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System Thinking Approach to Analyze Violations in the Distribution of Prescription Medicines in West Sumatra Province

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ABSTRACT

Indonesia has a high rate of illegal prescription medicine sales through unauthorized distribution facilities, and these violations have increased in the midst of the COVID-19 pandemic. Despite the fact that law enforcement has been conducted, it has continued to grow. Between 2018 and 2020, criminal cases related to this issue handled by the Indonesian Food and Drug Authority (BPOM) increased by 5.54 percent, and in the province of West Sumatra, which was the main focus of this study, cases of prescription medicine violations reached 68.35 percent in 2020. However, preventing and eradicating these cases has become increasingly difficult due to the interconnectedness of factors and actors. To address the issue, the system thinking approach was chosen as the best method for modeling the dynamic behavior of this complex system over time. To facilitate applicable solutions to resolve these violations that occur in West Sumatra Province, a tool known as a rich picture diagram (RPD) is proposed as a precursor to the development of a causal loop diagram (CLD). The study's system thinking approach enables the Indonesian Food and Drug Authority's business processes to fully comprehend the dynamics and develop robust systemic interventions during the supervision and investigation of such violations.

Keywords: system thinking, prescription medicines, Indonesian FDA, business process, law enforcement, COVID-19 pandemic

JEL Classification: C63, D81, I18, K42

INTRODUCTION

Illegal prescription medicine sales via unauthorized distribution facilities are massive in Indonesia (Mahendradhata et al., 2017). As a result, prescription medicines are misused and irrational drug use occurs. Reduced drug quality, increased morbidity and mortality, waste of resources, reduced availability of other critical drugs, increased costs, risk of side effects and rise of antimicrobial drug resistance (Chaturvedi et al., 2012).

Nationally, the percentage of prescription medicine cases investigated increased in 2018, despite a decrease in the previous three years. This trend continues in West Sumatra, where the author used the region's prescription medicine violations as a case study. These violations have increased over the last four years. In 2017, 42.28 percent of violations occurred, rising to 53.58 percent in 2018. The following year, the trend increased. (Provincial Office of Indonesian FDA in Padang, 2021).

It is hard to distinguish the point at which prescription medicine distribution becomes unauthorized (Wood, 2015). A large number of stakeholders in this distribution system, combined with the numerous triggering factors, further complexity the problem of prescription medicines being circulated in unauthorized facilities. It thus, of course, creates a conflict of interest, necessitating the use of a decision-making tools (Kurniawati et al., 2021). Moreover, the ineffective eradication was exacerbated by a lack of understanding of the root causes of prescription medicine sales in unauthorized facilities.

To model this complexity, System Thinking is a suitable method. Using a rich picture diagram (RPD) as a starting point, a causal loop diagram (CLD) can be developed to assist in resolving these violations in West Sumatra Province (Goodman, 2018). Thus, top management, employees, and other organizational stakeholders can view problems through the lens of integrated thinking. Moreover, organizations can make the greatest impact when their thinking skills are combined with their expertise and experience (Kurniawati et al., 2019).

LITERATURE REVIEW

Prescription Medicine Sales Violations

Several factors influencing the circulation of prescription medicines in unauthorized facilities have been identified. Unaware of the dangers of using dangerous substances without a doctor's prescription, the general public has a high demand for prescription medicines from unauthorized sources. One of the most serious issues with prescription medicine abuse is that users believe these drugs are safer than illicit drugs. Detrimental effects and drug interactions are unlikely to be fully disclosed. While these substances have therapeutic value, they can also cause problems comparable to or greater than those associated with illegal drug use (Kelly & Pawson, 2015).

According to the law, pharmacists must service and sell prescription medicines in pharmacies. The pharmacist also acts as a liaison between doctors and patients, advising patients on how to maximize medication efficacy while minimizing side effects (Sinha, 2014). Prescription medicines cannot be dispensed without a pharmacist present, making the facility illegal. Indeed, these unauthorized facilities obtained prescription medicines from pharmacies, indicating that the pharmacist's role in this issue was still inappropriate.

