

## Implementation Of Article 2 Paragraph (1) Of The Minister Of Health Regulation Number 7 Of 2012 Concerning The Registration Of Traditional Medicines Relating To The Distribution Of Traditional Medicines Without A Distribution Permit In Buleleng Regency

Ayu Made Evy Sephia Lestari <sup>1</sup>, Ngurah Ardhya <sup>2</sup>, Muhammad Jodi Setianto<sup>3</sup>

Faculty of Law and Social Sciences, Ganesha University of Education, Email:

[ayu.evy@undiksha.ac.id](mailto:ayu.evy@undiksha.ac.id)

Faculty of Law and Social Sciences, Ganesha University of Education, Email:

[ngurah.ardhya@undiksha.ac.id](mailto:ngurah.ardhya@undiksha.ac.id)

Faculty of Law and Social Sciences, Ganesha University of Education, Email:

[jodi.setianto@undiksha.ac.id](mailto:jodi.setianto@undiksha.ac.id)

### Article Info

Received: August 23, 2024

Accepted: October 23, 2024

Published: November 3,  
2024

### Keywords:

Traditional Medicine,  
Registration, Marketing  
Permit

### Corresponding Author:

Ayu Made Evy Sephia  
Lestari, email:

[Ayu.evy@undiksha.ac.id](mailto:Ayu.evy@undiksha.ac.id)

### Abstract

The aim of this research is to find out and analyze the implementation of Article 2 paragraph (1) of Minister of Health Regulation Number 7 of 2012 concerning Registration of Traditional Medicines Regarding the Distribution of Traditional Medicines Without a Marketing Permit and to find out how to enforce the law against business actors whose traditional medicine products do not have a distribution permit. . The type of research used is empirical legal research with descriptive research characteristics. The location of this research was carried out in Buleleng Regency. Technical data collection was used by means of literature study, observation and interviews. The sampling technique used was the Non-Probability Sampling Technique and the subject determination used Purposive Sampling. Qualitative data processing and analysis techniques. The research results show that the provisions of Article 2 paragraph (1) of Minister of Health Regulation Number 7 of 2012 concerning Traditional Medicine Registration which regulates distribution permits for traditional medicines have not been implemented properly. This is reflected in the fact that there are still business actors who do not process distribution permits in accordance with applicable regulations. Meanwhile, law enforcement against business actors takes the form of administrative sanctions as regulated in Article 23 of the Minister of Health Regulation Number 7 of 2012 concerning Registration of Traditional Medicines. There are administrative sanctions in the form of summons, coaching and warnings against traditional medicine businesses without distribution permits. And law enforcement through Law Number 17 of 2023 concerning Health Article 435 related to criminal sanctions and fines.

### 1. Introduction

Rapid economic development has created various goods and services that can be used and consumed. Goods and services are generally similar or complementary goods and services. The increasing variety of products and with the help of advances in

information and communication technology, it is clear that there has been an expansion of the flow of transactions from the goods and services offered, both those originating from domestic production and those originating from abroad. With the increasing need for goods and services from the community, one of the methods used by the government is to allow business entities to carry out development as widely as possible. With the increasing variety of goods and services in circulation, and supported by advances in information technology, the circulation is increasingly widespread across national borders. So this is also a new demand for the government to supervise the circulation of products that are widely circulated in the market, especially in the health sector because in health it is very risky if something happens that is not in accordance with what has been regulated.

Such a situation is beneficial for consumers because it allows them to meet their increasing needs with the freedom to choose products and services that suit their desires and needs. However, on the other hand, there is a potential for harm to consumers. This can result in an imbalance between business actors and consumers, where consumers are often in a weaker position, making their rights vulnerable to violation. Consumers are often targeted in business efforts to optimize profits through promotional strategies, sales practices, and the use of standard contracts that are often detrimental to consumers. Therefore, legal protection for consumers is very important, because in addition to having universal rights, consumers also have special rights that need to be protected. Rights are legal interests that are protected by law, while interests are demands that are expected to be fulfilled. Interests essentially contain elements of power that are guaranteed and protected by law in implementing them.

