SUPERVISION OF INDONESIAN FOOD AND DRUG AUTHORITY IN THE CIRCULATION OF ILLEGAL COSMETICS AFTER POST BORDER POLICY

Irmah Azis[1], Ratnawati, Birkah Latif[1], Sabir Alwy[1]

Article History: **Received:** 24.04.2023 **Revised:** 25.05.2023 **Accepted:** 28.06.2023

Abstract

This study aims to analyze the impact of post-border policies on the effectiveness of cosmetics control by Indonesia FDA, as well as to analyze the steps taken by Indonesia FDA in controlling the circulation of illegal cosmetics. The legal research method used is empirical, namely a legal research method that functions to be able to see the law in a real sense and research how the law works in society. The results of the study show that the post border policy has a significant influence on controlling the circulation of illegal cosmetics in Indonesia, especially in the Makassar City area, while the indicators in this policy cover pre-market and post-market supervision. Furthermore, the existence of legal loopholes at the Customs and FDA level has resulted in a rampant influx of goods and/or cosmetics into Indonesia. The steps taken by FDA in controlling the circulation of illegal cosmetics in Indonesia, especially in the Makassar City area, namely prevention and prosecution. Prevention in this case is carried out in three ways, including accurate supervision, timely supervision, and coordinated supervision organizational workflow. While enforcement is carried out by imposing administrative sanctions and criminal sanctions on perpetrators of illegal cosmetics distribution.

***Keywords**: Indonesian FDA, Post Border Policy, Illegal Cosmetics*

[1]Hasanuddin University, Indonesia

Corresponding Email: irmahazis@gmail.com

1. Introduction

The rule of law requires that the law must always be upheld, respected and obeyed by everyone without exception. This aims to create security, order, prosperity in the life of society and the state. In everyday life, humans in their lives have needs and interests, where to fulfill their needs and interests, humans think, behave and act. So that there is no friction between one human being and another human being in fulfilling their needs and interests, it is expected that the law exists in real life. The presence of law is interpreted as a guideline that provides boundaries for actions in order to achieve and fulfill these interests.

Health is one of the factors that determines the progress of a country and is a human right that must be maintained and protected by the state. The causality of this existence is because the State is obliged to provide health services and establish legal rules related to the interests of protecting the health of its people. The most common problem in health law that is rife is the large number of cosmetics circulating and being traded without having a distribution permit from the Indonesian Food and Drug Authority (Indonesian FDA).

According to Law Number 36 of 2009 concerning Health Article 1 point 4 Explains "Pharmaceutical preparations are drugs, medicinal ingredients, traditional medicines, and cosmetics". Cosmetics are materials or preparations intended for use on the outside of the human body (epidermis, hair, nails, lips and external genital organs) or teeth and oral mucosa especially for cleaning, perfuming, changing appearance and/or improving body

odor or protecting or keep the body in good condition (Latifah & Iswari, 2013).

Based on Article 106 paragraph (1) "Pharmaceutical preparations and medical devices can only be distributed after obtaining a distribution permit". From this understanding it is known that cosmetics are pharmaceutical preparations, meaning that every cosmetic that will be distributed and traded must have a distribution permit, which means that if a cosmetic is distributed without having a distribution permit, the perpetrators of the illegal cosmetics business will be subject to criminal sanctions as stipulated in contained in the Health Act. The cosmetics notification number is valid for a period of 3 (three) years.

On June 15 2017, the government under the leadership of President Joko Widodo issued the XV Economic Policy Package which focuses on business development and increasing the competitiveness of national logistics service providers (Birkah, 2020). One of the gaps in this package is how to facilitate the flow of prohibited and restricted imported goods (LARTAS), especially those that are raw materials for Indonesia's domestic industry. This policy package changes the inspection process for thousands of types of imported LARTAS goods that were previously carried out in the customs area (border) to be carried out "outside the customs area", which the government calls the "post border policy" (Basuki, 2020).

Prior to the existence of the post border policy, inspections of compliance with the provisions of imported LARTAS goods were carried out by officials of the Directorate General of Customs and Excise of the Ministry of Finance in the customs area. The post border policy regulates such inspection outside the customs area (for example in a warehouse owned by an importer) and the supervisors are Ministry/Technical Institution officials according to the type of product affected by the trade.