System Thinking

There are hard and soft system methods in systems thinking, with soft system methods providing invaluable insight into problem definition and stakeholder perceptions (Edson, 2008; Senge, 1990). According to Peter Checkland's Soft System Methodology (2000), rich picture concept was created to gather information about a complex situation and allow stakeholders to negotiate a shared understanding. Those RP help understand system behavior. However, modeling effectiveness is not a one-size-fits-all process. Modeling is the artistic interpretation of ideas. Each modeler's approach and style differ. Modeling is a feedback-driven process, not a linear one. Models are questioned, tested, and refined indefinitely (Sterman, 2000). Furthermore, not every solution is perfect, and our choices affect other parts of the system. Anticipating the consequences of each trade-off can mitigate or even benefit us. Thus, systems thinking aids decision making (Goodman, 2018).

RESEARCH METHOD

The concept of System Thinking was chosen as the best approach for modeling the behavior of the complex system in the study. This study combines hard system tools such as System Dynamics using Causal Loop Diagrams with soft system tools such as Rich Picture Diagrams. The case of unauthorized prescription medicine sales in West Sumatra Province is presented to illustrate the CLD's analysis. The data is collected using a combination of literature reviews, observation, and in-depth interviews with experts. Using Vensim PLE 8.2.1 software, a causal loop diagram between variables was created based on the methods.

RESULTS AND DISCUSSION

Data Collection

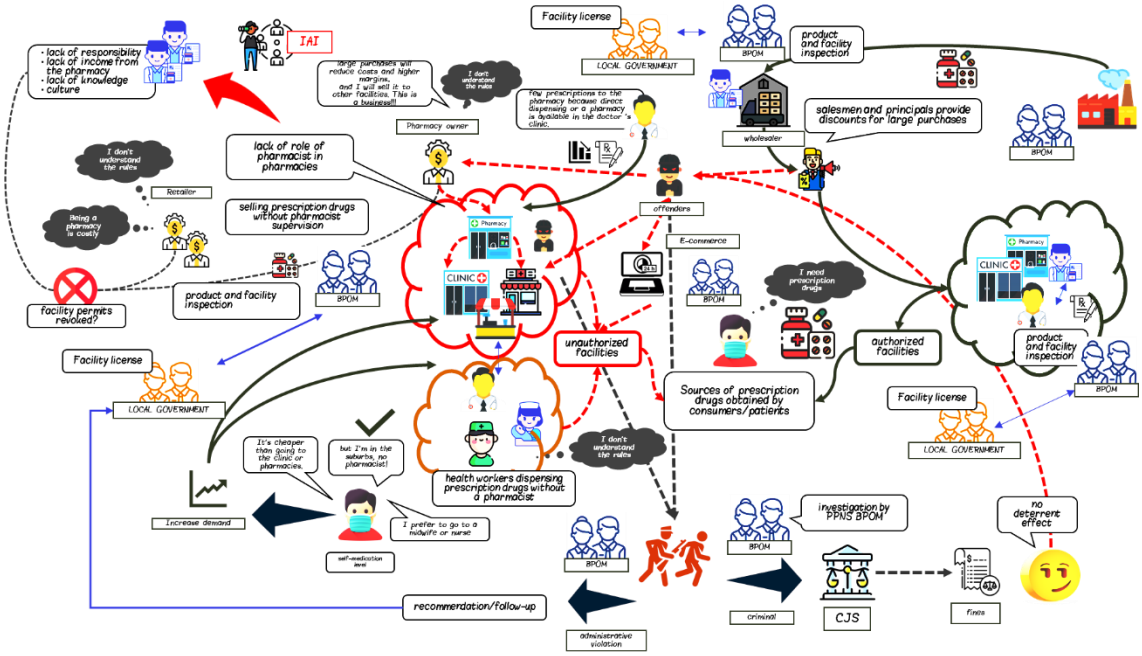
During the literature review, the authors looked at studies published in international and domestic journals on the circulation of prescription medicine. Then, at the Indonesian FDA representative in West Sumatra, observations and reviews were carried out on criminal case files concerning the sale of prescription medicines in unauthorized facilities and their SOP documents. The author takes photos and records the data, which is then analyzed to understand and capture the context of the problem.

Semi-structured and face-to-face interviews were conducted. Seven expert’s interviews took place in August – October 2021. MAXQDA Analytics Pro 2020 is used for codification of interview results. Additionally, the findings were combined to create rich picture diagrams (RPD) and causal loop diagrams (CLD).

