights.

Fulfillment of health and consumer protection legal principles by pharmaceutical AI

The findings of the study show that AI has not guaranteed the fulfillment of the principles of precautionary principle, informed consent, and patients' right to drug information in the context of Indonesian health law. The Ministry of Health stated that AI can only be used as a tool, not a substitute for professional decisions, and that the use of patient data requires explicit consent from patients[15]. However, neither the Health Law nor the Consumer Protection Law have included specific provisions on informed

[13] Muhammad Ikhsan and Sabda Wahab, "Kepastian Hukum Tenaga Kefarmasian Dalam Menyelenggarakan Pelayanan Kefarmasian," *Jurnal Hukum Kesehatan Indonesia* 01, no. 02 (2021): 106–120.

[14] Rayga Rayyan et al., "Kepastian Hukum Penggunaan Artificial Intelligence (AI) Dalam Pelayanan Kesehatan Dan Diagnosa Medis Di Indonesia" 2 (2025).

[15] Willa Wahyuni, "AI Di Bidang Kesehatan Mulai Diterapkan, Ini Yang Perlu Diketahui," *Hukum Online*, last modified February 21, 2025, accessed July 25, 2025, https://www.hukumonline.com/berita/a/ai-di-bidang-kesehatan-mulai-diterapkan--ini-yang-perlu-diketahui-lt67b8769b47f28/?utm_source.

consent in the use of AI in pharmaceutical services. In practice, algorithm transparency, explicit patient consent, and education about the risks and benefits of Pharmaceutical AI have not been explicitly regulated, presenting a normative vacuum that can jeopardize patients' rights as consumers of healthcare.

In the context of health law in Indonesia, the *precautionary principle* is one of the important foundations when introducing new technologies—including Artificial Intelligence (AI) systems in pharmaceutical services. This principle emphasizes that technological innovations that have the potential to pose risks to patients' health must be monitored and validated first before being implemented on a wide scale. However, regulatory reality shows that neither Law Number 17 of 2023 concerning Health nor the Regulation of the Minister of Health explicitly regulates AI risk validation procedures in the pharmaceutical sector. The absence of algorithm validation standards or technical audits in legal norms causes AI in the context of drug services not to go through an adequate accountability process. Without a legal validation mechanism, the use of AI can lead to the potential for incorrect dosage recommendations or unaccurately detected drug interactions, exposing risks to patient safety. As a result, the absence of a prudential framework in AI regulation exacerbates the gap between the potential benefits of technology and patient legal protection.

Another essential principle is the patient's right to information and informed *consent* when technologies such as AI begin to be involved in medical decision-making. The Ministry of Health itself has stated that AI should only function as an auxiliary tool, and the final decision should remain with health professionals such as pharmacists[16]. However, while this statement is important, neither the Health Law nor the Consumer Protection Law provide legal provisions that require explicit patient consent regarding the use of AI in pharmaceutical services. The absence of a legal obligation to convey to patients that some services are derived from AI systems—and to give patients the right to refuse or opt for manual alternatives—results in a major gap in the protection of the rights of healthcare consumers.

In practice in the field, many pharmaceutical AI systems are run without open communication to patients about how drug recommendations are generated. Drug education chatbots or online consultation applications often provide algorithmic answers to users without education or explanation of the risks. Algorithmic transparency remains an unresolved issue, as the law does not require the openness of the working model of AI systems, the databases used, and the logic of decisions behind drug recommendations. Without an audit mechanism or independent verification measures that are legally regulated, patients rely solely on a 'black box' system that can jeopardize their right to meaningful information. From the point of view of consumer protection, this is contrary to Law No. 8 of 1999 concerning Consumer Protection, which guarantees the right to obtain true, clear, and honest information about the conditions and guarantees of the goods/services provided.

