SALES CONTROL OF CLASS G DRUGS WITHOUT MEDICAL PRESCRIPTION BY THE NATIONAL AGENCY OF DRUG AND FOOD CONTROL OF BENGKULU

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ABSTRACT

The widespread circulation of prescription drugs sold without a doctor's prescription is very costly, both in terms of health and safety of consumers. The problems in this study were as follow: 1. How was the sales control of class G drugs without medical prescription by the pharmacists by the National Agency of Drug and Food Control of Bengkulu? 2. What were the barrier factors of sales control of class G drugs without medical prescription by the pharmacists by the National Agency of Drug and Food Control of Bengkulu? Juridical empirical research was done to see whether the implementation of law on legal events in the society had been in accordance with the provisions of the legislation. The data collection was done through interview, related observation and study of literatures. Based on the research result it was found that the sales control of class G drugs by the National Agency of Drug and Food Control of Bengkulu could not be implemented properly because there are many obstacles found in the field, both derived from governments, business communities and consumers.

Keywords: Legal Protection, Consumer, Class G Drugs, NA-DFC
A. INTRODUCTION
1. Background

The availability of drugs to society is one of the government's commitments in carrying out services in the field of public health. Health is a human right and is one of the elements of prosperity that must be realized in accordance with the ideals of the nation of Indonesia as stipulated in Pancasila and the 1945 Constitution of the Republic of Indonesia Article 28 H paragraph (1) "Every person shall have the right to live in physical and spiritual prosperity, to have a home and to enjoy a good and healthy environment, and shall have the right to obtain medical care.” Health is Human Rights that must be considered, then the development done by the government in the health sector must begin from the basic rights which are owned by the patient.

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Every effort of development must be based on insight of health which means that national development should pay attention to public health, and it is the responsibility of all parties, both government and society. The efforts that have been made by the government of course intended that public health is maintained. Indonesia as a state of law, which puts the law above anything else (the supremacy of law), has provided a guarantee of legal protection for the societies. In regard with the functions of the state as regulator and the characteristics of the state of law with prosperity that based on the Pancasila, it is still required state intervention in the form of regulation that is highly influential in the process of economic development and control of the free market itself in accordance with the functions of the state, which is in line with the opinion of W. Friedman who stated that the functions of the state are as provider, regulator, to intervene directly in the economy (entrepreneur), and the supervisor.
Answering the growing of legal needs in the community should the government’s obligation. Government as regulator functions to form legislation as a means of ensuring legal certainty to regulate, control and supervise the creation of a balance of interests between the entrepreneur and consumers.

In order to improve the accuracy of drug use, as well as to improve the safety and security of the distribution, the Government as the regulator did classification of drugs through the Regulation of Minister of Health No. 949/Menkes/Per/VI/2000 concerning the classification of drugs, where drugs are divided into several categories, namely free rugs, limited free drugs, prescription drugs, psychotropic and narcotics as well as mandatory drug for pharmacy (further will be referred as OWA/Obat Wajib Apotek). Prescription drugs which are often referred as class G drugs (from the word gevaarlijk which means dangerous) may only be submitted by the pharmacy on medical prescription basis. The provision is intended to prevent the wrong use of drugs of this class. Improper use of drugs of this class has a relatively high risk to health according to the origin of the word which means dangerous. Therefore, the legislation provides certain restrictions on the circulation of prescription drugs.

Prescription drugs can only be obtained from certain health facilities, one of which is the pharmacy, any handover should only be performed by authorized health personnel such as pharmacists, and pharmacists in the pharmacy can only dispense prescription drugs upon medical prescription request. Nevertheless, today there is the phenomenon of deviation from the distribution of prescription drugs in the society. Pharmacy services as one means of prescription drugs allegedly were doing a lot of prescription drug services illegally in the form of services of basic prescription drugs without a medical prescription.

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Class G drugs can be dangerous when used carelessly, even poison the body, exacerbating the disease or causing death. Hence the supervision to anticipate misuse of drugs known as G in society is highly needed. NA-DFC established by Presidential Decree No. 103 on the status, tasks, functions, powers, composition and working procedures of Non Departmental Government Institutions, as has been amended several times by Presidential regulation No. 64 of 2005. Under the Legislation, NA-DFCcarries out the task of government in the field of Food and Drug Control. Food and Drug Control is an integral part of health development efforts in Indonesia. NA-DFCmission in protecting the society from drug and food products that endanger the health set forth in the full spectrum control ranging from pre-market to post-market control accompanied by law enforcement and community empowerment efforts. Under these provisions, the head of NA-DFC established a decree of Head of National Agency of Drug and Food Control No. 02.001/SK/KNA-DFC on Organization and Working Procedures of National Agency of Drug and Food Control, which is based on a decision by the NA-DFCset forth in Article 2 that NA-DFC has the task of carrying out government duties in the field of food and drug control in accordance with the provisions of the applicable legislations. National Agency of Food and Drug Control has the tasks as follows:

a. Assessment and formulation of national policies in the field of drug and food control.

b. The implementation of certain policies in the field of drug and food control.

c. Coordination of functional activities in performing NA-DFCtasks.

d. Monitoring, mentoring and guiding to government activities and public in the field of drug and food control.

