

PRESCRIPTION DRUGS PRICE SETTING AND GENERIC DRUGS PRESCRIPTION CONCERNING CONSUMER PROTECTION LAW IN INDONESIA

Jenny Jatemin^{*}, Jovita Irawati

PT. Berlian Sakti, Jakarta

Faculty of Law Universitas Pelita Harapan, Jakarta

jjatemin@gmail.com, jovitaira@yahoo.co.id

Abstract

Health is one of the most important human rights in human life. Access to affordable prescription drugs is still a problem for people with out-of-pocket expenses. Generic prescription drugs that are much cheaper than non-generic drugs are still low, especially in non-government healthcare facilities. This research aims to provide suggestions of regulation on price control of prescription drugs and generic prescription drugs that will assure certainty and affordability for the public. The methodology is doctrinal legal research and is supported by empirical studies. The research finding consist of two things, namely the price of prescription drugs and the prescription of generic drugs. The first finding is that Highest Retail Price (HET) set by the manufacturer is potentially to be unlimited because there is no limit control. Currently, there are many drugs sold over HET with minimal supervision from the Government. The absence of law is found as the existing regulations are only for those listed in the National Formulary, while the rest have not been regulated. Therefore, the suggestion is to set ceiling prices for prescription drugs with comparison among generic drugs, branded generic drugs, and the originator; also create a refund mechanism for prices above HET to assure the consumers' rights to get compensation under the Consumer Protection Law. The second finding is that only a few doctors prescribe generic drugs. Additionally, patients have not been involved in the treatment decisions. Therefore, the suggestion is to associate "the action of prescribing generic drugs" with the extension of doctor's license, namely the Registration Certificate (STR); so that doctors will prescribe generic drugs without the need for close supervision due to their interests. With the increase of generic drugs' prescription, the financing of health services, nationwide as well as individually, can become more affordable.

Keywords: *Prescription Drugs Price Setting, Generic Drugs Prescription, Consumer Protection.*

1. INTRODUCTION

Health is one of the human rights in maintaining and improving the quality of life. Constitutionally, the Government is responsible to improve the health of the society by making various efforts and establishing policies. Among them, planning of sustainable health care programs, creation of regulations, supervision of its implementation, and conducting a thorough evaluation. The basic provisions of the 1945 Constitution (UUD 1945) in Article 28H paragraph (1) and Article 28I paragraph (4) and the operational guidance of the Law on Human Rights No. 39/1999 in Article 9 states that the Government has the responsibility to protect all Indonesians in light of embracing the general welfare and enrich the education of the people. In particular, the rights to healthcare and the rights to self-determination are the aspects of human rights in healthcare. This means that every person is entitled to health care and has the right to make decisions regarding his or her health autonomously. So far, healthcare services to the entire community are pursued through the implementation of quality and sustainable health development. Within that framework, every activity and effort to improve public health is implemented based on no discriminative, participatory, protective, and sustainable principles. All these principles are very important for

* Corresponding Author

the establishment of healthy, productive, and qualified Indonesian human resources, in line with the improvement of resilience and competitiveness of the nation. In short, the Government needs to implement optimal efforts to maintain and improve health (promotive), disease prevention (preventive), cure diseases (curative), and health recovery (rehabilitative), which is implemented thoroughly, integrated, and sustainably.

Drugs or medicine (hereinafter – drugs) is one of the important components in human healthcare. Therefore, affordable drugs become very important so that the mandate of the 1945 Constitution on healthcare and human rights protection can be realized. As meant by an affordable price is a cheap price or per the regulation so that the lower class or poor people can afford to buy it¹. The Business Competition Supervisory Commission (KPPU) and Pharmacoeconomics experts pointed out that drugs prices in Indonesia are among the highest in Southeast Asia². Therefore, it is necessary to conduct in-depth research on KPPU's constataion.

Regardless of other relevant variables, the focus of this research refers to the price of prescription drugs which is the final price paid by consumers. The Highest Retail Price (HET) is the highest selling price of drugs in pharmacies, hospitals, or clinics. HET is the selling price to consumers. Therefore, this research also intersects with the issue of consumer protection in Indonesia.

It should be noted that many factors cause the price of drugs to become less affordable in Indonesia. Among others, the imported medicinal materials, promotional costs, and patents. Meanwhile, except for the drugs prescribed in Indonesian National Health Insurance (hereinafter – BPJS), drugs prices in Indonesia refers to the market mechanism. In the marketplace, there are many drugs with different brand names but with the same active pharmaceutical ingredients (hereinafter – API). These drugs are sold at different price scales. Ironically there are non-generic drugs that cost up to 85 times more expensive than generic drugs³. BPJS recorded drug spending that reached Rp. 36 trillion in 2018 or 40% of total overall health spending (equipment, facilities, and health workers)⁴ compared to the standard 30%. In light of this huge expenditure on drugs, drugs price regulation becomes very important to ensure the achievement of efficiency and effectiveness in providing healthcare services to the society. The issue of drugs prices is also related to aspects of legal certainty and social justice for Indonesians, especially about the access to affordable drugs for the poor.

Admittedly, the Government has issued several regulations to control the price of drugs in the market. However, the drugs prices above HET and the big price disparity between generic and non-generic drugs have still not changed until now. In addition, society is faced with a situation where they cannot choose the type of prescription drugs (between generic or non-generic drugs), given the knowledge of the disease is less understandable by the layman (patient). Moreover, doctors generally provide limited information to the patients before prescribing the drugs. This

¹ Central Bureau Statistics: The poor are people who have an average monthly per capita expenditure below the poverty line. The Poverty Line in March 2020 was recorded at Rp. 454,652/capita/month. With 4.66 household members, the Poverty Line per poor household on average is IDR 2,118,678/month.

² Mila Novita, "Ini Penyebab Harga Obat Di Indonesia Lebih Mahal Dari Negara Lain," *Gaya Tempo*, accessed September 27, 2020, <https://gaya.tempo.co/read/1187633/ini-penyebab-harga-obat-di-indonesia-lebih-mahal-dari-negara-lain>.

³ Winda Syahdu, "Formularium Nasional (FORNAS) Dan e-Catalogue Obat Sebagai Upaya Pencegahan Korupsi Dalam Tata Kelola Obat Jaminan Kesehatan Nasional (JKN)," *INTEGRITAS* 4, no. 2 (December 11, 2018): 178, <https://jurnal.kpk.go.id/index.php/integritas/article/view/328>.

⁴ Alwan Ridha R., "Monopoli Obat Paten Bikin BPJS Jadi Defisit," *Indozone*, accessed September 28, 2020, <https://www.indozone.id/news/DNsQ39/monopoli-obat-paten-bikin-bpjs-kesehatan-defisit/read-all>.

shows fewer chances for consumers to participate in decision-making on the treatment of their healthcare.

