



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

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Abstract. During a pandemic Covid-19, 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. This study aims to see the level of understanding of small and medium enterprises of traditional medicine against packaging labelling regulations issued by the government. This study uses a qualitative method by observing one of the small traditional medicine manufacturers. As many as 30 samples of traditional medicines submitted to BPOM were taken for observation and analysis based on government regulations related to traditional medicine packaging labels. 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/marketing 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%. The level of knowledge of traditional medicine SMEs about packaging labelling is relatively low so it is necessary to follow up to increase their knowledge regarding packaging labelling.

Keywords: Traditional medicine · Labelling packaging · Regulation

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. Until now there is no right drug available for the treatment of Covid-19.

Traditional medicine is becoming an important part of people's cultures. The use of traditional medicine has not only become part of the Chinese, Brazilian and Ethiopian

communities but is popular in several Asian countries including Indonesia and India [2]. Traditional medicine has long been used by Indonesian people to maintain health and treat disease, one of which is by consuming herbal medicine. In China, traditional medicine has been shown to provide useful prevention for influenza virus infection and the SARS pandemic [3]. Indonesian traditional medicine has the same potential as traditional medicine in China. The consumption of traditional medicine in Indonesia in 2020 has increased. This is indicated by the increasing number of applications for registration of traditional medicines by 131.14%. Its two times greater than the application for registration of traditional medicines at the beginning of the pandemic [4]. This is related to the increasing use of traditional medicines which are believed to increase immunity and prevent virus infections. This is reinforced by research conducted by the Alodokter application, it was found that 45% of the 7699 respondents using the Alodokter application chose to use traditional medicine [5]. 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 [6]. With the increasing number of applications for registration of traditional medicines, it becomes a challenge for BPOM to ensure that traditional medicines circulating are safe and do not cause misleading information 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 businesspeople.

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). Until now, there is no data that measures the control of small businesses of traditional medicine producers on packaging labeling regulations issued by the government. Therefore, 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. This data can be used as a reference as a follow-up education to traditional medicine manufacturers regarding proper packaging labels in accordance with regulations.

2 Research Methods

This study uses a qualitative method by observing one of the small traditional medicine manufacturers. Researchers took as many as 30 samples of traditional medicinal products that are being submitted to BPOM. After the observations were made, a literature study

was then carried out with reference to BPOM regulations related to packaging label information. 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, there are 15 components of packaging labels that must be considered, including: efficacy claim, warning caution, composition, storage condition, product name, composition illustration image, traditional medicine’s logo, expiration date, contraindication, producer’s name and address, marketing number license, 2D barcode, packaging size, how to use, and medicine’s form. The researcher calculated the percentage of conformity and non-compliance with information labels on traditional medicine packaging. After that, a study was carried out to see the most information label errors in the traditional medicine packaging samples.

3 Results and Discussion

3.1 Results

3.2 Discussion

Based on Table 1, errors existed in all of the sample. Errors/misleading information mostly found in Efficacy Claims, Product Composition, and Warnings/Cautions (13%). Samples were taken from 30 Small and Medium Traditional Medicine Enterprises all over Depok residents. Traditional medicines had known as plethora of new hope to cure

Table 1. 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%

many diseases. However, without scientific proof for the efficacy claim, many leads to severe disease for consumers in Africa [7]. Some traditional medicine had a bombastic efficacy claim such could cure Covid-19 in Ethiopia [8]. Traditional medicine efficacy claims should be monitored properly, since most of the claim worked properly only in interaction with other medicines [9]. 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 [10]. 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 [11]. 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, Kambo, 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 [12]. Composition also found as core of efficiency of jamu, traditional medicine from Indonesia [2]. The high percentage of errors in composition (13%) may affect the trust given by consumers.

Regulatory systems on traditional medicine vary considerably worldwide. In general, regulatory approval of new pharmaceutical drugs requires the delivery of comprehensive information on the safety and efficacy of drugs, including traditional medicine. Based on Table 2, 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% [13]. Several things that become issues in the application of traditional medicine regulations include lack of research data, lack of financial support for research, lack of mechanism to monitor safety of traditional medicine practice, and lack of education and training [13]. And the most reported cases (cases in Southeast Asia) are the lack of research data and funding support for traditional medicine research. Research conducted related to traditional medicine is more concerned with the use and behavior consumption [14]. So far, there have been very few studies on the aspects of implementing regulations [15]. Research related to traditional medicine must be done collaboratively and comprehensively to overcome the problem of lack of research data [16].

