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Original Research Article

Pharmacists–Patients Relationship: Analysis from Indonesian Laws and Regulations

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Abstract

Pharmacists' role in medication shifted from drug oriented to patient-oriented. Therefore, it is important to understand pharmacists-patients' relationship. This research was aimed at explaining the legal relationship between pharmacists and patients and legal liabilities that arise from these legal relations. This research is normative legal research. It conducts a literature review to search the prevailing laws and regulations and explanation concerning pharmacy practice and pharmaceutical care in Indonesia. It uses secondary data which consist of primary legal sources, secondary legal sources, and tertiary legal sources. The collected data will be used to identify, explain, and understand the role of pharmacists in providing pharmaceutical care to patients,including the liability arisen from pharmacists–patients relation. The analysis will be conducted using content analysis as a qualitative approach. Results and discussion prove that there were two kinds of legal relationship existed between pharmacists and patients. First, is the non-contractual relationship established bylaws, and the second is the contractual relations created by pharmacists and patients. These two relations may co-exist in pharmaceutical care. It concludes that to know the legal liability of pharmacists to patients, understanding the nature of the legal relationship between pharmacists and patients become important.

Keywords: Pharmaceutical Care, Pharmacists Liability, Pharmacy Practice

INTRODUCTION

The role of pharmacist had changed since the World Health Organization (WHO) issued"Report of a Third WHO Consultative Group on the Role of the Pharmacist" in 1997 in Vancouver, Canada. In its Report, WHO (1997) introduced the term "seven-star pharmacist", which will become the knowledge, attitudes, skills and behaviour to support pharmacist's role in the "future". The idea was to increase the knowledge and enhance the competency of pharmacists. Pharmacists will not only become the dispenser of drugs based on the physician's prescription.

One of the roles of pharmacists in seven-star pharmacist is as a caregiver. Pharmacists shall be able to make a good decision. They should communicate with all stakeholders in healthcare settings and be able to manage every resource they have. Pharmacists shall never stop learning so that theymay improve at all time. They shall teach whatever they know so that knowledge can pass on to everybody and become the leader that would enable themto provide the best pharmaceutical care for the patients (Thamby and Parasuraman, 2014). Thamby and Parasuraman (2015) added two more roles of pharmacists to become a nine-star pharmacist. The two new functions are researcher and pharmapreneur. As a researcher, pharmacists do not only learn, but they may try to invent something that will be useful for the patient. As an entrepreneur, pharmacists can make a better calculation that will assist patients with optimum

medications without spending too much. Both of these new roles will support the main role of pharmacists as a caregiver.

It means that to be a caregiver; pharmacists must understand the needs of the patients, that made whatever actions conducted by pharmacists during pharmaceutical care must be patient-oriented, focus on patient's interest for patient safety. To be able to do patient-centred pharmaceutical care, an understanding of pharmacists -patients relation become very important.

This research aimed to explain legal relations between pharmacist and patient, and the liabilities that come together with these legal relations from the perspective of Indonesian laws and regulations.

RESEARCH METHOD

This research is normative legal research. All data used in this research were secondary data, in the form of primary legal sources, secondary legal sources and tertiary legal sources. The data were obtained through literature research using "google machine" by inserting keywords "pharmaceutical care", "pharmacist-patient relation" with combination "laws" and "legal aspect". Data obtained were then sorted through content analysis, until the researcher found the most relevant and important data, which mainly explained legal concepts and norms.

Data were analyzed using the qualitative method, with a descriptive-analytical approach. The analysis was conducted to explain the legal relationship between pharmacists and patients. It also discussed the obligations and liabilities arising as a result of the breach in the legal relation. The research will take the view from the perspective of Indonesian laws and regulations; however, some comparison will be made so that more comprehensive understanding can be achieved.