Based on the above-mentioned description of prescription drugs pricing and the pattern of prescribing generic drugs, the research questions are as follows firstly, how are 'the prescription drugs pricing and the generic drugs prescription' are regulated and their implementations in Indonesia? Secondly, how will be the ideal prescription drugs price setting and the generic drugs prescription concerning consumer protection in Indonesia?

Both research questions indicate the importance of the Government's role in realizing the basic principles of fair and equitable healthcare development. The assumption is, the Government must be present in the form of policies as the instruments of legislation with three legal objectives, namely justice, along with legal certainty and expediency. It is supported by the thought that "law is for man and not man for the law"⁵. Law for man requires adjustments between law and people or social behavior, including encouraging the desired social change in society. In line with that, efforts to improve the level of public health must be carried out in an integrated and comprehensive manner, both government, pharmaceutical industry, health workers and society.

2. RESEARCH METHODS

This research is doctrinal legal research supported by empirical juridical studies. Both methods examined the aspects of the prescription drugs pricing in the market and the prescribing of generic drugs by doctors, along with their implementation including the impact on people's lives. According to P.M. Marzuki, this research is a sociolegal research which is legal research that examines and analyzes legal behavior of individuals or communities concerning the law and the data come from primary data⁶. This research uses the statute approach and conceptual approach. In addition to secondary data, primary data is collected from the parties directly related to research questions such as patients, pharmacists, doctors, and others through the implementation of surveys, in-depth interviews and focus group discussions. Total respondents reached 362 people domiciled in Jakarta and several major and small cities. Quantitative and qualitative data analysis were carried out by organizing data, sorting it into manageable units, synthesizing, finding patterns and important facts, then deciding what to be disclosed⁷. Data validity is also conducted as an important and inseparable element of qualitative research to ensure the results can be trusted academically.

3. ANALYSIS AND DISCUSSION

3.1 Theories and Concepts

Legal research is a process to find the rule of law and legal doctrines to answer the legal issues⁸. Meanwhile, the essence of legal theory is to explain the values of the law up to the ground policy and its philosophy. The theory also functions as an important analysis tool to better understand the research questions. This research uses three theories namely the Law Triad by Gustav Radbruch, the Development Legal Theory by Mochtar Kusumaatmadja and the Contract Theory by Subekti.

⁵ Satjipto Rahardjo, *Ilmu Hukum* (Bandung: P.T. Citra Aditya Bakti, 2000), 5.

⁶ H. S. Salim and Erlias S. N., *Penerapan Teori Hukum Pada Penelitian Tesis Dan Disertasi* (Jakarta: Rajawali Press, 2018), 20.

⁷ Lexy J. Moleong, *Metodologi Penelitian Kualitatif* (Bandung: Remaja Rosdakarya, 2018), 248.

⁸ Peter Mahmud Marzuki, *Penelitian Hukum*, Revisi. (Jakarta: Kencana, 2010), 35.

In the context of these theories, firstly it is important to quote Radbruch's idea "the idea of law is defined through a triad of justice, utility and certainty." Meanwhile, the culture is the essence of the law, and justice (equality before the law) is the ultimate goal of every legal system. Through his thinking, Radbruch seemed to be more concerned with the value of justice over the statutory law.

In law-making process, the creation of a legal certainty is important as it will determine a clear, firm, and measurable protection. Parallely, legal norms must follow the purpose of the law as stated by Jeremy Bentham namely the greatest happiness of the greatest number. In short, the objective assessment of whether or not the law is good, fairly depends on the capability of the law to create order in society. Particularly, regarding drugs price regulation, the value of justice is also very important because being healthy is classified as human rights. If drug prices are affordable to poor people, it means the regulations surely reflect the value of justice, which in turn will improve their well-being. The phenomenon of HET violation shows that there is no legal certainty on this issue. As a result, it is difficult to actualize the expediency, especially in providing the affordable drugs access for society.

Kusumaatmadja believes that a good law must be in accordance with the living law⁹. The living law is a living and actual law that takes place in society. This means the law is not something static, but it keeps changing over time. The living law can be written and unwritten as the rules derived from culture or customs. This theory is modified from Roscoe Pound's Theory known as "Law as a tool of social engineering"¹⁰. According to Kusumaatmadja, order and regularity in the development are absolutely necessary. In this regard, the law or norms are expected to direct human activities towards the direction desired by the development. Similarly, prescription drug pricing setting and prescribing of generic drugs should be able to encourage and direct people activities towards a healthy life and to contribute to the healthy society in the long term.

Relating to the norm, an alliance is a legal relationship between two persons or parties, based on one party that has the right to demand something from the other party, and the other party is obliged to meet that demand. Subekti implies that the alliance is born because of an agreement. The agreement is also called consent. The Contract Law adheres to an open system. It means that the law provides freedom to the public or parties to enter into agreements with any contents as long as it does not violate public order and decency. Related to this research, prescribing generic drugs that occur in therapeutic transactions is also an agreement, namely an agreement between doctors and patients¹¹. Article 1320 of the Civil Code states that an agreement is considered valid if four conditions are fulfilled, namely the agreement between those who bind themselves (doctors and patients); the ability to ally (adult and not under guardianship); a particular subject matter (health efforts); and a cause that is not forbidden/halal (the purpose is the maintenance and improvement of health). In therapeutic transactions, all conditions are fulfilled.

⁹ A good law is in accordance with the living law and it can regulate the interaction between people with different interests to a balanced or proportional way so as not to occur chaos. Mochtar Kusumaatmadja, *Konsep-Konsep Hukum Dalam Pembangunan* (Bandung: P.T. Alumni, 2006), 14.

¹⁰ This theory postulates that law was born, developed and grew in accordance with Indonesian society. Bernard L. Tanya, *Teori Hukum Strategi Tertib Manusia Lintas Ruang Dan Generasi*, IV. (Yogyakarta: Genta Publishing, 2013), 155.

¹¹ Transaction Therapeutic is an agreement between doctor and patient in the form of in the form of legal relationship that gives birth to rights and obligations for both parties. Desriza Ratman, *Aspek Hukum Informed Consent Dan Rekam Medis Dalam Transaksi Terapeutik* (Bandung: Keni Media, 2018), 18.

Based on the drugs' content associated with patents, drugs can be classified into generic, branded generic, and patented drugs or the originators. The concept of originator is used by pharmaceutical industry to distinguish off-patented drugs from those of branded generic drugs. In practice, there are not many people understand the difference between these three types of drugs. Specifics about generic drugs, people with a better level of literacy understand that generic drugs are marketed with the brand of API content, while branded generic drugs are trademarked. Generic drugs are drugs with the official name International Non-Proprietary Names (INN) stipulated in Pharmacopoeia Indonesia¹². This type of drugs does not use the trademark, for example Paracetamol 500mg. These generic drugs can be produced by all pharmaceutical industries without the need to pay royalties because their patent protection has expired. An example of branded generic drugs for Paracetamol 500 mg is Panadol 500 mg.