One of the important human needs that cannot be left behind in everyday life is medicine. The regulation on medicine is stated in Article 1 Number 15 of Law Number 17 of 2023 concerning Health, namely that medicine is a material, a combination of materials, including biological products, which are used to influence or investigate physiological systems or pathological conditions in order to determine a diagnosis, prevention, healing, recovery, health improvement, and contraception for humans. Medicine is a material intended for use in determining a diagnosis, preventing disease, curing disease or symptoms of disease.

The public's fear of the negative stigma of using modern medicine increases the public's desire to seek alternatives by using herbal medicines or entering the category of traditional medicines which are considered to have minimal risk. Seeing this opportunity, business actors and producers compete to sell traditional medicines whose efficacy and benefits have not been tested. If associated with consumer rights to safety, then every drug must be accompanied by information in the form of clear instructions for use and have a distribution permit. The goal is to protect the public or in this case as consumers from the dangers of consuming traditional medicines without a distribution permit from the relevant parties.

Regulation of the Minister of Health Number 7 of 2012 Concerning Registration of Traditional Medicines provides an understanding of traditional medicine as stated in Article 1 Paragraph (1) which states that traditional medicine is a material or mixture of materials in the form of plant materials, animal materials, mineral materials, or a mixture of these materials that have been used for treatment for generations, and can be applied in accordance with the norms prevailing in society. However, at present, traditional

medicine no longer fully uses natural materials in the form of plant materials, animal materials and mineral materials, because to overcome the limitations of the period of use, preservatives are added which are not necessarily good and safe for consumer health. Even now, traditional medicine has also been packaged in a more modern way. This problem certainly concerns security, safety and physical and mental health, therefore consumers need to obtain consumer protection as regulated in Law Number 8 of 1999 concerning Consumer Protection.

Regarding the distribution permit for traditional medicine itself, it has been regulated in Article 2 Paragraph (1) of the Regulation of the Minister of Health Number 7 of 2012 concerning Registration of Traditional Medicines which stipulates that "Traditional medicines distributed in the territory of Indonesia must have a distribution permit". This means that the distribution of traditional medicines distributed as a mass-scale business must have a distribution permit before being distributed. The aim is to provide a guarantee of safety and security for consumers. The issuance of distribution permits is carried out by the government in this case represented by the Food and Drug Supervisory Agency of the Republic of Indonesia based on Presidential Regulation of the Republic of Indonesia Number 80 of 2017 concerning the Food and Drug Supervisory Agency in Article 2 Paragraph (1) which stipulates that: "BPOM has the task of carrying out government duties in the field of drug and food supervision in accordance with statutory provisions".

The Food and Drug Supervisory Agency is a Non-Departmental Institution (LPND) according to Presidential Decree of the Republic of Indonesia Number 103 of 2001 concerning the Position, Duties, Functions, Authorities, Organizational Structure, and Work Procedures of Non-Departmental Government Institutions that BPOM is a central government institution formed to carry out certain government duties from the president and is directly responsible to the president. The task of the Food and Drug Supervisory Agency is to supervise the circulation of drugs and food in Indonesia. In testing the eligibility of a drug and food product, BPOM has a crucial role and function. BPOM's activities in testing product sampling circulating in the community are a form of consumer protection against consumer rights to obtain comfort and safety in consuming a product that is fulfilled.

In its organization, BPOM has a Technical Implementation Unit (UPT) called the Center for the Food and Drug Supervisory Agency (BBPOM) in its environment. This Technical Implementation Unit is an independent work unit that carries out certain operational technical tasks in certain work areas. In addition, as one form of improving BPOM services to the community is by adding devices in the regions through the presence of the Drug and Food Supervisory Center (Loka POM) to strengthen the position of the Center and the existing POM Center. The addition of Loka POM itself is part of strengthening the BPOM organization in accordance with Presidential Regulation Number 80 of 2017 concerning the Food and Drug Supervisory Agency along with restructuring in central and regional work units, including the addition of deputy for enforcement and increasing the status of the Inspectorate to the Main Inspectorate. Loka POM itself is present as an extension of BPOM in the regions by primarily taking samples of products in circulation and organizing Communication, Information, and Education (KIE) to the local community.

