

SUPERVISION OF TRADITIONAL MEDICINES CONTAINING UNDECLARED SUBSTANCE: ANALYSIS OF INDONESIAN FDA MONITORING DATA FOR 2012 - 2021

*Widha Dianasari, **Mardiati Nadjib

*Master Program in Public Health, Health Policy and Administration, Faculty of Public Health, Universitas Indonesia, Kampus Depok, Jawa Barat, 16425, Indonesia

**Health Policy and Administration, Faculty of Public Health, Universitas Indonesia, Kampus Depok, Jawa Barat, 16425, Indonesia

Email : widha78@gmail.com

Abstract. Background: At a time when people believe in the efficacy and minimal risk of traditional medicines, government agencies that oversee traditional medicines often find chemicals that are intentionally added to traditional medicines. The purpose of this study is to present the findings of Undeclared Substance that have been added to traditional medicines for ten years, to analyze their relevance to the real situation related to diseases or health problems in Indonesia, and to examine the violations of related policies. **Methods:** This study used an observational design based on quantitative and qualitative data and analyzed descriptively. Quantitative data based on Traditional Medicines Monitoring data are published through the website (www.pom.go.id) in the category of public warning OT-BKO in 2012-2021. Further analysis, conducted in-depth interviews to explore the root cause of the problem at the level of policy makers. Documents and literature review were conducted to analyze the findings. Interviews with policy makers were also conducted to confirm findings and explore problems that were not obtained from documents and literature. **Results:** For ten years, Paracetamol was the most common type of Undeclared Substance found every year in traditional medicines. This is relevant to the high number of complaints related to indications for the use of Paracetamol, both from reports from health facilities and results from household surveys. Meanwhile, the findings of the Ephedrine Undeclared Substance - with indications for reducing respiratory disorders - only appeared in 2021. These findings are not only relevant to the COVID-19 pandemic and the entry of traditional medicines from foreign aid, which also contain Ephedra sinica. The Undeclared Substance' findings are inconsistent with the objectives of a number of regulations ranging from those related to traditional medicine to consumer protection. **Conclusion:** The findings of Undeclared Substance on traditional medicine were relevant to public health problems at that time. The emergence of traditional medicines with Ephedra shows that domestic producers do not understand the safety of traditional medicines. In addition, the existing policies and violations of these policies have not been understood by traditional medicine manufacturers.

Keywords: Traditional Medicine, Undeclared Substance, Traditional Medicine Policy

Abstrak. Latar Belakang: Di saat masyarakat percaya dengan khasiat dan minimnya risiko obat tradisional, lembaga pemerintah pengawas obat tradisional kerap menemukan bahan kimia yang sengaja ditambahkan pada obat tradisional. Tujuan studi ini menyajikan temuan Bahan Kimia Obat (BKO) yang ditambahkan dalam obat tradisional selama sepuluh tahun, menganalisis relevansinya dengan situasi riil terkait penyakit atau masalah kesehatan di Indonesia, serta menelaah pelanggaran kebijakan yang terkait **Metode:** Penelitian ini dilakukan dengan desain observasional menggunakan data kuantitatif dan kualitatif. Data kuantitatif berdasarkan data Pengawasan Obat Tradisional dipublikasikan melalui website (www.pom.go.id) dalam kategori public warning OT-BKO tahun 2012-2021. Analisis selanjutnya, dilakukan wawancara mendalam untuk menggali akar permasalahan pada level pemangku kebijakan. Dokumen dan telaah literatur dilakukan untuk menganalisis hasil temuan tersebut. Wawancara terhadap pemangku kebijakan juga dilakukan untuk memastikan temuan dan menggali masalah yang tidak didapatkan dari dokumen dan literatur. **Hasil:** Selama sepuluh tahun, Paracetamol merupakan jenis BKO yang paling banyak ditemukan setiap tahunnya pada obat tradisional. Hal ini relevan dengan tingginya keluhan terkait indikasi penggunaan Paracetamol, baik dari laporan fasilitas kesehatan maupun hasil survei rumah tangga. Sementara, temuan BKO Efedrin- dengan indikasi untuk mengurangi gangguan pernafasan- baru muncul pada tahun 2021. Temuan ini selain relevan dengan kondisi Pandemi COVID-19 dan masuknya obat tradisional yang berasal dari bantuan luar negeri, yang juga mengandung Ephedra sinica. Temuan BKO ini tidak sesuai dengan tujuan sejumlah peraturan mulai dari yang terkait obat tradisional hingga perlindungan konsumen. **Kesimpulan:** Temuan BKO pada obat tradisional relevan dengan masalah kesehatan masyarakat pada waktu tersebut. Kemunculan obat tradisional dengan Ephedra menunjukkan produsen dalam negeri belum paham terhadap keamanan obat tradisional. Selain itu, kebijakan yang telah ada dan pelanggaran kebijakan tersebut belum dipahami oleh produsen obat tradisional.