Therapeutic transactions are legal relationships that give birth to rights and obligations for doctors and patients. Therapeutic transactions are different from other transactions in general, as it does not promise the results or outputs (*resultaats verbintenis*) but the maximum efforts made for the recovery of patients (*inspannings verbintenis*)¹³. This is the nature of the agreement between the doctor and the patient, and to date relatively still puts the patient in a "lower" position of bargaining power. This situation also occurs in terms of the selection of types of prescription drugs.

In accordance with the Law on Consumer Protection No. 8/1999 (hereinafter – the LCP 1999, patients are consumers and doctors are entrepreneurs. This concept is agreed upon by most of the respondents in this research, including several doctors. This concept where the patient is a consumer be continuously socialized so that patients can have a better bargaining power than just listening and following the doctor's instructions, without asking for a clear explanation. This is a portrait of therapeutic transaction, which based on primary and secondary data, still shows paternalistic or guidance cooperation models¹⁴. In other words, it has not achieved an equal position between legal and medical aspects. Consumer protection is all efforts to ensure the existence of legal certainty in providing protection to consumers. By definition, a consumer is any user of goods and/or services available in society, whether for the benefit of oneself, family, others, or other living beings and not for trading¹⁵. The government established three institutions that specifically handle problems raised by consumers, namely the National Consumer Protection Agency (hereinafter – BPKN), the Consumer Dispute Settlement Board (BPSK), and the Non-Governmental Consumer Protection Agency (LPKSM). This shows the seriousness of the Government in fighting for consumer protection in Indonesia. As for consumer behavior¹⁶, it can include behavior before purchase, when purchasing and after

¹² Pharmacopoeia Indonesian is a standard and requirement for material of drugs and drugs distributed in Indonesia. Pharmacopoeia Indonesian Edition VI 2020 was developed by Committee of Constituent Pharmacopoeia Indonesia formed by the Minister of Health, and the Representative from Ministry of Health, National Agency of Drugs and Food Control, and for experts from various public and private universities.

¹³ Jovita Irawati, "Disharmoni Peraturan Perundang-Undangan Di Bidang Kesehatan Dan Implikasi Hukumnya Terhadap Praktik Medik Dan Eksistensi Majelis Kehormatan Disiplin Kedokteran Indonesia" (Universitas Pelita Harapan, 2016), 7.

¹⁴ Guidance Cooperation is a relationship between doctor and patient with the existence of communication from doctor to patient. But the decision making is still dominated by doctor, and patients are only given explanation about disease, treatment or action to be taken; Patients only follow doctor's decision. On this model, the medical aspect still dominates the legal aspect. Thomas S. Szasz, William F. Knoff, and March H. Hollender, "The Doctor-Patient Relationship and Its Historical Context." *American Journal of Psychiatry* 115, no. 6 (December 1958): 522, <http://psychiatryonline.org/doi/abs/10.1176/ajp.115.6.522>.

¹⁵ Article 1 paragraph (1) and (2). Indonesia, *Law Number 8 Year 1999 Concerning Consumer Protection*, 1999.

¹⁶ Consumer behavior is the process that a person/organization goes through in searching for, buying, using, evaluating and disposing of a product or service after being consumed to meet their needs. Tengku Ezni Balqiah and Hapsari Setyowardhani,

purchase. To this research, such behavior refers to the process before purchase, when consumers search for information related to goods/services to be purchased. However, in terms of prescription drugs, the search about the drugs, depends heavily on the doctor who performs healthcare services to the patient because it is the doctor with the expertise, competence, and authority to prescribe the drugs.

Basically, the focus of this research is the regulation of prescription drugs pricing and the regulation of prescribing generic drugs associated with consumer protection in Indonesia. Some regulations such as the Laws, Presidential Decree, Presidential Instructions, Ministerial Decree, and Regulations of National Agency of Drugs and Food Control (hereinafter – BPOM) are the main references in this research. Drugs pricing policy is one of the issues stipulated in the legislation. All model of drugs pricing policy basically led to the question of whether the existing policy has improved drugs access which in turn will also improve healthcare services. Therefore, drugs pricing policy is a very important part of health sector regulatory reform.

3.2 Prescription Drugs Price Setting and Generic Drugs Prescription Regulation and Its Implementation in Indonesia

Before analyzing specific regulations regarding drugs prices and generic drugs prescription, researcher will examine several regulations contain general provisions on healthcare and consumer protection. In general, the Law on Health No. 36/2009 (hereinafter – the LH 2009) governs several principles such as everyone has the rights to obtain safe, good quality, and affordable health services. In addition, everyone has the right to determine independently and responsibly his or her own health. Everyone is also entitled to obtain information about his/her health data including actions and treatments to be received from health workers. Moreover, everyone has the rights to accept or reject some or all proposed medical treatments after receiving and understanding the complete information about the treatment. It is also mentioned in the LH 2009, anything that causes public health problems will generate great economic harm to the country. In line with that, any efforts to improve the degree of public health also means an investment for the development of the country. Consequently, every development plan must have health insights as the foundation.

The Presidential Decree on National Medium Term Development Plan 2020-2024 No. 18/2020 (RPJMN) stated that the availability and irrational use of drugs are still happening. Along with that, the high dependence on the import of medicinal materials and medical devices, as well as drugs and food control systems are also considered not optimal. Improved effectiveness of drugs and food control, focused on expanding the scope and quality of pre- and post-market supervision of drugs and high-risk foods, need to be supported by the improvement of human resources' competence. Therefore, the pharmaceutical industry becomes one of the Government priorities sectors. This Presidential Decree was made before the Covid-19 pandemic (enacted in January 2020). This means that the Government has understood that pharmaceutical industry is a very important sector of its contribution in improving the quality of human resources and the success of national development ultimately.

Furthermore, the Presidential Instruction on Acceleration of Pharmaceutical and Medical Device Industry Development No. 6/2016 is drawn up to achieve independence and improve the competitiveness of the domestic pharmaceutical and medical devices industry and

encourage the mastery of technology and innovation; including the development of medicinal materials, drugs, and medical devices to meet domestic needs and exports.

Related to consumer protection issues, regulated in the LCP 1999 has been valid for more than 20 years. However, Indonesian consumers are still not used to filing lawsuits in case of violations of their rights as consumers. In short, consumer protection aims to increase awareness, courage, and independence of consumers to protect themselves; create a consumer protection system that contains elements of legal certainty and information transparency; and access to obtain information. In addition, to raise awareness of entrepreneurs on the importance of consumer protection so as to grow an honest and responsible attitude in improving the quality of goods and /or services that ensure the sustainability of production of goods and/or services; also, health, comfort, and safety of the consumers. In Indonesia, the conception of consumer protection is still not widely understood. This is evident from Indonesian Consumer Empowerment Index that is still low¹⁷. The main reason for frailty consumer is the low awareness level its rights¹⁸. This is mainly due to several factors such as low consumer education or literacy, and Indonesian culture that tends to "*nrimo* or surrender" or a considerable level of tolerance in terms of voicing dissatisfaction (complain habit) as a form of legal protection for its rights as a consumer. According to BPKN data, there are only about 200 complaints in 2017, 580 complaints in 2018, and 1518 complaints in 2019¹⁹. As many as 80% of the total complaints are housing issues, the financial issues (vehicle leasing, mortgages, credit card breaches, insurance, online loans and investments), and e-commerce²⁰. Meanwhile, according to Indonesia Consumer Foundation (YLKI) data, complaints about drugs prices and generic drugs prescription can be said to be almost non-existent²¹.