Rich Picture Diagram

The resulting rich picture diagram (RPD) is presented in Figure 1, and it depicts the existing scenario and conditions, as well as the parties involved in the legal and illegal distribution of prescription medicines. This RPD identifies 14 types of actors involved in the sale of prescription medicines in unauthorized facilities and reveals their relationship through their functions. They are Consumers, Indonesian FDA, Local Government, Pharmacy Facility Owners, Unauthorized Facility Owners, Pharmaceutical Principals and Wholesalers, E-Commerce, Pharmacists, Health Workers, Professional Organizations, Criminal Justice System, Salesmen, and Offenders.

Figure 1. Rich Picture Diagram



Events and entities in RPD are not always sequential. The detailed picture plot starts at the top right with prescription medicines distribution to pharmaceutical wholesalers. All agreed that drug distribution from licensed factories is rarely diverse at this stage. As a result, the red dotted line is absent still. However, participants stated that irregularities in prescription medicine distribution started between pharmaceutical wholesalers and other facilities. Because of the strict distribution process and the ease with which internal and external supervisors can track upstream sector details on the number of drugs produced and distributed, deviations from prescription medicines distribution are rare, according to the participant.

The Figure 1 indicates how complicated this system is because it involves so many stakeholders, and none of them can function properly on their own. The Indonesian FDA in West Sumatra Province monitors all distribution network, but it appears that loopholes for criminals exist. During supervision, participant P1 described his feelings about the following," …*This issue has a broad range of stakeholders, including pharmacists, other health care providers, local governments, professional associations, the criminal justice system, and owners. The consumer also directly contributes to the high demand for prescription medicines in these unauthorized facilities.*"

Demand and price are associated. Price is a major factor for consumers who continue to obtain prescription drugs illegally. P1 and P6 thought drugstores and supermarkets had lower drug prices than pharmacies, and that taking a patient to the clinic would be more expensive. Additionally, the demand is influenced by people's healthy living practices, which are defined as lifestyle choices that adhere to health ideals (Sulistiono & Winingsih, 2020). The practice of purchasing medicines from unauthorized facilities demonstrates a community's lack of understanding of basic health concepts.

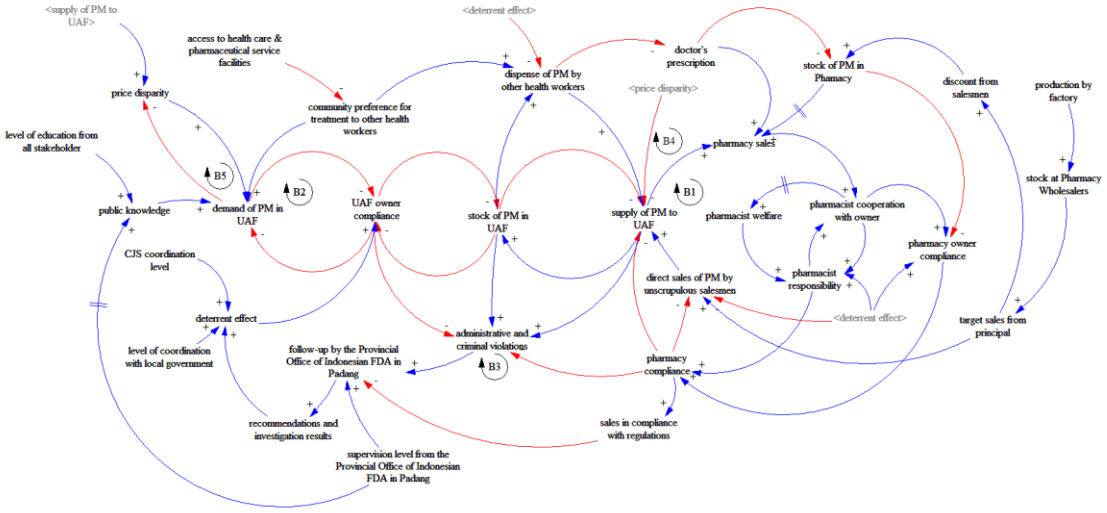
There is a huge price difference between unauthorized and authorized facilities. Paying pharmacists and complying with regulations costs extra money. To save money, consumers are more likely to buy prescription medicines without a prescription, leading them to consider even unauthorized facilities, according to Blackstone et al. (2014). As providers try to maintain adequate stock levels, there is a significant price disparity. To

keep selling their goods, pharmacies will ignore some regulations. From here, unauthorized facilities and health professionals like doctors and midwives began dispensing prescription medicine.