Kata kunci: Obat Tradisional, Bahan Kimia Obat (BKO), Kebijakan Obat Tradisional

INTRODUCTION

In various parts of the world and for centuries, plant materials have been used for medicine and making traditional medicines (1). Traditional medicine has been recognized and even established by the World Health Organization (WHO) as part of health care (2). In Asian countries, the demand for traditional medicine is very high, especially during the COVID-19 pandemic, where synthetic drugs have not been found. *Traditional medicine* is an alternative way that is not only in demand but is chosen because traditional medicine is believed to have minimum side effects.

Public interest in traditional medicine and medicine continues to increase in Indonesia. This can be seen, among others, from the Basic Health Research (Riskesmas) results in 2010 and 2018, which showed an increase in traditional health efforts by 44.3% (3). The high supply of traditional medicine also accompanies the high demand for traditional medicine. Licensing data from the Food and Drug Supervisory Agency (Indonesia FDA) shows an increase in the number of applications for registration of traditional medicinal products, particularly to maintain immunity, by 131.14% in 2020 compared to 2019 (4).

The increasing interest in using traditional medicines is also followed by the widespread circulation of traditional medicines that are added with Undeclared Substance. Undeclared Substance is a synthetic compound, or it could be a chemical product derived from natural ingredients which are generally used in modern medicine (5). The findings of traditional medicines that are added with Undeclared Substance (or Traditional Medicines Containing Undeclared Substance) are dominated by products with added Undeclared Substance Sildenafil Citrate, Paracetamol, Dexamethasone, and Phenylbutazone. These drugs are included in the limited over-the-counter drug category, namely drugs that are sold freely and can be purchased without a doctor's prescription but are accompanied by warning signs (6). Undeclared Substance must be accompanied by a dose or dose with clear instructions for use and warnings about the dangers in its use to maintain its users' safety. During the period 2019, the Indonesian FDA Agency found illegal traditional medicines and health supplements and/that contained Undeclared Substance worth 6.2 billion rupiahs (7). Traditional medicines and supplements containing Undeclared Substance have health risks, such as loss of vision and hearing, stroke, heart attack, liver damage, and even death (5).

He added that Undeclared Substance is not following the meaning of traditional medicine,

especially those stipulated in Indonesia. Law no. 36 of 2009 concerning Health defines *traditional medicine* as ingredients or ingredients in the form of plant materials, animal materials, mineral materials, preparations of extracts (galenic), or mixtures of these materials. In other words, additives other than substances derived from plants, animals, extracts, and their mixtures are not justified in traditional medicines, including those prohibited as Undeclared Substance.

Regarding the prohibition of Undeclared Substance, at least three written policies confirm that traditional medicines are prohibited from being added to these ingredients. From the ministry level, there is a Regulation of the Minister of Health of the Republic of Indonesia No. 007 of 2012 concerning Registration of Traditional Medicines, which expressly prohibits the presence of Undeclared Substance that are added to traditional medicines due to the toxic effects of uncontrolled consumption (9). At the institutional level, the Indonesian FDA compiles and stipulates several policies related to Undeclared Substance, including HK.00.05.41.1384 of 2005 concerning Criteria and Procedures for Registration of Traditional Medicines, Standardized Herbal Medicines, and Phytopharmaceuticals, and Regulation of the Head of the Indonesian FDA Agency No. HK.00.05.41.1384 concerning Criteria and Procedures for Registration of Traditional Medicines, Standardized Herbal Medicines, and Phytopharmacy. However, the three regulations above have prohibited the addition of Undeclared Substance to traditional medicines; every year, the Indonesian FDA Agency finds Undeclared Substance in traditional medicine sampling tests on a national scale (10).