The Center for Domestic Trade Studies in 2020 reported that during the 2015-2019 period, Imports of Cosmetics had increased, namely increasing by an average of 10.4% per year. If reviewed on an annual basis, cosmetic imports experienced an increase in 2018, which was up 33.2% compared to 2017, from USD 410.5 million to USD 546.8 million. As for 2019, cosmetic imports continued to increase by 3.5% compared to 2018 to USD 566.2 million. This indicates that the import control policy through the post border mechanism has led to an increase in cosmetic imports (Titis, 2020).

The agency that cooperates with the Directorate General of Customs and Excise to carry out supervision for Indonesian FDA. In accordance with Presidential Regulation Number 80 of 2017 concerning the FDA Supervisory Agency, Indonesia FDA has the task of carrying out government duties in the field of drug and food control in accordance with statutory provisions.

Based on FDA Regulation Number 14 of 2020 it is stated that the Importation of Medicines and Food Materials must also obtain approval from the Head of the Agency. This approval is in the form of an Import Certificate. SKI consists of SKI Border and SKI Post Border. SKI Border is a letter of approval for the entry of Medicinal Materials and Traditional Medicinal Materials into the territory of Indonesia in the context of monitoring the distribution of Drug and Food Materials. Whereas SKI Post Border is a letter of approval for the entry of Traditional Medicinal Materials in the Form of Quasi-Medicine Materials, Cosmetics Materials, Health Supplement Materials, and Processed Food Materials into Indonesian territory in the context of monitoring the distribution of Drug and Food Materials. SKI is only valid for 1 (one) time entry.

Indonesian FDA continues to strive to improve the effectiveness of supervision which is the responsibility of FDA in its field to ensure that cosmetics in circulation meet the requirements for safety, benefits, quality and product marking. The challenges continue to increase because the public's demand for cosmetics is increasing, the convenience in the product entry system by business actors causes the circulation of cosmetics to continue to increase.

Apriansyah, viewed from the side of the study, provides a counter-narrative conclusion that this policy has the potential to reduce the effectiveness of drug and food control (Apriansyah et al., 2020). The post border policy at the beginning of 2018 was taken without going through public consultation and

adequate considerations, causing a number of uncertainties. Determination of imported goods that are post-border is carried out in groups and has not differentiated product characteristics as raw materials or consumer goods and has not taken into account domestic supply conditions (whether it is sufficient or not). In addition, Ministries/Agencies have not taken into account the condition of supervisory resource capabilities (Basuki, 2020).

The theory of legal effectiveness according to Soerjono Soekanto is that the effectiveness or failure of a law is determined by 5 (five) factors, namely: (1) Its own legal factors (legislation); (2) Law enforcement factors, namely parties who form or apply the law; (3) Factors of facilities or facilities that support law enforcement; (4) Community factors, namely the environment in which the law applies or is applied; (5) Cultural factors, namely as the result of work, creation and taste based on human charities in the association of life.

Meanwhile, Achmad Ali examines factors that influence compliance with the law, including: the relevance of legal regulations in general, the clarity of legal formulations, optimal socialization of the regulations to all targets of the law, if the law is legislation, the regulations should be prohibitive in nature, the sanctions prescribed by the law must correspond to the nature of the violated law, the severity or leniency of the imposed sanctions should be proportional, the possibility for law enforcement agencies to process violations should be feasible, and the effectiveness or ineffectiveness of a regulation in general depends on the professionalism of law enforcement officials and the socio-economic living standards in society (Ali, 2015).

Based on the background description contained above, the researcher will analyze legal issues, the effectiveness of supervision of cosmetic circulation, which is one of the commodities that has undergone policy changes from border to post border (customs area) by Indonesian FDA, resulting in causal problems with regulations and accountability of each institution involved in the supervision of export-import goods.

2. Methods

This study used empirical legal research. Empirical legal research method is a legal research method that functions to be able to see the law in a real sense and examine how the law works in the community (Irwansyah, 2020). To examine the problems faced by the author using a statutory approach (statute approach) and a conceptual approach. The statutory approach is to examine all regulations related to the legal issues under study and the conceptual approach is to build legal arguments in dealing with the problems that occur. Sources of data used in the form of primary legal materials and secondary legal materials. Primary legal material was obtained from the results of direct interviews and secondary legal material was sourced from the results of literature studies, books, laws and regulations, archives or data and legal journals that support this research. The data obtained from the results of both primary and secondary research will then be collected and analyzed qualitatively descriptively.