So dangerous as prescription drugs for humans, the National Agency of Drugs and Food Control of Bengkulu City needs to monitor the circulation of prescription drugs in all pharmacies in
Bengkulu city in order to people are always maintained in healthy condition and safe from abuse of drugs purchased without using prescription, because in Bengkulu city it is still frequently encountered violations of the sale of prescription drugs.

2. Formulation of the Problems

Based on the background that the writer has explained, the writer tried to raise the issue as follows:

1. How is the monitoring the sales of class G drugs without a prescription by National Agency for Drug and Food Bengkulu?
2. What are the limiting factors in monitoring the sales of class G drugs without prescription by National Agency of Drugs and Food Control of Bengkulu city?

B. RESEARCH METHODOLOGY

The type of research is juridical empirical research which is a law research as scientific activity, based on the method, systematic and certain thought which aims to study one or more symptoms of a particular law, by way of analyzing it.\(^4\) Juridical empirical research was done to see whether the application of the law on legal events in the community has in accordance with the provisions of the legislation. The data collection was done with interviews, participant observation and study of literature.

C. RESULTS AND DISCUSSION

1. Sales Control of Class G Drugs without Prescription by Pharmacists by the Agency of Drugs and Food Control of Bengkulu.

In connection with the supervision of the drugs sale, the Ministry of Commerce (Kemendag) through the Directorate General of Standardization and Consumer Protection is in charge of coordinating the implementation of consumer protection together with the National Agency of Drugs and Food Control, along with other related ministries based on the Law on Consumer Protection in 1999. The Ministry of Commerce also oversees

non-food product, while NA-DFC is overseeing medicinal products and processed food.

Coordination meeting (coordination meeting) between the Ministry of Commerce and the Ministry of Health is conducted to discuss the standardization of health medicinal products, one of which related local herbal products that have health standards as well as other herbal products that the standardization will be governed according to regulations handled by the Ministry of Health, the Ministry of Commerce and NA-DFC. National Agency of Drugs and Food Control (NA-DFC) is the regulatory agency on drugs and food in Indonesia.

NA-DFC charges of carrying out government duties in the field of drugs and food control in accordance with the provisions of Law as stated in Article 67 of Presidential Decree No. 103 of 2001 on the Status, Tasks, Functions, Organizational Structure and Work Mechanism of Non Departmental Government Institutions, hereinafter the Technical Implementation Unit in the NA-DFC has the task of implementing the policies in the field of drugs and food control, which includes oversight of the therapeutic product, narcotics, psychotropic, an addictive substance, traditional medicines, cosmetics, complement and supervision over food safety and hazardous materials as set out in Article 2 of Regulation of Head of NA-DFC No. 14 of 2014 concerning on Organization and Technical Implementation Unit at the Environment of National Agency of Drugs and Food Control. The vision and mission of NA-DFC include:


b. Implementing Quality Management System Consistently.
c. Optimizing Partnerships with Stakeholders in various lines.

d. Empowering Society to be Able to protect their self at Risk of Drugs and Food on Health.

e. Building Learning Organization

In carrying out its vision and mission, NA-DFC has some great values as the cultural organization, namely:

a. Professional means that uphold professionalism with integrity, objectivity, perseverance, and commitment.

b. Credible is trustworthy and recognized by the wider society, national, and international.

c. Anticipative and responsive in overcoming the problem.

d. Teamwork needs transparency, mutual trust, and good communication.

e. Innovative means be able to perform the newel according to the latest science and technology.

The local government together with NA-DFC is obliged to oversee the sale of drugs in the society. To ensure the availability of drugs and food products are safe for the society, then the annual program NA-DFC is conducting the routine site inspection every month. Commodities become NA-DFC coverage include drugs, drug ingredients, cosmetics, traditional medicines, supplements, foods and beverages, narcotics, psychotropic substances, and hazardous materials. The local inspection activities conducted NA-DFC include production facilities, distribution facilities, and health care facilities. The mean of production is a mean that produces a commodity, the mean of distribution is the mean that distribute those commodities like PBF, and the mean of health care is hospital, health center, pharmacy, and clinics.