The finding of Undeclared Substance being added to traditional medicine is also in line with the public health situation at that time. For example, in 2015-2016, there was much advertising for male stamina-enhancing drugs. At the same time, the Indonesian FDA Agency found some Traditional Medicines Containing Undeclared Substance with sildenafil and its derivatives, which are the main ingredients for this indication (11). According to the test results for the 2020-2021 period, namely the COVID-19 pandemic, the Indonesian FDA Agency found a new trend in Traditional Medicines Containing Undeclared Substance findings where Undeclared Substance added to traditional medicines are Ephedrine and Pseudoephedrine (12). *Ephedrine* is a drug used for shortness of breath, allegedly reducing the symptoms of people with COVID-19. To respond to the high circulation of traditional medicines containing Undeclared Substance, research is needed on the amount and type of Undeclared Substance added to these traditional medicines. To date, there have been no published

studies on this matter, let alone evaluating it from the perspective of the public health situation and policies at the national level. In addition, analysis related to public health issues is essential for the government to pay attention to in the future. This study aims to provide evidence regarding the findings of traditional medicines containing Undeclared Substance in 2012-2021 and provide recommendations for the future.

METHOD

This research was conducted with an observational design using quantitative and qualitative data. Quantitative data based on Traditional Medicines Monitoring data are published through the website (www.pom.go.id) in the category of public warning Traditional Medicines Containing Undeclared Substance in 2012-2021. Further analysis, conducted in-depth interviews to explore the root cause of the problem at the level of policymakers using a systems approach, which consists of aspects of input (human resources and funds), process (organization of supervision), and outputs which are none other than the findings of the Traditional Medicines Containing Undeclared Substance. The criteria for the informants in this study were the supervisors of traditional medicines at the Central Indonesian FDA Agency and the UPT Indonesian FDA Agency. This study uses triangulation to validate the data, including (1) Triangulation of sources, namely interviews with the Coordinator of the Substance Group for Security and Quality Supervision and Import-Export of traditional medicines, quasi-drugs, and health supplements, as well as the Coordinator of the Indonesia FDA examination substance group in Jakarta. (2) Triangulation method, namely comparing information or data differently.

Informant Data

No	Informant	Agency
1	Informant 1	Indonesia FDA Center
2	Informant 2	Indonesia FDA Center
3	Informant 3	Indonesia FDA Center
4	Informant 4	FDA Branch in Jakarta
5	Informant 5	FDA Branch in Jakarta

RESULT

Findings of Traditional Medicines containing Undeclared Substance in 2012-2021

From the data for the last ten years, detailed Undeclared Substance findings were obtained by year, type, and an indication of Undeclared Substance (can be seen in the annex/attachment). For the record, the data in 2019 and 2020 became one report or one publication due to pandemic conditions that affected the work management of the Indonesian FDA Agency. Table 1 shows that in 2012 it was found that Paracetamol and Phenylbutazone were added to traditional medicines. Then in 2013, in addition to Paracetamol and Phenylbutazone, another Undeclared Substance was found, namely Sildenafil Citrate, which is efficacious as an aphrodisiac, and Dexamethasone, which is a steroid class drug. Paracetamol, Sildenafil Citrate, and Dexamethasone were consistently added to traditional medicine in the following years. New Undeclared Substance findings were widely added in traditional medicine in 2021, namely Ephedrine.