3. Results and Discussion

The Effect of Post border Policy on the Implementation of Supervision of Illegal Cosmetic Distribution in Indonesia

Policies within an institution, organization, or especially within a government are important, where a policy is expected to have a positive impact on the lives of citizens. A policy must be implementable by the executing organizational units. Policies need to be evaluated to determine their effectiveness in solving problems (Indar, 2022).

So far, the post border policy and supervision of trading activities have been carried out by the Directorate General of Consumer Protection and Orderly Commerce (Ditjen PKTN), Ministry of Trade. Supervision is carried out by Supervision Officers consisting of Central and Regional Commercial Supervisory Officers (PPTN), Central and Regional Trade Civil Servant Investigators (PPNS-DAG), and employees who have been appointed by the Central and Regional Governments. Supervisory officers carry out supervision of business actors on the basis of supervision which can be in the form of schedules/programs (periodic supervision), public complaints, information from the media, and/or other sources of information regarding issues of trading activities.

Meanwhile, the two parameters used are the legality of business actors and compliance with statutory provisions.

The results of supervision where violations are suspected will be carried out by the process of collecting information material (in the form of data on purchases, sales, distribution, supply, etc.), then the Directorate General of PKTN conducts an analysis to see whether there is a potential violation of law from the results of collecting information that has been carried out. In addition, an analysis of the next steps is also carried out if there is a discrepancy or potential violation, it will be continued into the law enforcement process. For alleged administrative violations of activities in the trade sector, the supervisory officer may provide recommendations for administrative sanctions. Sanctions in the form of withdrawal of goods from the distribution and/or destruction of goods; temporary ban on distribution of goods; termination of trading business activities; and/or revocation of permits in the trading sector. Meanwhile, if evidence of alleged criminal acts in the trade sector is found, the appointed PPTN and/or employees will report to PPNS-DAG or Police Investigators to conduct an investigation (Nurlaila et al., 2020).

This control mechanism applies to all goods circulating within the country, both local goods and those of imported origin. For goods originating from imports whose supervision is through the post border mechanism, there is an additional inspection mechanism for the fulfillment of the import licensing documents. Post border supervision is carried out based on data sharing on the import trade system (data on licensing of goods import activities). Data sharing is carried out through an e-reporting application managed by the Center for Data and Information Systems (PDSI) by processing PIB data from the Indonesia National Single Window (INSW) which is validated with data from INATRADE. Furthermore, from the report (e-reporting), the Directorate General of PKTN conducts an analysis point to determine which importers will be examined by visiting the importer's warehouse or company.

Based on data from the Center for the Study of Domestic Trade in 2020, it was reported that during the 2015-2019 period, Imports of Cosmetics had increased. This indicates that the import control policy through the post border mechanism has led to an increase in cosmetic imports (Titis K. 2020).

Table 1. Development of Cosmetic Imports

No	Unloading Port Province	Import Value: USD million			
		2016	2017	2018	2019
	Cosmetics and Household Health Supplies	400.0	405.4	546.8	566.2
1	Jakarta	204.6	246.3	340.0	380.8
2	West Java	132.76	83.56	85.87	73.10
3	East Java	38.6	36.7	39.9	38.6
4	Riau Islands	23.6	33.2	42.4	37.7
5	Central Java	4.0	6.1	10.2	16.5
	Other	1.7	4.7	28.3	19.5

Source: Center for Foreign Trade Studies, 2020

In the customs area, the inspection of compliance with import requirements is carried out by the Indonesian Directorate General of Customs and Excise (DJBC). One of DGCE's duties and functions is as a Community Protector, which is to provide protection to the public from prohibited or restricted items that may cause disruption to health and safety as well as morality.

Based on the Regulation of the Minister of Trade Number 51 of 2020 concerning Inspection and Supervision of Import Trade after passing through the Customs Area (Post border) Article 5, DGCE has the authority to carry out PIB compliance checks, special inspection of import documents, and/or supervision of import trade system obligations after goods through the Customs Area. PIB

documents namely Packing list, Manifest, Bill of lading, and permits from related agencies.

