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The Concept of Regulatory Technology-Based Supervision in Health Products to Strengthen Consumer Protection in The Digital Market

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ABSTRACT: The development of the digital market in Indonesia has facilitated public access to health products, but it has also given rise to social issues such as the rampant circulation of counterfeit medicines, illegal supplements, and misleading health claims. This situation shows that conventional oversight mechanisms have not been able to keep up with the speed and complexity of digital transactions. This study aims to analyse the urgency *of Regulatory Technology* as an instrument to strengthen the supervision of health products in the digital space. The issues are how the concept of Regulatory Technology is applied in the supervision of health products in various countries and how Regulatory Technology-based supervision can ideally strengthen consumer protection in the digital market. This study uses a normative juridical method with a legislative approach and a comparative approach, reinforced by a comparative study of the application of Regulatory Technology in the United States, the European Union, Singapore, Japan, and Australia. The results of the study indicate that Regulatory Technology has the potential to provide faster, more accurate, and more adaptive supervision through data integration, predictive analytics, and *marketplace* scanning automation. In addition, comparative studies show that effective digital supervision requires collaboration between many parties, a flexible legal framework, and strong and secure data infrastructure. In conclusion, the application of Regulatory Technology is a strategic step to strengthen consumer protection and ensure that the distribution of health products in the digital market is safe, transparent, and accountable.

KEYWORDS: Digital Market; Oversight; Consumer Protection; Health Products; Regulatory Technology.

I. INTRODUCTION

The development of digital technology has fundamentally changed the way people transact and consume goods and services. This transformation has brought enormous benefits in terms of economic efficiency, ease of access, and the growth of the digital industry, but at the same time it has presented serious challenges to the legal system that regulates the relationship between businesses, consumers, and the state.[1] One of the sectors that has been most significantly affected is the online trade of health products. Medicines, supplements, medical devices, cosmetics, and herbal products are now easily accessible through digital platforms.[2] However, this phenomenon also increases the risk of illegal, unregistered, counterfeit, or substandard products being circulated. This situation creates an urgent need to strengthen consumer protection and oversight mechanisms in the digital realm.[3]

In the context of national law, Law No. 8 of 1999 on Consumer Protection (UUPK) stipulates that every consumer has the right to comfort, safety, and security in consuming goods and/or services (Article 4 letter a).[4] However, the implementation of this protection faces serious obstacles in the digital era due to the cross-border, anonymous, and difficult-to-monitor nature of electronic transactions.[5] In addition, violations of these provisions are still rampant, especially on *e-commerce* and social media platforms, which are the main means of distribution.

The Food and Drug Supervisory Agency (BPOM) as the supervisory body faces major challenges in carrying out its supervisory duties regarding the online distribution of health products.[6] The BPOM's Cyber Food and Drug Directorate reported the results of

[1] Jeffriansyah Dwi Sahputra Amory and Muhtar Mudo, "Digital Economic Transformation and the Evolution of Consumption Patterns: A Literature Review on Changes in Shopping Behaviour in the Internet Age," *Jurnal Minfo Polgan* 14, no. 1 (2025): 28–37.

[2] Oeke Yunita and Alfian Hendra Krisnawan, *Digitalisation of Herbal Businesses* (Deepublish, 2023).

[3] Bahtiar Tamrin, "Legal Analysis of Consumer Protection in Digital Transactions in Indonesia: A Review of Law No. 8 of 1999," *Jurnal Kolaboratif Sains* 8, no. 6 (2025): 3246–3255.

[4] Onang Bambungan, "Legal Protection for Consumers Regarding Comfort, Security, and Safety in Consuming Goods or Services," *Lex Privatum* 11, no. 1 (2023).

[5] Marina Yetrin Sriyati Mewu and Kadek Julia Mahadewi, "Consumer Protection in Online Product Purchases: An Analysis of the Perspective of Consumer Protection Law in Indonesia," *Citizenship Journal* 7, no. 1 (2023): 441–450.

[6] Rahmi Yuningsih, "Public Health Protection Against the Circulation of Online Medicines and Food," *Aspirasi: Journal of Social Issues* 12, no. 1 (2021): 47–62.

its cyber patrols for the period January to March 2025. During those three months, BPOM successfully detected and identified 39,642 links that potentially promoted illegal and dangerous drug and food products on various online platforms. Of the total findings, the cosmetics product category dominated with 11,941 links or 30.12% of the total links detected. This was followed by processed foods with 9,138 links (23.05%), medicines with 8,118 links (20.48%), natural medicines with 6,568 links (16.57%), health supplements with 2,402 links (6.06%), and quasi-medicines with 1,475 links (3.72%). In addition, BPOM also released data on the seven provinces with the highest number of illegal links. The Special Capital Region of Jakarta ranked first with 15,865 links, followed by West Java with 5,535 links, East Java with 2,675 links, Banten with 2,525 links, Central Java with 1,661 links, North Sumatra with 1,506 links, and South Sumatra with 1,353 links.[7]

Although BPOM has issued BPOM Regulation No. 14 of 2024 concerning the Supervision of Medicines and Food Distributed Online, BPOM has integrated Regulatory Technology (RegTech) into the national supervision system as part of legal innovation in responding to the complexities of the digital era. RegTech itself refers to the use of digital technologies such as *artificial intelligence*, *machine learning*, *big data analytics*, and *blockchain* to support regulatory functions and legal compliance efficiently and in real-time. According to Arner, Barberis, and Buckley, RegTech serves as a form of legal transformation towards *smart regulation*, which is a regulatory system that is adaptive to technological developments and based on accurate data management.[8] Initially, RegTech developed in the financial services industry as a means of supporting business actors' compliance with Financial Services Authority (OJK) regulations, as stipulated in OJK Regulation Number 13/POJK.02/2018 concerning Digital Financial Innovation in the Financial Services Sector. However, the basic principles of RegTech are now beginning to be adopted in various non-financial sectors, including health and consumer protection.[9]

In its development, RegTech not only serves as an instrument for improving supervisory efficiency, but also plays an important role in ensuring the authenticity and safety of health products in the digital market.[10] In the context of drug and medical device supervision, RegTech can integrate *blockchain-based traceability* systems or *digital ledgers* to verify the distribution chain of products from manufacturers to end consumers. This technology allows every transaction and product movement to be recorded transparently and immutably, thereby minimising the risk of counterfeit drugs, illegal cosmetics, or unauthorised supplements circulating in the market.[11] With the implementation of *smart contracts* in the monitoring mechanism, BPOM or relevant authorities can automatically validate the authenticity of distribution permits, safety certificates, and ensure manufacturers' compliance with applicable legal provisions.[12]

Product authenticity assurance through RegTech is also in line with the principle of consumer protection as stipulated in the UUPK, which requires business actors to provide accurate, clear, and honest information about the conditions and guarantees of goods and/or services traded as stated in Article 4 letter c. In the digital context, the implementation of RegTech strengthens this responsibility through *automated compliance monitoring*, which can detect the circulation of unregistered products or those with misleading labels. Thus, RegTech is not only a technological instrument but also *an enabler* for preventive law enforcement, namely creating a responsive, transparent, and real-time data-based monitoring system to guarantee product authenticity in the digital market.

