A System Dynamics Model to Enhance the Indonesian Food and Drug Authority's Approach to Reduce Unauthorized Drug Sales in West Sumatra Province

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ARTICLE INFO	ABSTRACT / ABSTRAK
	Indonesia memiliki tingkat pelanggaran penjualan obat keras yang tinggi oleh sarana yang tidak memiliki keahlian dan kewenangan (TKK) seperti toko obat, gerai informal, serta oleh dokter dan profesional kesehatan lainnya. Berdasarkan Peraturan Pemerintah No. 51 tahun 2009 tentang Pekerjaan Kefarmasian, obat keras, psikotropika, dan narkotik tidak dapat diperoleh secara bebas. Obat-obat tersebut hanya dapat diperoleh dengan resep dokter dan diserahkan oleh apoteker. Penjualan obat keras yang tidak tepat mengakibatkan penyalahgunaan dan penggunaan obat yang tidak rasional yang akan berdampak pada penurunan kualitas terapi obat, peningkatan morbiditas dan mortalitas, pemborosan sumber daya, penurunan ketersediaan obat, peningkatan biaya, peningkatan risiko efek samping, dan munculnya resistensi obat anti mikroba. Dari tahun 2018 dan 2020, jumlah kasus pidana yang ditangani oleh Badan Pengawas Obat dan Makanan (BPOM) terkait pelanggaran tersebut meningkat dari 8,94% menjadi 14,48%, dan khusus di Provinsi Sumatera Barat meningkat dari 39,85% menjadi 68,35%. Penjualan obat keras di sarana TKK melibatkan banyak faktor/variabel dan para pihak. Penelitian ini bertujuan untuk memberikan rekomendasi yang dapat mengurangi pelanggaran penjualan obat keras tersebut di sarana TKK di Provinsi Sumatera Barat. Pendekatan sistem dinamis digunakan pada penelitian ini untuk menganalisis dan mensimulasikan faktor/variabel yang mempengaruhi penjualan obat keras di sarana TKK tersebut. Hasilnya, dari 31 faktor/variabel dan 10 skenario yang disimulasikan, menunjukkan bahwa peran apoteker memiliki dampak yang signifikan pada sistem penjualan obat keras. Variabel -variabel seperti peningkatan persepsi dan pemahaman masyarakat, tanggung jawab apoteker dan tenaga kesehatan lainnya, serta penegakan hukum adalah variabel yang harus diintervensi untuk menurunkan pelanggaran tersebut.

Indonesia has a high rate of violation of prescription drug sales by unauthorized facilities such as drug stores, retail stores, as well as by doctors and other health professionals. Based on Government Regulation No. 51 of 2009 on Pharmacy Profession, prescription drugs, psychotropics, and narcotics cannot be obtained freely. These drugs can only be obtained with a doctor's prescription and are administered by a pharmacist. Inappropriate prescription drug sales result in drug misuse and irrational use, reducing the quality of drug therapy, increasing morbidity and mortality, wasting resources, reducing drug availability, increasing costs, increasing the risk of side effects, and accelerating the |

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emergence of antimicrobial drug resistance. Between 2018 and 2020, the number of criminal cases handled by the Indonesian FDA (BPOM) related to this issue increased from 8.94% to 14.48%, and the number of violations increased from 39.85% to 68.35% in the Province of West Sumatra. Prescription drug sales violations are complicated, as it involves many factors/variables and parties. This study intends to produce recommendations for reducing violations associated with the sale of prescription drug in West Sumatra Province. This study applied a system dynamic approach to analyze and simulate the variables affecting the sale of prescription drugs at unauthorized facilities. As a result, 31 factors were discovered and 10 scenarios were simulated, showing that the pharmacist's role has a significant impact on the system. Increased public perception and understanding, pharmacists' and other health workers' responsibilities, and legal enforcement are variables that must be intervened to reduce these violations.

1. Introduction

Indonesia is alleged to have a high rate of illegal prescription drug sales by unlicensed drugstores, informal outlets, as well as by doctors and other health-care professionals (Mahendradhata et al., 2017). These prescription drugs are sold over the counter without a prescription or pharmacist's supervision and sold in unauthorized facilities. This is a violation of the laws governing prescription drug distribution (Government of Indonesia, 2009). However, violations of prescription drug sales result in prescription drug abuse, misuse, and irrational drug use. Prescription drug abuse and misuse are described as the intentional use of a medication without a prescription, non-prescribed manner, or for the experience or feeling the medication produces. It causes a decrease in the quality of drug therapy, increased morbidity and mortality, resource waste, decreased availability of other critical medications, increased costs, increased risk of adverse effects, and the emergence of antimicrobial drug resistance. Along these, addiction can develop as a side effect of medication use and is defined by continued drug use or problematic behaviors despite knowledge of the negative consequences (Chaturvedi et al., 2012; Perelló et al., 2021).
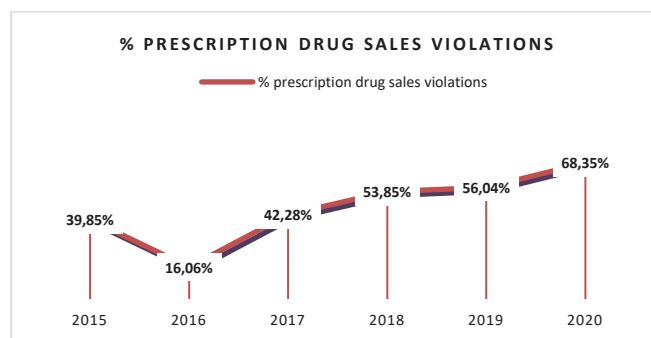

Figure 1. Violation of Prescription Drug Sales at Pharmacies and Drug Stores (Provincial Office of Indonesian FDA in Padang, 2016, 2017, 2018, 2019, 2020a, 2021a)

Prescription drug sales violations have increased over the last six years. The highest number of violations occurred in 2020, after the Covid-19 pandemic, reached 68.35% (figure 1). This increase was followed by community self-medication in West Sumatra, which increased from 57.84% in 2019 to 58.21% in 2020 (Central Bureau of Statistics, 2020). This demonstrates that rising prescription drug demand correlated with higher community self-medication, restricted movement due to PSBB,

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and specific drug issues rumored to be capable of curing or preventing COVID-19, such as dexamethasone, chloroquine, and amoxicillin. The community widely stocks those drugs due to their efficacy in treating inflammation and infection. It persuades people to obtain prescription medications from unauthorized facilities close to their homes.

In West Sumatra Province, between 2015 and July 2021, the economic value of prescription drugs seized by the Provincial Office of Indonesian FDA in Padang investigators totaled IDR 1,656,774,000 (Provincial Office of Indonesian FDA in Padang, 2016, 2017, 2018, 2019, 2020a, 2021a, 2021b). This is extremely concerning, as the health consequences are estimated to be greater than the economic costs associated with circulating illegal drugs (Septyowati et al., 2019).