Based on the 2023 release data, the Buleleng Regency POM Office has taken action and found goods without a distribution permit (TIE) with the classification of traditional

medicine that does not meet the distribution permit in one of the shops in Singaraja City. The following is the data on drug findings found by the Buleleng Regency POM Office in 2023:

Table 1 1Data on Traditional Medicines Found in 2023  
(Source: Buleleng Regency POM Station)

NO	DRUG NAME	FACTORY NAME	UNIT	QTY
1	Golin	Mandatory Jaya	Sachet	1.189
2	Kepenak Capsule	PJ. Triojaya	Sachet	26
3	White Lion Ginseng & Sanrego	PJ. Male Crocodile	Sachet	297
4	Arjuna's Arrow Powder	PT. Bima Sakti Bandung	Sachet	271
5	African Black Ant	-	Box	15
6	Arjuna Arrow Capsule	-	Sachet	622
7	Spider Strong and Long Lasting Medicine	PJ. Sinar Makmur Madura	Sachet	60
8	Strong Medicine X Class @ne	Acting Head of Makassar Goldfish	Sachet	60
9	Wild Horse Capsule Strong & Long Lasting	PT. Bima Sakti Bandung	Sachet	2
10	Love Coffee For Adult Men Only	CV. Victory	Wrap	230
11	Rahwana Stick Capsule Strong and Durable	PJ. Milky Way Bandung	Sachet	450
12	Mr. Mustache	CV. Sumber Sehat Lestari	Bottle	166
13	Mighty Horse	CV. Mahkota	Bottle	116
14	Strong Men's Wrestling	UD. Sido Mulyo	Bottle	78
15	Montalin	PJ. Air Madu	Sachet	640
16	Kintamani	PJ. Bali Indah	Sachet	12
17	Firefox	-	Sachet	9
18	Green Jos Coffee BAPAK	PT. Herbal Farm	Sachet	37
19	Jrenk Spice Coffee	PT. Intan Perkasa	Sachet	16
20	Black Stone Egypt	-	Bottle	13
21	Viagra 100 mg	-	Tablet	11
22	BLAK Leaf Wrap Oil	-	Bottle	4
23	Wild Wasp	PT. Maju Jaya Bersama	Box	9
24	Cobra X	PJ. Ragil	Sachet	39
25	Honey Vein	PJ. Honey Water	Sachet	239

Based on the background description above, the author is motivated to carry out an in-depth study regarding **"Implementation of Article 2 Paragraph (1) of the Minister of Health Regulation Number 7 of 2012 Concerning the Registration of Traditional Medicines Related to the Distribution of Traditional Medicines Without a Distribution Permit in Buleleng Regency"**.

### **Research Methods**

This research is an empirical legal research that aims to examine how the implementation of a recorded customary law or written law that basically experiences disharmony or gaps between applicable norms (*das sollen*) and practices in the field or legal reality (*das sein*). This research is descriptive in nature which provides data on a social condition or symptom that is developing in society so that with this research it is expected to obtain a comprehensive picture of the object to be studied with primary data obtained from the Buleleng Regency POM Office and secondary data obtained from laws, journals and previous studies related to this research. Furthermore, the data obtained will be analyzed and presented in qualitative form in the form of narratives descriptively and systematically.

## **2. Results and Discussion**

### **Implementation of Article 2 Paragraph (1) of the Minister of Health Regulation Number 7 of 2012 Concerning the Registration of Traditional Medicines Related to the Distribution of Traditional Medicines Without a Distribution Permit in Buleleng Regency**

Traditional medicine is medicine that is processed traditionally, passed down from generation to generation, based on ancestral recipes, customs, beliefs, or local habits, whether magical or traditional knowledge. According to current research, traditional medicines are indeed beneficial for health and are currently being used quite intensively because they are more accessible to the public, both in terms of price and availability. Traditional medicine is currently widely used because according to several studies it does not cause too many side effects, because it can still be digested by the body.

In the Provisions of the Minister of Health Regulation Number 7 of 2012 Concerning Traditional Medicine Registration in Article 2 Paragraph (1) it is stipulated that Traditional Medicines distributed in the territory of Indonesia must have a distribution permit. This is certainly to guarantee protection for both consumers and business actors. In Law Number 8 of 1999 Concerning Consumer Protection, there is a statement that all existing laws and those related to consumer protection remain in effect as long as they do not conflict with or have been specifically regulated by law. In addition to the applicable regulations, there is one related agency that helps realize the implementation of the Minister of Health Regulation Number 7 of 2012 Concerning Traditional Medicine Registration, namely the Food and Drug Supervisory Agency (BPOM) which also plays a role as a supervisor of the circulation of dangerous traditional medicines without a distribution permit, especially in Buleleng Regency.