To date, Indonesia does not have a normative legal framework that explicitly regulates the application of RegTech outside the financial sector, creating a gap between the emerging practice of technology-based supervision and the legal basis that supports it. This condition indicates a vacuum of norms in positive law regarding the use of regulatory technology, particularly in the supervision of health products. Therefore, a juridical study is important to analyse how the concept of health product supervision can be transformed into the RegTech paradigm as part of the renewal of the national legal system, with reference to the practices of other more advanced countries, such as Germany. Germany has systematically integrated regulatory technology through a digital health legal framework, including the regulation of digital health applications (*Digitale Gesundheitsanwendungen/DiGA*) as legally recognised medical devices integrated into the compulsory health insurance system.

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[7] Directorate of Cyber Drugs and Food, "BPOM Reveals 39,642 Illegal Links to Drug and Food Products on Online Media," last modified 2025, accessed 5 November 2025, https://siber.pom.go.id/berita/bpom-reveals-39,642-illegal-links-to-drug-and-food-products-on-online-media.

[8] Douglas W Arner, Janos Barberis, and Ross P Buckey, "FinTech, RegTech and the Reconceptualisation of Financial Regulation," *Nw. J. Int'l L. & Bus.* 37 (2016): 371.

[9] Arifin Pringgo Laksono, Candra Wahyu Saputro, and Ega Kesatrya Putra, "Comparison of Supervision of Digital Banking and Conventional Banking Based on Banking Regulations in Indonesia," *Technology and Economics Law Journal* 3, no. 2 (n.d.): 5.

[10] Alexsanro Gabe Simbolon et al., "The Effectiveness of Government Regulation and Supervision in Preventing Manipulation of Cosmetic Product Composition: A Legal and Health Study," *Jurnal Pustaka Cendekia Hukum dan Ilmu Sosial* 3, no. 2 (2025): 82–96.

[11] Vanessa Mathilde Harum and Gatot P Soemartono, "Consumer Protection in Electronic Transactions of Cosmetics Without Distribution Permits," *Journal of Education Management and Social Sciences (JMPIS)* 5, no. 4 (2024).

[12] Ambar Rika Samodra and S Maryam, "Information System for Verifying the Authenticity of Beauty Products Using Blockchain Technology" (Muhammadiyah University Surakarta, 2025).

Theoretically, this research also has significant implications for the development of legal science. In progressive legal theory, law must be able to keep pace with societal developments and respond to the needs of the times.[13] The integration of technology into the oversight system is a manifestation of progressive law that positions technology as an instrument for achieving substantive justice. Similarly, in responsive legal theory, the law must be adaptive to social changes, including digital technological innovations.[14] Therefore, the development of RegTech in the national legal system can be seen as a step towards responsive, adaptive, and evidence-based law.

From a practical perspective, the integration of RegTech can strengthen coordination mechanisms between supervisory agencies, business actors, and the public. For example, digital surveillance platforms can enable business actors to report their compliance automatically (*e-reporting*), while the public can access verified product information. In the long term, this can create a healthy, transparent, and equitable digital market ecosystem.

Beyond its academic relevance, this research also has high empirical urgency. UNCTAD's "E-Commerce and Digital Economy Programme: Year in Review 2023" notes that despite the growth in digital economy adoption, "digital divides are far from closed" and many developing countries face obstacles in infrastructure, regulation, and digital policy capacity.[15] In Indonesia, this condition is evident in the limited coordination system between supervisory agencies and the suboptimal use of technology for *real-time monitoring*. Therefore, updating the legal supervision system through RegTech integration is an inevitable strategic necessity in an increasingly complex and borderless digital economy.

From the above description, it can be concluded that this study is based on three main points. First, there is a gap between the development of digital technology and the capacity of the health product regulatory legal system, which is still conventional. Second, there is a need to strengthen consumer legal protection through a technology and data-based regulatory approach. Third, the need to reform the national legal system by integrating RegTech as an adaptive, effective, and equitable legal instrument. Thus, this study aims to contribute theoretically and practically to the development of a modern supervisory system in line with progressive legal principles and national digital transformation policies.

Therefore, the researcher formulates a problem, namely, how is the concept of Regulatory Technology applied in the supervision of health products in various countries? And what is the ideal Regulatory Technology-based supervision to strengthen consumer protection in the digital market? The objectives of this study are to determine the concept of Regulatory Technology in the supervision of health products in various countries and to analyse the ideal Regulatory Technology-based supervision to strengthen consumer protection in the digital market.

II. RESEARCH METHOD

This type of research is classified as normative legal research, which is conducted to study and explore law as norms, rules, principles, doctrines, theories, and other legal literature to find answers to legal issues that are the focus of the study.[16] Normative legal research is library-based, focusing on the study and analysis of primary and secondary legal materials.[17]

The approaches used by the author in this study are *the statute approach* and *the comparative approach*. The statute approach is carried out by examining legislation and regulations related to the legal issues at hand.[18] In addition, the comparative approach is carried out by comparing the legal systems or laws of one country with those of one or more other countries on the same subject, including court decisions. In legal comparisons, specific or general comparisons can be made. Comparisons are made to identify the similarities and differences between each.[19]

This research is a prescriptive type of research, which is research that aims to provide concrete and applicable suggestions regarding the steps that must be taken to overcome certain problems. This research focuses on solutions that can be applied to achieve the objectives or resolve the issues being studied. The nature of the analysis in this research is intended to provide arguments for the results of the research that has been conducted. These arguments are made by researchers to provide prescriptions or assessments of right or wrong, as well as what should be in accordance with the law regarding the facts or legal events found in the research results.[20]

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[13] Satjipto Rahardjo and Khudzaifah Dimyati, *Sociology of Law: Development, Methods, and Issues* (Muhammadiyah University Press, 2002).

[14] Philipe Nonet and Philipe Selznick, *Responsive Law* (Nusamedia, 2019).

[15] UNCTAD, "E-Commerce and Digital Economy Programme: Year in Review 2023," last modified 2023, accessed 10 November 2025, https://unctad.org/publication/e-commerce-and-digital-economy-programme-year-review-2023?utm_source=chatgpt.com.

[16] Muhaimin, *Legal Research Methods* (Mataram: Mataram University Press, 2020), p. 57.

[17] Muhammad Siddiq Armia, "Determining Legal Research Approach Methods" (Indonesian Constitutional Studies Institute (LKKI), 2022), p.12.

[18] Ika Atikah, "Legal Research Methods" (2022).

[19] Muhaimin, *Legal Research Methods*.

[20] Fajar Mukti and Yulianto Achmad Dualisme, "Normative and Empirical Legal Research" (Yogyakarta, Pustaka Pelajar, 2010), pp. 183–184.

III. RESULTS AND DISCUSSION

A. The Concept of Regulatory Technology in Health Product Supervision in Various Countries

The concept of RegTech in health product supervision has developed in response to the increasing complexity of the pharmaceutical supply chain, the acceleration of biomedical innovation, and the proliferation of medicines and supplements through cross-border digital platforms. RegTech is essentially the use of technology, including *big* data *analytics*, *machine learning, AI-driven surveillance, blockchain tracing*, and automated reporting systems to assist regulatory authorities in carrying out their supervisory functions more efficiently, responsively, and accountably.[21]

In the context of health product oversight, RegTech is not merely an administrative tool, but a socio-technological system that strengthens consumer protection while ensuring the safety and quality of health products circulating in both physical and digital markets.[22] In general, various countries are implementing RegTech to improve early risk detection, accelerate registration and *post-market surveillance* processes, and enhance law enforcement capabilities against drug and medical device safety violations.[23]

In the United States, *the Food and Drug Administration (FDA)* is one of the pioneers in the use of RegTech for health surveillance. Through initiatives such as *the FDA Sentinel System* and *MedWatch*, the government utilises *big* data and *predictive analytics* to identify patterns of drug side effects in *real time* based on millions of electronic medical records, insurance claims, and reports from manufacturers. *The FDA* has also developed *the Digital Health Innovation Action Plan*, which integrates *artificial intelligence* into the evaluation of software-based medical devices.[24]

The main legal framework is contained in *the Federal Food, Drug, and Cosmetic Act*, as well as the strengthening of the data system through *the 21st Century Cures Act.*[25] The application of RegTech in the United States shows that this country prioritises big data and predictive algorithms to drive faster surveillance than traditional manual mechanisms. The difference with other countries lies in the large volume of data, integration with the digital health sector, and highly advanced technological capacity.