Table 1. Findings of Undeclared Substance 2012-2021

Year	Number of Findings	Top Five
2012	28	Paracetamol, Paracetamol and Phenylbutazone, Sibutramine HCL, Paracetamol & Diclofenac Na, Cyproheptadine
2013	39	Sildenafil Citrate; Paracetamol; Paracetamol, Sildenafil Citrate & Tadalafil; Phenylbutazone; Phenylbutazone & Dexamethasone
2014	51	Sildenafil Citrate, paracetamol, Sildenafil Citrate and Paracetamol; Glibenclamide; Paracetamol and Phenylbutazone
2015	107	Sildenafil citrate & its derivatives; Paracetamol;

Year	Number of Findings	Top Five
		Phenylbutazone; Sildenafil Citrate; Paracetamol & Phenylbutazone
2016	44	Sildenafil Citrate & its derivatives; Allopurinol; Hydroxythiohomosildenafil and hydroxy-homo sildenafil; Dexamethasone; Phenylbutazone
2017	39	Phenylbutazone; Sildenafil Citrate; Sildenafil citrate & paracetamol; Paracetamol and Diclofenac; Paracetamol
2018	6	Phenylbutazone; Paracetamol; Sibutramine HCL; Tadalafil & Vardenafil HCL; Sildenafil Citrate
2019 & 2020	53	Paracetamol; Sildenafil citrate; Dexamethasone; Phenylbutazone; Sildenafil
2021	71	Dexamethasone; Sildenafil Citrate; Paracetamol; Ephedrine and Pseudoephedrine; Hydroxythiohomo sildenafil

Source: Public Warning on Traditional Medicines 2012-2021 (www.pom.go.id)

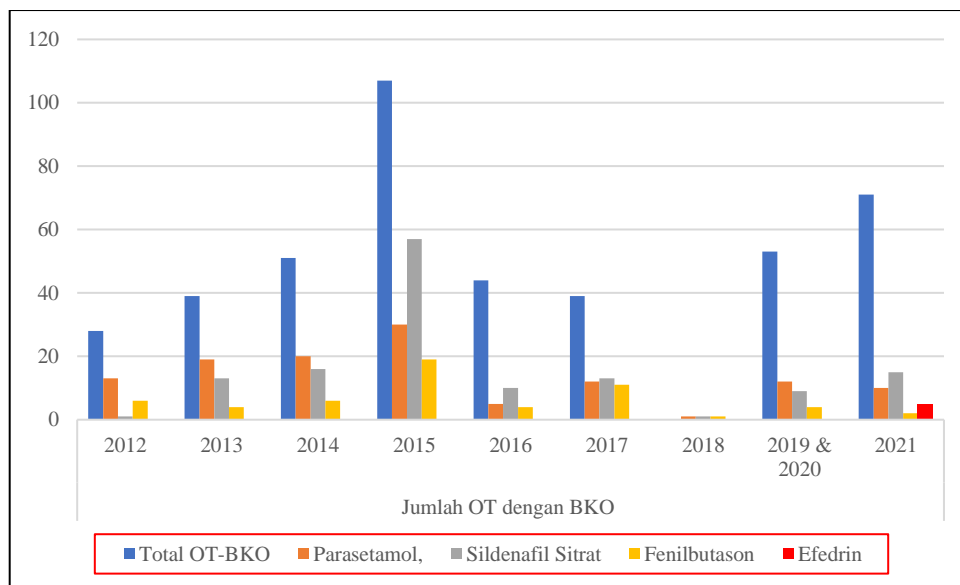


Figure 1. The trend of Undeclared Substance in traditional medicine in 2012-2021

Figure 1 shows the 4 (four) Undeclared Substance added to traditional medicines. The total number of Traditional Medicines Containing Undeclared Substance found annually is approximately 50 Traditional Medicines brands. In 2015, the number almost doubled due to instructions for intensifying

testing of traditional drugs with indications for increasing male stamina, specifically the drug sildenafil and its derivatives. The most visible number of Traditional Medicines was found in 2021. The search for monitoring data from the Indonesian FDA Agency in 2012 showed that there were 29

Traditional Medicines Containing Undeclared Substance, 20 of which were unregistered (illegal) Traditional Medicines products. Undeclared substances identified as contained in the Traditional Medicines were dominated by pain relievers and rheumatic drugs, such as paracetamol and phenylbutazone. Meanwhile, in 2013 there were 59 Traditional Medicines Containing Undeclared Substance, of which 57 were unregistered (illegal) Traditional Medicines products. Undeclared substances identified as mixed in the Traditional Medicines were dominated by pain relievers and rheumatism drugs such as paracetamol and phenylbutazone, as well as stamina enhancing/aphrodisiac drugs such as sildenafil.