Juridical analysis shows that this norm vacuum has the potential to have serious legal repercussions. For example, if a patient experiences side effects or complications due to an incorrect dosage recommendation from AI, there will be no legal reference governing whether the patient has the right to seek compensation for not being provided with sufficient information, or whether there was professional error from the technology provider. In modern health law, the credibility of the service system is largely determined by the enforcement of informed consent and risk education. But because AI in pharmaceuticals has not been protected by formal regulations regarding transparency or patient consent, patients' basic rights remain vulnerable to infringement without clear legal accountability on the part of the organizers.

A number of countries have taken a step forward through regulations requiring informed consent specifically for medical AI systems. For example, the EU AI Act requires disclosure to users when AI makes medical decisions, and provides the option of human oversight for end users. This approach has not been translated into Indonesian law, where patients do not have the legal right to choose to have a drug recommendation confirmed by a professional if they feel more comfortable. Sectoral regulations in the

[16] Ibid.

pharmaceutical sector need to include an informed consent AI clause, so that patients know their rights and get alternative options for manual services if desired. The absence of this norm in Indonesia reflects a systemic gap that requires immediate legal intervention so that consumer rights are guaranteed in the era of digital services.

The normative approach proposed in this study includes the integration of the principles of prudence and informed consent in new legal instruments in the pharmaceutical sector. Concretely, sectoral regulations could require that before AI is used for treatment recommendations, there must be independent validation provisions, model transparency, and explicit consent from patients. The informed consent document must also clearly explain that the services provided by the AI system are complementary to the pharmacist's decision, including the patient's right to object to the use of AI. This kind of obligation will mitigate legal risks and ensure that the existence of AI systems is carried out with full respect for the rights of patients and the professional authority of pharmacists.

Forms of legal liability in the event of errors or losses due to pharmaceutical AI

The application of artificial intelligence (AI) technology in pharmaceutical services marks an important shift in the digital transformation of the healthcare sector. AI has been applied in various forms, ranging from drug education chatbots, clinical decision support systems, to drug interaction prediction algorithms. However, the provisions in Indonesia's positive law regarding the use of AI in pharmaceutical services are still very limited. In general, the applicable legal framework such as Law No. 36 of 2009 concerning Health, Law on Pharmaceutical Practice No. 36 of 2014, and Law on Information and Electronic Transactions (UU ITE) No. 11 of 2008 (jo. Law No. 19 of 2016) have not explicitly regulated the role of AI as a digital entity that processes pharmaceutical data or provides treatment recommendations. In fact, Government Regulation No. 5 of 2021 concerning the Implementation of Risk-Based Licensing and Permenkes No. 26 of 2020 concerning Medical Records have not included aspects of artificial intelligence as a system that has decision-making authority in the clinical or pharmaceutical realm. The absence of this explicit provision shows a legal vacuum, especially in terms of algorithm validation, the protection of automatically processed patient data, and professional control over AI-generated recommendations. This is an urgent issue considering that the WHO in a 2021 report has emphasized the importance of establishing legal governance that is adaptive to AI in the health sector to ensure accountability and patient safety[17].

The urgency of further regulation in Indonesia's positive law also arises due to the increasing use of AI in the absence of strict standardization. The use of AI in the healthcare sector will grow by 40% per year globally, and Indonesia will not be spared this trend. Despite this, Indonesia does not yet have a regulatory authority that specifically handles the standardization and supervision of AI for pharmaceuticals. This is contrary to the precautionary principle that underlies modern health law, where new potentially risky new technologies must be closely monitored before they are widely used. In the Indonesian context, the absence of an AI algorithm testing agency, the unavailability of ethical guidelines for the pharmaceutical profession in dealing with interactions with AI, and the weak integration of health law with digital law show the weak normative readiness of the state in facing this era of digital disruption. As a result, pharmacists, technology developers, and healthcare providers are in a position to be prone to violations of the law without adequate normative signage.