The FDA Sentinel System is one of the most advanced RegTech implementations in the global healthcare sector. This system was built as a national network that collects and analyses health data from various sources, including electronic medical records, insurance claims, laboratory data, and pharmaceutical data, with an analysis population reaching hundreds of millions of people.[26] Sentinel enables *the FDA* to detect potential drug side effects in near *real time* through *active surveillance*, unlike traditional passive approaches. The system utilises *machine learning* and advanced statistical models to assess the correlation between the use of certain drugs and the occurrence of side effects, so that decisions such as drug recalls, dose adjustments, or label revisions can be made more quickly and based on strong quantitative evidence.[27]

Furthermore**,** *MedWatch* serves as a reporting channel for the public and healthcare professionals regarding adverse events. Through the digitisation of reporting forms, *the FDA* can integrate this data into Sentinel analyses so that even manual reports can be processed using *text mining* and *Natural Language Processing (NLP)* algorithms that focus on the ability of computers to understand, process, and generate human language**,** both in text and voice form, to identify relevant keyword patterns. As a result, reports that previously took a long time to process can now be analysed automatically to speed up regulatory responses.[28]

The FDA's implementation of RegTech through the Digital Health Innovation Action Plan demonstrates the transformation of health surveillance towards a data-driven and smart technology approach, including through the Pre-Certification Programme, which assesses the capabilities and quality systems of software-based medical device developers, including artificial intelligence and machine learning, as well as the development of Good Machine Learning Practice guidelines. The FDA also utilises advanced analytics, big data, web scraping, artificial intelligence, and natural language processing to detect illegal drug sales, monitor digital marketing activities, and optimise the use of real-world evidence in post-marketing drug safety and efficacy evaluations. This approach has been shown to increase the speed and accuracy of risk detection, strengthen transparency, and promote operational efficiency, while creating a regulatory framework that is more adaptive to digital health innovations. However, the implementation of RegTech also presents significant challenges, such as the complexity of harmonising and validating data across

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[21] Asnawi Asnawi, Tiarsen Buaton, and Parluhutan Sagara, "Legal Analysis of the Regulation of Supervisory Authority over Pharmaceutical Products and Medical Devices in the Perspective of Law No. 17 of 2023 on Health," *Jurnal Cahaya Mandalika ISSN 2721-4796 (online)* 4, no. 1 (2023): 1107–1115.

[22] Shada Adila Abadi et al., "Innovation and Challenges in Drug Packaging: A Review Study on the Role of Packaging in Pharmaceutical Product Quality," *Pharmacy Genius* 4, no. 2 (2025): 40–48.

[23] Tri Astuti et al., "Law Enforcement Against Criminal Acts of Distributing Medicines Without a Distribution Permit: (Study of Decision Number 1/Pid. Sus/2023/Pn. Pre)," *Jurnal Hukum Positum* 9, no. 1 (2024): 1–16.

[24] Andrea T Borchers et al., "The History and Contemporary Challenges of the US Food and Drug Administration," *Clinical Therapeutics* 29, no. 1 (2007): 1–16.

[25] Joseph L Hackett and Steven I Gutman, "Introduction to the Food and Drug Administration (FDA) Regulatory Process," *Journal of Proteome Research* 4, no. 4 (2005): 1110–1113.

[26] Richard Platt et al., "The FDA Sentinel Initiative—an Evolving National Resource," *New England Journal of Medicine* 379, no. 22 (2018): 2091–2093.

[27] Jeffrey S Brown et al., "The US Food and Drug Administration Sentinel System: A National Resource for a Learning Health System," *Journal of the American Medical Informatics Association* 29, no. 12 (2022): 2191–2200.

[28] Benny Firmansyah, Arry Akhmad Arman, and Widya Sri Wahyuni, "Regtech Solutions: Generic Business Process Analysis and Modelling," in *Proceedings of the International Conference on Data Science and Official Statistics*, vol. 2023, 2023, 13–25.

sources, health data privacy and security issues, the risk of bias and lack of transparency in artificial intelligence algorithms, gaps in the technical expertise of regulatory human resources, and the need for continuous policy updates to keep pace with technological developments. The success of RegTech therefore depends heavily on the FDA's institutional capacity to manage these challenges strategically and sustainably.

Meanwhile, the European Union is also developing RegTech through integrative cross-border policies. *The European Medicines Agency (EMA)* has implemented the *EudraVigilance* system, *a cloud-based* platform for monitoring drug safety across Europe. This system collects reports of side effects from healthcare facilities, the pharmaceutical industry, and patients directly, enabling authorities in each member state to conduct coordinated risk analysis.[29] In addition, the European Union has implemented *the Falsified Medicines Directive*, which is integrated with a *blockchain-style serialisation* system to track medicines from the factory to the pharmacy. The European Union also has a stricter regulatory approach than the United States, particularly with regard to *cross-border enforcement* between member states. RegTech-based supervision in the European Union focuses on cross-border data integration, supply chain transparency, and consumer protection through harmonised safety standards.[30]

The EU has developed a highly structured and integrated cross-border RegTech ecosystem through coordination between *the EMA* and the medicines authorities in each member state. One of its main foundations is *EudraVigilance*, a *cloud-based* platform designed to collect, store, and analyse reports of adverse drug reactions from various sources, including hospitals, healthcare professionals, the pharmaceutical industry, and patients directly. Unlike national models such as *the FDA Sentinel System*, *EudraVigilance* operates in a multi-country context that requires data harmonisation, enabling every health authority in the European Union to conduct coordinated risk analysis. This system supports algorithm-based signal detection and accelerates regulatory actions across Europe, such as label changes, safety warnings, or restrictions on drug use.

In the drug supply chain sector, the European Union has implemented *the Falsified Medicines Directive*, which is integrated with *a blockchain-like* serialisation system, where each drug package is given a unique identifier that can be tracked from production to delivery to pharmacies.[31] This verification system enables *real-time* monitoring to detect counterfeiting, distribution irregularities, or potential manipulation at any point in the supply chain. The application of this technology provides a high level of transparency and ensures that patients only receive legitimate, verified, and safe medicines. The success of this system provides a new model for digital-based medicine monitoring through *end-to-end* tracking, which is rarely implemented comprehensively in other regions.

In addition, the European Union has a tradition of stricter regulation than the United States, particularly on issues of privacy, data security, and cross-border law enforcement. With *the General Data Protection Regulation* in place, all RegTech activities must comply with very high standards of personal data protection, including the treatment of medical data as sensitive personal data. Cross-border coordination also requires the use of harmonised data standards so that different systems, platforms, or applications can communicate, exchange data, and use information effectively without technical barriers and without compromising information security. These strict regulations make RegTech in the European Union highly focused on cross-border data integration, supply chain transparency, and consumer protection, thereby creating a very strong digital health surveillance model oriented towards public safety.