In carrying out this policy, Customs and Excise also continues to optimize supervision efforts, including by improving the quality of human resources through technical training in intelligence, inspection of goods and documents, and analyzing points; encourage the strengthening of institutions in combating the circulation of psychotropic narcotics, and their precursors, transnational organized crime, and carry out maritime patrols continuously; running a joint program with the Directorate General of Taxes, the Indonesian National Armed Forces, the Republic of Indonesia Police, the Financial Transaction Reports and Analysis Center, the Corruption Eradication Commission, and related Ministries/Institutions, as well as; encourage the use of system automation both for passengers, export/import goods, as well as shipments and postal goods.

There have been changes in the Prohibition and Restriction (Larangan dan Pembatasan - Lartas) from border to post-border. In terms of regulations, changes have occurred in 25 regulations from 7 ministries/institutions, namely:

1. Ministry of Trade
2. Ministry of Health
3. Ministry of Agriculture
4. Ministry of Energy and Mineral Resources
5. Ministry of Communication and Informatics
6. FDA (Indonesia's Food and Drug Authority)
7. Ministry of Industry.

The shift in cosmetics supervision to a post border mechanism creates a gap with the duties and functions of FDA in protecting the public from dangerous drugs and food and DGCE as protecting the public (Apriansyah, et al., 2020).

Indonesian FDA as an institution that has the task of carrying out government tasks in the field of drug and food control has made regulations as a response to changes in the control mechanism. These regulations include; (a) FDA Regulation No. 26 of 2022 concerning Control over the Import of Medicines and Food Materials into Indonesian Territory; (b) FDA Regulation No. 27 of 2022 concerning Control of the Entry of Drugs and Food into Indonesian Territory; (c) FDA Regulation No. 10 of 2021 concerning Standards for Business Activities and Products in the Implementation of Risk-Based Business Licensing in the Drug and Food Sector.

In terms of monitoring the entry of imported cosmetics, the Indonesian FDA has the authority to issue Import Certificates (SKI) for each shipment of cosmetic imports carried out by importers. An Import Certificate is one of the requirements for imported cosmetics to circulate in Indonesia. Since the implementation of the post border policy in 2018, SKI Cosmetics from the FDA is not a requirement for the clearance process for imported cosmetics from the customs area. This can have an impact on increasing the risk of distribution of illegal/containing hazardous/prohibited cosmetics in Indonesia because these cosmetics can leave the customs area and circulate directly in Indonesia without SKI from the Indonesian FDA. With this policy, it becomes a challenge for FDA supervision to be able to be more intensive in conducting post market supervision for imported cosmetics.

Through the post border mechanism, an Import Certificate (SKI) can be submitted after the goods leave the customs area. This makes the FDA need to make optimal efforts to anticipate the entry of cosmetics without a distribution permit and/or containing prohibited/dangerous ingredients. One of the efforts made by the Indonesian FDA to strengthen post-border supervision is the implementation of import realization data flow for the entry of cosmetics and cosmetic ingredients from the Directorate General of Customs and Excise to the FDA through the Indonesia National Single Window (INSW) system. This supervision is carried out by evaluating import realization data based on risk analysis.

Business actors (importers) as principals as well as distributors of Health Supplement Materials, Cosmetics Materials and/or Processed Food Materials post border are required to have SKI Post Border no later than 7 (seven) days from the issuance date of the approval letter for the release of goods issued by the competent authority.

Pre Market Supervision

Pre-market supervision is the supervision / assessment (safety, benefits / efficacy, quality) of products before circulating on the market (certification process). The pre-market surveillance system consists of; (1) standardization which is a function of drafting standards, regulations, and policies related to drug and food supervision. Standardization is carried out centrally, intended to avoid differences in standards that may occur due to each province making its own standards; (2) Assessment (pre-market evaluation) which is an evaluation of the product before obtaining a distribution permit number and finally can be produced and circulated to consumers. The assessment is carried out centrally, intended so that products that have a distribution permit are valid nationally.

Issuance of SKI is one of the Indonesian FDA efforts to carry out supervision before products are circulated (pre-market), so that medicinal ingredients, traditional medicines, cosmetics, health supplements and food imported into Indonesian territory comply with applicable regulations. By shifting the fulfillment of SKI documents after the goods enter Indonesia, this will cut the chain of control for cosmetic safety guarantees when they enter Indonesia.