Article 1 Paragraph (2) of the Regulation of the Minister of Health Number 7 of 2012 concerning Registration of Traditional Medicines provides an understanding of distribution permits. Distribution permits are a form of approval for registration of traditional medicines to be distributed in the territory of Indonesia. Regarding distribution permits for traditional medicines, this has been regulated in Article 2 Paragraph (1) of the Regulation of the Minister of Health Number 7 of 2012 concerning



Registration of Traditional Medicines, which stipulates that "Traditional medicines distributed in the territory of Indonesia must have a distribution permit". This means that the distribution of traditional medicines distributed as a mass-scale business must have a distribution permit before being distributed. The aim is to provide a guarantee of safety and security for consumers.

In reality, in the field, many business actors sell traditional medicines without legalization of distribution permits from the authorities, one of which is the Food and Drug Supervisory Agency (BPOM). The phenomenon of traditional medicines without distribution permits in Buleleng Regency is often found by officers at the Buleleng Regency POM Office. The factors that influence it vary greatly, namely there are traditional medicine business actors who do not know about the legalization of distribution permits for the products they produce. Lack of knowledge about the requirements that must be prepared, because they assume that the products they produce do not have to take care of it to that extent because the business they do is a small business that is done at home. Furthermore, they do not know the existence of the Minister of Health Regulation Number 7 of 2012 concerning the Registration of Traditional Medicines. In particular, the regulation in Article 2 Paragraph (1) states that traditional medicines distributed in the territory of Indonesia must have a distribution permit.

Lack of knowledge that every product produced and traded, especially products consumed, must have a legal distribution permit. Then the next factor is that there are business actors who know that traditional products or medicines produced must have a distribution permit, but they are reluctant to take care of it because the costs incurred are too expensive and they do not get much profit if they have to take care of the distribution permit related to the products sold to the public. To find out more clearly about the Implementation of Article 2 Paragraph (1) of the Regulation of the Minister of Health Number 7 of 2012 concerning Traditional Medicine Registration, the things that were done were to conduct interviews with 3 (three) informants who were on duty at the Buleleng POM Office, namely Mrs. Mellisa, S.Farm., Apt as the coordinator in the Information and Communication field, Mrs. Arta Maria Hutagaol, S.Farm., Apt as the coordinator in the Enforcement Function field, and Mrs. Desak Laksmi Brata, SH as a member in the Examination field.

Based on the interview conducted at the Buleleng Regency POM Office, in order to distribute a product, in this case traditional medicine, a distribution permit must be obtained from the BPOM regarding the composition of the ingredients contained in the product, the manufacturing method, a clean and hygienic product manufacturing location and legalization from the relevant parties regarding traditional medicine sold to the public. This is in accordance with the provisions of the Minister of Health Regulation in Article 2 Paragraph (1) Number 7 of 2012 concerning Traditional Medicine, in this article it is stipulated that traditional medicine that is distributed must have a distribution permit before being distributed.

When associated with Lawrence M. Friedman's legal system theory, which states that the realization of a rule depends on the success or failure of a law enforcer that contains three basic theories of legal implementation. There are three theories of legal implementation known as *the Legal System Theory* which consist of legal substance, legal structure, and legal culture. When viewed from the legal substance, everything related

to traditional medicine distribution permits has been clearly regulated in the Minister of Health Regulation Number 7 of 2012 concerning Traditional Medicine Registration. And in terms of substance, the distribution permit for traditional medicines is actually good so that any violation of the provisions of the distribution permit for traditional medicines can be subject to legal sanctions. And in terms of substance, it has reflected that there is already a legal substance that has been created by the government to regulate the distribution of traditional medicines without a distribution permit. Furthermore, when viewed from the legal structure, based on the results of interviews with informants at the Buleleng Regency POM Office, the supervision carried out by the legal structure on the provisions of the distribution permit for traditional medicines in Buleleng Regency has not been optimal. This is because it is difficult to conduct direct supervision by visiting each business actor because of the large number of business actors in Buleleng Regency so that it is impossible to do it for all business actors in Buleleng Regency. And if viewed from the legal culture based on the results of research at the Buleleng Regency POM Office, it can be said that business actors still have low legal awareness. This is evident from the lack of knowledge of business actors regarding the existence of the Minister of Health Regulation Number 7 of 2012 concerning Traditional Medicine Registration so that this is what causes there to still be traditional medicine business actors who distribute traditional medicines without a distribution permit. In addition, due to ignorance of the procedure on how business actors can obtain a distribution permit, know the composition, recommended use and expiration of a product that is being traded.