The implementation of RegTech in the European Union provides various strategic benefits in strengthening cross-border health surveillance systems. Through the *EudraVigilance* platform, the European Union is able to centrally collect and analyse reports of adverse drug reactions from all member states, enabling faster and more coordinated detection of safety signals. This system utilises *cloud architecture*, which is the design and organisation of all components, such as *servers*, storage, networks, and *software*, that work together to provide *cloud* services via the internet and risk analytics, enabling regulators to assess patterns of side effects based on much larger and more diverse data sets than national surveillance models. [32]

The implementation of RegTech in various jurisdictions shows a variety of approaches with different benefits and challenges, as seen in the European Union, Singapore, and Japan. In the European Union, the implementation of the Falsified Medicines Directive with digital serialisation technology strengthens the transparency of the drug supply chain, reduces the risk of counterfeiting, and increases public confidence. It is supported by cross-border regulatory harmonisation and strict data protection through the General Data Protection Regulation, despite facing challenges such as cross-border data integration, the complexity of privacy compliance, slow multinational decision-making, and high compliance costs for the industry. Singapore, through the Health Sciences Authority, has adopted a more concise and responsive RegTech with digital licensing, risk-based analytics, online marketplace monitoring, and the use of machine learning to predict the circulation of illegal drugs, thereby increasing the speed of enforcement, efficiency of surveillance, and early detection capabilities. although it still faces risks related to data quality, algorithmic bias, the need for continuous technological updates, and the burden of adaptation for small businesses. Meanwhile, Japan is developing RegTech through an artificial intelligence-based system by the Ministry of Health, Labour and Welfare and

[29] Nicolò Sentinelli and Lucia Biagiotti, "Evdas (Eudravigilance Data Analysis System): New Tool for Signal Detection Process," *Italian Journal of Pharmacoeconomics and Drug Utilisation* 11, no. 4 (2019): 24–26.

[30] G Smith, J A Smith, and D A Brindley, "The Falsified Medicines Directive: How to Secure Your Supply Chain," *Journal of Generic Medicines* (SAGE Publications Sage UK: London, England, 2014).

[31] Piotr Merks et al., "The European Falsified Medicines Directive in Poland: Background, Implementation and Potential Recommendations for Pharmacists," *European Journal of Hospital Pharmacy* 25, no. 1 (2018): 10–15.

[32] Guntoro Barovih and Salimin Salimin, "Medicine Monitoring Architecture Model Using the TOGAF ADM and Cloud Database Approach," *Jurnal Sisfokom (Information Systems and Computers)* 7, no. 2 (2018): 155–162.

the Pharmaceuticals and Medical Devices Agency, focusing on pharmacovigilance, long-term product safety, data-based medical device surveillance, and integration with national clinical research, supported by revisions to the Pharmaceuticals and Medical Devices Act to accommodate digital health and artificial intelligence-based medical devices.[33]

RegTech-based health product surveillance in Japan is developing through a highly systematic and long-term safety-oriented approach, utilising digital infrastructure built by the Ministry of Health, Labour and Welfare together with *the PMDA*. Japan has implemented *an artificial intelligence-based Pharmacovigilance Planning* System to project drug risks more precisely, especially for the significant elderly population.[34] This system enables the analysis of *pharmacovigilance* data, which is a collection of information on drug safety, including side effects (adverse drug reactions) and other drug-related issues, collected to detect, assess, understand, and prevent drug risks after the drug is marketed, in order to increase benefits and protect public health on a large scale, including side effect reports, *real-world evidence* data, and integrated medical records so that regulators can identify risk patterns that may not be detected through conventional methods.[35] In addition, Japan has developed *the PMDA Medical Device Single Audit Programme*, which utilises automated data from the production and distribution processes to monitor the compliance of medical device manufacturers in *real time*.[36] The revision *of the Pharmaceuticals and Medical Devices Act* also strengthens the legal basis for supervision, particularly for digital health, *artificial intelligence-based* medical devices, *software as a medical device* (SaMD), and digitally audited software update processes.

The implementation of RegTech in Japan and Australia demonstrates a significant strengthening of health oversight quality through a data-driven approach, risk prediction, and transparency. In Japan, the integration of big data and artificial intelligence by the Ministry of Health, Labour and Welfare and the PMDA enables effective predictive regulation, particularly to protect the elderly population through early detection of risks associated with medicines and medical devices, while accelerating audits, improving industry compliance, and maintaining product safety consistency. Meanwhile, Australia, through the Therapeutic Goods Administration, emphasises participatory and transparent RegTech with a mandatory online reporting system, digital pharmacovigilance, real-time drug shortage tracking, and active community involvement, thereby accelerating regulatory response, increasing public trust, and strengthening cross-stakeholder coordination in health surveillance.

However, both countries also face important challenges that are relevant lessons for Indonesia. Japan faces issues of data quality and variation, algorithmic bias risks, the need for transparency and artificial intelligence audits, and the burden of adaptation for small industries, while Australia faces issues of industrial data quality variation, the risk of public information misinterpretation, challenges of cross-state system integration, and cybersecurity. The differences in RegTech models between countries confirm that there is no universal approach, but all provide valuable references for Indonesia, which still faces data fragmentation, weak marketplace oversight, limited technological capacity, a regulatory vacuum in digital oversight, and limited human resources. From the perspective of legal protection and progressive law, RegTech is a strategic instrument for transforming the supervision of medicines and health products in Indonesia towards a more predictive, integrated, and adaptive system, with the main prerequisites being gap analysis, regulatory strengthening, data infrastructure, and institutional capacity.[37]

Through cross-country comparative analysis, Indonesia can design a relevant and realistic RegTech roadmap by adapting best practices from various jurisdictions, such as the use of big data and risk prediction in the United States, cross-agency data integration in the European Union, strict supervision of digital marketplaces in Singapore, the use of artificial intelligence for health risk prediction in Japan, and the strengthening of transparency and public participation in Australia. The implementation of RegTech in Indonesia is becoming increasingly urgent given the rampant circulation of illegal drugs and the increasing consumption of health products through e-commerce. With an adaptive legal framework, inter-agency synergy, and strengthened technological capacity, RegTech has the potential to transform the health surveillance system to be faster, more effective, and more modern, while addressing the limitations of conventional surveillance approaches in the digital age.

From a consumer protection perspective, RegTech is a normative reinforcement of the state's mandate as emphasised in Philipus M. Hadjon's legal protection theory and Satjipto Rahardjo's progressive legal theory. RegTech expands preventive protection through early detection of product risks and real-time warning systems, and strengthens repressive protection through digital traces that support legal evidence, information transparency, and enforcement against illegal businesses. In the Indonesian context, challenges such as data fragmentation, weak early warning systems, and the proliferation of counterfeit drugs in the digital market indicate that consumer protection cannot be optimally realised without technological support. RegTech integration enables countries to fulfil consumers' rights to safety, information, and justice more substantially, while empowering consumers through access to digital information, so that health product supervision is no longer reactive, but predictive, adaptive, and oriented towards public safety in the long term.

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[33] Aisyah Dinda Ayuni and Imam Asmarudin, "Comparison of Blockchain Use in Indonesia and Singapore," *Pancasakti Law Journal (PLJ)* 2, no. 2 (2024): 267–276.