Furthermore, the form of legal responsibility that can be imposed in the event of an error or loss due to the use of AI in pharmaceutical services has not yet received specific regulations in the Indonesian positive legal system. The ITE Law has indeed recognized the principle of strict liability to electronic system operators, as stipulated in Article 15 paragraph (3) of the ITE Law which regulates the obligations of system providers to ensure reliability and security. However, this norm does not yet cover the complexity of AI systems that can autonomously perform analysis and provide drug recommendations. In the context

[17] WHO, *Ethics And Governance Of Artificial Intelligence For Health* (WHO, 2021).

of pharmaceutical services, AI can suggest doses, recommend drug types, or detect potential drug interactions—all of which have a direct impact on patient safety[18.19] But when losses occur, such as misdoses due to AI output, positive law has not yet determined who is specifically responsible: whether it is the pharmacist as a user, the AI developer as a technology provider, or a healthcare institution as the owner of the system. The concepts of vicarious liability and professional liability in Indonesian law have not been adapted to assess liability for non-human entities such as AI.[20] In the Anglo-Saxon legal system, discussions about liability-sharing in the AI ecosystem have developed[21], but Indonesia has yet to adopt such an approach. This gap has implications for legal uncertainty and potential conflicts between users, providers, and victims due to the use of AI in the pharmaceutical sector.

The urgency of establishing special regulations becomes inevitable when considering that the development of AI is going much faster than the regulatory readiness of the state. Research by Nur Aliya Rasyidah et al. (2024) shows that the current approach to telematics law is only reactive and does not yet have a legal basis to anticipate the risks of AI systems that are autonomous and continue to learn from data[22]. The need for regulations that not only close the legal loophole, but also regulate ethical and professional responsibilities in the use of AI in the health and pharmaceutical sectors. Therefore, the normative recommendations of this study include several important points: first, the need for sectoral regulations that contain AI algorithm validation standards before they are used in pharmaceutical services; second, the existence of a periodic algorithm audit mechanism; third, the obligation of system transparency (transparency by design) so that professional users can understand the basis of AI decisions; fourth, the establishment of a legal liability scheme that includes strict liability and vicarious liability options; and fifth, the need for the formulation of a new informed consent document that explicitly mentions the involvement of AI in the service process. International regulatory models such as the EU AI Act and legal practices in China that have adopted a risk-based regulatory approach can be used as a reference for adaptation in the Indonesian context.

In comparison with previous research, there are several important gaps that this study aims to bridge. The study of Harefa and Dewi (2022) only discusses the use of digital technology in pharmaceutical services without touching on the legal responsibility aspects of autonomous systems such as AI. Another study by Putri and Ramadhan (2023) emphasizes the protection of patient data in electronic systems, but has not discussed AI as a decision-making entity. Even the Ministry of Health's report (2023) on the digital transformation roadmap does not include an in-depth discussion of artificial intelligence regulation in pharmaceuticals. This research seeks to fill this gap with a normative juridical approach that comprehensively examines legal arrangements, potential liabilities, and regulatory recommendations to answer legal challenges that have not been thoroughly touched before. Thus, the contribution of this research not only enriches the academic treasures of health law and digital law in Indonesia, but also provides a strong argument base for policymakers, pharmaceutical institutions, and health technology industry players.

This research also makes a direct contribution to digital health practices and governance in Indonesia.

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[18] Ramli M. Ahmad, "Regulasi Penggunaan AI Dalam Layanan Kesehatan Dan Industri Vaksin," *Kompas*, last modified September 16, 2024, accessed July 25, 2025, https://health.kompas.com/read/24I16095325468/regulasi-penggunaan-ai-dalam-layanan-kesehatan-dan-industri-vaksin?utm_source.

[19] Rayyan et al., "Kepastian Hukum Penggunaan Artificial Intelligence (AI) Dalam Pelayanan Kesehatan Dan Diagnosa Medis Di Indonesia."