RESULTS AND DISCUSSIONS

The researcher found that there have not been many discussions on pharmacists-patients relation, especially from a legal point of view. Even a report of the task force on the definition of a Patient-Pharmacist Relationship did not recommend any definition to describe the patient-pharmacists relation (Wiesner et al., 2017). Other papers discussed the rights and obligations of pharmacists and patients without providing any or less explanation of the relation between pharmacists and patients. The researcher found that Haddad has written a Commentary to the Pharmacist-Patient Covenant, which referred to the pharmacist-patient relationship (Haddad, 2018). The writing referred further to several discussions backed to 1975. Those discussions did not directly relate to pharmacist-patient relation, but somehow discussed the relationship between healthcare givers and patients (Miller, 1990), in specific the relationship between physician and patient (May, 1975) (Li, 1996).

The discussions on those papers try to explain the relationship between healthcare givers and patients. According to May, the relation between physician and patient is governed by covenant, neither based on code nor contract. The covenant includes obligations given by code and the minimal terms of an agreement between physician and patient. The physician must at least meet the minimum standard, which may consist of ethics, which cannot be excluded by way of contract.

Black's Law Dictionary (1990) defined covenant as agreement, convention or promise of two or more parties, by deed in writing, signed and delivered. Meanwhile, in Black's Law Dictionary of 2004,a covenant is defined as a formal agreement or promise usually in a contract or deed. Those definitions made covenant have no difference at all with a contract. Casey and Afable (2004) wrote an article that tries to distinguish between contract and covenant. According to them, a contract is based on the outcome; meanwhile,a covenant is not straight forward and timeless based on emphatic and forgiveness. The assumption made by them ends up with the conclusion that a physician shall do what he/ she can do to the patient at any time the patient may need; which indeed is not wrong at all.

By nature, legal relations can be created when two or more people need each other. To develop such a legal relation, they must agree on something. Agreement or contract (used interchangeably) under Indonesian law is governed by Indonesian Civil Code (1CC) which derived from the Old Dutch Civil Code backed to 1847, which was then inaugurated and enforced in Dutch Indie (Indonesia before the independency in 1945). Regulations on the agreement itself, based on the structure of ICC belongs to Book III with the big title "Obligation". Within Book III of ICC, the general terms and conditions of the agreement are regulated in Chapter II under the title of "Obligations arising from Agreement" starting from article 1313 until article 1351. The existence of Chapter II cannot be separated from provision regulated in article 1233 ICC. Article 1233 ICC stipulated that obligations can exist because of agreements or by law. The obligations that came from agreements/ contract are known as contractual obligations, and the obligations that arose from rules and regulations are called non-contractual obligations (Widjaja and Muljadi, 2014).

Article 1320 ICC provides four conditions for an agreement to exist. The four states are:

1. Consensus between the parties of the object of the agreement;
2. The capacity of the parties concerning the execution/ delivery of the object of the agreement;
3. The object of the agreement that must able to perform/ deliver;
4. The object of the agreement must not violate the laws and regulations, ethics and morality, and public order.

Based on the content of article 1320 ICC, as stipulated above, an agreement made by two or more parties need not be made in writing. When there was a consensus between the parties on the object of the deal, then the agreement existed. Every person (including legal person/ legal body) are free to make consensus on everything. The consensual principle brings consequences that people are free to agree/ make a contract as long as the object of the agreement is not in violation against the laws and regulations, ethics and morality, and public order (Muljadi and Widjaja, 2003).

According to article 1339 ICC, an agreement between the parties shall bind them not only for those specifically agreed; but everything that is stipulated, authorized and enforceable bylaws and regulations, including guidance, ethics and disciplinary code issued by the relevant profession institutions/ organizations. It means that the obligations that were authorized by laws and regulations are embedded within the agreement/ contract. Every person who agreed/deal should know and understand the laws and rules governing the object of the agreement. These laws and regulations will provide the non-contractual obligations that must be followed by the parties. In some conditions, the non-contractual obligations may be waived, subject to the philosophy and the content of the laws and regulations (Muljadi and Widjaja, 2003).