Studies about circulating prescription drugs cannot be separated from the pharmaceutical industry's growth and the nation's drug consumption. In other words, strong demand fuels industrial growth. Between 2015 and 2019, the domestic pharmaceutical industry added 132 new industries, growing from 198 in 2015 to 230 in 2019, while the drug raw material industry expanded from 8 in 2016 to 14 in 2019. Additionally, the pharmaceutical industry, which is involved in the supplement sector, grew 9.39 percent (YoY) in 2020, the highest growth rate among the fifteen Non-Oil and Gas Processing Industry groups (figure 2) (Ministry Of Industry of the Republic of Indonesia, 2021). On the other hand, this trend may signal an increase in drug sales violations, particularly prescription drugs.
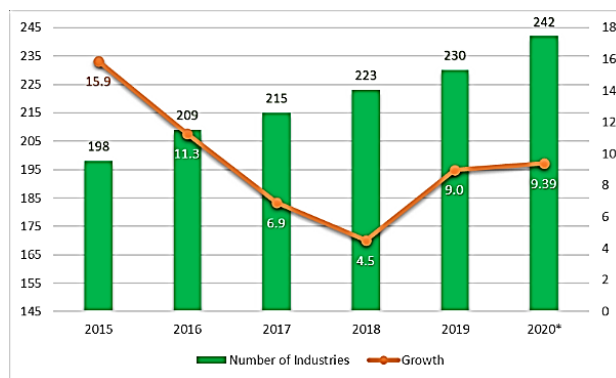

Figure 2. Number of Pharmaceutical Industry and Pharmaceutical Industry GDP Growth (Indonesian Food and Drug Authority, 2021a; Ministry Of Industry of the Republic of Indonesia, 2021)

Prescription drug sales violations are complicated, as it involves many factors/variables and parties. This study intends to produce recommendations for reducing violations associated with the sale of prescription drug in West Sumatra Province, including:
1. Determining variables that influence the violation of the sale of prescription drugs in unauthorized distribution facilities in West Sumatra Province.
2. Analyzing the changes in key variables in simulations affect the unauthorized distribution of prescription drugs in West Sumatra Province and finding the best scenario to have the impact of reducing the violation cases.

This study applied system dynamics to analyze the variables and simulate a possible solution that the Indonesian FDA could implement to reduce administrative and criminal regulatory violations related to the sale of such prescription drugs in unauthorized distribution facilities in West Sumatra Province. System dynamics is a way of thinking and a set of conceptual tools for comprehending the structure and dynamics of complex systems. Thus, we can gain insight into the long-term consequences of actions, accelerate learning, deepen our understanding of complex systems, and create structures and strategies that increase our chances of success (Sterman, 2000). System dynamics is one of the tools available in the inquiry process stage of the systems thinking function. Integration can lead to a new avenue of cross-disciplinary studies. This integration enables the social

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and natural sciences to combine quantitative and qualitative research to educate communities while also assisting stakeholders and policymakers (Edson, 2008; Nyabadza & Coetzee, 2017).

2. Research Methods

In this study, a qualitative and quantitative methodology was applied. The author developed a system dynamics modeling to clearly understand the causal relationship between the factors influencing prescription drug sales in unauthorized facilities. Vensim PLE 8.2.1 is used for model development. Furthermore, the process of system dynamics modeling consists of five steps in its application (Sterman, 2000): (1) Problem Articulation (Boundary Selection); (2) Formulation of Dynamic Hypothesis; (3) Formulation of a Simulation Model; (4) Testing; and (5) Policy Design and Evaluation.

The author collected data and identified variables in this study through three methods: literature reviews, observations, and in-depth interviews. The literature that has been reviewed consists of research published in international and domestic journals related to circulation, violations, agents involved, regulations, and global perspectives related to prescription drugs. Furthermore, observations were made at the Provincial Office of Indonesian FDA in Padang, including the observation and review of 24 criminal case files involving the sale of prescription drugs at unauthorized facilities, four standard operating procedure documents pertaining to supervision, and four standard operating procedure documents pertaining to investigations. Additionally, observations were made on how the authorities followed up on facilities that violated the West Sumatra area. The author documents the data with photographs and notes and then analyzes it to comprehend and capture the context of the problem.

Three interviews were conducted in August 2021, one in September 2021, and three in October 2021, ranging in duration from 28 to 1 hour and 21 minutes per interview. Participants were selected from: representatives of drug and food investigators and supervisors from the Provincial Office of Indonesian FDA in Padang, pharmacists, business actors, pharmacist organizations, and academics. The interviews were semi-structured and face-to-face. The interview findings were combined with the literature reviews and observations obtained 31 variables used to create a stock and flow diagram (SFD). Following the development of the SFD, a follow-up interview was conducted to confirm the model and variables.

Table 1. List of interview participants

Participant	Organization/Community	Brief profile
A1	Indonesian FDA	(1) Sub-coordinator of supervision at the Provincial Office of Indonesian FDA in Padang (2) Pharmacist
A2	Indonesian FDA	(1) Investigation Coordinator at Provincial Office of Indonesian FDA in Padang (2) Pharmacist
A3	Pharmacy owner	(1) Experienced in the pharmaceutical distribution sector for 30 years (as a salesman, drugstore owner, and now a pharmacy owner) (2) Lead of an association of pharmacy owners in one of Padang City's drug market areas
A4	Indonesian Pharmacist Ethics and Discipline Council	(1) Ex-Head of the Provincial Office of Indonesian FDA in Padang (2) Head of the Provincial Office of Indonesian FDA in Palembang
A5	Health Office	(1) Ex-Director of Padang Panjang Hospital (2) Chairman of the Regional Supervisory Board of the Indonesian Pharmacists Association
A6	Pharmacy owner	(1) Head of the Indonesian Pharmacist Association in Bukittinggi (2) Doctor of Pharmacy Faculty of Andalas University
A7	Pharmacist in distribution facilities	7 years as a pharmacist in charge of a pharmaceutical wholesaler in West Sumatra

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2.1 Problem and Key Variables

Based on the interview findings were combined with the literature reviews and observations, the boundaries will focus on three main factors: the public's perception and knowledge that forms the demand, the responsibility of pharmacists and other health workers who impact supply opportunities, and law enforcement by the authorities.

Table 2. Variable for System Dynamics Model of Prescription Drugs Sales Violations in Unauthorized Facilities in West Sumatra Provinces

Type of factors	Variable	Description	Source of Data	Type	Unit
Public's perception and knowledge (Kelly & Pawson, 2015)	Public awareness	People's drug use habits can be changed if they know more about drugs and how to find the right information about them, such as their side effects. This is about the use of prescription drugs, which can have dangerous side effects if they are not used properly (Ranjbar et al., 2017).	Provincial Office of Indonesian FDA in Padang	Auxiliary	Dmnl
	Public knowledge	In the Prescription Drug control sub-system, public knowledge related to Prescription Drugs that meet the requirements must be created. Prescription drugs that are produced and circulated in the market (community) still have the potential to not meet the requirements, so that people must be smarter in choosing and using drugs that are safe, efficacious/useful, and of good quality. This level of knowledge can be measured by the public knowledge index (Provincial Office of Indonesian FDA in Padang, 2020b)	Provincial Office of Indonesian FDA in Padang	Auxiliary	Dmnl
	Price disparity	The disparity in prescription drug prices between unauthorized facilities and pharmacies is a result of the two entities' extremely large capital disparities. Additionally, sales at pharmacies will be consistent with the highest retail price, whereas prices at unauthorized facilities will tend to be below market prices (interview findings).	Respondent	Auxiliary	Dmnl
	Access to health-care and pharmaceutical services facilities	Almost all participants explained that people purchase prescription drugs from unauthorized facilities due to limited access to health care facilities and pharmacies, particularly in suburban areas. As a result, people believe that facilities are irrelevant as long as they can obtain the necessary medication (interview findings).	BPS	Auxiliary	1/Year
	Self-medication rate	Comparison of the proportion of those with illness who self-medicate and the proportion of those who complain of symptoms	BPS	Auxiliary	1/Year