Thus, events bordering on: consumer demand and knowledge, the responsibility of pharmacists and other health workers (Sinha, 2014), and law enforcement (Alrasheedy et al., 2020) by the authorities, are all shown in the rich picture diagram. Furthermore, after collecting stakeholder expressions and stakeholder involvement experiences in cases of prescription medicine sales violations in West Sumatra Province in the RPD (Figure 1), the CLD that will be built will then assist in system modeling.

Causal Loop Diagram
The following is the CLD for the violation of the sale of prescription medicines at unauthorized facilities in the Province of West Sumatra, based on the RPD above:

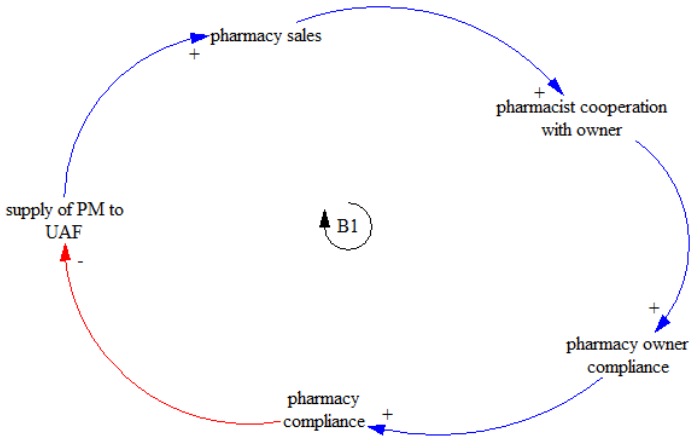
Figure 2. The CLD



There are five feedback loops that are highlighted from the CLD above, which are representations of stakeholders focusing on the variables of consumer demand and knowledge, the responsibility of pharmacists and other health workers in supply, and law enforcement by the authorities:

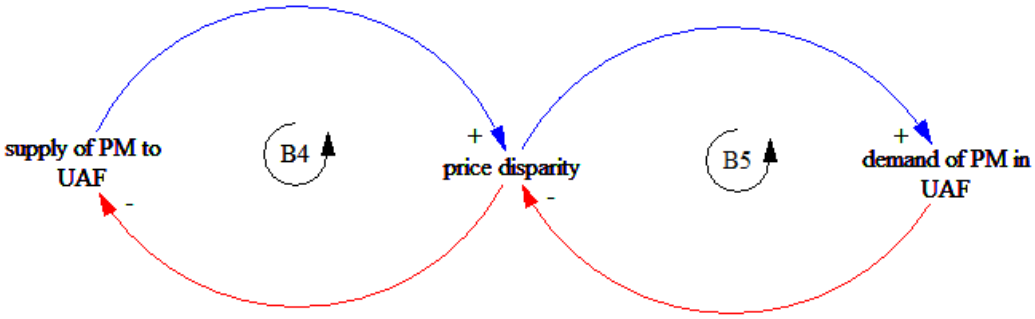
1. B1 (Balancing 1)
The loop indicates that the more pharmacies comply with regulatory provisions, the supply of PM to UAF will decrease, and vice versa. The large supply of PM to UAF has a positive impact on sales at pharmacies where this scheme is used to increase revenue despite the fact that it is illegal. Finally, this loop creates a balancing loop, which by principle has a gap between the goal (or desired level) and the actual level.

Figure 3. Feedback loop for prescription medicines supply at unauthorized facilities



2. B2 (Balancing 2), B4 (Balancing 4), and B5 (Balancing 5)

Figure 4. Feedback loop for prescription medicines demand at unauthorized facilities (B4 and B5)