Supervision of Traditional Medicines Containing Undeclared Substance by the Indonesian FDA

The trend of adding medicinal chemicals into traditional medicine is influenced by public demand. This was confirmed by informants who explained that new medicinal chemicals were added to traditional medicines at the onset of COVID.

“The Indonesian FDA Agency published a public warning in 2021 for the results of monitoring and testing for July 2020 to September 2021, when it was still a pandemic. The findings are an increase in Traditional Medicines Containing Undeclared Substance findings, especially with claims or indications related to COVID-19 symptoms, for example, to relieve sore throats and colds. After testing, we found that the Traditional Medicines contains ephedrine which may be added from the banned substance lianhua, or ephedrine, which contains ephedrine alcohol. In addition, the number of findings of Undeclared Substance dexamethasone also increased” (Informant 2)

“Undeclared Substance Ephedrine was only discovered in 2020. Since the start of the COVID-19 pandemic, we have found that traditional medicines contain Ephedra in circulation. Ephedra in other countries is allowed as a medicinal ingredient, but in Indonesia, it is prohibited. Ephedra contains ephedrine, which is claimed to reduce or reduce the symptoms caused by COVID-19, such as coughing, sore throat, etc. Regarding the indication of ephedrine, it is possible that drug manufacturers intentionally add this ingredient to their medicines, especially when there are so many cases of the Delta variant of COVID-19, drugs that claim to be efficacious are sought after by the public” (Informant 1)

The regulation clearly states that adding medicinal chemicals to traditional medicines is prohibited. Business actors intentionally adding medicinal

chemicals are subject to administrative and criminal sanctions. Administrative sanctions include, among others, a stern warning, revocation of the distribution permit number, and temporary suspension of production activities. Law no. 36 of 2009 concerning Health for business actors who deliberately distribute traditional medicines containing medicinal chemicals are subject to a maximum sanction of 10 years in prison and a maximum fine of 1 billion rupiahs. However, in practice, the criminal sanctions set by the court are still very light so that they do not cause a deterrent effect.

“The legal sanctions are not sufficient. I also see that the process is also too long and convoluted. At that time, he also participated in Deputy 4 regarding Traditional Medicines Containing Undeclared Substance. On average, the Traditional Medicines Containing Undeclared Substance business actor cannot go through the legal process quickly. New years can be executed. So, during that period, he could also do production, right?” (Informant 3)

To overcome the problem of the distribution of traditional medicines containing medicinal chemicals, the government has taken various steps and policies, including intensification of supervision, cross-sectoral cooperation, and IEC to the public. This is as explained by the informants, namely:

“Traditional Medicines Containing Undeclared Substance is still rampant because people’s demand is still high. The steps we are taking are to make the community smart, in this case, improving KIE here. Hence, the smart community chooses traditional medicines that meet the quality and safety requirements. The steps are already there, thus breaking the Traditional Medicines Containing Undeclared Substance chain, so the community is getting smarter to know the content of medicinal chemicals” (Informant 3)

“In 2021, we have extended the Traditional Medicines Containing Undeclared Substance completion in Banyuwangi as the pilot project. Previously, a Pokjanas (National Working Group) for Traditional Medicines Containing Undeclared Substance Management had been formed. So far, there has been intensive coordination among stakeholders” (Informant 2)

“This year, we are focusing on activities to handle Undeclared Substance, starting from the upstream handling. We cooperate with related

agencies, namely with the local government, because the production of traditional Undeclared Substance medicines is concentrated in several areas, for example, in Banyuwangi, East Java. It started last year to intervene there. The approach of the local government, then to the business actors, then to the professional associations of health workers. Then, we also cooperate with the Indonesian FDA Agency regarding the possibility of the Undeclared Substance leaking in distribution facilities.” (Informant 1)

DISCUSSION

Based on data from the Indonesian FDA Agency, a public warning has been issued to 1,094 traditional medicinal products and health supplements because they contain Undeclared Substance. From an economic perspective, the circulation of products containing Undeclared Substance can be detrimental to legal producers of traditional medicines because of unfair competition and increased public health costs due to side effects. Meanwhile, from a legal perspective, if no action is taken, it has the potential to cause legal uncertainty to affect the circulation of traditional medicines containing Undeclared Substance.(13)