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Type of factors	Variable	Description	Source of Data	Type	Unit
		that interfere with their activities (Central Bureau of Statistics, 2020)			
	Unmet need for health services	Unmet need for health services or the percentage of the population who have health complaints and their activities are disrupted but do not seek outpatient treatment (Central Bureau of Statistics of West Sumatra Province, 2020)	BPS	Auxiliary	1/Year
	Community preference for treatment to other health workers	In this study, it was discovered that the tendency for people in West Sumatra to self-medicate inappropriately and seek treatment from health workers other than doctors is still high. This trend creates a market in which health care providers, including doctors, directly distribute and sell prescription medications without the assistance of pharmacists (Central Bureau of Statistics of West Sumatra Province, 2020)	BPS	Auxiliary	1/Year
	Demand for prescription drugs in unauthorized facilities	By analyzing the relationship between Figure 2 on prescription drug sales as well as Figure 1 on Prescription Drug Sales Violations at Pharmacies and Drug Stores, it is clear that the market is growing. Demand for prescription drugs in large quantities in unauthorized facilities contributes to an increase in violations involving the sale of prescription drugs. This variable will undoubtedly have an effect on supply via the feedback loop (interview findings/(Tempo Scan Pacific, 2021)).	Annual Reports of several Pharmaceutical Industries	Auxiliary	Dmnl
Responsibility of pharmacists and other health workers (Ajie et al., 2018; Alrasheedy et al., 2020; Yuliani et al., 2019)	Pharmacist responsibility	This variable is intended to assess the level of responsibility of pharmacists, especially in pharmacies, pharmaceutical wholesalers, and industries (Dominica et al., 2016).	Journal	Auxiliary	1/Year
	Number of pharmacies	The number of pharmacies is the number of pharmacy facilities in West Sumatra Province based on Provincial Office of Indonesian FDA in Padang Annual Report. This variable determines the systemwide circulation of prescription drugs. (interview findings/(Provincial Office of Indonesian FDA in Padang, 2019))	Provincial Office of Indonesian FDA in Padang	Stock	Facilities
	Number of other facilities	This variable indicates facilities other than pharmacies that offer hard drugs, including drug stores, midwives, and doctors' clinics (interview findings/(Provincial	Provincial Office of Indonesian FDA in Padang	Stock	Facilities

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Type of factors	Variable	Description	Source of Data	Type	Unit
		Office of Indonesian FDA in Padang, 2019))			
	Business growth rate	Business growth shows the growth of facilities from 2015 to 2019 based on Provincial Office of Indonesian FDA in Padang Annual Report (interview findings/(Provincial Office of Indonesian FDA in Padang, 2020a))	Provincial Office of Indonesian FDA in Padang	Auxiliary	Facilities /Year
	Pharmacy growth rate	Pharmacy growth shows the growth of pharmacy facilities from 2015 to 2019 based on Provincial Office of Indonesian FDA in Padang Annual Report (interview findings/(Provincial Office of Indonesian FDA in Padang, 2020a))	Provincial Office of Indonesian FDA in Padang	Flow	Facilities /Year
	Other facilities' growth rate	The growth of other facilities shows the growth of facilities other than pharmacies from 2015 to 2019 based on Provincial Office of Indonesian FDA in Padang Annual Report (interview findings/(Provincial Office of Indonesian FDA in Padang, 2020a)).	Provincial Office of Indonesian FDA in Padang	Flow	Facilities /Year
	Administrative and criminal violations in UAF	According to the follow-up conducted by the Provincial Office of Indonesian FDA in Padang, prescription drug sales violations fall into two categories: administrative violations and criminal violations (interview findings/(Provincial Office of Indonesian FDA in Padang, 2020a))	Provincial Office of Indonesian FDA in Padang	Stock	Facilities
	Prescription drug sales violations	This study addresses prescription drug sales violations. The Provincial Office of Indonesian FDA in Padang Annual Report can calculate this prescription drug sales violation (interview findings/(Provincial Office of Indonesian FDA in Padang, 2020a))	Provincial Office of Indonesian FDA in Padang	Auxiliary	Dmnl
	Owners' compliance index	Pharmacist owner compliance is to follow all existing provisions in the distribution of prescription drugs. The Provincial Office of Indonesian FDA in Padang Performance Report defines this variable as the compliance index of business actors in the sector of drugs and food (interview findings/(Provincial Office of Indonesian FDA in Padang, 2020a))	Provincial Office of Indonesian FDA in Padang	Auxiliary	1/Year

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Type of factors	Variable	Description	Source of Data	Type	Unit
	Compliance rate in pharmacy	This variable reflects the pharmacy's compliance with regulations. The data is used to determine the amount of violations by comparing the number of violations to the number of inspected facilities by The Provincial Office of Indonesian FDA in Padang. If pharmacies follow the rules, the illegal sale of prescription drugs will decrease. This is because the majority of prescription medicines discovered in unauthorized facilities derived from pharmacies (interview findings/(Provincial Office of Indonesian FDA in Padang, 2020a))	Provincial Office of Indonesian FDA in Padang	Auxiliary	1/Year
	Compliance rate in other facilities	This variable reflects the other facility's compliance with regulations. The data is used to determine the amount of violations by comparing the number of violations to the number of inspected facilities by The Provincial Office of Indonesian FDA in Padang (interview findings/(Provincial Office of Indonesian FDA in Padang, 2020a))	Provincial Office of Indonesian FDA in Padang	Auxiliary	1/Year
	Pharmacy violation growth rate	The growth variable for pharmacy violations is determined by comparing the number of violations at pharmacies to the number inspected (interview findings/(Provincial Office of Indonesian FDA in Padang, 2020a))	Provincial Office of Indonesian FDA in Padang	Flow	Facilities /Year
Law enforcement (Government of Indonesia, 2009; Sinha, 2014)	Other facilities violation growth rate	The growth variable for other facilities violations is determined by comparing the number of violations at other facilities to the number inspected (interview findings/(Provincial Office of Indonesian FDA in Padang, 2020a))	Provincial Office of Indonesian FDA in Padang	Flow	Facilities /Year
	Performance rate	The performance variable indicates the effectiveness of the Provincial Office of Indonesian FDA in Padang in terms of supervision (interview findings/(Provincial Office of Indonesian FDA in Padang, 2020a))	Provincial Office of Indonesian FDA in Padang	Auxiliary	1/Year
	Pharmacy inspection realization rate	Realization of pharmacy inspections is a comparison between the number of pharmacies inspected by officers and the total number of pharmacies (interview findings/(Provincial Office of	Provincial Office of Indonesian FDA in Padang	Auxiliary	Dmnl

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Type of factors	Variable	Description	Source of Data	Type	Unit
		Indonesian FDA in Padang, 2020a))			
	Other facilities' inspection realization rate	Realization of other facilities inspections is a comparison between the number of other facilities inspected by officers and the total number of pharmacies (interview findings/(Provincial Office of Indonesian FDA in Padang, 2020a))	Provincial Office of Indonesian FDA in Padang	Auxiliary	Dmnl
	Number of pharmacies inspected	The number of pharmacies inspected was obtained from the Provincial Office of Indonesian FDA in Padang annual report data (interview findings/(Provincial Office of Indonesian FDA in Padang, 2020a))	Provincial Office of Indonesian FDA in Padang	Auxiliary	Facilities
	Number of other facilities inspected	The number of other facilities inspected was obtained from the Provincial Office of Indonesian FDA in Padang annual report data (interview findings/(Provincial Office of Indonesian FDA in Padang, 2020a))	Provincial Office of Indonesian FDA in Padang	Auxiliary	Facilities
	Follow-up by the Provincial Office of Indonesian FDA in Padang	Follow-up cases according to standard operating procedures at the Provincial Office of Indonesian FDA in Padang are in the form of recommendations to local governments and investigations if there is sufficient evidence that they have violated criminal law (interview findings/(Provincial Office of Indonesian FDA in Padang, 2020a))	Provincial Office of Indonesian FDA in Padang	Flow	Facilities /Year
	Recommendations and investigation	The results of follow-up on the variables here are the number of recommended and investigated cases by Provincial Office of Indonesian FDA in Padang (interview findings/(Provincial Office of Indonesian FDA in Padang, 2020a))	Provincial Office of Indonesian FDA in Padang	Stock	Facilities
	Level of coordination with local government	Coordination with local governments is important when it comes to administrative and criminal punishments, as they are responsible for revoking permits for infringing facilities and providing other guidance (interview findings/(Provincial Office of Indonesian FDA in Padang, 2020a))	Provincial Office of Indonesian FDA in Padang	Auxiliary	Dmnl
	Criminal Justice System coordination level	Coordination with the criminal justice system is an effort to optimize the investigation so that the decision will have a deterrent effect on the defendant (interview findings/(Provincial Office of	Provincial Office of Indonesian FDA in Padang	Auxiliary	Dmnl