Based on the explanation above, it can be concluded that the Regulation of the Minister of Health Number 7 of 2012 Concerning Registration of Traditional Medicines, especially Article 2 Paragraph (1) of the Regulation of the Minister of Health Number 7 of 2012 Concerning Registration of Traditional Medicines, has not been implemented optimally, because public awareness, especially traditional medicine business actors, is still very low. This is proven by their ignorance of the existence of these regulations, causing them not to take care of the distribution permits for the traditional medicines they produce in accordance with applicable regulations.

When associated with Lawrence M. Friedman's legal system theory, seen from the legal substance, everything related to traditional medicine distribution permits has been clearly regulated in the Minister of Health Regulation Number 7 of 2012 concerning Traditional Medicine Registration. In addition, it is supported by the UUPK which clearly regulates the rights and obligations of consumers and business actors. Furthermore, the legal structure is reflected in the existence of related agencies or bodies to help realize the Minister of Health Regulation Number 7 of 2012 concerning Traditional Medicine Registration, namely the Buleleng Regency POM Office. However, in the legal structure, the Buleleng Regency POM Office does not provide enough guidance to traditional medicine business actors regarding traditional medicine distribution permits. This happens because it has not been able to reach remote areas in Buleleng Regency, considering that Buleleng Regency is the largest region or regency in Bali Province. Based on its legal culture, legal awareness in society is very important because to implement the substance of the law, there needs to be a high level of awareness from the community. However, the legal awareness of traditional medicine business actors in Buleleng Regency is still relatively low so that many are not aware of

the existence of the Minister of Health Regulation Number 7 of 2012 concerning the Registration of Traditional Medicines and the need to have a legal distribution permit.

### **3. Result and Discussion**

#### **3.1 Law Enforcement Against Business Actors Whose Traditional Medicine Products Do Not Have Distribution Permits in Buleleng Regency**

Law enforcement is the process of making efforts to enforce or function legal norms in real terms as a guideline for behavior in traffic or legal relations in social and state life. Law enforcement is more or less an effort made to make the law, both in a narrow formal sense and in a broad material sense, a guideline for behavior in every legal act, both by the legal subjects concerned and by law enforcement officials who are officially given the task and authority by law to ensure the functioning of legal norms that apply in social and state life (Yulia, 2023: 18).

Article 1 Paragraph (2) of the Regulation of the Minister of Health Number 7 of 2012 concerning Registration of Traditional Medicines provides an understanding of distribution permits. Distribution permits are a form of approval for registration of traditional medicines to be distributed in the territory of Indonesia. Regarding distribution permits for traditional medicines, this has been regulated in Article 2 Paragraph (1) of the Regulation of the Minister of Health Number 7 of 2012 concerning Registration of Traditional Medicines, which stipulates that "Traditional medicines distributed in the territory of Indonesia must have a distribution permit". This means that the distribution of traditional medicines distributed as a mass-scale business must have a distribution permit before being distributed. The aim is to provide a guarantee of safety and security for consumers.

However, in reality, the circulation of traditional medicines without a distribution permit in the community does not seem to reflect the obligation of traditional medicine business actors in good faith to take care of the distribution permit for the traditional medicines traded. The issuance of distribution permits is carried out by the Government, in this case represented by the Food and Drug Supervisory Agency of the Republic of Indonesia, based on Presidential Regulation of the Republic of Indonesia Number 80 of 2017 concerning the Food and Drug Supervisory Agency in Article 2 Paragraph (1) which stipulates that: "BPOM has the task of carrying out government duties in the field of drug and food supervision in accordance with statutory provisions". If business actors violate the mandate of the Minister of Health Regulation Number 7 of 2012 concerning Traditional Medicine Registration, then there will be accountability. In addition to regulating the distribution permit, Minister of Health Regulation Number 7 of 2012 concerning Traditional Medicine Registration also regulates sanctions for traditional medicine business actors if they do not fulfill the requirements for traditional medicine registration, including traditional medicine distribution permits, properly and correctly. This is regulated in Article 23 Paragraph (1) and Paragraph (2) which is a form of law enforcement against traditional medicine business actors who do not have a distribution permit. Where Article 23 Paragraph (1) of Minister of Health Regulation Number 7 of 2012 concerning Traditional Medicine Registration stipulates that the Head of the Agency can impose administrative sanctions in the form of revocation of the distribution permit.