From the data on Undeclared Substance findings for ten years, it is known that paracetamol is the most frequently added contaminant in traditional medicines. Paracetamol is the most commonly prescribed analgesic and antipyretic by health practitioners and is used by the public because it is freely marketed (14). The use of paracetamol at the correct levels provides effective results. However, abnormal paracetamol levels can lead to severe diseases such as liver disorders, nephrotoxicity, and liver necrosis (9). In a particular study of Paracetamol side effects in patients with osteoarthritis, long-term use of paracetamol was associated with impaired liver function, and there was evidence of a trigger for liver failure due to accidental paracetamol overdose (15). Concerning Undeclared Substance, no specific studies show a negative interaction between the addition of paracetamol and the raw materials of traditional herbal medicines. However, the uncontrolled addition of paracetamol can have side effects on public health problems.

Besides Paracetamol, Dexamethasone is also a contaminant in traditional medicine, which is the most frequently found in Traditional Medicines Containing Undeclared Substance testing. (10) Traditional medicines containing Undeclared Substance Dexamethasone are often found in claims for aches and pains. Media reports explain that dexamethasone can be used as a COVID-19 drug.

The reason is that researchers at the University of Oxford, England, say that the drug can reduce the risk of death in Corona patients, but only in cases of patients with severe symptoms and is not helpful for mild and moderate COVID-19 cases or those who are not hospitalized and cannot be cured—used for the prevention of COVID-19. (16) As it is known that dexamethasone is a steroid class that is classified as a hard drug where its purchase must be with a doctor's prescription and its use is under the supervision of a doctor. Dexamethasone, used without medical indications and a doctor's prescription for a long time, can cause side effects, including lowering the immune system, increasing blood pressure, diabetes, moon face, and other dangerous side effects.

In 2015, the number of Traditional Medicines Containing Undeclared Substance findings doubled from the previous and following years. That year, the Indonesian FDA Agency intensified supervision of traditional medicines with claims for male stamina. The Indonesian FDA Agency issued a Public Warning twice, unlike in previous years, which was carried out once. The Indonesian FDA Agency responds to the widespread supply of traditional medicines with indications to increase male vitality. The Indonesian FDA tests and supervises many traditional medicines on the market to prevent public health problems caused by Traditional Medicines Containing Undeclared Substance (11). The Indonesian FDA Agency has followed up on the findings of the Traditional Medicines Containing Undeclared Substance by withdrawing it from circulation for further destruction as well as cancellation of distribution license numbers for products that have been registered. In 2015, the Indonesian FDA Agency destroyed Traditional Medicines worth 75.7 billion rupiahs and Traditional Medicines raw materials worth 63.55 billion rupiahs. (12)

In 2021, during the Coronavirus disease -19 (COVID-19) pandemic, the Indonesian FDA Agency discovered a trend for new Undeclared Substance, namely the types of Ephedrine and Pseudoephedrine. Since no (synthetic) medicine is claimed to cure this disease, traditional medicine has become an alternative for the community, especially in China. As a country that has gone through a difficult period of the COVID-19 pandemic, the State of China has also sent herbal medicines that are claimed to be able to relieve symptoms due to this infection to Indonesia. Several studies have shown the use of Ephedra sinica containing the compound Ephedrine. This plant produces ephedrine compounds, an herbal ingredient widely used to treat COVID-19 in China (20).

The finding of Ephedrine type Undeclared Substance also indicates a new trend in adding Undeclared Substance indications to Traditional Medicines, namely the reliever of flu symptoms. Considering the condition of the COVID-19 pandemic in the past year, this has become quite relevant to the findings of the Undeclared Substance. Traditional medicines that contain these medicinal chemicals are mistakenly associated with the prevention and/or cure of COVID-19 infection. The existence of imported traditional medicines containing the herbal Ephedra sinica, which is recommended to relieve symptoms of COVID-19, may trigger the addition of ephedrine and its derivatives to Traditional Medicines. However, traditional medicines containing ephedrine and pseudoephedrine are at risk of causing health problems, namely dizziness, headache, nausea, nervousness, tremors, loss of appetite, stomach irritation, allergic reactions (rash, itching), difficulty breathing, tightness in the chest, swelling (mouth, lips, and face), or difficulty urinating – if not used correctly or according to clinical trials (22).