[34] H-P Wang et al., "From Pharmacovigilance to Pharmacovigilance Planning—The System Building for Safe Medication," *Journal of Food and Drug Analysis* 15, no. 4 (2007): 6.

[35] Dwi Nofiarny, "Introduction to Pharmacovigilance: What It Is and Why It Is Needed," *Medicinus* 29, no. 1 (2016): 53–56.

[36] Kenichi Ishibashi, Masuo Kondoh, and Tetsuya Kusakabe, "Current Application of the Medical Device Single Audit Programme (MDSAP) as a Global Regulatory Reliance Framework for the Inspection of Medical Devices," *Therapeutic Innovation & Regulatory Science* 58, no. 6 (2024): 1172–1179.

[37] Perdhana Ari Sudewo, Clara Diana Setyawati, and Ritti Piany Sangadji, "Risk and Opportunity Analysis of Artificial Intelligence in the Drug and Food Supervision Business Process," *Jurnal Widyaiswara Indonesia* 4, no. 3 (2023): 99–114.

B. Ideal Regulatory Technology-Based Oversight to Strengthen Consumer Protection in the Digital Market

RegTech-based supervision that is ideal for consumer protection in the digital market is an integrated ecosystem between law and technology that integrates regulation, monitoring, enforcement, and remediation through data analytics and intelligent automation. RegTech is a response to the increasing risks of the digital market and the limitations of traditional supervision, so it must be supported by a strong normative framework, accountable governance, legal protection principles, and progressive public policies in order to protect consumers effectively and sustainably.[38]

The normative foundation in RegTech oversight serves to ensure that the use of technology remains grounded in legal principles, particularly legal protection theory and progressive legal theory. Legal protection theory requires the state to guarantee consumer safety through effective, predictive regulations that provide certainty.[39] The ultimate goal is to protect consumers' rights to safety, comfort, accurate information, and access to remedies. Meanwhile, progressive legal theory demands that the law be responsive to technological developments and capable of changing as society undergoes digital transformation. This means that RegTech should not be positioned as a tool for freezing norms, but rather as a dynamic means of helping regulators move adaptively in line with the pace of innovation in the digital market. Thus, the legal framework governing RegTech must be flexible, allowing for innovation, for example through *sandboxes*, delegated regulations, and technical guidelines, without losing the principles of accountability, transparency, and protection of consumers and personal data.[40]

On the technical side, the ideal RegTech surveillance architecture includes a modular-based design that allows for the integration of data from various sources such as *marketplace* transactions, seller *logs*, advertising metadata, consumer complaint reports, logistics audit records, electronic payment records, and even public signals from social media. All of this data must be managed in a secure and standardised *data lake*, applying the principles *of interoperability*, audit *trails*, and access control. At the analytical layer, RegTech surveillance uses a combination of *machine learning* models, *NLP*, *anomaly detection*, and *computer vision* techniques to detect dangerous products through images. This capability allows regulators to identify patterns of fraud, abnormal spikes in complaints, automatic price manipulation, and the existence of illegal products that were previously difficult to monitor manually. However, the use of *artificial intelligence* in surveillance requires *explainability* so that every decision can be legally justified, especially when surveillance decisions form the basis for administrative enforcement, sanctions, or access restrictions.[41] Without adequate explanation, the use of RegTech can be legally challenged and potentially violate the rights of the subjects being investigated.

RegTech's operational functions include prevention, detection, enforcement, and continuous remediation through the use of automation and data analytics. Prevention is carried out through automatic monitoring before products or content are distributed, especially for high-risk products, with the support of technologies such as natural language processing to identify misleading or illegal claims. At the detection stage, RegTech acts as an early warning system by monitoring suspicious transaction patterns and behaviour, which then triggers rapid action through automated workflows, including product suspension, clarification to sellers, and notifications to consumers, even enabling cross-platform violation tracking. In terms of remediation, RegTech provides a fast, efficient, and transparent digital dispute resolution mechanism through a smart complaint system, the use of digital evidence, and the use of smart contracts to ensure transaction security. This approach enables the effective resolution of individual and collective disputes, so that RegTech not only serves to suppress violations, but also realises substantive justice and stronger consumer protection in the digital marketplace.

Governance plays an important role in determining the success of RegTech implementation. RegTech requires a supervisory agency that has the legal authority and technical capacity to integrate the entire digital supervision process.[42] The agency must have a clear mandate regarding platform data access, the ability to request technical clarification, and the authority to impose automated administrative sanctions based on system evaluation results. Governance must also include a technology ethics committee, independent audits of *artificial intelligence* models, public reporting mechanisms, and complaint processes for businesses or consumers affected by automated decisions. Without strong governance, the use of RegTech is prone to bias, misidentification, or even abuse of authority.

Human resources are also an integral part of RegTech oversight. The use of advanced technology without the support of experts will only result in an ineffective system. Ideal oversight requires data analysts, digital legal experts, software engineers, and cyber forensic investigators.[43] Therefore, countries must invest in the education, training, and competency development of regulators. Collaboration with academics, research communities, and the private sector also helps strengthen oversight

[38] Ahmadi Miru, *Legal Protection Principles for Consumers in Indonesia* (Depok: Raja Grafindo Persada, 2013).

[39] Megawati Simanjuntak, "Ensuring the Safety and Convenience of E-Commerce Transactions in an Effort to Protect Consumers," *Policy Brief on Agriculture, Marine Affairs, and Tropical Biosciences* 5, no. 2 (2023): 562–566.

[40] Saifullah Saifullah et al., "Regulatory Technology and the Fintech Law Landscape in Indonesia: A Normative Legal Perspective to Mitigate Illegal Fintech," *Jurisdictie: Journal of Law and Sharia* 14, no. 02 (2023).

[41] Ns Hendrik Probo Sasongko et al., *Health Revolution: Collaboration Between Technology, Innovation, and Policy* (PT. Nawala Gama Education, 2025).

[42] Bob Wahyuddin and Redyanto Sidi, "Regulation and Legal Impact of Herbal Medicine Products in Efforts to Fulfill Health Rights in Indonesia," *JIIP-Journal of Educational Science* 6, no. 9 (2023): 6754–6762.

[43] Aaron William Pantow et al., "Evidence Against Criminal Acts of Selling Imported Health Medicines," *Multidisciplinary Academic Journal* 1, no. 5 (2024): 177–190.

capabilities. Without adequate human resources, RegTech has the potential to become *a* technologically sophisticated but substantively ineffective *framework*.

From a privacy perspective, digital surveillance poses serious challenges. Ideal RegTech must be designed with the principle *of privacy by design* and the use *of privacy enhancing* technologies *(PETs)* such as *federated learning, differential privacy, pseudonymisation*, and high-level encryption. Regulations must define the limits of data use, legitimate processing purposes, and oversight mechanisms for data requests by regulators. The aim is to prevent oversight from turning into a form of massive data collection that violates individual rights. Good oversight is efficient, proportionate, and accountable.

