International Symposium on Social Sciences, Education, and Humanities (ISSEH 2018)

Level of Understanding of the Small and Medium Enterprises Traditional Medicine to Regulations Labelling Packaging

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***Abstract*—** **During a pandemic like this, the use of traditional medicines is increasing, therefore the role of packaging labels is very important to provide information about these products. The label on the packaging of traditional medicinal products must contain objective, complete and clear information and not mislead the public. The method used are observation and literature study. The results of this method can be concluded that UKOT producers still do not understand well about labelling of traditional medicine packaging because based on the data table graph shows that 30 of their product designs are still not in accordance with the provisions of labelling/marking traditional medicine and from pie chart data, information can be obtained. False or misleading information that most often occurs is information on Efficacy Claims, Product Composition, and Warnings / Cautions by 13%. Knowledge level of traditional medicine SME concerning labelling of package relatively low.**

***Keywords—regional plan; public relations; tourism***

1. INTRODUCTION

The spread of Covid 19 began in Wuhan in late 2019 until now it has spread to the whole world [1]. Based on data from Covid19.go.id, the number of Indonesians infected with Covid 19 as many as 4,259,439, Indonesians who recovered as many as 4,110,574, and Indonesians who recovered as many as 143,960 (data update December 14, 2021). The pandemic is not yet predictable when it will end.

Traditional medicine is becoming an important part of people's cultures, especially people in developing countries. People in developing countries rely heavily on traditional medicine for up to 80% of their health needs [2]. Based on research conducted by the Alodokter application, it was found that 45% of 7699 respondents to Alodokter application users chose to use traditional medicine [3]. Traditional medicine is an ingredient or herb in the form of plant ingredients, animal ingredients, minerals, sarian preparations (galenik) or mixtures of these ingredients that have been used for generations for treatment, and can be applied in accordance with the prevailing norms in the community.

Traditional medicine can be one of the people's choices to maintain the body's immunity. Utilization of traditional medicine in addition to being used to maintain health, can also be used during public health emergencies and national disasters covid 19 [4]. During pandemic times, the need for traditional medicine also increases. This increase is an opportunity for the development of traditional Indonesian medicine that meets the requirements of safety, quality, labels and advertising. This is one of the responsibilities of the POM Agency to oversee the development of quality traditional medicine products in the pandemic era. One of the programs carried out by BPOM to maintain quality traditional medicine is by educating the KLIK movement (Check Packaging, Check Label, Check Edar Permit, and Check Expiration) for business people.

Based on BPOM RI Regulation Number HK.00.05.41.1384 on Criteria and Procedures for Registration of Traditional Medicine, Standardized Herbal Medicine, and Phytoarmaka information that must be listed on the packaging label Traditional medicine includes: Product name, dosage form, net weight, composition, industrial address, license number, production code, traditional drug logo, expiration, claim of use, contraindications (if any), side effects (if any), drug interactions (if any), means of storage, special information (information on non-halal sourced ingredients, alcohol content, and use of artificial sweeteners). The author is interested in raising the theme in the form of a level of understanding of traditional medicine business actors in understanding the information that must be listed on the packaging.

II. RESEARCH METHODS

This study used observation methods in one of the small business manufacturers of traditional medicine by taking 30 traditional medicine products that are being submitted to BPOM. After observation, then a literature study was conducted with reference BPOM regulations related to information on packaging labels.

III. RESULTS AND DISCUSSIONS

1. *Result*

Table. I. The rate of errors that often occur on traditional medicine packaging labels

|  |  |
| --- | --- |
| **Type of Errors** | **Error Rate** |
| Efficacy Claim | 13 % |
| Warning/caution | 13 % |
| Composition | 13 % |
| Storage condition | 11 % |
| Product name | 10 % |
| Composition illustration image | 8 % |
| Traditional medicine’s logo | 8 % |
| Expiration date | 6 % |
| Contraindication | 5 % |
| Producer’s name and address | 3 % |
| Marketing numbers license | 3 % |
| 2 D barcode | 2 % |
| Packaging size | 2 % |
| How to use | 2 % |
| Medicine’s form | 1 % |