Ephedrine and Pseudoephedrine, apart from being synthetic compounds, are also naturally found in plants, which are the active ingredients of the Ephedra sinica or Ma Huang plant, which is commonly found in Traditional Chinese Medicine (TCM). Several studies have demonstrated the use of Ephedra sinica, a plant that produces the compound ephedrine, as a widely used herbal ingredient for treating COVID-19 in China (20). This Ephedra content is also contained in Lianhua Qingwen Capsules (LQC) without a distribution permit from the Indonesian FDA, widely circulated in the community in 2020. (23) Based on studies by experts in Indonesia, the use of Ephedra sinica in traditional medicine is misused in preventing and curing COVID-19. The traditional medicinal product containing Ephedra sinica did not slow down the severity, did not reduce the mortality rate, and did not accelerate the conversion of the swab test to negative. The use of Ephedra can actually endanger health, that is, affect the cardiovascular system, and can even cause death (26).

Ephedra sinica is one of the prohibited ingredients in Traditional Medicines and Health Supplements following the Regulation of the Head of the Indonesian FDA Agency Number HK.00.05.41.1384 of 2005 concerning Criteria and Procedures for Registration of Traditional Medicines, Standardized Herbal Medicines, and Phytopharmaceuticals, as well as Regulation of the Indonesian FDA Agency Number 11 of 2020 concerning Criteria and Procedure for Registration of Health Supplements.

In Indonesia, clinical studies on traditional medicinal ingredients in Indonesia are still limited, including the interactions between traditional medicines and medicinal chemicals. The Indonesian FDA Agency stated that traditional medicines in Indonesia are not allowed to add Undeclared Substance because traditional medicines in Indonesia are circulated freely (they are Traditional Medicine products) so that consumers can use them any time they want. If traditional medicine contains Undeclared Substance, continuous or excessive use will pose a risk that endangers the health of the body. (5).

Judging from the existing regulations, the Indonesian Government strictly prohibits using and distributing traditional medicines with Undeclared Substance. These regulations cover all levels of the policy hierarchy, from laws to technical regulations in the regions. The Indonesian Government has regulated the circulation of traditional medicines in some regulations. The mandate of Law Number 36 of 2009 concerning Health, among others, mentions Article 104 paragraph (1), which states that drugs and traditional medicines must be used rationally. In addition, Article 105 paragraph also mentions traditional medicines that must meet the standards and/or requirements that have been set. At the level of the law, there is also the Consumer Protection Law No. 8 of 1999 in Article 4, which states that the rights of consumers are to get comfort, security, and safety in consuming goods and or services and to have the right to clear, accurate and honest information regarding the conditions and guarantees of goods and services-if services available. At the next level, Permenkes No. 007 of 2012 concerning Registration of traditional medicines in article 7 states that the prohibition of the use of isolated or synthetic chemicals with medicinal, narcotic, or psychotropic properties and protected animals or plants. Meanwhile, at the institutional level, the Indonesian FDA Agency compiles and stipulates several policies related to traditional medicine, namely Perka Badan Indonesian FDA No. HK.00.05.41.1384 concerning criteria and procedures for registering traditional medicines, standardized herbal medicines, and phytopharmaceuticals. The Indonesian FDA Agency also compiles and stipulates Perka Indonesian FDA Agency number 5 of 2016 concerning the withdrawal and destruction of traditional medicines that do not meet the requirements and National Food and Drug Administration Regulation No. 19 of 2021 concerning Guidelines for Follow-up on Results of Supervision of Traditional Medicines, and so on. The Indonesian FDA uses these regulations to function as a traditional medicine supervisor.