And in Article 23 Paragraph (2) it is stipulated that "In addition to being able to impose administrative sanctions as referred to in paragraph (1), the Head of the Agency may impose other administrative sanctions in the form of an order to withdraw from circulation and/or destroy traditional medicines that do not meet the standards and/or requirements". In accordance with Article 1 Number (12) that "Pharmaceutical Preparations are Medicines, Drug Ingredients, Natural Medicines, including Natural Medicines, cosmetics, health supplements, and quasi-drugs". Furthermore, Article 435 of Law Number 17 of 2023 concerning Health also stipulates that "Any person who produces or distributes Pharmaceutical Preparations and/or Medical Devices that do not meet the standards and/or requirements for safety, efficacy/benefit, and quality as referred to in Article 138 Paragraph (2) and Paragraph (3) shall be punished with imprisonment for a maximum of 12 (twelve) years or a maximum fine of IDR 5,000,000,000.00 (five billion rupiah)".

Based on the research results, the statement above is in line with the information provided by three informants from the Buleleng Regency POM Office that traditional medicine business actors who market their products without a distribution permit are subject to administrative sanctions in the form of a warning and revocation of the distribution permit. The revocation of the distribution permit applies to medicines that already have a distribution permit and if in the future or during an evaluation every 5 (five) years it is found to contain BKO (Chemical Drug Ingredients) or other hazardous substances, the distribution permit for the traditional medicine product will be revoked. Furthermore, for traditional medicines that do not have a distribution permit at all, the traditional medicine will be withdrawn and destroyed and if traditional medicines are still distributed without a distribution permit, criminal sanctions will be imposed by the POM Office through applicable legal channels.

Law enforcement against business actors through summons, coaching, warnings, stern warnings, revocations up to criminal sanctions, namely Minister of Health Regulation Number 7 of 2012 concerning Registration of Traditional Medicines, Law Number 8 of 1999 concerning Consumer Protection, Law Number 17 of 2023 concerning Health and Presidential Regulation Number 80 of 2017 concerning the Food and Drug Supervisory Agency is intended to direct traditional medicine business actors without distribution permits not to commit unlawful acts. Where the implications will later help to succeed in better economic development and can create a healthy business climate. For this reason, sanctions are a form of law enforcement that can restore the situation to its original state when a violation occurs as well as a preventive legal effort for other business actors so as not to repeat the actions of business actors who have previously violated the law.

#### **4. Conclusion**

Based on the description above, the author puts forward the following conclusions:

1. The implementation of the provisions of Article 2 Paragraph (1) of the Regulation of the Minister of Health Number 7 of 2012 has not been implemented properly. This is reflected in the fact that there are still traditional medicine business actors who do not take care of the distribution permits for the traditional medicines they produce as per the applicable provisions. The ineffectiveness of the regulation lies in the less than optimal role of the government in terms of coaching and

socialization to business actors and the community. This occurs because it has not been able to reach remote areas in Buleleng Regency, considering that Buleleng Regency is the largest region or regency in Bali Province.

Law enforcement against traditional medicine business actors without distribution permits can be in the form of administrative sanctions in the form of cancellation of distribution permits by the head of the agency as regulated in Article 23 Paragraph (1) and providing other administrative sanctions in the form of orders to withdraw from circulation/destroy traditional medicines that do not meet the requirements as regulated in Article 23 Paragraph (2) of the Minister of Health Regulation Number 7 of 2012 concerning Registration of Traditional Medicines. And law enforcement through Law Number 17 of 2023 concerning Health in Article 435 relating to criminal sanctions and fines.

