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Legal Implications and Considerations of Evidence Based Medicine in Prescribing Medications by Doctors with An Ethical Dilemma Related to The Ethical Principles of Autonomy

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ABSTRACT : Doctors are a profession that in practice is inseparable from law and ethics. Ethical guidelines guide doctors to work well in providing both prevention, treatment and care services. Drug prescription is a service provided to the community as an effort to realize a healthy and quality life. Evidence-Based Medicine is an effort by doctors to provide appropriate treatment to patients. As an effort to fulfill the patient's right to receive appropriate treatment and care according to indications. In this regard, doctors can face ethical dilemmas if the patient's desire to receive treatment is not in accordance with the standard and purpose of treatment, so that it can prevent legal implications by making the right decision. This makes doctors always work with caution in accordance with medical disciplines and standard operational procedures. The method used by the author in this research is a normative legal research method using reference sources from applicable laws and regulations. The research results show that the existing legal regulations in Indonesia relate to the administration of drugs that have gone through pre-clinical testing and clinical trials in accordance with EBM principles to provide health services according to standards as a fulfillment of patient rights as part of human rights. This is explicitly seen in various regulations in the form of laws, namely in the Indonesian Health Law, as well as in various regulations issued by health departemnt as well as rules and codes of ethics for the medical profession.
KEYWORDS: *ethical dilemma, autonomy, legal considerations, EBM, standard operating procedures*

I. INTRODUCTION

Public health development is getting better and more open, thereby creating independence and encouraging the development of the national health industry at regional and global levels as well as encouraging improvements in safe, quality and affordable health services for the community to improve the quality of life of the community. The 2023 Law on Health states that health is a person's healthy condition, both physically, mentally and socially and not just being free from disease to enable them to live a productive life. This health effort is realized by medical personnel and other health workers. The difference between the two includes that Health Human Resources are someone who works actively in the Health sector, whether they have formal Health education or not, which for certain types requires authority to carry out Health Efforts. Meanwhile, medical personnel are anyone who dedicates themselves to the health sector and has a professional attitude, knowledge and skills through medical or dental professional education who requires authority to carry out health efforts. Meanwhile, a Health Worker is any person who dedicates themselves to the field of Health and has a professional attitude, knowledge and skills through higher education, which for certain types requires authority to carry out Health Efforts.(1), (2)

Health services can be provided in health facilities such as hospitals, community health centers, clinics, either primary clinics or main clinics in accordance with the provisions in Law No. 44 of 2009. In accordance with Law of the Republic of Indonesia Number Forty-Four of Two Thousand and Nine Concerning Hospitals, Article One Paragraph One explains the meaning of Hospital Institutions (Law of the Republic of Indonesia, 2009). Doctors in carrying out their duties in hospitals or hospitals are obliged to work according to their authority as doctors as medical personnel, as explained in accordance with the written regulations of Law of the Republic of Indonesia Number Forty-Four of 2009 concerning Hospitals and the 2023 Law concerning Health (Law of the Republic of Indonesia, 2009; Law of the Republic of Indonesia, 2023). The medical profession is required to have good ethics in carrying out their duties as a doctor. Apart from that, they are also required to be responsible for the authority to provide patient services, including prevention, treatment and patient care.(3),(2)

Treatment is a therapeutic action carried out by a doctor. This action is important in managing patient complaints. Treatment measures are generally carried out in the form of prescriptions. Apart from chemical

medicines, administering herbal or natural medicines or traditional medicines can also be an alternative treatment for patients. Medicines prescribed by doctors have a permit from BPOM (Food and Drug Supervisory Agency) as legality based on standard processes according to Evidence Based Medicine (EBM). The steps in EBM will vary from one country to another and may also change from time to time in accordance with applicable regulations. However, it is often necessary to obtain distribution permits for herbal medicines in many jurisdictions. [4], [5]

II. METHOD

The research method I use is normative with an approach to written legal rules. Primary Material includes written legal rules. Basic secondary legal materials include journals or articles and tertiary materials related to the development of cases that are discussed and combined with views or perspectives from the researcher's point of view.