[20] Kukuh Dwi Kurniawan and Dwi Ratna Indri Hapsari, "Pertanggungjawaban Pidana Korporasi Menurut Vicarious Liability Theory," *Jurnal Hukum Ius Quia Iustum* 29, no. 2 (2022): 324–346.

[21] U. Pagallo, "The Legal Challenges of Big Data: Putting Secondary Rules First in the Field of EU Data Protection," *European Data Protection Law Review* 3, no. 1 (2017): 1–11.

[22] Nur Aliya Rasyidah, Muhammad Aksay, and Muhammad Firdaus Akmal, "Urgensi Pembuatan Regulasi Penggunaan AI (Artificial Intelligence) Di Indonesia," *Jurnal Penegakan Hukum Indonesia* 5, no. 1 (2024): 42–51.

The normative recommendations offered can be important input for the Ministry of Health, the POM Agency, and Communication and Informatics in formulating cross-sectoral regulations that are in accordance with the characteristics of AI technology. For pharmaceutical practitioners, the results of this study are an initial reference to understand their legal position when using AI-based systems in services. Meanwhile, for the wider community, legal clarity on the use of AI in pharmaceutical services has direct implications for the protection of patients' rights, the safety of drug use, and the assurance of service professionalism. At the academic level, this research opens up a new space for discussion on the integration of health law and digital law, while encouraging the development of a legal approach that is more responsive to current and future disruptive technologies.

The urgency of specific regulations and normative recommendations offered

Normative juridical studies of the implementation of artificial intelligence (AI) in pharmaceutical services show a high urgency to establish specialized sectoral regulation. This is based on the fact that current laws and regulations in Indonesia, both general ones such as the ITE Law, the PDP Law, and the Health Law, have not explicitly and detailed regulated the use of AI as an autonomous entity in health services, especially in the pharmaceutical sector. The absence of comprehensive sectoral norms has direct implications for a legal vacuum that not only limits the space for innovation, but also opens up loopholes for violations of patients' rights and legal accountability. In the context of the pharmaceutical service system that is now increasingly digitized, especially in terms of providing drug recommendations, patient education, and even AI-based digital dispensing, the formation of special legal norms is inevitable. Health law has precautionary principles, the right to information, and the principle of professional accountability, all of which are at risk of being ignored if AI does not have a clear operational legal framework.

Research by Nur Aliya Rasyidah et al., (2024) highlights the lack of effectiveness of telematics law currently in answering the challenges of AI implementation, especially in data-based and algorithm-based public services. Their research indicates that the existence of the ITE Law and its derivative rules has not been able to respond to the typical traits of AI, such as machine learning, predictive capabilities, and big data-based decisions[23]. They proposed regulations on specific sectors, one of which is in the pharmaceutical sector, so that the principle of accountability and the right to safe health services can be guaranteed. This is in line with Nashatra Prita's opinion, which states that the regulatory gap will hinder patient protection from biased, invalid, or non-transparent AI decisions[24]. Without specific regulations, there are no clear legal obligations regarding algorithm validation, transparency of AI decision-making processes, and legal liability when losses occur due to system errors.

The normative recommendations that can be offered from this study include several concrete steps. First, it is necessary to establish a Regulation of the Minister of Health that specifically regulates the use of AI in pharmaceutical services, starting from the scope of its use, the type of data processed, to the system validation requirements. The validation must be carried out by independent institutions, not just technology developers. Second, algorithmic audit mechanisms should be required periodically to ensure the AI system does not develop biases or prediction patterns that harm patients. These audits must also be accessible to regulators and professional associations. Third, AI systems must meet the principle of algorithmic transparency, namely openness in the logic and data used by the system in making decisions. This is very important so that pharmacists and patients can understand the basis of the drug recommendations provided by AI. Fourth, expanded informed consent arrangements are needed, not only for medical procedures but also in the use of AI systems. Patients have the right to know that the services they receive are partly from the AI system and have the right to refuse if they feel uncomfortable.