3.2.1 Prescription Drugs Price Setting and Its Implementation in Indonesia

One of the important drugs prices settings conducted by the Government is the Decree of Ministry of Health on the Provision of Information of Highest Retail Price of Drugs No. 98/2015 (hereinafter –the MOH 2015), which governs the HET on the smallest packaging of the drugs. The provision of HET information aims to ensure the affordability of drugs prices as well as to meet the principles of accountability, transparency, and provide legal certainty to the public.

HET is the price set by the pharmaceutical industry with an additional margin of about 28% of the Pharmacy Net Price (hereinafter – HNA²². The 28% is the margin for pharmacies and hospitals/clinics. In the pharmaceutical industry, HNA is one of the

¹⁷ Public Discussion Program with Indonesia Consumer Club and BPKN: Consumer Empowerment User (IKK) has four levels, that are 80-100 Empowered; 60-80 critical; 40-60 capable; 20-40 understand, and 0-20 aware. In year of 2019 and 2020, IKK of Indonesian are 41.70 and 49.07 respectively. This means Indonesian is still at the level "capable" but not yet too active fighting for its rights as consumer or the complaint habit is still low.

¹⁸ Explanation Part of the LCP/1999, Part I. General: The main reason of frailty consumer is the low awareness level upon its rights. This is mainly due to low level of consumer education.

¹⁹ BPKN, "Dipilih Jadi Anggota BPKN, Andre Garu: Empat PR Besar Harus Kami Selesaikan," *JPNN*, accessed January 17, 2020, <https://www.jpnn.com/news/dipilih-jadi-anggota-bpkn-andre-garu-empat-pr-besar-harus-kami-selesaikan>.

²⁰ BPKN, "Ada 3269 Aduan Konsumen 3 Tahun Terakhir, Terbanyak Soal Perumahan," *IDN Times*, accessed February 6, 2021, <https://bpkn.go.id/posts/show/id/1736>.

²¹ Based on the in-depth interview with Tulus Abadi as YLKI Chairman on May 29, 2021.

²² Article 1 paragraph (3): Pharmacy net Price (HNA) is the selling price inclusive of value added tax (VAT) from Big Pharmacy Distributor (PBF) to pharmacies, drugstores and hospitals/clinics. Minister of Health of the Republic of Indonesia, *Minister of Health Decree Number 98/2015 Concerning the Provision of Information of the Highest Retail Price of Drugs*, 2015.

mandatory data to be informed by the owner of the Marketing Authorization Number (hereinafter – NIE) to BPOM at the time of registering the new product. HET of one product is initially proposed by pharmaceutical company as the NIE owner to BPOM for registration purposes. Thus, the price can be set following the pharmaceutical company's wishes. Furthermore, this HET setting does not limit the frequency of price increases allowed in a certain period e.g., one year. This means the HET has the potential to become unlimited because of the following provisions:

- a. HET set by the pharmaceutical industry
- b. Price changes can be made at any time
- c. Price changes can be done simply by reporting, without the need for approval from the Government.

In its implementation, not only the pharmaceutical company is obliged to include HET on the smallest outer packaging of drugs, but pharmacists are also obliged to provide communication, information and education (hereinafter – KIE) about HET to the public²³. However, the reality shows that surveillance is difficult to do as evidenced by the number of pharmacies that sell drugs beyond HET. In addition, pharmacists rarely conduct KIE even though it has been stipulated in the MOH 2015. Moreover, the public's understanding of HET is also still very lacking, so the violations have not been a problem for consumers so far. This phenomenon has been going on for quite a long time, considering the HET inclusion regulations came into force since 2006 and no real action or sanctions that can give a deterrent effect to the violation of this Decree.

Regarding the control, both by the Central and Local Governments, it has not been effective because there are still many pharmacies sell drugs above HET, even reached 2.64 times²⁴. Functionally BPOM has a duty and responsibility in terms of comprehensive supervision to ensure the quality, efficacy, and safety of drugs and medicinal materials, as well as to prevent irregularities in the management of drugs and drug ingredients during distribution. In conducting drugs surveillance (post-market), BPOM is more focused on violations related to counterfeit drugs, expired drugs, and drugs that are distributed illegally. Three things that become the focus of BPOM supervision is the quality, safety, and efficacy of the drugs. In other words, price or HET has not been the focus of BPOM so far.

Additionally, BPOM admits that they find it difficult to implement the law enforcement despite finding violations. This is what encourages BPOM to continue to fight for the Draft of Law (Bill) of BPOM that allows the provision of sanctions to create a deterrent effect, considering the form of regulation is the Law, no longer Ministerial Decree or BPOM Regulation.

The MOH 2015 regulates HET for all drugs except drugs listed in the National Formulary (hereinafter – FORNAS). Drugs prices in FORNAS are determined by the Government through tendering and negotiation with pharmaceutical companies²⁵. FORNAS 2019 includes 1043 generic names in API. Other than FORNAS, there are

²³ *Ibid.*, Article 8.

²⁴ Collection of primary data for 28 generic drugs, 28 branded generic drugs and 17 originators in December 2020 at some pharmacies in Jakarta and some other cities in Indonesia.

²⁵ Syahdu Winda, *Op. cit.*, p.184: FORNAS are drugs that have been selected by the Government after considering quality, efficacy and the most efficient cost. These drugs are expected to overcome 80% of diseases suffered by the community.

generic drugs whose prices are also determined by the Government through the Decree of the Minister of Health on Generic Drugs' HET No. 525/2015 which includes 197 generic names in API²⁶.

In addition to the drugs in FORNAS and generic drugs regulated by the Government, there are no other regulation on price setting of non-generic drugs. This means that the regulation of drug prices governs a limited number of the drugs distributed in Indonesia (about 17%)²⁷, where prescription is required through BPJS in public healthcare facilities. Thus, the price setting of other drugs which is the largest amount (about 83%), has not existed until now or there is an absence of law. As a consequence, the price of such drugs is determined based on market mechanism. The reality shows that the price of these drugs becomes uncontrolled or expensive. The following are the findings of primary data on the price comparison of some drugs resulted from a survey to some pharmacies in December 2020:

- a. Branded generic drugs sold at 9.9 times of generic drugs' price
- b. Originators sold at 9.6 times of generic drugs' price
- c. Originators sold at 2.0 times branded generic drugs' price

Based on the above price disparity, it appears that the prices of originators and branded generic drugs are not too much different. While the price disparity of these two types of drugs with generic drugs are far enough, that is almost 10 times. This phenomenon indicates that the drugs price setting, especially prescription drugs, should be established by the Government in order to solve the issue of the absence of law to improve the health of the community.