III. RESULTS AND DISCUSSION

The 1945 Constitution also emphasizes that health is a human right. In the 1945 Constitution, Article 28 Letter (h), every person has the right to live in physical and spiritual prosperity, to have a place to live, and to have a good and healthy environment and the right to receive health services. These rights of every people are followed by the implementation of government programs as an implementation of the 1945 Law in Article 34 paragraph (3) which states that the State is responsible for providing adequate health service facilities and public service facilities. This right allows every person in the country to have the right to obtain and exercise it. The doctors also researched it as an effort to provide services to the community. The definition of health in Law Number 17 of 2023 Article 1 paragraph 1 states that Health is a person's healthy condition, both physically, mentally and socially and not just being free from disease to enable him to live a productive life. Therefore, various efforts need to be made to meet the needs of the community to get the best treatment that is affordable in terms of cost and easy to obtain so that the development of chemical and herbal medicines continues to be carried out.[6],[7]

The treatment or care provided by the doctor to the patient will affect the level of patient satisfaction with the services provided by the doctor. Although satisfaction is influenced by the quality of care, it is also influenced by the accessibility of care, cost, health status, expectations, and direct outcomes of care. The cost factor is usually determined by the price of the drugs administered. In a survey study on patient experience, which tested one factor that is used as an indicator of satisfaction, the high cost of treatment was one of the causes of dissatisfaction. This feeling of dissatisfaction drives patients to seek alternative treatment. In fact, a research study showed that what was thought to be influential in producing high satisfaction: low expectations for the quality of care. This means that people think that good quality service has a high cost burden, even though they hope that high quality can be obtained at a cost that is not too high and affordable for the community.[8], [9], [3]

Other research finds that improvements in the technical quality of health services, combined with responsive service delivery, fair treatment, and minimal financial risk, are associated with increased trust in government. This means that the government has a role in realizing people's hopes in bridging high costs with good quality services and treatment. Similarly, better user experience (communication and time spent with providers) is associated with better trust in health systems in Latin America and the Caribbean. Research shows that quality, especially as perceived by patients, may influence the utilization of health services, satisfaction during treatment, and influence people's decisions to choose facilities, drugs, and other procedures and accompanying services.[9]

Dinucleotide acid (DNA) mutations and drug resistance and side effects cause drugs or therapy to become less effective. This encourages researchers, practitioners and the public to look for the latest treatments. The newest treatments that are being developed are traditional medicines or herbal medicines.[10],[11], [12]

Law Number 17 of 2023 explains in the general provisions of article 1 paragraph 17 that the herbal medicines in question are called Natural Medicines. In Law No. 17 of 2023, it is defined that natural medicines are ingredients, ingredients, or products originating from natural resources in the form of plants, animals, microorganisms, minerals, or other ingredients from natural resources, or mixtures of these ingredients that have been used for generations, or have been proven to be efficacious, safe, and of good quality, used for health maintenance, health improvement, disease prevention, treatment, and/or health restoration based on empirical and/or scientific evidence. [13]

Apart from chemical medicines, administering herbal or natural medicines or traditional medicines can also be an alternative treatment for patients. The definition of traditional medicine in Article 1 number 16 of Law no. 36 of 2009 concerning Health Traditional Medicine is a treatment effort carried out by traditional health workers based on experience, knowledge and skills passed down from generation to generation in the community to prevent, overcome and cure disease and maintain health using ingredients available in the surrounding environment and/or traditional medicines recognized by the local community and carried out in accordance with applicable religious and legal norms. Paragraph 2 states that: Pharmaceutical preparations in the form of

natural medicines must meet standards and/or requirements, in the form of the Indonesian herbal pharmacopoeia and/or other recognized standards.[14]

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The administration of medication by a doctor considers the evidence base that comes from tests carried out by the doctor or research team. Herbal medicine marketing authorization requirements are often required to obtain a marketing authorization for herbal medicines in many jurisdictions before use. Medicines and materials must meet standards, including having gone through pre-clinical testing and clinical trials. This test in medical science is known as evidence- based medicine. The steps in EBM will vary from one country to another and may also change from time to time in accordance with applicable regulations. [4]