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Type of factors	Variable	Description	Source of Data	Type	Unit
		Indonesian FDA in Padang, 2020a))			
	Deterrent effect	Deterrent effect is a variable affecting the repetition of violations (interview findings/(Provincial Office of Indonesian FDA in Padang, 2020a))	Provincial Office of Indonesian FDA in Padang	Auxiliary	Dmnl

*Dmnl = Dimensionless

2.2. Time Horizon

Based on data collected from the Provincial Office of Indonesian FDA in Padang, cases of violations of prescription drug sales have increased over the last six years (2015-2020). The highest number of violations occurred in 2020, after the Covid-19 pandemic, which reached 68.35 percent of the total pharmaceutical service and distribution facilities that were routinely inspected. Meanwhile, from 2015 to 2021, investigation cases fluctuated, but the trend increased. Thus, the historical time horizon is defined for the last six years.

The simulation will begin in 2020, with 2025 as the initial scenario because the National Medium-Term Development Plan will be completed in 2024, and the National Long-Term Development Plan will be completed in 2025. In addition, a new National Long-Term Development Plan will be created. Furthermore, 2045 was chosen for the final time in the simulation because this year has been designated as the year of achievement of the Golden Indonesia Vision designed by the Ministry of National Development Planning/Bappenas (Team for Drafting Indonesia Vision 2045, 2019).
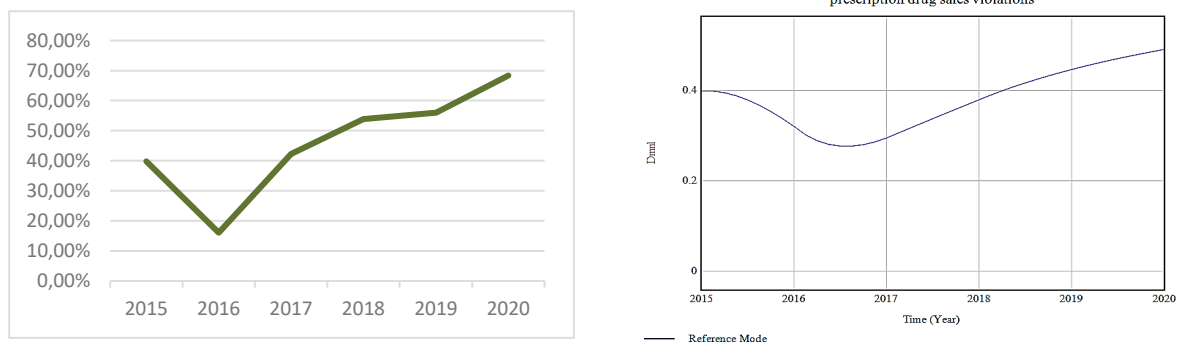
2.3. Reference Mode

Figure 3. Reference Mode

The system dynamics modeler requires a reference mode, which is a collection of graphs and other descriptive data that illustrates the evolution of the problem over time in order to accurately describe the historical behavior of key concepts and variables (Sterman, 2000). As a result of the business issues discussed in this study, the author uses data on the increase in prescription drug sales violations in West Sumatra from 2015 to 2020 as a reference mode. The data have been modeled in a graph using Vensim PLE 8.2.1 (Figure 3) and then becomes the reference mode for the model in SFD.

2.4. Development of mathematical correlation between variables

The next step in redefining these variables as stock and flow diagrams is to define each variable's quantitative correlation using the available data. The following are the calculations made between variables in order to generate a quantitative correlation:

1. Compliance rate in pharmacy - pharmacy responsibility - owners compliance index - demand of PD in UAF rate. The equation: y= -0.296 + (1.636 × owners compliance index × pharmacy responsibility) + (1.699 × demand of PD is obtained in UAF rates).
2. Compliance rate in OF - compliance rate in pharmacy - owners compliance index. The equation: y= 0.784+ (0.134 × owners compliance index) - (0.1 × compliance rate in pharmacy).
3. Deterrent effect - level of coordination with local government - CJS coordination level - recommendations and investigation. The equation y= 0.727666+(-0.000212828 × Recommendations and investigation) + (1.06236 × (CJS coordination level × level of coordination with local government)).
4. Owners' compliance index - deterrent effect. The equation y = (0.739255 + (-0.00327091 × deterrent effect). This equation is obtained from the compliance data of business actors in the Provincial Office of Indonesian FDA in Padang performance report.
5. Self-medication rate - access to health-care & pharmaceutical service facilities. The equation y = 1.53506 + (-1.61956 × access to health-care and pharmaceutical service facilities).
6. Community preference for treatment to other health workers – the unmet need for health services. The variable's equation in linear regression is y = 0.90298 + (-0.927327 × unmet need for health services).

2.5. Scenario Development

A simulation was run on a model with ten (10) scenarios based on nine (9) parameters and three (3) factors to answer the question of how changes in key variables affect the unauthorized distribution of prescription drugs in West Sumatra Province. The factors define the model's boundaries, as previously described, namely: public perception and knowledge, pharmacists and other health workers' responsibility, and law enforcement. the simulation will begin in 2020, with 2025 as the initial scenario because the National Medium-Term Development Plan will be completed in 2024, and the National Long-Term Development Plan will be completed in 2025. In addition, a new National Long-Term Development Plan will be created. Furthermore, 2045 was chosen for the final time in the simulation because this year has been designated as the year of achievement of the Golden Indonesia Vision designed by the Ministry of National Development Planning/Bappenas (Team for Drafting Indonesia Vision 2045, 2019).

Table 3. Scenario Configuration

Scenario	Intervention Variable	Baseline (2020)	Scenario 1 (P-1)		Scenario 2 (P-2)		Scenario 3 (P-3)		Scenario 4 (P-4)		Scenario 5 (P-5)	
			2025	2045	2025	2045	2025	2045	2025	2045	2025	2045
Public's perception and knowledge	Knowledge index	0.803	0.9	1								
	Awareness index	0.8114	0.9	1								
	Unmet need for health services	0.3952	0.2	0								
Responsibility of pharmacists and other health worker	Pharmacy responsibility	0.4309			0.7	1						
Law enforcement	Level of coordination with local government	0.2					0.5	1				
	CJS Coordination level	0.5					0.8	1				

Scenario	Intervention Variable	Baseline (2020)	Scenario 1 (P-1)		Scenario 2 (P-2)		Scenario 3 (P-3)		Scenario 4 (P-4)		Scenario 5 (P-5)	
			2025	2045	2025	2045	2025	2045	2025	2045	2025	2045
	Pharmacy inspection realization rate	0.5461							0.7	0.9	0.7	0.9
	OF inspection realization rate	0.2257							0.5	0.7	0.5	0.7
	performance rate	0.75									1	1