As a normative reference, Indonesia can adopt a risk-based approach as applied in the EU AI Act.

[23] Ibid.

[24] Wahyuni, "AI Di Bidang Kesehatan Mulai Diterapkan, Ini Yang Perlu Diketahui."

The European Union divides AI systems into four levels of risk—minimal, limited, high, and prohibited—and establishes different legal obligations for each category. AI in pharmaceutical services is likely to fall into the high-risk category, as it is directly related to patient safety and health. Thus, the EU AI Act requires high-risk AI to meet the requirements of technical documentation, internal governance, independent audits, and process transparency. Meanwhile, in China, the government requires AI systems used in the health sector to undergo clinical trials and obtain certification before being widely used. These international models can be used as a reference for drafting regulations that are contextual with the Indonesian legal system, especially by considering approaches based on the principles of prudence and consumer protection.

In an institutional context, the establishment of AI regulations in the pharmaceutical sector must involve various stakeholders. It is not enough to only involve the Ministry of Health, but also BPOM, the Indonesian Pharmacists Association (IAI), as well as consumer protection institutions and the health technology community. BPOM, for example, needs to be involved in the standardization aspect of AI systems as they are authorized in terms of quality testing of pharmaceutical products. IAI can develop a new professional code of ethics that regulates the role of pharmacists in supervising or accompanying AI systems. In addition, the Information Commission and the Ministry of Communication and Informatics must also ensure that AI systems meet the strict principles of patient personal data protection. With this cross-agency collaboration, the regulations formed will have a solid legal, ethical, and technical foundation.

Without clear sectoral regulations, the existence of AI can actually create a gap in legal responsibility that endangers society. If a patient is harmed due to incorrect AI recommendations, without clear regulations, no party can be held accountable definitively. This can cripple law enforcement efforts and hurt a sense of justice. Even from an investment and innovation perspective, legal uncertainty will create doubts for the tech industry to develop AI in the pharmaceutical sector due to the potential for litigation and legal uncertainty. Thus, regulations will actually provide legal certainty for all parties: developers, professionals, health institutions, and especially patients as service recipients.

Overall, the urgency of establishing AI-specific regulations in the pharmaceutical sector is very real, both from the perspective of normative law, patient rights protection, service accountability, and certainty for the business and technology world. This regulation must be able to bridge innovation with the basic principles of health law and consumer protection. This study expressly recommends concrete steps to establish a regulatory framework that includes validation, auditing, transparency, accountability, and informed consent. Without these regulations, the potential of AI in improving the efficiency and quality of pharmaceutical services will not be maximized, and instead risks causing legal, ethical, and social losses. Therefore, the presence of adaptive, participatory, and public safety legal norms is very important and urgent to be realized immediately

PENUTUP

The implementation of Artificial Intelligence (AI) technology in pharmaceutical services in Indonesia does not yet have a specific sectoral legal basis, thus creating a vacuum of norms that risk patient legal protection and professional accountability. Although several laws such as the Health Law, ITE Law, and Consumer Protection Law touch on technology aspects in general, there are no explicit provisions governing algorithm validation, system transparency, and specific informed consent mechanisms related to the use of AI in pharmaceutical services. This causes the principle of prudence, the patient's right to drug information, and clarity of legal responsibility not to be adequately fulfilled. In addition, the lack of regulations regarding forms of legal accountability for errors in AI recommendations reinforces legal uncertainty that can harm patients, pharmacists, and technology developers. Therefore, the urgency of establishing sectoral regulations is very important to ensure patient safety, system transparency, professional accountability, and creating legal certainty in the AI-based pharmaceutical service ecosystem. The study recommends regulations that include algorithm validation mechanisms, periodic audits, system

transparency, legal accountability schemes, and AI-based informed consent arrangements as concrete steps towards ethical and responsible health technology governance.

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