Concerning the laws and regulations, the researcher found that the laws and rules that regulate the duty of pharmacists in conducting pharmaceutical care to patients are as follows:

1. Law No.36 Year 2009 regarding Health (Law36/09);
2. Law No.38 Year 2014 regarding Healthcare Givers (Law36/14);
3. Government Regulation No.51 Year 2009 regarding Pharmaceutical Work (GR51/09);
4. Minister of Health Regulation No.72 Year 2016 regarding Standard of Pharmaceutical Care in Hospital (MoHR72/16);
5. Minister of Health Regulation No.73 Year 2016 regarding Standard of Pharmaceutical Care in Pharmacy (MoHR73/16);
6. Minister of Health Regulation No.74 Year 2016 regarding Standard of Pharmaceutical Care in Community Health Center (MoHR74/16);

Besides,several regulations must be attended by pharmacists concerning their duties in providing pharmaceutical care to patients:

1. Law No.44 Year 2009 regarding Hospital (Law44/09);
2. Government Regulation No.72 Year 1998 regarding Safeguard of Pharmaceutical Preparations and Medical Devices (GR72/98);
3. Minister of Health Regulation No.9 Year 2014 regarding Clinic (MoHR9/14);
4. Minister of Health Regulation No.75 Year 2014 regarding Community Health Center (MoHR75/14)
5. Minister of Health Regulation No.9 Year 2017 regarding Pharmacy (MoHR9/17).

Those laws and regulations are obligations that must be followed by pharmacists. From those laws and regulations, the main rules that govern pharmaceutical care are MoHR72/16 for pharmacists working at the hospital, MoHR73/16 for community pharmacists working at pharmacy and MoHR74/16 for pharmacists working at the community health centre. In principle, those three regulations regulate two main roles that must be performed by pharmacists, with slightly different functions. They are management of pharmaceutical preparations, medical devices and consumable medical substance, and clinical pharmacy care.

According to MoHR72/16, pharmacists who work at the hospital shall provide:

1. Management of pharmaceutical preparations, medical devices, and consumable medical substance, by doing the following:
a. Choosing the right pharmaceutical preparations, medical devices, and consumable medical substance,
b. Planning the same,
c. Procuring,
d. Accepting,
e. Storing;
f. Distributing,
g. Annihilating and withdrawal,
h. Controlling and
i. Administering everything mentioned above; and
2. clinical pharmacy care in the form of:
a. Recipe assessment and dispensing,
b. Monitoring drug use history,
c. Drug reconciliation,
d. Drug information servicing,
e. Counselling,
f. Patient visiting,
g. Monitoring drug therapy,
h. Monitoring drug side effect,
i. Evaluating drug use,
j. Sterile preparations dispensing, and
k. Monitoring drug levels in the blood.

Meanwhile,MoHR73/16 stated that pharmacists who work as community pharmacists at pharmacy shouldprovide:

1. Management of pharmaceutical preparations, medical devices, and consumable medical substance, to do the following:
a. Planning,
b. Procuring,
c. Accepting,
d. Storing,
e. Annihilating,
f. Controlling and
g. Recording and reporting all the above activities; and
2. Clinical pharmacy care in the form of:
a. Assessment of recipe,
b. Dispensing,
c. Drug information servicing,

d. Counselling,
e. Providing homecare pharmacy,
f. Monitoring drug therapy, and
g. Monitoring drug side effect.

MoHR74 providesthe provisions that require pharmacists who work at the community health centre toprovide:

1. Management of pharmaceutical preparations, medical devices, and consumable medical substance, by doing the following:
a. Planning,
b. Requesting,
c. Accepting,
d. Storing,
e. Distributing,
f. Controlling,
g. Recording, reporting, andfiling, and
h. Monitoring and evaluation; and
2. clinical pharmacy care in the form of
a. Recipe assessment, dispensing and providing drug information,
b. Drug information servicing,
c. Counselling,
d. Visiting patient,
e. Monitoring and reporting drug side effect,
f. Monitoring drug therapy, and
g. Drug use evaluation.

Despite some differences, the above duties must be performed; starting from determining the right drugs until the evaluation of the drug. Those must focus on and forthe benefit of the patients. These are all based on patient-centred medication for patient safety. It means that pharmacists shall do their best while conducting pharmaceutical care only for patient safety.