Scenario	Intervention Variable	Baseline (2020)	Scenario 6 (P-6)		Scenario 7 (P-7)		Scenario 8 (P-8)		Scenario 9 (P-9)		Scenario 10 (P-10)	
			2025	2045	2025	2045	2025	2045	2025	2045	2025	2045
Public's perception and knowledge	Knowledge index	0.803					0.9	1			0.9	1
	Awareness index	0.8114					0.9	1			0.9	1
	Unmet need for health services	0.3952					0.2	0			0.2	0
Responsibility of pharmacists and other health worker	Pharmacy responsibility	0.4309			0.7	1			0.7	1	0.7	1
Law enforcement	Level of coordination with local government	0.2	0.5	1	0.5	1	0.5	1			0.5	1
	CJS Coordination level	0.5	0.8	1	0.8	1	0.8	1			0.8	1
	Pharmacy inspection realization rate	0.5461	0.7	0.9	0.7	0.9	0.7	0.9			0.7	0.9
	OF inspection realization rate	0.2257	0.5	0.7	0.5	0.7	0.5	0.7			0.5	0.7
	performance rate	0.75	1	1	1	1	1	1			1	1

Variables in the Public's perception and knowledge factor that intervened in the scenario were the knowledge index, awareness index, and unmet need for health services. The variable of the responsibility of pharmacists and other health workers factor that given the intervention was pharmacy responsibility. Then the law enforcement factor that intervened were the level of coordination with local government, CJS Coordination level, pharmacy inspection realization rate, OF inspection realization rate, and performance rate. In this study, the intervening variables were determined by the created loops and the expert judgments.

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3. Result and Discussion

3.1. Result

3.1.1 Stock and Flow Diagram

The stock and flow diagram (SFD) in Figure 5 depicts prescription drug sales violations at unauthorized facilities in the West Sumatra province. Four stock variables are represented in the diagram, and the equations given to these stocks are as follows:

1. Administrative and criminal violations in unauthorized facilities (UAF)

$Administrative\ and\ criminal\ violations\ in\ UAF\ (t)$

$$= \int_{t_0}^{t} [pharmacy\ violation\ growth\ rate(s) + OF\ violation\ growth\ rate(s)$$
$$- follow\ up\ by\ the\ Provincial\ Office\ of\ Indonesian\ FDA\ in\ Padang(s)]ds$$
$$+ Administrative\ and\ criminal\ violations\ in\ UAF(t_0)$$

2. Recommendations and investigation

$Recommendations\ and\ investigation\ (t)$

$$= \int_{t_0}^{t} [follow\ up\ by\ the\ Provincial\ Office\ of\ Indonesian\ FDA\ in\ Padang(s)]ds$$
$$+ Recommendations\ and\ investigation(t_0)$$

3. Number of pharmacies

$$Number\ of\ pharmacies(t) = \int_{t_0}^{t} [pharmacy\ growth\ rate(s)]ds + Number\ of\ pharmacies(t_0)$$

4. Number of other facilities (OF)

$$Number\ of\ OF(t) = \int_{t_0}^{t} [OF\ growth\ rate(s)]ds + Number\ of\ OF(t_0)$$
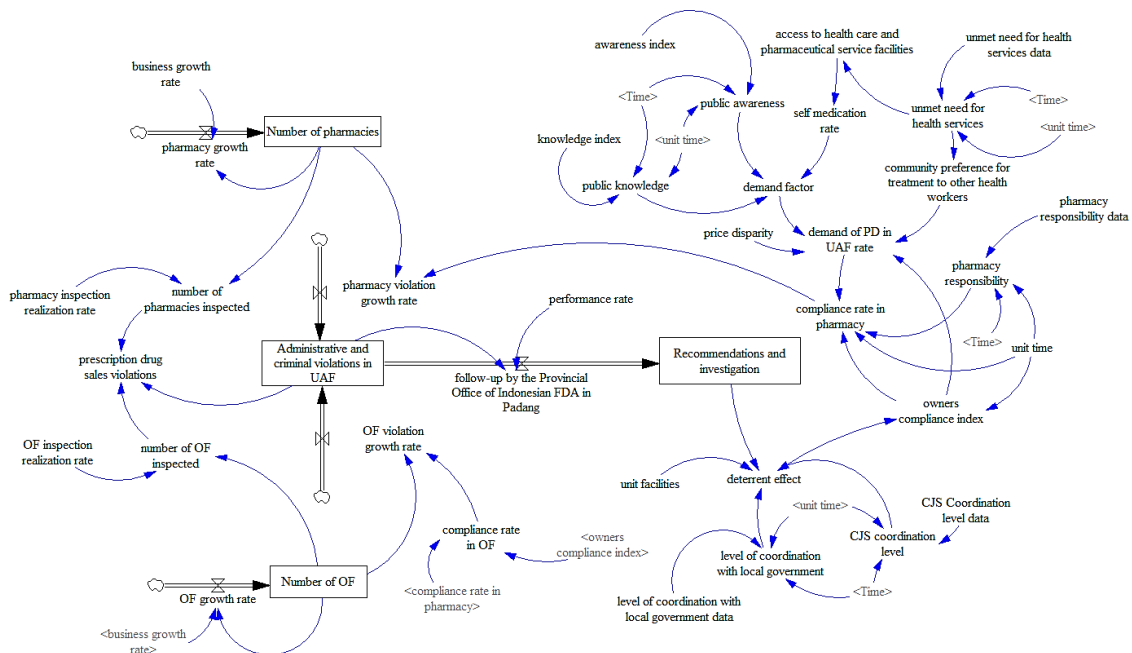

Figure 4. Stock and Flow Diagram related to the violation of the sale of prescription drugs in unauthorized distribution facilities in West Sumatra Province

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3.1.2 Model Verification and Validation

The SFD model above has been tested with a dimensional consistency test, a comparison to historical data, and an extreme condition test, whose results show that the model is valid and verified.

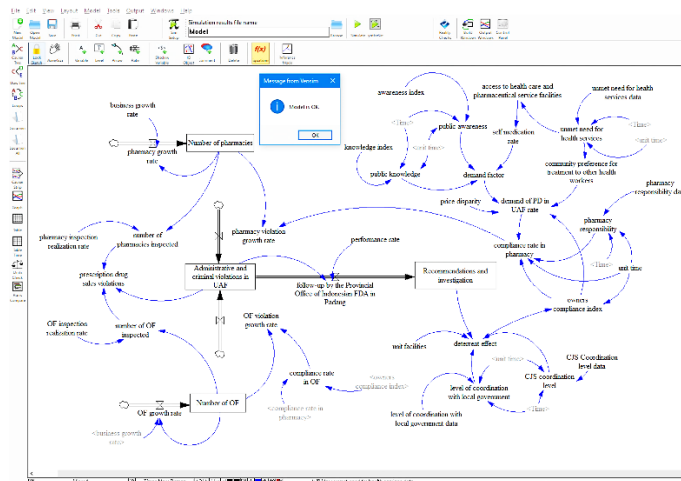### 3.1.2.1. Dimensional Consistency Test

Figure 5. Model Check

One of the most basic tests is dimensional consistency. This test determines whether the unit of measure for each variable in the model is consistent. Unit errors make it difficult to understand the structure or decision process being modeled (Sterman, 2000). The results are "Model is OK" (Figure 6) and "Units are OK,"(Figure 7) indicating that the models and units used in this modeling were consistent.