In addition, RegTech supervision requires cross-integration of government systems, such as taxation, customs, business registration, and national product registration systems. This integration enables automatic checking of business licences, distribution permits, halal status, and product labelling. In the context of health, for example, the surveillance system must be able to directly link drug product listings with the official distribution permit registry.[44] In the event of a discrepancy, the system must be able to automatically withdraw the product from the platform. *Blockchain* technology can increase supply chain transparency, but its implementation must take into account the capacity of business actors and the readiness of the ecosystem.[45]

RegTech-based supervision must be placed in a transnational context because digital markets are cross-border, requiring international cooperation, digital intelligence exchange, global platform compliance with local standards, and a common normative framework to prevent consumers from being harmed by jurisdictional differences. At the same time, the application of RegTech needs to be socially sensitive by protecting the sustainability of MSMEs through a tiered compliance approach and simple compliance technology support. From a progressive legal perspective, RegTech serves as an instrument of social justice that expands protection for vulnerable groups through fast and inclusive digital mechanisms. It must be implemented gradually and transparently, starting from a sandbox to full integration of national policies to be more effective, accountable, and accepted by all stakeholders.[46]

Ideal RegTech-based supervision is a consumer-oriented system, with regulators acting as guides, digital platforms as mandatory partners, and technology as a catalyst that ensures supervision takes place in real time, objectively, and accountably, so that it is not only repressive but also builds public trust, maintains market integrity, protects consumer rights, and encourages inclusive digital economic innovation. The urgency of its implementation in Indonesia is growing stronger in line with the rapid growth of the digital economy and the expansion of online services, which create new complexities in risk. RegTech is therefore a strategic solution to replace conventional supervision with a more effective, efficient, and adaptive regulatory system in ensuring compliance, security, and consumer protection.[47]

The urgency of implementing RegTech in Indonesia stems from various structural challenges faced by the country in supervising the digital economy, which is developing much faster than conventional regulatory capabilities, ranging from the digital finance, health, and food sectors to cross-border trade. The proliferation of illegal fintech, unlicensed medicines and supplements, digital fraud, data leaks, and cybercrime shows that manual supervision is no longer adequate when transaction volumes reach millions per day. RegTech enables real-time monitoring, risk detection based on analytics and machine learning, cross-agency data integration, and automated reporting that improves bureaucratic efficiency and law enforcement effectiveness, while overcoming the limitations of human resources for supervision. Furthermore, as stated by Muthia Sakti, RegTech strengthens harmonisation with international standards so that national products and industries remain globally competitive, encourages transparency and public participation through open data access, and maintains public trust in the government and business actors. In the context of increasingly digital consumption patterns, RegTech is a strategic instrument to ensure that Indonesia's digital economic transformation takes place safely, accountably, and with a focus on consumer protection and long-term public interests.[48]

Overall, the urgency of RegTech in Indonesia is an inherent necessity in facing the complexity of the digital economy, public health risks, and demands for regulatory efficiency and transparency, so that it is no longer just an option for modernisation. The implementation of RegTech has the potential to strengthen consumer protection, increase global competitiveness, improve supervision, and ensure healthy and sustainable digital economic growth, but it requires a gradual and systematic approach. A crucial initial step is the establishment of a national RegTech regulatory framework that provides a legal basis for the use of technology in supervision, reporting, and enforcement of compliance, covering definitions, scope, digital reporting standards, data governance, cybersecurity, and technology system audit mechanisms. A clear and uniform legal framework—through presidential

[44] Yuningsih, "Public Health Protection Against the Circulation of Medicines and Food Online."

[45] Nurul Hidayati Indra Ningsih et al., *Digital Economy Law: Business Regulation in the Technological Era* (PT. Nawala Gama Education, 2025).

[46] Priscilla D Z Saragih, Paramita Prananingtyas, and Hendro Saptono, "Analysis of the Regulatory Sandbox Mechanism in the Implementation of Financial Technology in Indonesia," *Diponegoro Law Journal* 8, no. 1 (2019): 633–649.

[47] Dani Habibi, "Reconstruction of the Health Law System in Indonesia Using a Comparative Approach to Health Systems in Developed Countries," *Jurnal Medika Hutama* 1, no. 03 April (2020): 156–162.

[48] Abdul Hamid, Muhamad Afifullah, and Muthia Sakti, "Freedom, Oversight, and Sanctions in Digital Financial Services: Toward Sustainable Development Goals in Indonesia", *Journal of Law and Justice (JHK)*, Vol. 2, No. 6 (2025, pp. 1-8. DOI: https://doi.org/10.61942/jhk.v2i6.448

regulations or sectoral regulations—will form the foundation for collaboration between the government, industry, technology players, and academics in the responsible adoption of technologies such as artificial intelligence, risk analytics, and blockchain.[49] The second step in implementing RegTech in Indonesia is the development of a national data infrastructure that ensures interoperability between institutions, as the effectiveness of RegTech depends on the availability of complete, structured data that can be securely exchanged between regulators, industry, marketplaces, healthcare facilities, and financial institutions through integrated data format standards and APIs. Next, the third step is the adoption of automated surveillance technology based on data analytics, machine learning, and artificial intelligence, including web-crawling to monitor the circulation of risky products, transaction anomaly detection, historical data-based risk assessment, and the use of blockchain for tracking the supply chain of strategic products, so that surveillance can be carried out in real time and is able to keep pace with the speed of innovation and the complexity of the digital economy.

The fourth step is the establishment of *a* RegTech *Innovation Hub* or national RegTech innovation centre that functions as a space for collaboration between regulators, industry players, technology developers, and academics. In this innovation centre, regulators can test new digital surveillance systems within a *sandbox* or testing space that does not directly impact the public.[50] This mechanism is important to ensure that the technology to be adopted by regulators is safe, accurate, and widely applicable. In addition, the innovation hub can be a place to exchange knowledge and develop nationally compatible technology standards. Many developed countries utilise innovation hubs to accelerate the adoption of RegTech, so Indonesia also needs to do the same in order not to fall behind in global regulatory transformation.

The fifth step in implementing RegTech in Indonesia is to strengthen the capacity of regulators' human resources through continuous training and recruitment of new talent in the fields of data science, analytics, artificial intelligence, and cybersecurity, as the success of RegTech greatly depends on the ability of officials to understand and operate surveillance technology. Furthermore, strengthening digital reporting obligations for businesses in high-risk sectors is crucial through a standardised automated reporting system that is directly connected to regulators, so that data access becomes faster, more accurate, and more transparent, while minimising data manipulation and increasing the effectiveness of technology-based supervision.

The implementation of RegTech also requires the integration of marketplaces into the surveillance system. Indonesia is the largest *e-commerce* market in Southeast Asia, so *marketplaces* play an important role in the distribution of goods, including health, food, and cosmetic products.[51] To that end, *marketplaces* need to be required to connect their internal systems with the regulator's *API* so that supervision can be carried out automatically. With this integration, the regulator's system can directly identify unauthorised products, block illegal sellers, remove harmful advertisements, and send *real-time* violation notifications. Marketplaces must also take responsibility for conducting initial screening of high-risk products so that the government's supervisory burden can be reduced.[52]

Further steps in the implementation of RegTech in Indonesia include the development of digital audit standards to ensure data security, algorithm accuracy and transparency, and decision-making accountability, so that the risks of bias, system errors, and reporting manipulation can be minimised. At the same time, the public needs to be involved as part of the oversight ecosystem through online reporting mechanisms, public dashboards, and increased digital literacy so that violations can be detected more quickly and consumer protection can be more effective. The implementation of RegTech also requires close collaboration between stakeholders, ranging from government agencies, digital industry players and strategic sectors, academia and research, to the public as consumers, so that the entire technology-based oversight process can run in an integrated, transparent and sustainable manner.[53]

With these steps, Indonesia can begin to implement RegTech systematically and gradually. RegTech is not merely a technological innovation, but an important foundation for improving the quality of supervision, strengthening consumer protection, accelerating the regulatory process, and adapting to the increasingly complex dynamics of the digital economy. With cross-sector collaboration and strong policy support, RegTech has the potential to become a tool for regulatory transformation that can lead Indonesia towards a more modern, responsive, and trustworthy governance system.