After the cosmetic product is inspected for compliance with the requirements by DGCE at the customs area until the process of transportation to the importer's storage or warehouse, there is a gap where there is no supervision of the product. Indonesian FDA has not carried out supervision at this point where there is a chance of fraud where products can circulate/enter cosmetic products illegally or without a distribution permit to the Indonesian market before obtaining SKI. Required equipment and sophisticated technology as well as intelligent systems for supervision at this stage.

Post Market Surveillance

Post-market supervision, namely supervision after the product has been distributed to see the consistency of product quality, safety and product information which is carried out by sampling Drug and Food products in circulation, as well as inspection of Drug and Food production and distribution facilities, monitoring of pharmacovigilance and supervision of labels/marking and advertising . Post-market supervision is carried out nationally and is integrated, consistent and standardized. Post-market supervision is carried out nationally and is integrated, consistent and standardized. This supervision involves the Central Office/FDA Center in 33 provinces and areas that are difficult to reach/borders carried out by the Food and Drug Monitoring Post (FDA Post).

In addition, laboratory tests were carried out. Products that have been circulating in the market are sampled based on risk and then tested through a laboratory to find out whether the Medicines and Food meet the safety, efficacy/benefits and quality requirements. The results of this laboratory test are the scientific basis used to determine products that do not meet the requirements to be withdrawn from circulation.

Another form of supervision is law enforcement in the field of drug and food control. Law enforcement is based on evidence from tests, examinations and initial investigations. The process of law enforcement up to projusticia can end with the imposition of administrative sanctions such as being banned from distribution, withdrawn from circulation, revoked distribution permit, confiscated for destruction. If the violation enters the criminal realm, then the violation of Drugs and Food can be processed according to criminal law.

The Indonesian FDA carries out comprehensive supervision to stop the circulation of illegal cosmetics and/or containing hazardous materials, through efforts to cut off the supply chain and cut off the demand chain. Termination of the supply chain is carried out on the source of obtaining illegal cosmetics and/or containing hazardous materials through inspections of distribution facilities and carrying out market cleaning of illegal cosmetics and/or containing hazardous materials through joint operations both nationally and regionally.

Meanwhile, to break the demand chain, the FDA increases the role of the community through Information and Education Communication (IEC) in the form of disseminating information to the public by utilizing various media including online social media which is currently booming/becoming a

trend in society through outreach, workshops, interactive dialogue in the media, talk shows, distribution of brochures/leaflets, podcasts so that it is expected to increase public understanding of safe, useful and quality cosmetics and then the public can protect themselves by not buying/using cosmetics that do not meet the requirements or contain prohibited/dangerous ingredients.

From the results of supervision carried out by the Directorate of Cosmetic Supervision of Indonesian FDA, there were a number of findings for cosmetic products that did not meet the requirements.

Table 2. Findings of Illegal Cosmetics 2016-2021

Year	TIE/BB cosmetic findings	
	Pcs	Economic Value (Rp)
2016	2.949.533	95.305.124.657
2017	2.301.392	72.666.397.296
2018	1.243.271	128.673.308.118
2019	1.268.988	185.850.970.171
2020	311.168	69.208.604.081
2021	48.192	31.000.000.000

Source: Directorate of Cosmetic Supervision FDA RI

Based on the table above, there is an increase in the value of findings in 2018 and 2019 after the post border policy was enforced. Meanwhile, in 2020-2021, it can be seen that the economic value has decreased. The decline in TIE/BB cosmetic findings is possible due to the economic slowdown due to the influence of the Covid-19 pandemic, where there is a shift in people's lifestyle trends that switch to personal care, such as the use of hand sanitizers, restrictions on community activities including offline trade and limited examinations based on risk analysis.

Furthermore, according to a report by the Indonesian Ministry of Industry, after this regulation was enacted, the import value of several products that were posted border (shifted supervision to post border) allegedly experienced a surge, including fertilizer products, cosmetics and Household Health Supplies (PKRT), tires, ceramic tiles, apparel and other ready-made textile products, as well as footwear (Ministry of Industry of the Republic of Indonesia, 2019). This surge in import value is thought to have occurred because importers of post-border lartas took advantage of weaknesses in supervision outside the customs area. This condition, if it continues, can cause uncertainty in the form of disruption to the planned development of domestic industrial products (Basuki, 2020).