Based on observations and interviews conducted by researcher at five pharmacies in Bengkulu city, the prevention efforts undertaken by NA-DFC of Bengkulu city on the sales of Class G drugs in pharmacies in Bengkulu city were only done to the prescription drugs categorized as narcotics, psychotropic substances and precursors. While the supervision on Class G drugs which should be
undertaken by prescription is less special attention. Moreover based on the interview to Kimia Farma pharmacist in the sale of class G drugs which should be by prescription outside of narcotics, psychotropic substances and precursors do not need any reporting and documentation to NA-DFC and Health Office of Bengkulu City. This is in contrast to the sale of prescription drugs of class G of narcotics, psychotropic substances and precursors that in sales there should be reporting by sending it to the Health Office and NA-DFC once a month and there must be documentation of goods in and goods out.\(^8\) Based on the data and the results of interview done by the researcher, it could known that there was lack of supervision by NA-DFC of Bengkulu city at the pharmacies in Bengkulu city. It is based on the data obtained by the researcher from five pharmacies in Bengkulu city, where the fifth Pharmacy was never conducted surveillance of class G drugs outside of narcotics, psychotropic substances and precursors.

The supervision from NA-DFC has functions on:

a. The study and arrangement of national policy concerning on drugs and food.

b. Implementation of certain policies on supervision of drugs and food.

c. Coordinating functional programs in performing the role of NA-DFC.

d. Monitoring, guiding and training of government institution programs in controlling drugs and food.

e. Conducting training and service of general administration in sections of general planning, administration, organization and management, employee affair, financial, archive, coding, equipment and household

However in the implementation despite of the existence of supervision boards on product supervision such NA-DFC, government concerns on consumers’ protection is still low.\(^9\) Controlling on the sale of drugs class G from

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\(^8\)Interview result with Antoni, the Apothecary of Kimia Farma of Bengkulu city, on May 10\(^{th}\) 2016, at 11.00 WIB.

\(^9\)Firman Tumantara Endipraja, Hukum Perlindungan Konsumen (Filosofi Perlindungan Konsumen dalam Perspektif Politik Hukum Negara Kesejahteraan), Setara Press, Bandung, 2016, p.18.
pharmacists by NA-DFC has not been optimal since these drugs are still sold freely in 5 drugs stores where the this study taken place. Drugs class G that can be bought without medical prescription include antibiotic amoxicillin with various brands such ambroxol, trifamycetin, kloramfenikol, salbutamol, domperidone, imodiumloperramideHCL and tramadol.

2. Obstacles in Supervision of Drug class G sales without medical prescription by National Agency of Drug and Food Control (NA-DFC) Bengkulu

In supervision of Drug class G sales without medical prescription by National Agency of Drug and Food Control (NA-DFC) Bengkulu, the obstacles found are:

a. The lack of coordination among NA-DFC Bengkulu, Department of Health, and Police Department that supervise the circulation of prescription drugs

The supervision of Drug class G is done by (NA-DFC) Bengkulu coordinating with Department of Health, and Police Department in Bengkulu city. However in its implementation, the performance is not very satisfactory due to the the different policies among those institutions that overlap one to each other and cause some problems for NA-DFC to perform the supervision.

Besides, the number of drug stores reaches 157 outlets, thus the supervision is mainly done to those that have never been supervised before, new drug stores, and drug stores with bad report in the previous supervision. If along the supervision some problems or violations are found, NA-DFC Bengkulu according to the procedures will report them to Local Government through Department of Health or Department of Licensing. This report will be followed out or get penalty according to the Regulation of Ministry of Health of Republic of Indonesia No. 1332/Menkes/SK/X/2002 concerning on alteration of the Regulation of Ministry of Health of Republic of Indonesia No. 922/Menkes/Per/X/1993 concerning on Conditions and Procedures for Pharmacies Licensing.
It is stated in article 30 paragraph (1) that the supervision on pharmacies done gradually from center government level to local government level according to ministry technical instruction. While in article 30 paragraph (2) it is stated that supervision and controlling mentioned in paragraph (1) are done by Department of Health, Sub-department of Health and NA-DFC. Thus, the responsible party to give penalty of supervision, warning, temporary stop and license withdrawal, is Department of Health in Regency or municipal level.

b. Deliberate action of Drug stores in selling prescription drugs

In implementing consumer protection concerning prescription drugs in Bengkulu city, producers or business owners tend to be careless and try to sell the drugs class G illegally or without medical prescription. According to health, security, and safety principles, the supervision of drugs class G should be the priority based on consumer protection Law due to the serious impact to consumers’ life. However, the sale of drug class G tends to be profit orientation of certain parties rather than people’s health. It is expected that law enforcer could give serious attention to any violations of rules and regulations in order to protect society.