CONCLUSIONS

The concept of RegTech in the supervision of health products in various countries shows that regulatory digitalisation has become a global strategy to improve the effectiveness, speed, and accuracy of supervision in the increasingly complex health sector. The United States utilises *big* data and predictive analytics for *real-time pharmacovigilance*. In addition, the European Union

[49] Aditya Hermawan et al., "The Use of Smart Contracts in Supply Chain Transformation Through Blockchain Technology," *Journal of Informatics Education and Research* 9, no. 3 (2023): 471–478.

[50] Siti Nur Kholifah, Eko Arif Susanto, and Khoiril Latifah, "Consumer Supervision and Protection Through Regulatory Sandbox in Indonesia," *HUKAMA: Journal of Islamic Law* 3, no. 2 (2024): 108–119.

[51] Rini Yustiani and Rio Yunanto, "The Role of Marketplaces as Business Alternatives in the Information Technology Era," *Komputa: Scientific Journal of Computers and Informatics* 6, no. 2 (2017): 43–48.

[52] Rizkinil Jusar, Palmawati Taher, and Inge Dwivismiar, "The Responsibility of Business Actors and Marketplaces for Violations of the Principle of Good Faith in E-Commerce Transactions," *Sultan Jurisprudence: Journal of Legal Research* 3, no. 1 (2023): 62–72.

[53] Simbolon et al., "The Effectiveness of Government Regulation and Supervision in Preventing Manipulation of Cosmetic Product Composition: A Legal and Health Study."

integrates cross-border data and strengthens supply chain security through cloud systems and drug serialisation. Furthermore, Singapore optimises digital market oversight with *machine learning* to detect illegal drugs. Japan also applies artificial intelligence in drug risk assessment and medical device compliance. Meanwhile, Australia emphasises public transparency and automatic reporting by industry. These varying approaches show that there is no universal model, but all countries are moving towards data-driven oversight, automation, and inter-agency collaboration. RegTech has become an important pillar in ensuring the safety, effectiveness, and integrity of health products in the digital age, while strengthening consumer protection through more responsive, measurable, and transparent oversight.

Ideal RegTech-based oversight to strengthen consumer protection in the digital marketplace must be able to deliver fast, accurate, and data-driven oversight through automated reporting, cross-agency data integration, and predictive analytics to detect risks before they cause harm. RegTech enables regulators to monitor compliance in *real time*, oversee digital *platform* algorithms, increase business transparency, and strengthen responses to consumer complaints through smart complaint systems. However, the success of this supervision requires adaptive regulations, collaboration between stakeholders, and strong data protection standards so that technology truly protects consumers and maintains fairness in the digital ecosystem. Thus, RegTech becomes a strategic foundation for ensuring that digital innovation takes place responsibly and in favour of consumers.

REFERENCES

1) Aaron William Pantow et al., "Evidence Against Criminal Acts of Selling Imported Medicines," *Multidisciplinary Academic Journal* 1, no. 5 (2024): 177–190.
2) Abdul Hamid, Muhamad Afifullah, and Muthia Sakti, "Freedom, Oversight, and Sanctions in Digital Financial Services: Toward Sustainable Development Goals in Indonesia", *Journal of Law and Justice (JHK)*, Vol. 2, No. 6 (2025, pp. 1-8. DOI: https://doi.org/10.61942/jhk.v2i6.448
3) Aditya Hermawan et al., "The Use of Smart Contracts in Supply Chain Transformation Through Blockchain Technology," *Journal of Informatics Education and Research* 9, no. 3 (2023): 471–478.
4) Ahmadi Miru, *Legal Protection Principles for Consumers in Indonesia* (Depok: Raja Grafindo Persada, 2013).
5) Aisyah Dinda Ayuni and Imam Asmarudin, "Comparison of Blockchain Use in Indonesia and Singapore," *Pancasakti Law Journal (PLJ)* 2, no. 2 (2024): 267–276.
6) Alexsanro Gabe Simbolon et al., "The Effectiveness of Government Regulation and Supervision in Preventing Manipulation of Cosmetic Product Composition: A Legal and Health Study," *Jurnal Pustaka Cendekia Hukum dan Ilmu Sosial* 3, no. 2 (2025): 82–96.
7) Ambar Rika Samodra and S Maryam, "Information System for Verifying the Authenticity of Beauty Products Using Blockchain Technology" (Muhammadiyah University Surakarta, 2025).
8) Andrea T Borchers et al., "The History and Contemporary Challenges of the US Food and Drug Administration," *Clinical therapeutics* 29, no. 1 (2007): 1–16.
9) Arifin Pringgo Laksono, Candra Wahyu Saputro, and Ega Kesatrya Putra, "Comparison of Supervision of Digital Banks and Conventional Banks Based on Banking Regulations in Indonesia," *Technology and Economics Law Journal* 3, no. 2 (n.d.): 5.
10) Asnawi Asnawi, Tiarsen Buaton, and Parluhutan Sagara, "Juridical Analysis of Regulatory Authority Supervision of Pharmaceutical Products and Medical Devices in the Perspective of Law No. 17 of 2023 on Health," *Jurnal Cahaya Mandalika ISSN 2721-4796 (online)* 4, no. 1 (2023): 1107–1115.
11) Bahtiar Tamrin, "Legal Analysis of Consumer Protection in Digital Transactions in Indonesia: A Review of Law No. 8 of 1999," *Jurnal Kolaboratif Sains* 8, no. 6 (2025): 3246–3255.
12) Benny Firmansyah, Arry Akhmad Arman, and Widya Sri Wahyuni, "Regtech Solutions: Generic Business Process Analysis and Modelling," in *Proceedings of the International Conference on Data Science and Official Statistics*, vol. 2023, 2023, 13–25.
13) Bob Wahyuddin and Redyanto Sidi, "Regulation and Legal Impact of Herbal Medicine Products in Efforts to Fulfill Health Rights in Indonesia," *JIIP-Journal of Educational Science* 6, no. 9 (2023): 6754–6762.
14) Dani Habibi, "Reconstruction of the Health Law System in Indonesia Using a Comparative Approach to Health Systems in Developed Countries," *Jurnal Medika Hutama* 1, no. 03 April (2020): 156–162.
15) Directorate of Drugs and Food Cyber, "BPOM Reveals 39,642 Illegal Links to Drug and Food Products on Online Media," last modified 2025, accessed 5 November 2025, https://siber.pom.go.id/berita/bpom-reveals-39,642-illegal-links-to-drug-and-food-products-on-online-media.
16) Douglas W Arner, Janos Barberis, and Ross P Buckey, "FinTech, RegTech and the Reconceptualisation of Financial Regulation," *Nw. J. Int'l L. & Bus.* 37 (2016): 371.
17) Dwi Nofiarny, "Introduction to Pharmacovigilance: What It Is and Why It Is Needed," *Medicinus* 29, no. 1 (2016): 53–56.
18) Fajar Mukti and Yulianto Achmad Dualisme, "Normative and Empirical Legal Research" (Yogyakarta, Pustaka Pelajar, 2010), pp. 183-184.
19) G Smith, J A Smith, and D A Brindley, "The Falsified Medicines Directive: How to Secure Your Supply Chain," *Journal of Generic Medicines* (SAGE Publications Sage UK: London, England, 2014).
20) Guntoro Barovih and Salimin Salimin, "Medicine Monitoring Architecture Model Through the TOGAF ADM and Cloud Database Approach," *Jurnal Sisfokom (Information Systems and Computers)* 7, no. 2 (2018): 155–162.