Ideally, since the implementation of the post-border policy, one of the monitoring systems that can be conducted by the National Food and Drug Authority (FDA) is through the flow of import realization data provided by the Customs and Excise through the integrated E-FDA system with the NSW system. The E-FDA system categorizes data based on "No Permit Yet" and "Permit Obtained" statuses. In order to monitor the compliance with the Cosmetic Notification Number (SKI) requirement after the 7-day period, FDA can evaluate the data for products that have not obtained a permit yet. Imported cosmetic products that do not have an SKI have not met the requirements of the regulations to be circulated in Indonesia.

However, in its implementation and evaluation of the SKI compliance requirements, FDA still encounters technical challenges in the field when it comes to integration with the NSW system and subsequent reference to the Customs' release of goods through the Customs Declaration (PIB).

Another weakness found in the SKI is that it is still manually conducted to verify whether the importer has obtained or not obtained the SKI. Facility inspections are carried out to check if importers have met the SKI requirements based on risk analysis and the track record of the company.

If cosmetics are found to be imported without the required SKI, FDA will issue a Warning Letter or immediately conduct facility

inspections on the importer. Sanctions against importers who commit violations are applied in accordance with applicable laws and regulations, ranging from Warning Letters to the suspension of imports, either by FDA or through recommendations to relevant cross-sector authorities. However, the ideal process described above is hindered by the reality on the ground, particularly in the post-border context, where goods and/or cosmetics are no longer required to wait for 7 days after obtaining the SKI permit and can be directly released based on customs clearance approval (PIB).

Steps Taken by Indonesian FDA in Supervising the Circulation of Illegal Cosmetics

Since the implementation of the post border policy, one of the monitoring systems that can be carried out by the Indonesian FDA is through the flow of import realization data provided by Customs through the E-FDA system which has been integrated with the NSW system. In the E-FDA system, there is a data categorization based on Permits Not Yet Available and Permits Already Available. In order to be able to supervise the provisions for fulfilling SKI after these 7 days, FDA can conduct an evaluation for SKI data that does not yet have a permit. However, this evaluation is done manually to ensure the truth that the importer has/does not have SKI.

If imports of cosmetics are found indicating that they do not have SKI, FDA will issue a Warning Letter or immediately carry out inspection of the means to the importer. Determination of facility inspection is carried out based on risk analysis and track record of the company. Sanctions for importers who commit violations are applied in accordance with applicable laws and regulations, starting from warning letters to import freezes either from the Indonesian FDA or recommendations to related cross-sectors.

There are steps taken in overseeing the distribution of illegal cosmetics sold in the market, namely:

Prevention (Preventive)

Prevention efforts carried out by FDA continue to be tightened to block the circulation of illegal cosmetics that are harmful to the cosmetic user community. To find out if the cosmetic product used has a distribution permit or not, you can check it by entering the registration number/product name/brand/quantity and packaging/ dosage form/composition/registrant's name on the cosmetics used.

If the cosmetic product used is not registered or does not have a distribution permit, the product data will not be released. The public can also report this to HaloBPOM (FDA Contact) at 1500533 for complaints related to cosmetics and other information. This is intended so that the community is also involved in supervising the circulation of illegal/unlicensed cosmetics. So, post-market surveillance of illegal cosmetics distribution through social media is carried out by having a special team that monitors online shops on social media, and a cosmetic advertisement monitoring system. to supervise advertisements that do not comply with provisions that may mislead consumers and their registrants

To assess the success of supervision carried out by FDA, researchers use indicators of effective supervision as described by T. Hani Handoko, namely accurate, timely, and coordinated with the work flow of the organization which is as a guide and accepted by members of the organization.

1) Accurate

Accurate information in monitoring activities is very important. If the data from the surveillance system is inaccurate, it will lead to errors in taking action which can lead to problems in obtaining data related to the number of illegal cosmetics circulating both on the market and on social media. This is very difficult to do because of the wide circulation that exists on social media.

Based on observations made by researchers during the research, supervision of the number of business actors who enter illegal cosmetics still experiences difficulties in collecting data because it is still done manually.