3.2.2 Generic Drugs Prescription and Its Implementation in Indonesia

The Law on Medical Practice No. 29/2004 (hereinafter – the LMP 2004)²⁸ governs a series of activities carried out by doctors to the patients, including prescription of drugs, in carrying out health services based on science, competence and code of ethics to serve the community. In medical practice, each patient has different characteristics than other patients so there will not be two similar cases due to various factors that affect it, among others clinical conditions, metabolism, and complications that may arise. The best practice of relationship model between doctors and patients or therapeutic transactions has the character of *mutual participation*²⁹.

Furthermore, the regulation that requires doctors to prescribe generic drugs is the Decree of the Minister of Health on The Obligation to Use Generic Drugs in Government Healthcare Facilities No. HK.02.02/MENKES/068/I/2010, which revised the same regulation set in 1989. This shows that the Government has been making efforts to promote generic drugs in improving the health of the Indonesian people since 1989. The achievement of generic drugs prescription is about 76% in government healthcare facilities. It is due to the drugs available in these facilities are almost all generic drugs. Given that the obligation is only imposed in the government facilities, then doctors have

²⁶ *Ibid.*, p. 187.

²⁷ *Ibid.*

²⁸ Fred Ameln. 1991. *Kapita Selekta Hukum Kedokteran*. Jakarta: Grafika Tama Jaya. p. 34: Medical practice is held based on an agreement between doctors and patients in healthcare services.

²⁹ Fred Ameln, *Kapita Selekta Hukum Kedokteran* (Jakarta: Grafika Tama Jaya, 1991), 34.

no legal obligation to prescribe generic drugs in private healthcare facilities. Consequently, the generic drugs prescription is relatively low. This view is supported by primary and secondary data that pointed out that generic drugs are still rarely prescribed in private facilities.

So far, the view which says that generic drugs have less efficacy compared to non-generic drugs is the opinion of most respondents. In such cases, it is not easy for patients or pharmacists to replace prescription drugs with generic drugs that contain the same API, except when the availability of the drug becomes a problem. On the other hand, primary data shows that patient's confidence is still high in the expertise of the doctors. In these conditions, the role of doctors to ask patients about the choice of drugs type (generic or non-generic) is a concrete fulfillment of the patients' human rights in therapeutic transactions. This concrete action can have a considerable impact on the increase in prescription of generic drugs in Indonesia.

Ironically, doctors generally consider patient's affordability only from the appearance such as clothing or other visible objects, or the insurance form carried by the patient, assuming that patients who possess health insurance are among those who are in middle to high class level of society as the access to insurance in total is still very low (about 1.73% of Indonesia GDP as of January 2021)³⁰.

It should be clearly stated that legal obligation of a doctor is to diagnose the disease, treat the disease, provide information to the patient (whether requested or not), and obtain approval from the patient after providing information. Consent can be done orally or in writing (informed consent). Currently, informed consent³¹ is only used for cases at great risk, unpredictable result, or cases that may cost very expensive. Informed consent is the process in which a healthcare provider (mostly doctor) educates a patient about the risks, benefits, and alternatives of a given procedure or intervention. From legal point of view, it is an agreement to do something or to allow something to happen, made with complete knowledge of all relevant facts, such as the risks involved or any available alternatives³².

The Decree of the Minister of Health on Patient Safety No. 11/2017 stipulates that it is the rights of the patient and his/her family to obtain information about the diagnosis, procedures, and purpose of medical actions, alternative actions, risks, and complications that may occur, the prognosis of the actions performed, and the estimated cost of treatment. This means that patients as consumers are entitled to an estimate of treatment cost. By having this information, patient can ask the doctor for alternative treatment and choose the appropriate one according to his/her clinical condition and financial capabilities.

Provisions on the obligation of doctors in terms of providing information or explanations about diseases and medical actions, are also regulated completely in several laws and regulations such as the LMP 2004, the Law on Hospital No. 44/2009, and

³⁰ "Bonus Demografi Berpotensi Tambah Ceruk Bisnis Asuransi," *Media Asuransi News*, accessed March 1, 2021, <https://mediaasuransinews.co.id/news-in-brief/bonus-demografi-berpotensi-tambah-ceruk-bisnis-asuransi.html>.

³¹ Desriza Rahman, *Op., cit.* p. 45: Informed Consent is an agreement or approval from the patient for medical actions that will be done by the doctor to the patient, after the patient has obtained all information from the doctor about the medical actions to be taken to help him, as well as information about any risks that may occur.

³² Legal Information Institute, "Informed Consent," *Cornell Law School*, accessed August 14, 2021, https://www.law.cornell.edu/wex/informed_consent.

Regulation of the Indonesian Medical Council on Professional Discipline of Doctors and Dentists No. 4/2011 (hereinafter – the KKI 2011). However, the provision of providing information on medical treatment cost is not listed in the LMP 2004, but it is listed in the KKI 2011³³. Institutionally KKI is an autonomous, independent, non-structural, and independent body, that has the function of regulation, ratification, determination, and coaching of doctors who practice medicine in order to improve the quality of medical services. Therefore, doctors should be guided by the KKI 2011 that regulates more specific things (the principle of *lex specialis derogat legi generali*)³⁴. If the KKI 2011 is compared to the LMP 2004, from the point of the hierarchy of legislation there is a principle namely *lex superior derogat legi inferiori*³⁵ which confirms that the position of the Law is higher than the KKI Regulation. It is clear that there are inconsistencies of norms in the KKI 2011 that has no normative basis in the LMP 2009, and this may create doubts or confusion in compliance with the law. Drugs prescription is basically the authority of doctors based on expertise and competence as medical workers who have obtained a Registration Certificate (STR) from the Indonesian Medical Council. Therefore, control or monitoring on generic drugs prescription is basically not possible even though this has been stipulated in the Decree of the Minister of Health on The Guideline for Fostering and Supervising the Use of Generic Drugs in Government Healthcare Facilities No. HK.03.01/MENKES/159/I/2010. This Decree is considered not doable because it requires the report of prescriptions to be sent manually to the Ministry of Health. Therefore, its implementation did not run effectively. Furthermore, actually there are rules on disciplinary punishment for those who violate it. Based on in-depth interviews with several doctors, there is no such thorough monitoring of generic drugs prescription or the imposition of sanctions due to not prescribing generic drugs.

On the other hand, patients have the rights to choose the type of drugs after listening to the explanation from the doctors. The doctors should not refuse to prescribe generic drugs when requested by the patients. The problem is that the patients are still reluctant or less courageous to ask more details to the doctors, including asking about whether or not generic drugs can cure the disease. The reason is due to information asymmetry³⁶ as well as “*nrimo* culture or surrender” attitude which is still strong in Indonesian culture.