Regarding the use of the herbal plant Ephedra sp as raw material for traditional medicines, considering that in some countries it has been used with restrictions and based on clinical trial results, it has been proven to have a therapeutic effect on COVID-19 patients, the Government, in this case, the Indonesian FDA Agency, needs to re-evaluate the ban on the use of Ephedra sp as a raw material for traditional medicine/natural medicine in Indonesia. To encourage innovation and development of traditional medicines to support the treatment of certain diseases and conditions, the Government may issue policies related to using certain herbs as raw materials for traditional medicines for limited purposes.

The findings of Undeclared Substance on traditional medicines circulating in the community also show the public's lack of good promotion and education mechanisms regarding using traditional medicines. Communication and education to the community are very important related to the safe use of herbal medicine. Products registered by the Food and Drug Administration are at least guaranteed to be safe for use and, therefore, should be the first criteria to be considered before consumption. Furthermore, certain products' packaging, labels, and expiration date should be checked before use. In addition, from the side of business actors, it is necessary to carry out more intensive socialization and supervision efforts so that business actors promote their products and do not overclaim and mislead the public. (27)

Asmiati Proverbs, in her research entitled Implementation of Supervision of Traditional Medicines containing Medicinal Chemicals as an effort to protect the community, stated that one of the factors causing the widespread circulation of Traditional Medicines containing Undeclared Substance is that public demand is still high. This is due to the lack of socialization among the public about traditional medicinal products that are prohibited from circulating and the dangers of traditional medicine containing Undeclared Substance. To overcome the problem of circulating Traditional Medicines containing Undeclared Substance, the Indonesian FDA as a drug and food supervisory agency cannot work alone. It is necessary to have an active role from relevant agencies such as the Health Service, Industry, and Trade Office to supervise all products that endanger public health, including traditional medicinal products. containing Undeclared Substance. (28)

Although regulations are available and supervision is always carried out, the findings of Traditional Medicines Containing Undeclared Substance every year become an issue that needs to be evaluated and followed up. During the pandemic, self-medicating practices increased, including interest in traditional

medicine. With the high demand from the public, the traditional medicine industry has a more significant opportunity to meet these needs. Thus, further studies are needed to determine the public's perception of Traditional Medicines containing Undeclared Substance so that it can be a more comprehensive input for handling the circulation of Traditional Medicines containing Undeclared Substance.

In terms of the system that is the scope of the Traditional Medicines Containing Undeclared Substance supervision policy, this study finds that human resources at the central and regional levels are a strategic element in implementing supervision. There are still limited human resources at the provincial level UPT, resulting in efforts to control drugs and food, including efforts to spread communication, information, and education to all regions in the district/city, which cannot be carried out optimally. For example, the UPT Badan Indonesian FDA in Sofifi, North Maluku province, only has 25 human resources. This condition is considered insufficient to carry out the overall supervisory function in 10 districts/cities.

Limitations of the study, although public opinion on traditional medicine is critical, this study does not include public perception of Traditional Medicines Containing Undeclared Substance. However, based on informant interviews, information was obtained that the community's demand for Traditional Medicines Containing Undeclared Substance is still high.

SUMMARY

From the data analysis of Traditional Medicines containing Undeclared Substance in the last ten years, it is known that as many as 73.8% of Traditional Medicines Containing Undeclared Substance found are traditional medicines without distribution permits. Undeclared Substance, which is found every year and widely used by the traditional medicine industry, is an analgesic class, one of which is Paracetamol. During the COVID-19 pandemic, a new Undeclared Substance was found, namely ephedrine. The indications for using ephedrine are relevant or following the treatment of COVID-19 symptoms that generally attack the respiratory tract. Although the policy prohibiting adding medicinal chemicals into traditional medicine has existed at all levels of the policy hierarchy, the circulation of Traditional Medicines Containing Undeclared Substance is still rampant. This is because high public demand and legal sanctions still do not provide a deterrent effect. For this reason, it is necessary to strengthen the supervision of traditional medicines by the government by involving all cross-sectors; besides

that, further research is also needed to determine public perceptions of traditional medicines containing Undeclared Substance.

Research Ethics

This research was conducted after obtaining recommendations and considerations from the FKM UI Research Ethics and Community Service Commission with the number: Ket-32/UN2.F10.D11/PPM.00.02/2020 dated March 2, 2022.

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