The research was carried out through several stages, namely pre-clinical testing and clinical testing. Pre-clinical tests consist of in vitro tests and in vivo tests. In vitro tests are carried out at the cellular level, for example testing bacteria or body cells carried out in the laboratory. In vivo tests are carried out in the laboratory on experimental animals starting with mice, rats, cats, dogs, pigs and monkeys. Next is the clinical trial stage. Clinical trials or clinical trials are research conducted on human subjects as subjects where the drug being developed will later be used, so generally, clinical trials are carried out on patients. According to Bennet & Brown, clinical trials or clinical experimental research are divided into four phases, namely phase I clinical research, the initial phase of introducing new compounds by excretion in humans, phase II clinical pharmacology tests on patients and/or healthy people, phase III exploratory tests on the effects of drug therapy on 300 patient subjects and phase IV drug efficacy tests on approximately 1000 patients.[16],[17], (4)

Clinical trials are carried out to provide assurance regarding the benefits and safety of a drug or herbal medicine. Not all herbal medicines are free from the risk of side effects, so clinical trials need to be carried out for herbal medicines to avoid danger to society. Herbal medicines that will undergo clinical trials register their products with BPOM. The number of registered phytopharmacies is still relatively small compared to other natural products such as herbal medicines and herbal medicines circulating in the community. Standardized herbal medicines to improve public health. This is due to testing of phytopharmaceutical products from pre-clinic to the clinical trial stage. This process will require standardization of raw materials and products. Therefore, in determining the quality of herbal raw materials, one of the parameters that needs to be considered is the identity or chemical compounds contained in simplicia, herbal plant extracts.
(17), (5)

Based on BPOM regulations, BPOM Regulation Number 27 of 2022 concerning medicinal and food ingredients that will be imported into Indonesian territory must have a distribution permit and must comply with statutory provisions. Apart from that, importing medicines can only be done by those who have a business license or proxy. The distribution permit in question is a form of approval for registration of medicines, whether traditional medicines, chemical medicines, health supplements, and processed food, or a form of approval for cosmetics, approval for processed food to be distributed in Indonesian territory. [7],[18]

Drug distribution is also regulated in the 2023 Law, Article 143: Every person who produces and/or distributes pharmaceutical preparations, medical devices must comply with business licensing from the Central Government or Regional Government in accordance with their authority based on norms, standards, procedures and criteria in accordance with the provisions of laws and regulations. It is also explained in the Republic of Indonesia Minister of Health Regulation Number Nine of the Year Two Thousand and Seventeen in writing that it explains that a Pharmacist (Pharmacist) must work and be ethical in accordance with the rules in the code of ethics, such as the Republic of Indonesia Minister of Health Regulation Number Nine of the Year Two Thousand and Seventeen Concerning Pharmacies in Article 16 explains that every Pharmacist and Pharmaceutical Technical Personnel must work in accordance with professional standards, standard operational procedures, service standards, professional ethics, respecting or appreciating the rights of patients and prioritizing the interests of patients or patients priority.[19] [20]

Generally, the costs required to test a herbal ingredient are very expensive and require a long testing time. This makes professionals including doctors use drugs without complete clinical trials. However, not only doctors, pharmacists, drug manufacturers also often use and abuse the distribution of drugs to the public. Apart from that, the patient's autonomy as a community also makes the dilemma of using herbal medicines increasingly

complex, allowing for inappropriate decision making and this can have legal implications.[21], (22)
Problems that have occurred for a long time and are still ongoing, in the form of writing doctor's prescriptions that are difficult to read and incomplete administration of prescriptions. This is a source of information about the medicines that will be given and can be one of the causes of medication errors in health services. This prescription will be written by the doctor, after the doctor has conducted an interview (anamnesis) to obtain information from the patient regarding complaints and important information regarding the disease. This anamnesis process is carried out to establish a temporary diagnosis and other supporting examinations so that the correct diagnosis is obtained. The doctor must write the prescription clearly and completely to avoid misinterpretation between the prescriber, in this case the doctor, and the dispenser, in this case the pharmacist.[11]
In the code of ethics, ethics has been explained in the Indonesian Medical Code of Ethics regarding the ethics of doctors and patients. As explained, doctors are medical personnel who have a professional obligation to provide preventive, curative and rehabilitative services to the public or their patients. Patients are people who really need fast and precise treatment, so fast treatment services are really needed, including drug prescriptions.[11],[23]
Because it is important for doctors to adhere to the ethical principles of beneficence and autonomy. This is an effort to prioritize the interests of patients above their own and must ensure that the safety and quality of patient health improves. If you cannot follow the code of ethics procedures properly, a code of ethics violation will easily occur. Violations of the code of ethics often result in Medication Errors cases.[23]
The errors that occur in Medication Errors are Prescribing Error, Transcribing Error, Dispensing Error, and Drug Administration Error. The meaning of the terms above is Prescribing Error, namely an error in writing a prescription, Transcribing Error, namely an error in analyzing a prescription, Dispensing Error, namely an error in preparing medication, Administration Error, namely an error in administering medication. The Institute of Medicine (IOM) provides data on the results of around 44,000 people (forty-four thousand) up to ninety-eight thousand people who lost their lives due to medical errors.[24], [23]
The results data presented by the IOM realize that unexpected events from the use or consumption of drugs are not only caused by the pharmacological properties of the drug, but involve all processes in the use of the drug or therapy. Medication errors occur in various drug use processes, from the drug use process starting from prescribing or errors in reading prescriptions (1.5%-15%). Dispensing by Pharmacy (2.1%-11%), Medication Administration to patients (5%- 19%). (21),(21)