Another factor that also greatly affects the prescription of the drug is the drugs formulary in each hospital. So far, discounts given by the pharmaceutical companies are used by the hospitals for various hospital interests, including to ensure that the hospital

³³ Article 3 paragraph (2h): Failure to provide honest, ethical, and adequate information to patients or their families in conducting medical practice is one of 28 types of disciplinary violations. Indonesian Medical Council on Professional Discipline of Doctors and Dentists, *Regulation of the Indonesian Medical Council on Professional Discipline of Doctors and Dentists No. 4/2011*, 2011.

³⁴ *Lex Specialis Derogat Legi Generali* means If there is a conflict between the specific laws and the general ones, then the special ones will apply. Enny Agustina, *Etika Profesi Dan Hukum Kesehatan* (Bandung: Refika Aditama, 2020), 38.

³⁵ *Lex Superior Derogat Legi Inferiori* means If there is a conflict between high and low laws and regulations, the high one must take precedence. *Ibid.*

³⁶ Information asymmetry is a term in economics that was first used by Kenneth J. Arrow to describe a condition in the field of health care, namely the occurrence of an imbalance in the acquisition of information, because one party to a transaction has more or better information than the other party. Nanik Trihastuti and Kanyaka Parjnaparamita, “Akibat Dari Informasi Asimetris Dalam Pelayanan Kesehatan: Suatu Studi Dalam Perspektif Dalam Hukum Progresif” (Universitas Diponegoro, 2018).

business can continue running well³⁷. In this regard, doctors practicing in hospitals are obliged to prescribe the drugs listed in the formulary, unless the required drugs is not available in the formulary. Along with the vigorous promotion by the pharmaceutical industry, generic drugs prescription at affordable prices indeed a hard thing to do except with the intervention from the Government in the form of a clear and firm legislation. In other words, generic drugs prescription is necessary so that doctors are willing to prescribe generic drugs even if they are not in the formulary, especially in private healthcare facilities.

In addition, the LMP 2004 also stipulates that every doctor is obliged to carry out quality control and cost control. What is meant by cost control is that the healthcare cost charged to the patient must be strictly in accordance with the patient's medical needs based on rates set by the regulations³⁸. Therapeutic transaction as an agreement with the concept of *inspanning verbintenis*, is said to be *lex specialis* of the Law on Consumer Protection. This means that if there are any disputes between a doctor and a patient, then the doctor cannot be blamed as long as the doctor has practiced medicine according to standards. In practice, the patient often given a simple and short explanation about the disease, and treatment decisions are made by the doctor with little involvement of the patient. This can be understood because the position of doctors and patients are not in a mutual participation model. Supposedly as a fellow legal subject, there should be no dominance of either party over the other. In principle, rights and obligations must be exercised in full by both parties, including the obligation of the doctor to provide the patient with a choice of drugs and the rights of the patient to choose the type of drugs following the complete information from the doctor.

3.3 The Ideal Prescription Drug Price Setting and Generic Drug Prescription Concerning Consumer Protection in Indonesia

Regarding the ideal rules, it is necessary to pursue interests balancing between the public interests or social interests with personal interests. Law should be able to choose the greater interests through the use of power or by conducting consensus, if possible. Based on this thinking, the law can be used as a tool to reach a consensus or agreement between stakeholders. This is what is meant by the interest balancing. The ideal regulations on prescription drug price setting and generic drugs prescription in relation to consumer protection in Indonesia, must be formulated in two separate regulations to ensure the effective and efficient implementation. A good drugs price setting regulation should be able to improve public access to the drugs, which ultimately lead to improving public healthcare services. This means that drugs price setting is a very important part of health sector reform.

3.3.1 The Ideal Prescription Drug Price Setting Concerning Consumer Protection in Indonesia

The current generic drugs price setting is good enough so that the prices are cheap and affordable by the poor people. But it only covers about 17% of the total drugs with

³⁷ Tim Investigasi Tempo.co, "Eksklusif: Suap Obat, Bos Rumah Sakit Blak-Blakan Terima Duit," *Tempo*, last modified 2015, accessed July 8, 2021, <https://nasional.tempo.co/read/715680/eksklusif-suap-obat-bos-rumah-sakit-blak-blakan-terima-duit/full%26view%3Dok>.

³⁸ Article 49 on Control Quality and Cost Control. Indonesia, *Law Number 29 Year 2004 Concerning Medical Practice*, 2004.

NIE. Consequently, there is still about 83% of the drugs whose prices are not regulated and follow market mechanisms. So, the absence of law in terms of price setting of prescription drugs, in this case the branded generic and the originators are expected to be immediately taken care of by the Government with the development of the Regulations.

The MOH 2015 is intended to control the price of drugs. However, the determination of HET needs to be revised in order to accommodate the interests of stakeholders, especially pharmaceutical companies, consumers or patients, and the Government. Thus, the substance of drugs price setting will become clear and lead to the development of public health.

Based on the researcher's analysis, the ideal prescription drugs price setting should cover all drugs (other than patented drugs) whose current price is not regulated by the Government. Facts shows that the price of branded generic drugs is much more expensive than generic drugs even though the period of patent protection has expired. Therefore, a pricing policy with restrictions on price comparison between those three types of drugs, need to be established in Indonesia. The method used by such a policy model is known as Internal Price Referencing (IPR)³⁹. International experts confirmed that the decline in drugs prices is considerable and the effects of IPR implementation are quite successful, associated with the savings of state health budget, patients, and society⁴⁰. Examples of restrictions on price comparison are as follows:

- a. Price of branded generic drugs must not exceed 10 times that of its generic drugs' price
- b. Price of originator must not exceed 1.5 times that of its branded generic drugs' price
- c. or another restriction scheme that locks the HET from sky-rocketing indefinitely as pharmaceutical company's wish.

Regarding consumer protection, the LCP 1999 Article 4 (h) grants the rights to consumers to obtain returns, compensation, and/or replacement if the goods received are not in accordance with the agreement. Therefore, it is necessary to compensate HET excess to consumers in order to educate the pharmacies, hospitals and clinics to carry out their obligations in providing compensation.

3.3.2 The Ideal Generic Drugs Prescription Concerning Consumer Protection in Indonesia

Doctors' prescribing act is not much regulated considering the complexity of other factors beyond the reach of doctors, such as patients' endurance, age, physical condition, the level of disease suffered, patient compliance, quality of drugs and availability of health care facilities. In addition, basically doctors have full authority in drugs prescription to the patients as stipulated in the LMP 2004. The current regulation only mandates doctors to prescribe generic drugs in public healthcare facilities. Monitoring of its implementation that did not run effectively, shows that there needs to be a mechanism that makes doctors encouraged to prescribe generic drugs in order to cure the

³⁹ IPR is the practice of using the price(s) of identical medicines or similar products or even with therapeutically equivalent treatment (not necessarily a medicine) in a country to derive a benchmark or reference price for the purposes of setting or negotiating the price or reimbursement of the product in the same country. Lisa Bero, Fatima Suleman, and Sabine Vogler, "Access to Medicine and Health Products," in *WHO Guideline on Country Pharmaceutical Pricing Policies*, 2nd ed. (Geneva: World Health Organization, 2020), 77.