Figure 6. Unit Check

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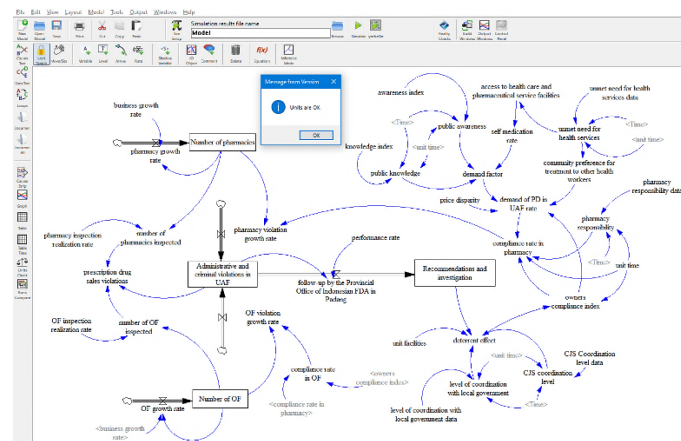
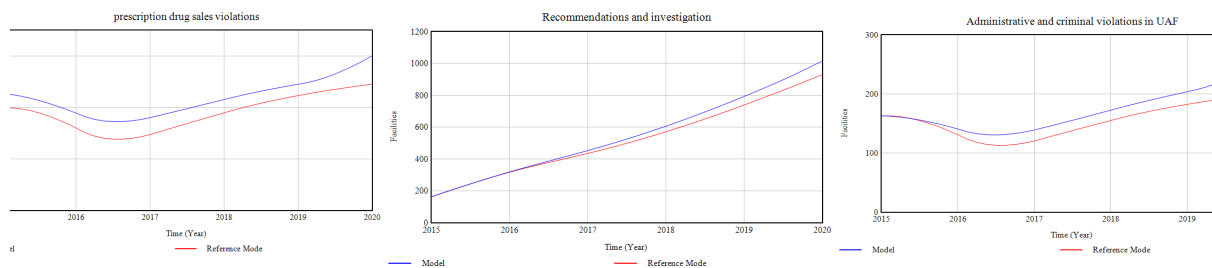### 3.1.2.2. Comparison to Historical Data

Figure 7. Comparison of Model vs Historical Data (reference mode) for prescription drug sales violations

The model is validated by comparing the simulation result to historical data for key parameters (i.e., prescription drug sales violations, Administrative and criminal violations in UAF, and Recommendations and investigation). The model is valid if it has a similarity and no significant deviation/historical fit (Law, 2019).

The comparison of the figures above demonstrates that the value of prescription drug sales violations, Administrative and criminal violations in UAF, and Recommendations and investigation in models and historical data presents similar patterns and characteristics. The values of Root Mean Square Error (RMSE) are 0.11, 27.65, and 44.54, respectively.

3.1.2.3. Extreme Condition Test

Models must be able to withstand extreme conditions. It means that the model should behave realistically even if subjected to inputs or policies that are far beyond its normal range. Models are tested under extreme conditions, such as zero or infinity, to see if they behave appropriately (Sterman, 2000). The author uses two extreme-conditions scenarios as a policy in this test. The first scenario (EC-1) is when the performance rate is 0, which indicates that the Provincial Office of the Indonesian FDA in Padang is not performing well in terms of eradicating prescription drug sales violations. Thus, the impact is illustrated in the figure below (Figure 9), where no follow-up in the form of recommendations or investigations occurs. This means that the model depicts realistic conditions even under extreme circumstances.
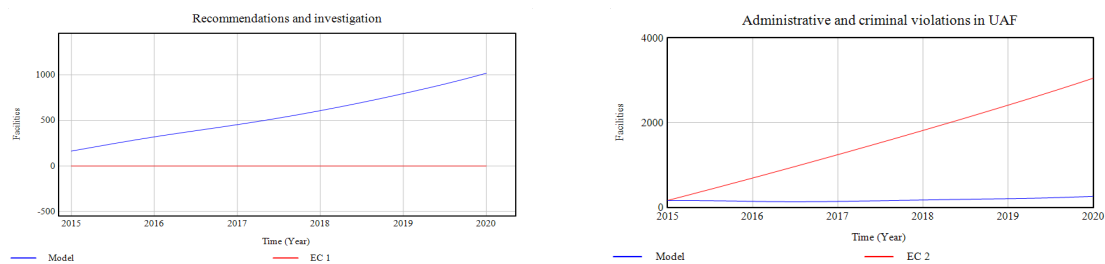

Figure 8. Results of Extreme Condition-1 (EC-1) and Extreme Condition-2 (EC-2)

Furthermore, in the second scenario, in addition to performance being zero, the pharmacist responsibility variable is also zero, implying that there is no pharmacist responsibility at all while under pharmacy supervision. This, logically, will result in an increase in prescriptions being sold illegally. Figure 9 depicts the outcome of the scenario, which is consistent with its alleged nature. When the pharmacist's responsibility is zero, violations will increase. The extreme condition test results indicate that the system dynamic model used in this study produces the correct results under extreme conditions.

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3.1.3   Scenario Simulation Result

The purpose of this study is to use system dynamics to analyze variables and simulate possible solutions that the Provincial Office of Indonesian FDA in Padang can implement to reduce administrative and criminal violations related to the sale of these prescription drugs at unauthorized distribution facilities in West Sumatra Province. Eventually, this scenario simulation is also used to determine the impact of changes in nine variables on unauthorized prescription drug distribution in West Sumatra Province.

Previously, ten scenarios were constructed, and each one will be analyzed using a comparison graph based on several parameters, including the value of prescription drug sales violations, the number of administrative and criminal violations in unauthorized facilities, the deterrent effect index, and the pharmacy compliance rate.

3.1.3.1. Prescription drug sales violations

The author wants to see which treatment can provide a decreasing trend value from year to year or a graph with a downward trend in the scenario discussed in the previous section. Figure 10 depicts the simulation results for the baseline and single scenarios model.
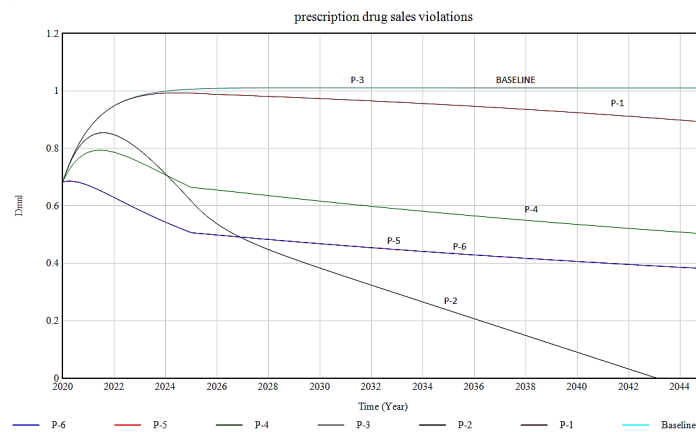

Figure 9. Simulation result of prescription drug sales violations with baseline and single scenarios model

As shown in Figure 10, only scenario P-3 does not cause graphical degradation out of the six single scenarios (scenarios that only involve one factor), which are P-1, P-2, P-3, P-4, P-5, and P-6.; The findings showed that strengthening coordination alone will not reduce these violations.

On the other hand, P-2 was the best at reducing violations, followed by P-5 and P-6. P-2 is a situation in which the pharmacist has more responsibilities, especially when it comes to being at the pharmacy and giving service in accordance with the rules. In this scenario, the pharmacist responsibility index is only 0.4309 in 2020, but it is expected to be 0.7 in 2025 and 1 in 2045. This finding also demonstrates the critical role of pharmacists in the distribution of prescription drugs, which confirmed the experts' previous in-depth interviews.

Furthermore, scenarios P-7 to P-10 are combined scenarios in which three factors, namely public perception and knowledge, pharmacists' and other health workers' responsibility, and law enforcement are combined in providing intervention. The results of the combination scenario simulation are shown in figure 11 below, along with a P-2 graph indicating which scenario has the greatest impact, as discussed previously.