Based on the Government Regulation No. 133/Menkes/SK/X/2002 concerning on alteration of the Regulation of Ministry of Health of Republic of Indonesia No. 922/Menkes/Per/X/1993 concerning on Conditions and Procedures for Pharmacies Licensing, it is stated that if the pharmacist of drug store cannot perform his duty then the he shall appoint co-pharmacist. In case the pharmacist of drug store and appointed co-pharmacist cannot perform their duty, pharmacist of drug store shall appoint pharmacist replacement. This action is proposed to prevent the out controlled sale of drugs from drug stores to people. However, the implementation of this regulation does not work in some drug stores where this study taken place, people still
could buy prescription drugs through the mere pharmacist assistance.

c. The Lack of Consumer Knowledge Against Class GDrugs

The interest of society against drugs is not only the economic aspects but also the health aspect. Consumer attitudes towards different drugs compared with their attitudes to other consumables. The consumers in this case have a weak position, because they do not have extensive knowledge about the drug itself, do not understand the rights belonging to them and not all consumers have the knowledge and education on health. Therefore, the pharmacist is required in delivering and be a source of information for people accordance with the profession in the context of healthcare and education. Besides, it should be able to account for the pharmacy as a business entities owned by pharmacists as entrepreneurs. But in reality that is happening in the community, the professionalism of a pharmacist cannot be implemented properly, both as health workers in the field as well as entrepreneurs.

d. The Lack of Standard Operational Procedures in the Class GDrugs Services at the Pharmacy of Bengkulu City.

The large number of pharmacies that sell Class GDrugs due to Standard Operational Procedures (SOP) that has not been well documented, there is even a pharmacy that does not have an SOP. The not existence of SOP by a pharmacy in the Bengkulu city was also researchers known from the statement of Desy Ariyanti as Pharmacist Manager of Apotek Sejahtera, Aslimahyani as Pharmacist Manager of Apotek Pagar Dewa, and Zul Amri as Pharmacist Manager of Apotek Paten, who claimed that the absence of SOP at the pharmacy that they were manage. Article 23 Paragraph 1 PP Number 51 of 2009

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10 The results of Author Interviews With Oktar Tamba, A Pharmacist Manager of Apotek Hasian at Bengkulu city, on May 19th, 2016 at 20:00 GMT.
11 The results of Author Interviews With Oktar Tamba, Desy Ariyanti as Pharmacist Manager of Apotek Sejahtera, Aslimahyani as Pharmacist Manager of Apotek Pagar Dewa, and Zul Amri as Pharmacist Manager of Apotek Paten, on May 19th, 2016.
mentioned that in doing the work of the pharmacy, the pharmacist as stipulated in Article 20 should be set the SOP and on paragraph 2 mentioned that it must be made in writing and updated continuously appropriate with development of science and technology in the field of pharmacy in the provisions of the legislation. Therefore, this SOP should be reflect that the certainty of any existing work processes and they were traceability in the event of irregularities. A pharmacist must be able and willing to carry out the duties and responsibilities, namely to guarantee that drugs given to consumers is a drug that guaranteed both quality and quantity as well as the consumer can get the information of the drug used.

D. CONCLUSION AND SUGGESTION

1. Conclusion

Based on the explanation which has been described above, then it can be concluded that:

1) The supervision of drugs Class G sales by the National Agency of Drugs and Foods Controls (NA-DFC) has yet to be implemented well, where there are still many Class G Drugs that are sold without a prescription in pharmacies of Bengkulu city.

2) The obstructions in the sale of prescriptions surveillance by NA-DFC Bengkulu were the lack of coordination with relevant agencies as for surveillance against prescriptions done by NA-DFC Bengkulu in coordinating with Department of Health of Bengkulu City, as well as police in the Bengkulu city, there is the deliberate action of the pharmacy to sell prescriptions, the lack of consumer awareness that his rights protected by law, the lack of consumer knowledge towards the Class G Drugs, the absence of SOP in the service of the Class G Drugs at the pharmacy of Bengkulu City.

2. Suggestion

The supervision of Class G drugs sales without medical prescription by NA-DFC Bengkulu should be done
regularly or continually and it’s need to maximize cooperation between relevant agencies as to the Department of Health and Police of Bengkulu City.

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