



Study of Implementation of Pharmaceutical Destruction In Pharmacies In Denpasar City

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Abstract

Destruction of pharmaceutical preparations is one of pharmaceutical cares in Pharmacy which regulated in Permenkes RI No. 73 of 2016. The aim of this study is to describe the implementation of pharmaceutical care standard about destruction of pharmaceutical preparations in several pharmacies in Denpasar City. This study uses descriptive qualitative research through interviews. Data was collected by survey in 12 pharmacies in Denpasar City with 12 respondents on June 2020. This study uses total sampling technique in which the entire populations are used. Based on the identification results, the destruction of pharmaceutical preparations in majority of pharmacies are not in accordance with applicable regulation.

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1. INTRODUCTION

Forensic pharmacy is the application of pharmaceutical sciences to law. Pharmacists are required to obtain legal certainty so that pharmaceutical practices can fully provide professional services, comply with the standards and requirements of safety, quality and usefulness [1]. Pharmacy is a pharmaceutical facility where pharmacists do the practice. Pharmacists who run pharmacy services at the pharmacies must practice according to standard pharmaceutical services in pharmacies specified in Minister of Health Regulation No 73 Year 2016 [2].

Destruction of pharmaceutical preparations is one of the managerial

pharmaceutical services at pharmacies. Destruction is an activity to finish pharmaceutical supplies which are not used due to expired, damaged, or unqualified by making a finish pharmaceutical supplies proposal to related parties in accordance with applicable procedures [3]. In the destruction of pharmaceutical preparations often encountered several obstacles such as destruction procedures, applicable regulations, marking and destruction techniques of pharmaceutical preparations.

Destruction of pharmaceutical preparations has been regulated in Government Regulation of Republic Indonesia Number 72 Year 1998 concerning Safeguarding Pharmaceutical Supplies and

Medical Devices. [4]. Destruction of pharmaceutical preparations is carried out by business entities that produce and / or distribute pharmaceutical preparations, and / or authorized people in health facilities and / or the government. The destruction of pharmaceutical preparations related to criminal is carried out by the government. Destruction of pharmaceutical preparations must regard to the impact on human health and environmental and must be reported to the Minister [4]. Based on Standard of Pharmaceutical Services in Pharmacies, destruction of pharmaceutical preparations must be adjusted to the type and form of pharmaceutical preparations [2]. Based on BPOM regulations, Pharmacists or Pharmaceutical Technical Personnel must ensure that the packaging including the label of the pharmaceutical preparation has been destroyed [5].

Based on those regulations, the procedure for destruction of pharmaceutical preparations in accordance with the regulations can be described as follows: (1) Making list of pharmaceutical preparations that will be destroyed; (2) Certified such destruction activities; (3) Checking the pharmaceutical preparations that will be destroyed; (4) Destruction of pharmaceutical preparations is based on the type and form of the pharmaceutical preparation and must preserving the environmental sustainability; (5) Recording and reporting of destruction activities of pharmaceutical preparations.

The importance of pharmaceutical destruction procedures is because pharmaceutical preparations those were expired, damaged or withdrawn from circulation harmful to humans. If pharmaceutical preparations those were expired, damaged, or withdrawn from circulation are disposed of without procedures, it will cause problems for environmental preservation and allow them to be misused by certain parties [6].

Previous research has been carried out on the pharmaceutical waste management at selected hospitals and homes in the Ghana. The results of the study showed that the visited hospitals did not have any separate collection and disposal programs for pharmaceutical waste and the majority of respondents at home disposed of pharmaceutical waste through the normal waste bins which end up in the landfills or dump sites [7].

Pharmacy is a pharmaceutical facility that has been chosen by many peoples. Every day there are sales by consumers and purchases from PBF, so good management of pharmaceutical preparations is needed. Futhermore, there has not been any published study that specifically explain the destruction of pharmaceutical preparations in pharmacies. This study aims to determine the suitability of the procedure for destruction of pharmaceutical preparations in pharmacies in Denpasar City with applicable regulations.

2. METHODS

2.1. Material and Equipment

The equipments used in this study such as notebooks, pens and mobile phone during interviews

2.2. Method

This research design used descriptive study with survey and interview method. Descriptive research has the main objective to make a picture of a situation objectively. The location of the study was conducted in 12 pharmacies in Denpasar City in June 2020. The total research respondents were 12 respondents consist of pharmacists that managing pharmacies or companion

pharmacists. This research was conducted using a total sampling technique in which the entire population were used. Interview data were collected and analyzed descriptively to know a picture of the destruction of pharmaceutical preparations in pharmacies in Denpasar City and then adjusted to the regulations that related to the destruction of pharmaceutical preparations.