21) H-P Wang et al., "From Pharmacovigilance to Pharmacovigilance Planning—The System Building for Safe Medication," *Journal of Food and Drug Analysis* 15, no. 4 (2007): 6.
22) Ika Atikah, "Legal Research Methods" (2022).
23) Jeffrey S Brown et al., "The US Food and Drug Administration Sentinel System: A National Resource for a Learning Health System," *Journal of the American Medical Informatics Association* 29, no. 12 (2022): 2191–2200.
24) Jeffriansyah Dwi Sahputra Amory and Muhtar Mudo, "Digital Economic Transformation and the Evolution of Consumption Patterns: A Literature Review of Changes in Shopping Behaviour in the Internet Age," *Jurnal Minfo Polgan* 14, no. 1 (2025): 28–37.
25) Joseph L Hackett and Steven I Gutman, "Introduction to the Food and Drug Administration (FDA) Regulatory Process," *Journal of proteome research* 4, no. 4 (2005): 1110–1113.
26) Kenichi Ishibashi, Masuo Kondoh, and Tetsuya Kusakabe, "Current Application of the Medical Device Single Audit Programme (MDSAP) as a Global Regulatory Reliance Framework for the Inspection of Medical Devices," *Therapeutic Innovation & Regulatory Science* 58, no. 6 (2024): 1172–1179.
27) Marina Yetrin Sriyati Mewu and Kadek Julia Mahadewi, "Consumer Protection in Online Product Purchases: An Analysis of the Perspective of Consumer Protection Law in Indonesia," *Jurnal Kewarganegaraan* 7, no. 1 (2023): 441–450.
28) Megawati Simanjuntak, "Ensuring the Safety and Convenience of E-Commerce Transactions in an Effort to Protect Consumers," *Policy Brief on Agriculture, Marine Affairs, and Tropical Bioscience* 5, no. 2 (2023): 562–566.
29) Muhaimin, *Legal Research Methods* (Mataram: Mataram University Press, 2020), p. 57.
30) Muhammad Siddiq Armia, "Determining Legal Research Approach Methods" (Indonesian Constitutional Studies Institute (LKKI), 2022), p. 12.
31) Nicolò Sentinelli and Lucia Biagiotti, "Evdas (Eudravigilance Data Analysis System): Nuovo Strumento Per La Signal Detection Evdas (Eudravigilance Data Analysis System): New Tool for Signal Detection Process," *Giornale Italiano di Farmacoeconomia e Farmacoutilizzazione* 11, no. 4 (2019): 24–26.
32) Ns Hendrik Probo Sasongko et al., *Health Revolution: Collaboration between Technology, Innovation, and Policy* (PT. Nawala Gama Education, 2025).
33) Nurul Hidayati Indra Ningsih et al., *Digital Economy Law: Business Regulation in the Technological Era* (PT. Nawala Gama Education, 2025).
34) Oeke Yunita and Alfian Hendra Krisnawan, *Digitalisation of Herbal Businesses* (Deepublish, 2023).
35) Onang Bambungan, "Legal Protection for Consumers Regarding Comfort, Security, and Safety in Consuming Goods or Services," *Lex Privatum* 11, no. 1 (2023).
36) Perdhana Ari Sudewo, Clara Diana Setyawati, and Ritti Piany Sangadji, "Risk and Opportunity Analysis of Artificial Intelligence in the Drug and Food Supervision Business Process," *Jurnal Widyaiswara Indonesia* 4, no. 3 (2023): 99–114.
37) Philipe Nonet and Philipe Selznick, *Responsive Law* (Nusamedia, 2019).
38) Piotr Merks et al., "The European Falsified Medicines Directive in Poland: Background, Implementation and Potential Recommendations for Pharmacists," *European Journal of Hospital Pharmacy* 25, no. 1 (2018): 10–15.
39) Priscilla D Z Saragih, Paramita Prananingtyas, and Hendro Saptono, "Analysis of the Regulatory Sandbox Mechanism in the Implementation of Financial Technology in Indonesia," *Diponegoro Law Journal* 8, no. 1 (2019): 633–649.
40) Rahmi Yuningsih, "Public Health Protection Against the Circulation of Online Medicines and Food," *Aspirasi: Journal of Social Issues* 12, no. 1 (2021): 47–62.
41) Richard Platt et al., "The FDA Sentinel Initiative—an Evolving National Resource," *New England Journal of Medicine* 379, no. 22 (2018): 2091–2093.
42) Rini Yustiani and Rio Yunanto, "The Role of Marketplaces as Business Alternatives in the Information Technology Era," *Komputa: Scientific Journal of Computers and Informatics* 6, no. 2 (2017): 43–48.
43) Rizkinil Jusar, Palmawati Taher, and Inge Dwivismiar, "The Responsibility of Business Actors and Marketplaces for Violations of the Principle of Good Faith in E-Commerce Transactions," *Sultan Jurisprudence: Journal of Legal Research* 3, no. 1 (2023): 62–72.
44) Saifullah Saifullah et al., "Regulatory Technology and the Fintech Law Landscape in Indonesia: A Normative Legal Perspective to Mitigate Illegal Fintech," *Jurisdictie: Journal of Law and Sharia* 14, no. 02 (2023).
45) Satjipto Rahardjo and Khudzaifah Dimyati, *Sociology of Law: Development, Methods, and Problem Selection* (Muhammadiyah University Press, 2002).
46) Shada Adila Abadi et al., "Innovation and Challenges in Drug Packaging: A Review Study of the Role of Packaging in Pharmaceutical Product Quality," *Pharmacy Genius* 4, no. 2 (2025): 40–48.
47) Simbolon et al., "The Effectiveness of Government Regulation and Supervision in Preventing Manipulation of Cosmetic Product Composition: A Legal and Health Study."
48) Siti Nur Kholifah, Eko Arif Susanto, and Khoiril Latifah, "Consumer Supervision and Protection Through Regulatory Sandbox in Indonesia," *HUKAMA: Journal of Islamic Law* 3, no. 2 (2024): 108–119.
49) Tri Astuti et al., "Law Enforcement Against Criminal Acts of Distributing Medicines Without Distribution Permits: (Study of Decision Number 1/Pid. Sus/2023/Pn. Pre)," *Jurnal Hukum Positum* 9, no. 1 (2024): 1–16.

50) UNCTAD, "E-Commerce and Digital Economy Programme: Year in Review 2023," last modified 2023, accessed 10 November 2025, https://unctad.org/publication/e-commerce-and-digital-economy-programme-year-review-2023?utm_source=chatgpt.com.
51) Vanessa Mathilde Harum and Gatot P Soemartono, "Consumer Protection in Electronic Transactions of Cosmetics Without Distribution Permits," *Journal of Education Management and Social Sciences (JMPIS)* 5, no. 4 (2024).
52) Yuningsih, "Public Health Protection Against the Circulation of Medicines and Food Online."