In Indonesia, the percentage of ME based on National Data on negligence in administering medication is the highest or main case at twenty-four point eight percent of the top ten incidents or cases in hospitals that have ever been reported. Unexpected cases or incidents related to medication use (Medication Error) amounted to 76 cases (26%) of all these incidents. The most frequently occurring medication errors were administration 81.32%, the incidence of administration errors, for the prescribing phase 15.88% and the transcribing phase 2.8%. [21]
Acts or actions that fall into the category of violations are classified as pure ethical violations and ethical violations (Muhammad, A.K. 2006). Purely ethical violations are actions that violate ethical norms as regulated in the Medical Ethics Code (KODEKI). Ethical violations are actions or actions that violate ethical norms and at the same time fulfill the elements of violating the law. Every violation that meets the law automatically violates ethics, but ethical violations do not necessarily violate the law (KODEKI).
As explained above, pharmacists can also work in hospitals, according to the Republic of Indonesia Law No. 44 of 2009 concerning Hospitals Article 1 Paragraph 1 explains that a hospital is an institution or health service institution that provides health services or health services in the field of personal/individual services, as well as in a comprehensive manner providing inpatient, outpatient and ER services (Law of the Republic of Indonesia, 2009). Pharmacists who carry out duties in health institutions such as hospitals or hospitals have the authority as pharmacists in the field of clinical pharmacy. This has been explained in the Republic of Indonesia Law Number Forty-Four of 2009 concerning Hospitals Article 15 Paragraph 1. Pharmaceutical procedures in
Article 7 Paragraph 1 must guarantee the availability of quality, useful, safe and affordable or high- quality pharmaceutical preparations and medical devices. [21],[12]

There is also a Code of Ethics which is a professional code of ethics, namely professional ethics according to a system of behavioral norms that should be carried out by professionals (Aini, 2018). The Professional Code of Ethics also depends on each profession. Cases of Ethical Conflict are the same as violating the Code of Ethics rules in the discipline of doctors while on duty. An example of a case is the brain wash method which was directly used on patients but the test report was found to be incomplete or had not even been carried out, so it received ethical sanctions from the health professional membership. If the administration of this treatment causes dangerous effects for the patient, it will result in legal action and could end up in court. As is known, law is divided into two, namely: Civil Law or Criminal Law. 1) Civil Law or Private Law is a law that regulates the interests of citizens or society, one individual versus another individual citizen. Criminal Law or Public Law According to criminal law or public law experts, criminal law or public law explains that criminal law or public law is the law or rules contained in rules or norms with the character of binding an action that fulfills each specific demand of the action which has an impact, namely in the form of a crime. In the cases above, criminal law can be imposed, because: a fatal error occurred as a result of administering the drug. [2],[25], [26], [27]

IV. CONCLUSION

Drug distribution must meet established standards. The test stages according to the EBM (Evidence Based Medicine) principle start from pre-clinical tests in vitro and in vivo on experimental animals and continue with clinical trials in up to 4 phases on patient subjects. Incidents of ethical violations according to the Indonesian Medical Code of Ethics are subject to sanctions in the form of a warning. In cases that result in serious injury or even death to the patient, criminal law must be applied as Law of the Republic of Indonesia Number Thirty-Six of 2014 concerning Health Personnel Criminal Provisions.

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