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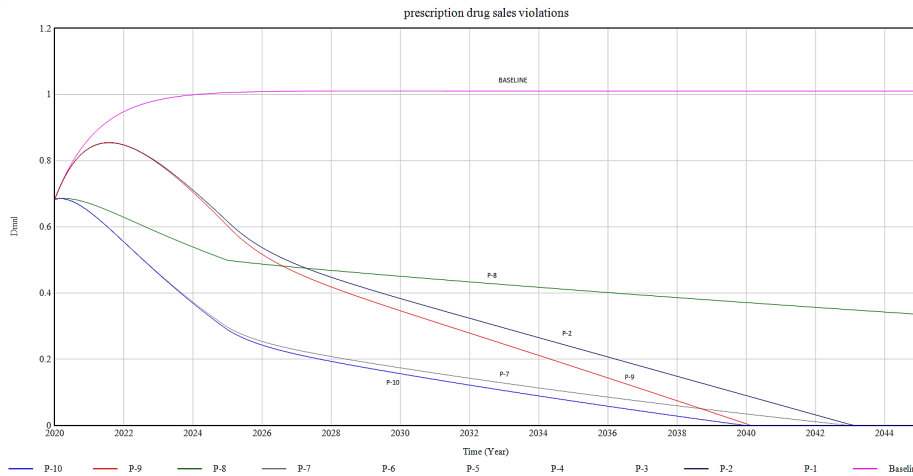to Reduce Unauthorized Drug Sales in West Sumatra Province*

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Figure 10. Simulation result of prescription drug sales violations with baseline and combined scenarios model

P-10 is a three-factor, nine-variable scenario that has been shown to have a greater impact on lowering the value of prescription drug sales violations than a single scenario or a two-factor combination. Thus, from highest to lowest, the recommended scenario in the prescription drug sales violation variable parameter is P-10, followed by P-7, P-9, P-2, P-8, P-5, P-6, P-4, and P-1.

3.1.3.2. The number of administrative and criminal violations in unauthorized facilities

The number of administrative and criminal violations in unauthorized facilities is a variable stock which is an integral function of the number of prescription drug violations that occur in pharmacies and other facilities each year. Figure 12 shows the simulation results of 10 scenarios which have two graph behaviors: exponential decay and exponential growth. Additionally, it was found that not all scenarios that have decreased value behavior in prescription drug sales violations also provide similar behavior on this variable. Only scenarios P-10, P-9, P-7, and P-2 give a behavioral simulation result of decreasing the number of violations in unauthorized facilities. The similarity of these scenarios is the intervention given to the pharmacist's responsibility value. This demonstrates that the pharmacist's responsibility variable significantly impacts this simulation model.
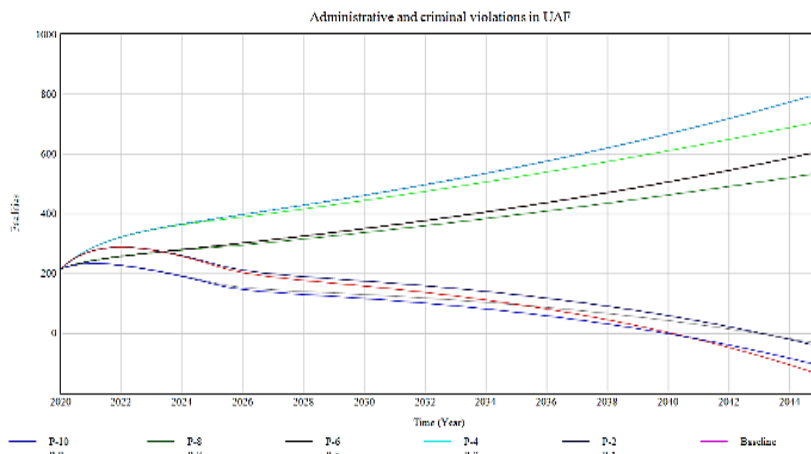

Figure 11.Simulation result of the number of administrative and criminal violations in unauthorized facilities with baseline and scenarios model

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3.1.3.3. Pharmacy compliance rate

The pharmacy compliance rate is calculated by comparing the number of pharmacies in compliance with the population of pharmacies in the Province of West Sumatra, where population growth has been estimated at 3.7 percent over the last five years (Provincial Office of Indonesian FDA in Padang, 2016, 2017, 2018, 2019, 2020a, 2021a).

According to the findings of interviews and a literature review conducted for this study, many sources of prescription drugs sold by unauthorized facilities are obtained from this facility. The baseline simulation yields a constant value each year of 0.56, indicating that only 56% of pharmacies meet the requirements. With ten scenarios, it is possible to see which impacts pharmacy compliance most. The simulation results for the ten scenarios are displayed below.
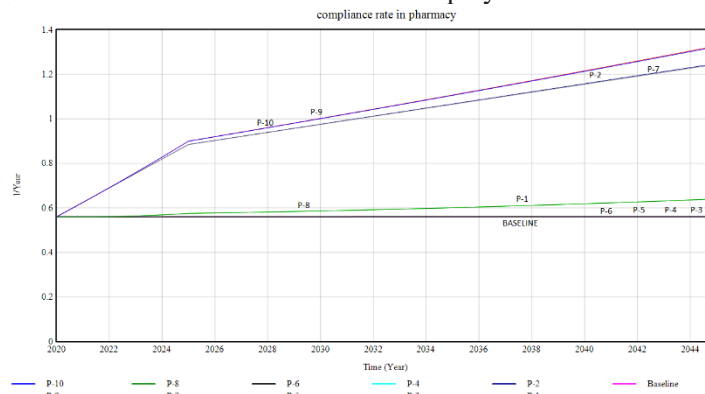

Figure 12. Simulation result of compliance rate in pharmacy with baseline and scenarios model

Only six scenarios, P-1, P-2, P-7, P-8, P-9, and P-10, increased the value of pharmacy compliance. The intervention of the public's perception and knowledge factor, as well as the responsibility of pharmacists and other health workers, or both, is the similarity of treatment in these scenarios. Only P-9 and P-10, followed by P-2 and P-7, have the greatest impact of the six scenarios. This is because the two factors mentioned above are only combined in P-9 and P-10. As a result, it was concluded that law enforcement had minimal impact on pharmacy compliance.

3.1.3.4. Deterrent effect

The author calculated and analyzed the deterrent effect based on the average value of the increase in administrative violations and the index of the comparison of decisions, threats, and evidence of criminal cases related to prescription drugs. As previously stated, the value of this deterrent effect continued to decline from 2015 to 2020 (figure 14), resulting in an increase in cases of violations in the last five years.
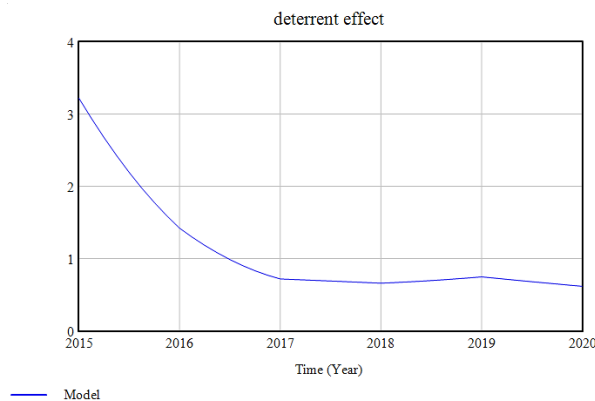