Table 2. Level of compliance of traditional medicine packaging labels to regulations.

Name of product	Level of compliance	Level of in compliance
Luminous Skin	90%	10%
M-Slim	90%	10%
Middle 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%

4 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. That condition can lead to misinformation so that it is necessary to follow up to overcome this in the form of collaborative research and guidance to traditional medicine producers, especially small and medium industries.

References

1. Novanda, G. D. (2020). Advocacy and legal aid during Covid-19 pandemic: How Indonesia survives? *The Indonesian Journal of International Clinical Legal Education*, 2(2), 101–110.
2. Sumarni, W., Sudarmin, S., & Sumarti, S. S. (2019). The Scientification of Jamu: A study of Indonesian's traditional medicine. In *Journal of Physics: Conference Series* (Vol. 1321, no. 3).
3. Khiyaaroh, A., & Triratnawati, A. (2021). Jamu: Javanese doping during the Covid-19 pandemic. *Indones. J. Med. Anthropol.*, 2(2), 92–98.
4. BPOM. (2021). 濟無.
5. alodokter. (2016). 濟無 (Vol. 4, no. 1. pp. 1–23).
6. Kementerian Kesehatan Republik Indonesia. (2020). *Surat Edaran Pemanfaatan Obat Tradisional Untuk Pemeliharaan Kesehatan*. Pencegahan Penyakit, Dan Perawatan Kesehatan
7. Okaiyeto, K., & Oguntibeju, O. O. (2021). African herbal medicines: Adverse effects and cytotoxic potentials with different therapeutic applications. *International Journal of Environmental Research and Public Health*, 18(11).
8. Chali, B. U., Melaku, T., Berhanu, N., Mengistu, B., Milkessa, G., Mamo, G., Alemu, S., & Mulugeta, T. (2021). Traditional medicine practice in the context of Covid-19 pandemic: Community claim in Jimma Zone, Oromia, Ethiopia. *Infection and Drug Resistance*, 14, 3773–3783.
9. Yimer, G., Ekuadzi, E., Fasinu, P., de Melo, A. C., & Pillai, G. (2021). Traditional medicines for COVID-19: Perspectives from clinical pharmacologists. *British Journal of Clinical Pharmacology*, 87(9), 3455–3458.
10. Mensah, M. L. K., Komlaga, G., Forkuo, A. D., Firempong, C., Anning, A. K., & Dickson, R. A. (2019). Toxicity and safety implications of herbal medicines used in Africa. *Herbal Medicine*, 1–32.
11. Fokunang, E. T., Fonmboh, D. J., Mballa, R. N., Nyuyki, A. B., Fokunang, L. B., Kaba, N., Abong, T. B., Duerr, R., Richard, E., Ondoua, M.-T. A., & Fokunang, C. N. (2020). Pharmacovigilance of natural herbal medicines research for efficacy, safety and quality assurance of phytomedicine products. *Journal of Complementary and Alternative Medical Research*, (January 2021), 21–37.
12. Yuan, H., Ma, Q., Ye, L., & Piao, G. (2016). The traditional medicine and modern medicine from natural products. *Molecules*, 21(5).
13. WHO Report. (2019). *WHO global report on traditional and complementary medicine 2019*. World Health Organization.
14. Yudiatmaja, W. E., Prastya, I. Y., Meilinda, S. D., & Samnuzulsari, T. (2021). A systematic literature review of the research on traditional medicine policy. *MIMBAR: Jurnal Sosial dan Pembangunan*, 37(1), 24–35.

15. Guan, X., Yang, M., Man, C., Tian, Y., & Shi, L. (2018). The effect of the implementation of low price medicine policy on medicine price in China: A retrospective study. *The International Journal of Health Planning and Management*, 33(3), e798–e806.
16. Ijaz, N., & Boon, H. (2018). Statutory regulation of traditional medicine practitioners and practices: The need for distinct policy making guidelines. *Journal of Alternative and Complementary Medicine*, 24(4), 307–313.

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