⁴⁰ *Ibid.*, p. 10.

patients. Thus, the doctors can improve public health with the support from personal motivations because their interests are fulfilled.

In relation to the obligation of the doctor to fulfill the patient's right in terms of "providing information about the disease and medical actions in full" can be fulfilled if the doctor him/herself has the motivation to promote generic drugs directly to the patient. The patient's high trust in doctors will help the patient's understanding of the efficacy of generic drugs. This is evident from the facts in the field which shows that even pharmacist is authorized to replace the prescription drugs with other drugs with the same efficacy or drugs with same API, it cannot function effectively although the drugs are regarded as expensive by the patient.

4. CONCLUSION

HET is the price set by the industry with 28% of margin (for pharmacies, hospitals/clinics) on top of HNA. HET is proposed by pharmaceutical company as the NIE owner to BPOM for registration purposes. Generally, BPOM approves the company's proposal. Furthermore, there is no limit on the frequency of price increase allowed in a certain period. In other words, HET has the potential to be unlimited as price changes can be done simply by reporting, without the approval from the Government. The monitoring of its implementation is difficult to do as many pharmacies sell drugs beyond HET. Moreover, the public's knowledge of HET is very limited, so the violations have not been problem despite the affordability. This phenomenon has been going on for a long time, since 2006 and no real action was taken to the violation of this Decree. Drugs prescription is basically the authority of doctors based on expertise and competence. Therefore, control on generic drugs prescription is basically not possible even though this has been regulated only for government healthcare facilities. Consequently, the generic drugs prescription is very low in private healthcare facilities. Generic drugs have less efficacy compared to non-generic drugs, is the opinion of most respondents. In such cases, it is not easy for patients or pharmacists to replace prescription drugs with generic drugs. On the other hand, patient trust in doctors is still high and they have rights to decide the treatments after getting the clear explanation from the doctors. This means doctors' action to proactively ask patients about the drugs type (generic or non-generic) can have a considerable impact in prescription of generic drugs in Indonesia.

Regarding the ideal prescription drug price setting concerning consumer protection in Indonesia, the Government should draw up a new law that includes all prescription drugs that have not been regulated. Considering the contents, the proposed regulation is a Presidential Decree (not only directed by the LH 2009, but also the formulation and stipulation will be simpler as it is stipulated by the President) that essentially contains several important provisions.

Firstly, setting the highest limit of the price comparison between the price of generic drugs, branded generic drugs and originator drugs with the aim that the HET does not depend on the wish of pharmaceutical company. To be more specific, HET of branded generic drugs and originator are associated with HET of generic drugs contains the same API. Determination of HET is stipulated after careful calculation using various pricing methods recommended by WHO and by involving stakeholders in the pharmaceutical industry. An example of the HET determination referred is HET of branded generic drugs should not exceed 10 times of the HET of generic drugs. Secondly, restriction on the frequency of the increase per year. Finally, if the pharmacies, hospitals, and clinics sell any type of drugs beyond HET, this price setting provides

a refund mechanism of the difference between selling price and HET. This is to ensure that this idea is in line with the consumer protection to obtain the compensation if the goods received are not in accordance with the agreement or label. The refund mechanism is a form of sanctions to regulate drugs selling practices that violates HET, to create a deterrent or preventive effect for other violations. The consumers rights to have accurate, clear, and honest information can be fulfilled by this refund mechanism because consumers become aware of the HET in accordance with applicable regulations. Additionally, it also indirectly improves the literacy of the community as consumers of drugs. It is highly recommended to utilize a user-friendly information technology (IT) based applications to be able to implement the refund mechanism of HET effectively and efficiently.

To formulate the ideal regulation of generic drugs prescription concerning consumer protection in Indonesia, it is recommended to link the prescriptions to the Registration Certificate (STR). The Government needs to revise the provisions in the LMP 2004 as the contents related to STR is stipulated in this Law. To ease patient's understanding, before prescribing the doctor should explain the safety and efficacy of the generic drugs following the clinical condition of the patient. Surely the safety and efficacy of generic drugs must be the most important things as there are diseases for which there are no treatment or therapy with generic drugs. In short, motivation to prescribe generic drugs should come from the doctor him/herself. Under this circumstance, the doctor will explain about the quality, safety, and benefits of the generic drugs. It is highly recommended that the generic drugs prescription to be included in the composition of SKP appraisals system at a certain weight, in addition to the existing SKP factors that have been determined by Indonesian Doctors Association (IDI). Because it is associated with STR, this regulation applies to all doctors in public and private healthcare facilities. Therefore, it is strongly recommended to develop a control mechanism using IT-based application to actualize the monitoring as expected. In this regard, the confidentiality of patient data may become a concern for doctors and healthcare facilities. However, it should not be worried because the monitoring report does not need to have the patient's name as the recipient of the generic drugs prescription. Simply the doctor's name and the generic drugs prescribed are necessary. Consequently, the privacy and confidentiality of the patient's medical data will be well maintained according to the prevailing laws.

REFERENCES

- “Bonus Demografi Berpotensi Tambah Ceruk Bisnis Asuransi.” n.d. Media Asuransi News. Accessed March 1, 2021. <https://mediaasuransinews.co.id/news-in-brief/bonus-demografi-berpotensi-tambah-ceruk-bisnis-asuransi.html>.
- Agustina, Enny. 2020. *Etika Profesi Dan Hukum Kesehatan*. Bandung: Refika Aditama.
- Ameln, Fred. 1991. *Kapita Selekta Hukum Kedokteran*. Jakarta: Grafika Tama Jaya.
- Anief, Mohammad. 1986. *Penggolongan Obat Berdasarkan Khasiat Dan Penggunaan*. II. Yogyakarta: Universitas Gadjah Mada Press.
- Babar, Zaheer-Ud-Din. 2015. *Pharmaceutical Prices in the 21st Century*. Edited by Zaheer-Ud-Din Babar. Cham: Springer International Publishing. <https://doi.org/10.1007/978-3-319-12169-7>.