## **5. Recommendation**

Furthermore, based on this research, there are a number of suggestions that can be proposed to several parties regarding the Implementation of Article 2 Paragraph (1) of the Minister of Health Regulation Number 7 of 2012 Concerning the Registration of Traditional Medicines Related to the Distribution of Traditional Medicines Without a Distribution Permit in Buleleng Regency, namely as follows:

### **1. For the Community**

For the public as consumers, they should be required to pay attention to the products they consume, especially traditional medicines such as herbal medicines, or traditional aphrodisiacs. This aims to prevent consumers from losses such as overdose, worsening diseases, causing other diseases, and even death caused by unclear content and correct usage rules because there is no distribution permit from BPOM.

### **2. For Business Actors**

For business actors to continue to pay attention to the safety of the products produced by taking care of the distribution permit for the traditional medicines produced. This is in accordance with Article 2 Paragraph (1) of the Minister of Health Regulation Number 7 of 2012 concerning Registration of Traditional Medicines. Then business actors must also continue to pay attention to their obligations as business actors and pay attention to the rights that consumers must obtain from business actors. This can be realized by taking care of the distribution permit for traditional medicines produced in accordance with that stated in the Minister of Health Regulation Number 7 of 2012 concerning Registration of Traditional Medicines and Law Number 8 of 1999 concerning Consumer Protection.

### **3. For the Government**

For the government, especially law enforcers, they must make more optimal efforts to overcome traditional medicine business actors without distribution permits. This is certainly so that consumers will not suffer losses due to not obtaining traditional medicine with distribution permit legalization. The government can provide guidance through more optimal socialization and reach remote areas, especially those in Buleleng Regency. After providing guidance, the government can carry out more intensive supervision by emphasizing the distribution permit process for a traditional medicine.

## **6. References**

### **Books**

- Ali, Zainuddin. 2016, *Legal Research Methods*. Sinar Grafika: Jakarta.
- Atsar, A., & Apriani, R. 2019. *Textbook of Consumer Protection Law*. Deepublish.
- Az. Nasution. 1995. *Consumers and the Law*, Sinar Harapan Library, Jakarta.
- Bambang Sunggono, 2003. *Legal Research Methodology, An Introduction*. Jakarta: PT. Raja Grafindo Persada
- Barkatullah, AH 2019. *Consumer rights*. Nusamedia.
- Diantha, I Made Pasek. 2017. *Normative Legal Research Methodology in Justification of Legal Theory*. Jakarta: Prenada Media Group.
- Ishaq. 2017. *Legal Research Methods*. Bandung: Alfabeta.
- Janus Sidabolok 2010, *Consumer Protection Law in Indonesia*. Bandung: PT. Citra Aditya Bakti.
- Kristiyanti, CTS 2022. *Consumer protection law*. Sinar Grafika.
- Miru, Ahmadi and Sutarman Yodo, 2014. *Consumer Protection Law*. Jakarta: PT Raja Grafindo Persada.
- Muhammad Syahrums, ST 2022. *Introduction to Legal Research Methodology: Normative and Empirical Research Studies, Proposal Writing, Thesis and Dissertation Reports*. CV. Dotplus Publisher.
- Qamar, N., Syarif, M., Busthami, DS, Hidjaz, MK, Aswari, A., Djanggih, H., & Rezah, FS 2017. *Legal Research Methods*. CV. Social Politic Genius (SIGn).
- Ramdhan, M. (2021). *Research methods*. Cipta Media Nusantara.
- Sugiyono, 2016. *Qualitative Research Methods, Qualitative, and R&D*. Bandung: CV Alfabet.
- Tri Siwi Kristiyanti, C. 2008. *Consumer protection law*. Indonesia: Sinar Grafika.

### **Legislation**

- Law Number 8 of 1999 concerning Consumer Protection (State Gazette of the Republic of Indonesia 1999 Number 22).
- Law Number 17 of 2023 concerning Health (State Gazette of the Republic of Indonesia 2023 Number 105).
- Presidential Regulation Number 80 of 2017 concerning the Food and Drug Supervisory Agency (State Gazette of the Republic of Indonesia 2017 Number 180).
- Regulation of the Minister of Health Number 7 of 2012 concerning Registration of Traditional Medicines.
- Regulation of the Food and Drug Supervisory Agency Number 23 of 2021 concerning Amendments to Regulation of the Food and Drug Supervisory Agency Number 22 of 2020 concerning the Organization and Work Procedures of Technical Implementation Units within the Food and Drug Supervisory Agency.