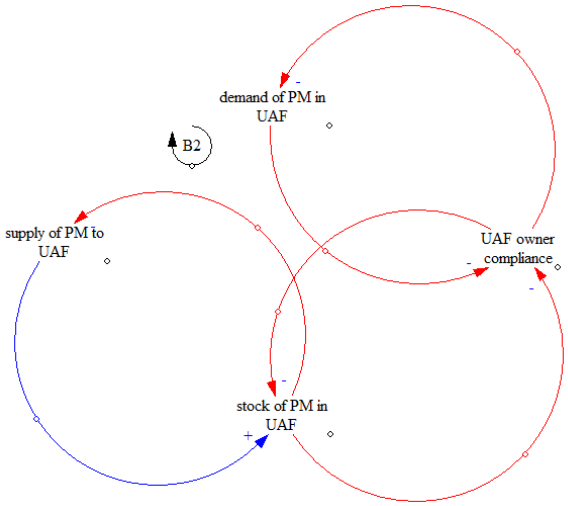


This loop demonstrates how demand is generated from the price disparity and supply variables. The demand variable's relationship to the price disparity (B5) is a negative relationship. While the relationship between price disparity and demand is generally positive. This means that as the price disparity between authorized and unauthorized facilities widens, and price of prescription medicine in UAF become cheaper, demand will increase, and vice versa.

The higher the supply of prescription medicines to unauthorized facilities, the higher the price disparity. Figure 4 shows two balancing loops where feedback enhances the impact of a balance. When an action has an effect on other actions, the rate of growth or decline is reinforcing, otherwise it is establishing a balance (El-Sayed & Galea, 2017).

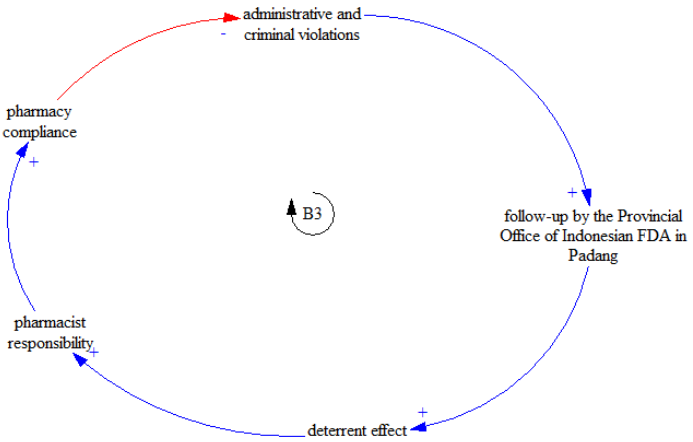
Furthermore, supply affects and is influenced by the stock variable in the feedback loop in the Figure 5, whereas demand is indirectly influenced by the owner of the UAF facility. Only supply to stock has a positive connectivity in this loop; the rest is negative, forming a balancing loop.

Figure 5. Feedback loop for prescription medicines supply and demand at unauthorized facilities (B2)



3. B3 (Balancing 3)

Figure 6. Feedback loop for pharmacist responsibilities at unauthorized facilities



The feedback loop described above relates to compliance and violation variables, with pharmacy compliance having a negative effect on administrative and criminal violations. Furthermore, the connectivity of these variables is positive to follow-up, deterrent effect, pharmacist responsibility, and pharmacy compliance. However, the deterrent effect on the loop system in Figure 6 is not only influenced by follow-up, there is also a coordination variable as an exogenous variable.

CONCLUSION

This study identifies 14 distinct types of actors involved in the unofficial sale of prescription medicines and dives deep into their relationships such as through their functions. Consumers, Indonesian FDA, Local Government, Pharmacy Facility Owners, Unauthorized Facility Owners, Pharmaceutical Principals and Wholesalers, E-Commerce, Pharmacists, Health Workers, Professional Organizations, Criminal Justice System, Salesmen, and Offenders are among them.

The study revealed 31 factor variables in three categories (consumer demand and knowledge, the responsibility of pharmacists and other health workers in supply, and law enforcement by the authorities) as determinants of the problem. The relationship

between them is illustrated in a causal loop diagram which was developed by interpreting the data from literature review, observation, and interviews. The analysis revealed five feedback loops in the CLD, which represent stakeholders' perspectives on demand, supply, law enforcement, and pharmacist professionalism. Additionally, there are five balancing loops among the five feedback loops.

This study helps governments and policymakers understand the illegal sale of prescription medicines, which can help them formulate and implement policies to prevent it. This study can help the pharmaceutical industry collaborate with the community to reduce conflicts and ensure professionalism and business coexist.

LIMITATION

This study will focus on prescription medicines in West Sumatra Province. Unauthorized pharmacies, drug stores, retail traders, and other entities not authorized to dispense prescription medicines to the general public are included in this study.

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DECLARATION OF CONFLICTING INTERESTS

The authors declare no conflicts of interest in preparing this article.

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