- Balqiah, Tengku Ezni, and Hapsari Setyowardhani. 2017. *Perilaku Konsumen*. Tangerang Selatan: Universitas Terbuka.
- Bero, Lisa, Fatima Suleman, and Sabine Vogler. 2020. "Access to Medicine and Health Products." In *WHO Guideline on Country Pharmaceutical Pricing Policies*, 2nd ed. Geneva: World Health Organization.
- BPKN. n.d. "Dipilih Jadi Anggota BPKN, Andre Garu: Empat PR Besar Harus Kami Selesaikan." JPNN. Accessed January 17, 2020. <https://www.jpnn.com/news/dipilih-jadi-anggota-bpkn-andre-garu-empat-pr-besar-harus-kami-selesaikan>.
- BPKN. n.d. "Ada 3269 Aduan Konsumen 3 Tahun Terakhir, Terbanyak Soal Perumahan." IDN Times. Accessed February 6, 2021. <https://bpkn.go.id/posts/show/id/1736>.
- Ibrahim, Johny. 2007. *Teori Dan Metodologi Penelitian Hukum Normatif*. Malang: Bayumedia.
- Indonesia. 1999. *Law Number 8 Year 1999 Concerning Consumer Protection*.
- _____. 1999. *Law Number 39 Year 1999 Concerning Human Rights*.
- _____. 2004. *Law Number 29 Year 2004 Concerning Medical Practice*.
- _____. 2009. *Law Number 36 Year 2009 Concerning Health*.
- _____. 2020. *The Presidential Decree on National Medium Term Development Plan 2020-2024 No. 18/2020*.
- _____. 2016. *The Presidential Instruction on Acceleration of Pharmaceutical and Medical Device Industry Development No. 6/2016*.
- Indonesian Medical Council on Professional Discipline of Doctors and Dentists. 2011. *Regulation of the Indonesian Medical Council on Professional Discipline of Doctors and Dentists No. 4/2011*.
- Irawati, Jovita. 2016. "Disharmoni Peraturan Perundang-Undangan Di Bidang Kesehatan Dan Implikasi Hukumnya Terhadap Praktik Medik Dan Eksistensi Majelis Kehormatan Disiplin Kedokteran Indonesia." Universitas Pelita Harapan.
- Isfandyarie, Anny. 2006. *Tanggung Jawab Hukum Dan Sanksi Bagi Dokter*. Jakarta: Prestasi Pustaka.
- Koeswadi, Hermin Kadiati. 1998. *Hukum Kedokteran Studi Tentang Hubungan Hukum Dalam Mana Dokter Sebagai Salah Satu Pihak*. Bandung: P.T. Citra Aditya Bakti.
- Komalawati, Veronica. 2002. *Peranan Informed Consent Dalam Transaksi Terapeutik (Persetujuan Dalam Hubungan Dokter Dan Pasien Suatu Tinjauan Yuridis)*. Bandung: P.T. Citra Aditya Bakti.
- Kusumaatmadja, Mochtar. 2006. *Konsep-Konsep Hukum Dalam Pembangunan*. Bandung: P.T. Alumni.
- Legal Information Institute. n.d. "Informed Consent." Cornell Law School. Accessed August 14, 2021. https://www.law.cornell.edu/wex/informed_consent.
- Lubis, M. Sofyan. 2008. *Konsumen Dan Pasien Dalam Hukum Indonesia*. Yogyakarta: Liberty.
- Marzuki, Peter Mahmud. 2010. *Penelitian Hukum*. Revisi. Jakarta: Kencana.
- Mertokusumo, Sudikno. 1993. *Bab-Bab Tentang Penemuan Hukum*. Bandung: P.T. Citra Aditya Bakti.
- Minister of Health of the Republic of Indonesia. 2015. *Minister of Health Decree Number 98 Year 2015 Concerning the Provision of Information of the Highest Retail Price of Drugs*.

- _____. 2015. *Minister of Health Decree Number 525 Year 2015 Concerning Generic Drugs' HET*.
- _____. *Minister of Health Decree Number 11 Year 2017 Concerning Patient Safety*.
- Moleong, Lexy J. 2018. *Metodologi Penelitian Kualitatif*. Bandung: Remaja Rosdakarya.
- Novita, Mila. n.d. "Ini Penyebab Harga Obat Di Indonesia Lebih Mahal Dari Negara Lain." *Gaya Tempo*. Accessed September 27, 2020. <https://gaya.tempo.co/read/1187633/ini-penyebab-harga-obat-di-indonesia-lebih-mahal-dari-negara-lain>.
- R., Alwan Ridha. n.d. "Monopoli Obat Paten Bikin BPJS Jadi Defisit." *Indozone*. Accessed September 28, 2020. <https://www.indozone.id/news/DNsQ39/monopoli-obat-paten-bikin-bpjs-kesehatan-defisit/read-all>.
- Rahardjo, Satjipto. 2000. *Ilmu Hukum*. Bandung: P.T. Citra Aditya Bakti.
- Ratman, Desriza. 2018. *Aspek Hukum Informed Consent Dan Rekam Medis Dalam Transaksi Terapeutik*. Bandung: Keni Media.
- Salim, H. S., and Erlias S. N. 2018. *Penerapan Teori Hukum Pada Penelitian Tesis Dan Disertasi*. Jakarta: Rajawali Press.
- Shidarta, ed. 2012. *Mochtar Kusumaatmadja Dan Teori Hukum Pembangunan: Eksistensi Dan Implikasi*. Jakarta: Epistema Institute.
- Sitepoe, Mangku. 2007. *Mendapatkan Harga Obat Yang Wajar*. Jakarta.
- Soebekti, R. 2008. *Hukum Perjanjian*. Jakarta: Intermedia.
- Sungguh, As'ad. 2014. *Kode Etik Profesi Tentang Kesehatan, Kedokteran, Psikologi, Kebidanan, Keperawatan, Apoteker, Dan Rumah Sakit*. Jakarta: Sinar Grafika.
- Suteki, Taufani, and Galang. 2018. *Metodologi Penelitian Hukum (Filsafat, Teori Dan Praktik)*. Jakarta: Sinar Grafika.
- Syahdu, Winda. 2018. "Formularium Nasional (FORNAS) Dan e-Catalogue Obat Sebagai Upaya Pencegahan Korupsi Dalam Tata Kelola Obat Jaminan Kesehatan Nasional (JKN)." *INTEGRITAS* 4, no. 2: 30. <https://doi.org/10.32697/integritas.v4i2.328>.
- Szasz, Thomas S., William F. Knoff, and March H. Hollender. 1958. "The Doctor-Patient Relationship and Its Historical Context." *American Journal of Psychiatry* 115, no. 6: 522–28. <https://doi.org/10.1176/ajp.115.6.522>.
- Tanya, Bernard L. 2013. *Teori Hukum Strategi Tertib Manusia Lintas Ruang Dan Generasi*. IV. Yogyakarta: Genta Publishing.
- Tim Investigasi Tempo.co. 2015. "Eksklusif: Suap Obat, Bos Rumah Sakit Blak-Blakan Terima Duit." *Tempo*. 2015. <https://nasional.tempo.co/read/715680/eksklusif-suap-obat-bos-rumah-sakit-blak-blakan-terima-duit/full%26view%3Dok>.
- Trihastuti, Nanik, and Kanyaka Parjnaparamita. 2018. "Akibat Dari Informasi Asimetris Dalam Pelayanan Kesehatan: Suatu Studi Dalam Perspektif Dalam Hukum Progresif." Semarang: Universitas Diponegoro.
- Tutik, Titik Triwulan, and Shinta Febrina. 2010. *Perlindungan Hukum Bagi Pasien*. Jakarta: Prestasi Pustaka.