3. RESULT AND DISCUSSION

Results of the research of pharmaceutical preparations destruction conducted through interview can be seen in **Table 1.**

Table 1. Study on the Destruction of Pharmaceutical Preparations in Pharmacies in Denpasar (n=12)

Variable	Category	Amount	Percentage
Standard Operating Procedures (SOP) of Pharmaceutical Destruction	Available	0	0.0
	Unavailable	12	100.0
Storing Defective and Expired Pharmaceutical Preparations	Bad	5	41.7
	Good	7	58.3
Recording Defective and Expired Pharmaceutical Preparations	Bad	8	66.7
	Good	4	33.3
Destruction of Pharmaceutical Preparations	Bad	4	33.3
	Good	2	16.7
	Unavailable	6	50
Recording and Reporting Destruction of Pharmaceutical Preparations Activities	Bad	10	83.3
	Good	2	16.7

Based on Government Regulation Number 72 Year 1998 about Securing Pharmaceutical Preparations and Medical Devices, destruction of pharmaceutical preparations is conducted to preparations that are: (1) produced without complying the applicable requirements; (2) expired; (3) not complying the requirements for use in health services or scientific interests; (4) revoked access permission by the government; and (5) related to criminal offenses in the field of pharmaceutical preparations and medical devices [4].

In this research, the elimination of pharmaceutical preparations discussed was only in the form of pharmaceutical preparations that didn't contain narcotics and psychotropic substances. Destruction of pharmaceutical preparations and narcotics and psychotropic substances was carried out by Pharmacists and witnessed by other pharmaceutical personnel who have practice licenses [8]. According to the Minister of Health Regulation No. 73 Year 2016, the destruction of pharmaceutical preparations must be adjusted to the type and form of preparations [2]. It has been explained in Government Regulation No. 72 Year 1998, in the implementation of the destruction of pharmaceutical preparations must pay attention to the impact on human health and environmental preservation efforts [4].

The availability of standard operating procedures (SOP) needs to ensure that each pharmaceutical activity complies applicable

standard. In this case, it is pharmaceutical service standards at the pharmacy. Based on the results of the interviews, all respondents stated that they didn't have an SOP regarding the destruction of pharmaceutical preparations. The unavailability of SOP is due to the fact that although there are legal regulations regarding the elimination of pharmaceutical preparations, there is no regulation that that would clearly define, explains, classify, and provide proper guidelines of destruction of pharmaceutical preparations [9].

In storing defective and expired pharmaceutical preparations, there were 58.3% of respondents storing the preparations well. The damaged or outdated/expired pharmaceutical preparations should be stored in a room or special place separated from other pharmaceutical preparations and given special information to prevent errors in the sale of pharmaceutical preparations to consumers. For pharmaceutical preparations that are close to expiration date (3-6 months), it should be stored separately and also given special marking [8]. The pharmaceutical dispensing system uses the First Expired First Out system, where products with expiration dates are first issued (sold) first. 41.7% of respondents didn't store pharmaceutical preparations that were defective or expired properly. Storage of pharmaceutical preparations that are not good such as storage of expired preparations

are only stored behind preparations that have not expired and behind good quality product. There were still pharmaceutical preparations with an expiration date 2 years ago. Expiration can be interpreted as the expiration time of the product for consumption. In a good and correct storage, the expiration period can be adjusted to the date stated in a product. However, when the product is stored incorrectly such as not in the right temperature or exposed to sun exposure, it can accelerate the expiration of the product

Recording defective and expired pharmaceutical preparations needs to carry out. 66.7% of respondents didn't record defective and expired pharmaceutical preparations properly. Recording aims to monitor pharmaceutical supplies transactions that come in and out of the pharmacy. Recording can be conducted manually or electronically with a system that is validated, traceable and can be printed. Recording must be conducted every time a pharmaceutical preparation is defective or expired. Recording will ease officers to trace if there is a sub-standard quality of pharmaceutical preparations and must be withdrawn from the market [8]

Recording and checking pharmaceutical preparations should be conducted in each product in process of accepting. Thus, it can be known the expiration date and condition of each product. Checking through stock opname

should be carried out routinely to ensure there are no expired pharmaceutical preparations. In pharmacies with a network system, dead stock is treated in that the products contained in a pharmacy are not sold during the specified period of time that can be distributed (spreading product) to pharmacies that are still one network with the pharmacy. The system can reduce the amount of drugs that will expire.