Figure 13. Value of deterrent effect in 2015-2020

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Based on the simulation results of 10 scenarios shown in figure 15, only scenarios P-7 and P-10 gave an increase in the value of the deterrent effect, and the rest gave a decreasing behavior. This is because P-7 and P-10 contain a scenario intervention that integrates pharmacists and other health-care workers' responsibilities with law enforcement factors. As a result, it can be concluded that if these two factors are addressed, the deterrent effect will be enhanced.
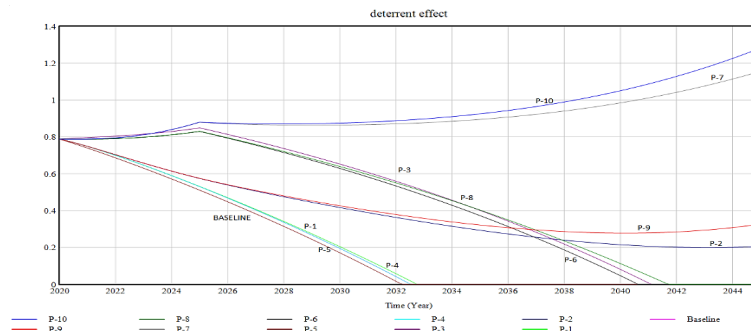

Figure 14. Simulation result of deterrent effect with baseline and scenarios model

3.2. Discussion

The simulation graph analysis demonstrates that the most impactful scenario for a single scenario is scenario P-2, where increasing pharmacist responsibility plays a critical role in reducing cases of selling prescription drug violations. In terms of the combination scenario, the P-7 scenario has a significant impact by increasing pharmacist responsibility and law enforcement. Furthermore, the perfect scenario is the P-10 scenario, in which the violation is significantly reduced by integrating these three factors.

The public's perception and lack of knowledge about the dangers of using prescription drugs without a doctor's prescription, resulting in a high demand for prescription drugs in unauthorized facilities. In general, 45.12 percent of the population of West Sumatra seeks treatment services through the practice of doctors and midwives. In 2019, the people of West Sumatra preferred private/individual practices run by doctors/midwives rather than hospitals, clinics, health centers, pustu, or UKBM (Community-Based Health Efforts) (Central Bureau of Statistics of West Sumatra Province, 2020). Based on interviews conducted with experts from the Provincial Office of Indonesian FDA in Padang, people, particularly those who live in suburban areas, prefer to visit a midwife or nurse rather than a puskesmas, clinic, or other health service facility. Some of these facts were influenced by cost, the scarcity of physicians in the area, and cultural norms. As a result, these midwives and nurses distribute prescription drugs that should not be permitted due to high demand. This is also one of the reasons why many drugstores are owned by midwives, nurses, and other healthcare professionals.

The prevalence of self-medication in the community due to a lack of knowledge about good medicine contributes to the high demand for prescription drugs. People prefer self-medication to treat common health problems because it is more convenient, cost-effective, and time efficient. Furthermore, from 2018 to 2020, there has been an increase in self-medication in the community. The percentage of West Sumatra's population who self-medicated in the past month was 54.84, 57.84, and 58.21, respectively. Some of the major causes of self-medication are deficiencies in healthcare systems, particularly in low-income countries, such as inaccessibility, unregulated pharmaceutical distribution, inequitable distribution, a lack of healthcare professionals, high costs, and patients' attitudes toward healthcare providers (Ansari, 2018; Central Bureau of Statistics, 2020). Furthermore, according to the 2013 Basic Health Research (2013) results, 35.2% store medicine for self-medication. Prescription drugs contributed to 35.7 %, while antibiotics were approximately 27.8%. As many as 81.9% of prescription drugs and 86.1% of antibiotics of that amount were obtained without a prescription. This triggers new health problems, such as bacterial resistance.

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According to a study conducted by Alrasheedy et al., (2020), law enforcement, including the threat of substantial fines and loss of license to practice, is effective at reducing the dispensing of antibiotics without a prescription. Unfortunately, society's trust in law enforcement officers is considered low in Indonesia. Although numerous regulations have been supported, antibiotics are frequently dispensed without a prescription in Jakarta's community pharmacies. As a result, a good law should be accompanied by an effective implementation structure and a supportive culture to ensure that law enforcement is as effective as possible (Ajie et al., 2018; Yuliani et al., 2019).

Concerning the application of dynamic systems in the pharmaceutical sector, Nyabadza & Coetzee (2017) has conducted research on drug abuse and drug-related crime, concluding that law enforcement will decrease crime. This is inversely proportionate to the findings of this study, which indicate that law enforcement has no substantial influence on reducing prescription drug sales violations unless other variables are also intervened. The author hypothesizes that this is possible due to threats and insufficient judgements by courts regarding these violations (Indonesian Food and Drug Authority, 2021b), which simply result in fines and hence lack a deterrent effect.

The service and sale of prescription drugs in pharmacy facilities must be carried out by pharmacists (Government of Indonesia, 2009). Additionally, the pharmacist serves as a liaison between doctors and patients, counseling and advising the patient on maximizing the drug's desired effect while minimizing any untoward/adverse effects (Sinha, 2014). This means that dispensing prescription drugs without the presence of a pharmacist is illegal, and the facility is thus deemed unauthorized. Indeed, prescription drugs obtained by these unauthorized facilities were obtained from pharmacies, indicating that the pharmacist's role in this issue was still less than optimal.

The presence of pharmacists in pharmacies adds another level of complexity to the process of distributing prescribed drugs to facilities lacking authority. Pharmacists are represented in pharmacies in Padang City, the capital city of West Sumatra province, only at a rate of 58.67%, while pharmaceutical services are represented at a rate of 54.69% (Dominica et al., 2016). Additionally, as of 2020, there were 154 cases of violations in the distribution of prescription drugs from pharmacies to unauthorized parties/facilities as a result of pharmacists' absence and carelessness in West Sumatra (Provincial Office of Indonesian FDA in Padang, 2021a). Pharmacies can provide prescription drug services if only pharmacists are available (Government of Indonesia, 2009). Without pharmacists on-site, pharmacy technicians or facility owners can freely sell prescription drugs to irresponsible parties and then resell those in unauthorized facilities.

Given these facts and the findings of this study, it is not surprising that three factors (Public's perception and knowledge, Responsibility of pharmacists, and Law enforcement) have a significant impact on reducing the sale of prescription drugs in unauthorized facilities. The challenge for the Indonesian FDA is to figure out how to incorporate these three factors into policies that will have an impact on all stakeholders.

4. Conclusion

The variables that influence the violation of the sale of prescription drugs in unauthorized distribution facilities in West Sumatra Province have been identified through the development of system dynamics, namely 31 variables from the factors: public perception and knowledge, responsibility of pharmacists and other health workers, and law enforcement. The changes in key simulations variables affect the unauthorized distribution of prescription drugs in West Sumatra Province. This is demonstrated through simulations on the SFD model, involving ten scenarios for each key variables representing three factors: public perception and knowledge, pharmacist and other health worker responsibility, and law enforcement. Based on these scenarios, the variables with the greatest impact are those that affect the pharmacist's responsibility. However, the reduction in violations will be maximized if nine variables, namely the Knowledge index, Awareness index, Unmet need for health services, Pharmacy responsibility, Level of coordination with local government, CJS

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Coordination level, Pharmacy inspection realization rate, OF inspection realization rate, and Performance rate, are simultaneously intervened.

5. Recommendation

Indonesian FDA must be able to develop policies and inspection related to prescription drugs with other stakeholders that are focused on increasing knowledge index, awareness index, pharmacy responsibility, level of coordination, inspection of facilities, and reducing unmet need for health services. These policies might range from collective agreements to the development of operational guidelines for the provision of communication, information, education, inspection, and enforcement. In the event that there are insufficient resources, it is probable that the varied responsibilities of the pharmacist will be given higher priority for intervention from Indonesian FDA. Joint inspections and rewards for independent reporting by pharmacists with knowledge of drug-related crimes are policies that can be routinely and instantaneously adopted.

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