Table. II. Level of compliance of traditional medicine packaging labels to regulations

|  |  |  |
| --- | --- | --- |
| **Name of product** | **Level of compliance** | **Level of incompliance** |
| Luminous Skin | 90 % | 10 % |
| M-Slim | 90 % | 10 % |
| Midle Slim | 90 % | 10 % |
| Slim Secret | 90 % | 10 % |
| Zeneva Slim | 90 % | 10 % |
| Albapro | 80 % | 20 % |
| Imunaturaid | 80 % | 20 % |
| Bodha Jointix | 70 % | 30 % |
| Bodha Slim | 70 % | 30 % |
| CL Skin | 70 % | 30 % |
| Gemuk Fit | 70 % | 30 % |
| Asi Well | 60 % | 40 % |
| Bodha Miss V | 60 % | 40 % |
| GWS Skin | 60 % | 40 % |
| Mel-B | 60 % | 40 % |
| Amzi Vit | 50 % | 50 % |
| Gabets | 50% | 50 % |
| Imunit Tea | 50% | 50 % |
| Me You Honey Slim | 50% | 50 % |
| NSH Slim | 50% | 50 % |
| Promitas Pria | 50% | 50 % |
| Saeba | 50% | 50 % |
| Zilivit | 50% | 50 % |
| Zimavit | 50% | 50 % |
| Bodha Maag | 40 % | 60 % |
| Diabifine | 40 % | 60 % |
| Lumbrefit | 40 % | 60 % |
| Zikovit | 40 % | 60 % |
| Promitas wanita | 30 % | 70 % |
| Moringa SH | 10 % | 90 % |

*B. Discussion*

Samples were taken from 30 Small and Medium Traditional Medicine Enterprises all over Depok residents. From all 30 samples, errors existed in all of the sample. Errors/ misleading information mostly found in Efficacy Claims, Product Composition, and Warnings / Cautions (13%). Traditional medicines had known as plethora of new hope to cure many diseases. However, without scientific proof for the efficacy claim, many leads to severe disease for consumers in Africa [5]. Some traditional medicine had a bombastic efficacy claim such could cure Covid-19 in Ethiopia [6]. Traditional medicine efficacy claims should be monitored properly, since most of the claim worked properly only in interaction with other medicines [7]. Although only 13 % of product had error in efficacy claim, but it may lead to severe case for consumers.

Study on toxicology and safety implication of traditional medicines always intriguing since many in vivo tests on aqueous extracts largely support the safety of herbal medicines, whereas most in vitro tests on isolated single cells mostly with extracts other than aqueous ones show contrary results [8]. That’s why warning/caution labels had to be regulated and monitored properly in every traditional medicines. Monitoring of warning/caution labels for traditional medicines products presented unique challenges, and as such, preparations were available from a wide range of sources where limited by qualified healthcare professionals that available. The ethics-legal issues and regulatory approval mechanism of herbal medicine varied from country to country [9]. Based on what found on the field (13 % errors for warning/caution), the government needed to improve the monitoring of traditional medicine products.

  Natural products and traditional medicines are of great importance. Such forms of medicine as traditional Chinese medicine, Ayurveda, Kampo, traditional Korean medicine, and Unani have been practiced in some areas of the world and have blossomed into orderly-regulated systems of medicine. However, to reproduce such magnificent result, they need proper guidance to show the composition contained [10]. Composition also found as core of efficiency of jamu, traditional medicine from Indonesia [11]. The high percentage of errors in composition (13 %) may affect the trust given by consumers.

Level of compliance to the regulation in small and medium traditional medicine enterprises varied from 90 % to 10%. However, there’s only 5 out of 30 Small and Medium enterprise with 90 % level of compliance to regulation. More than half of the samples had 50 to 10 % level of compliance. This reflect how poor the level of understanding for Small and Medium Traditional Medicine Enterprises to regulation of package labelling. Based on WHO report, compliance level of traditional medicine to regulation was less than 52% [12].

IV. CONCLUSION

All samples of traditional medicines produced by small and medium enterprises found to had errors. The errors vary from 13% to 1 %. Most of errors found in information on Efficacy Claims, Product Composition, and Warnings / Cautions label (13%). More than half of the samples had 50 to 10 % level of compliance. Knowledge level of traditional medicine SME concerning labelling of package relatively low.

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