Destruction of pharmaceutical preparations is based on the type and form of the preparation. Improper completion of pharmaceutical preparations can be dangerous if it leads to contamination of water supplies or local sources used by the surrounding community, animals and plants. Indiscriminate disposal of pharmaceutical preparations may be used by scavengers and children if the landfills are not proper [6].

There are many ways conducted by pharmacy to finish pharmaceutical preparation. The habit of destructing pharmaceutical preparations depends on the social economic culture as well as regulation guidelines, norms that apply in a country. The most common method used is the destruction of drugs in the sink, toilet and trash. Yet, the method is considered not environmentally friendly [6]. Based on South African State regulations, the destruction of pharmaceutical preparations should not be carried out by means of disposal through the sewage system [10]. In the European Union and the United States,

drug return services that are not used to community pharmacies have been put in place for drug destruction [9]. Before conducting the destruction, the pharmacist is required to ensure that the packaging including the label of the pharmaceutical preparation has been destroyed [4].

Food and Drug Administration of United States or well-known as FDA recommends procedures for the settlement of pharmaceutical preparations that are not used such as solid medicines. They must be mixed with unattractive materials such as cat litter or coffee grounds, put in disposable containers, and placed in trash cans or disposed of through drug return programs the community. Liquid medicines must be mixed with salt, flour, charcoal, or spices such as turmeric or mustard to give an unattractive mixture of aromas and textures [11]. The destruction of pharmaceutical preparations can also be carried out using high temperature incinerators. Burning drugs at low temperatures or in open containers results in the release of toxic pollutants into the air [12]. However, the cost of destructing drugs with high temperatures above 1200 °C is higher than manufacturing costs. The cost of disposing of high-temperature combustion pharmaceutical waste in Croatia, Bosnia and Herzegovina is about US \$ 2.2 / kg - US \$ 4.1 / kg [12].

Based on the results of interview, 50% respondents had not been conducted

destruction pharmaceutical preparations by themselves. Destruction of pharmaceutical preparations from respondents was carried out by a third party, namely PBF. 33.3% respondents didn't destruct pharmaceuticals properly. In this case, pharmaceutical preparations that couldn't be returned to PBF were destroyed themselves by means of disposal to the trash or toilet according to the type and form of the damaged or outdated preparations. Destruction of pharmaceutical preparation was conducted well by 16.7% of respondents. The extermination included making the minutes of the extermination and the implementation of the annihilation by paying attention to aspects of security for humans and the environment. Some obstacles were presented by the interviewees regarding the implementation of the destruction of pharmaceutical preparations such as expensive costs, the required land was quite extensive, and there was no detailed rules regarding the implementation of the destruction of pharmaceutical preparations.

In recording and reporting destruction of pharmaceutical preparations, 83.3% of respondents didn't conduct it properly. Respondents generally only removed pharmaceutical preparations from available stock without reporting the implementation of the destruction. Recording and reporting should be considered given the function of annihilation, namely efforts to release goods from the liability in force [13].

According to Government Regulation Number 72 of 1998, reports on the destruction of pharmaceutical preparations must at least contain the following information: (1) The time and place of the destruction of pharmaceutical preparations and medical devices; (2) Amounts and types of pharmaceutical preparations and medical devices; (3) Name of person who is responsible for implementing the destruction of pharmaceutical preparations and medical devices; and (4) the name of a witness in the destruction of pharmaceutical preparations and medical devices. Reports on the destruction of pharmaceutical preparations were signed by the person in charge and witness in the implementation of the destruction of pharmaceutical preparations and medical devices. [4]

Pharmacists play important role in managing the destruction of pharmaceutical preparations. Pharmacists are expected to be able to conduct procedures for the destruction of pharmaceutical preparations that are appropriate and not harmful to humans and the environment. Pharmacist is also expected to implement procedures in managing pharmaceutical preparations properly from the planning stage to reporting. Therefore, it can minimize numbers of defective and expired pharmaceutical preparations.

4. CONCLUSSION

This study reported the

implementation of the destruction of pharmaceutical preparations in several pharmacies in the city of Denpasar. The conclusion in this study is the management of pharmaceutical preparations in the form of destruction of preparations in several pharmacies in the city of Denpasar not in accordance with the Pharmaceutical Services Standards in Pharmacies.

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