As mentioned above, according to ICC, a contract under Indonesian law does not need to be result-oriented, based on the outcome, but can be made based on the needs and requirements of the parties.A contract under Indonesian law can include the covenant as mentioned by Casey and Afable. The conditions that the parties shall have enough, necessary skill and competencies, the implementation of the agreement, as Casey and Afable's covenant become possible. In healthcare-providing contract, the parties may agree on best efforts that can be done with minimal requirements. Those may be stipulated in the laws and regulations, the standard of care and diligence issued by the relevant healthcare profession institutions/ organizations, and the contractual terms that have been agreed must be followed. In Indonesia, the organization that takes care of pharmacists profession is *Ikatan Apoteker Indonesia* (IAI), the Indonesian Pharmacists Association.

IAI has issued the ethics code and discipline guidance for Indonesian pharmacists. From the ethics code issued by IAI, there is only one article that refers to pharmacists ethical conduct to the patient. According to the ethics code, pharmacists must prioritize community interest, respect to patients human rights than protect human being. On the other hand, disciplinary guidance will provide minimum skills and competencies that pharmacists should have so that the pharmacists can deliver pharmaceutical care according to the needs of the patients. IAI also issued the program for continuing professional education for pharmacists, as the consequences that pharmacists shall have the required skills and competencies from time to time. Pharmacists can then deliver pharmaceutical care as agreed between the pharmacists and the patients at best.

The agreement between pharmacists and patients are somehow different from physicians and patients and therefore cannot be copied in whole. The physician has a direct relationship with patients. When patients are sick, they look for and come to a physician. Meanwhile, in pharmacists-patient relation, it can be said that pharmacists never had a direct relationship with patients. When patients need medicine, either it is based on a prescription for ethical products or the needs for over the counter products, they come to a pharmacy (store). It can be said that they rarely or maybe never look for or come to pharmacists directly. Pharmacists-patients relationship occurs when apatient entersa pharmacy (store) to "buy" medicine/ drugs/ medical devices/ others and to obtain any further information concerning a certain medicine/ drugs/ medical devices/ others, that the patient will "buy" or has "bought". This entry point will be the beginning of when the pharmacists-patients relation started. It becomes the consensual agreement between the patient and the pharmacist. This agreement may be followed by other kinds of contract such as sale and purchase of the medicine/drugs/ medical devices/ others. The beginning of the relation between the patient and pharmacists is subject to the regulations that pharmacists shall provide any kinds of information as may be required by the patients before patients could make his/ her decision or give his/ her (inform) consent to "buy". It reflects one of the ten "R" in medication safety, as mentioned by Edward and Axe (2015). The ren "R" are right patient, right drug, right dosage, right time and right route, right to refuse, right knowledge and understanding, right questions being asked, right advice and right response or outcome.

The obligation of pharmacists to provide the information required by patients is the obligations instructed in the MoHR72/16, MoHR73/16 and MoHR74/16 that must be followed by pharmacists. This non-contractual obligation is the result of/ become part of the facts that the patient was entering the hospital pharmacy (store). Other actions taken by the patient, such as seeking for dispensing of recipes from pharmacists to buy ethical products or asking for certain over the counter drugs will be the starting point to create the real contractual obligations. Those both obligations, either contractual obligations or non-contractual obligations, can/ will co-exist at the same time in the pharmacists-patients relation during pharmaceu-tical care, even sometimes we cannot differentiate them.

The liability of breaching the obligations, either contractual or not, may result in civil remedies, in the form of monetary value or in kind. Besides, the breach can also cause administrative consequences such as the revocation of professional license as pharmacists; and criminal/ penal sanction, if the act of infringement is categorized as a crime. For the pharmacists and the patients to achieve the best result of their relation, it is suggested that both pharmacists and patients must understand each other role in pharmaceutical care.

CONCLUSION

Pharmacists-patients relation can be created by agreement/ contract and bylaws. The relation will create contractual relations based on the agreed terms and non-contractual relations as may be established bylaws. These two relations co-exist at the same time. Pharmacists shall understand their obligations as given by law and content of their agreement with the patients as part of pharmaceutical care. To avoid disputes and create good relation, both pharmacists and patients shall understand their role, rights, obligations and liabilities as stipulated in the laws and regulations as well as the guidances and ethics issued by IAI. Bad relation may result in civil remedies, administrative and penal sanction.

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