2) On Time

The information obtained must be immediately collected, submitted and also evaluated if there are improvements to be implemented.

Supervision carried out by FDA must be timely to prevent unwanted deviations from occurring. This is also demanded by the community where the handling of violations is carried out quickly and precisely.

This also applies to supervision carried out through social media, there is a special party from the supervisory sector who has the duty to monitor social media and also advertisements on television, if there is a deviation it will be followed up immediately.

3) Coordinated with Organizational Workflow

Monitoring information must reach all personnel in the organization who need it this is because the work process affects the success and failure of the entire operation. Supervision of cosmetic distribution is handled by the Directorate of Cosmetic Control and the Directorate of Drug and Food Investigation. With a wide coverage area of supervision, it is realized that the number of competent resources owned by FDA is not sufficient, so that cooperation is needed with other agencies.

Tofa Afriansyah explained that the advantage of implementing this post border policy is that it increases opportunities for collaboration with other relevant agencies, especially DJBC in handling cases of illegal product distribution in Indonesia. Accurate and precise exchange of information between FDA and DGCE will strengthen the monitoring system starting from the customs area to outside the customs area.

To increase supervision carried out in accordance with Presidential Instruction Number 3 of 2017 concerning Effectiveness of Drug and Food Control, it is emphasized that supervision is not only the responsibility of FDA but also a shared responsibility. In this case Indonesian FDA and other relevant agencies are working together to take steps according to their respective duties, functions and authorities to increase effectiveness and strengthen drug and food control.

For the South Sulawesi Province area, the Center for Food and Drug Monitoring in Makassar (Center of FDA in Makassar) has taken several supervisory steps to prevent business actors from distributing illegal cosmetics in Makassar City. Among others;

(a) Through cooperation with other relevant agencies (Primary Prevention).

Improving the quality of work is not only carried out within the scope of Center of FDA in Makassar, but the need for collaboration involving other agencies. This is important in order to ensure that the policies developed in an effort to overcome problems related to the effectiveness of supervision and law enforcement on the distribution of cosmetics have the support of all parties. The collaboration with other related agencies includes: (1) Police; (2) Industry and Trade Service; (3) Health Service; (4) DJBC

b) Carry out Supervision

The supervision carried out by Center of FDA in Makassar on the circulation of cosmetics is to carry out routine inspections at cosmetic production and distribution facilities throughout the year. This supervision is a form of guidance to cosmetic business actors so that they continue to distribute products according to applicable regulations and as protection for the community by ensuring the safety of cosmetics used by consumers. Supervision is also carried out to follow up on all the results of the supervision by taking steps to deal with business actors who commit violations.

c) Carry out Observations

This task was carried out by the intelligence team to find out information regarding the criminal act of illegal cosmetics distribution without the supervision of Center FDA in Makassar City and to prevent these illegal cosmetics from circulating widely in society by going directly into the field.

Monitoring the distribution of illegal cosmetics through e-commerce is carried out through cyber patrol activities that function to monitor product distribution, compile profiles of violations/crimes in the cyber realm and conduct digital forensic analysis. Cyber patrols are an early detection step to increase the effectiveness of drug and food control.

d) Community empowerment

In this case Center FDA in Makassar has carried out several community empowerment programs such as information dissemination, socialization, and training in the form of direct counseling, exhibitions and through social media by educating the public to choose

cosmetics that are safe and FDA certified. The Center for Drug and Food Control in Makassar City also directly educates cosmetic business actors and distributes brochures and also conducts socialization through other print or electronic media regarding cosmetics.

Delivering regulations related to cosmetics, as well as educating business actors and the public to become smart consumers, by checking packaging, labels, distribution permits, expiration (check CLICK) before buying products through Communication, Information and Education (KIE) activities. KIE is one of FDA's strategies in drug and food control with the hope that the public can increase knowledge and awareness regarding safe cosmetics and can increase awareness in choosing safe drugs and food so that they are able to protect themselves from drug and food products that are at risk to health.

e) Enforcement of sanctions

In accordance with the Follow-up Pattern for Supervision of Cosmetic Products, FDA Regulation No. 19 of 2021 concerning Guidelines for Follow-up on Monitoring Results of Traditional Medicines, Quasi-Drugs, Health Supplements and Cosmetics, follow-up action for perpetrators of distribution of illegal cosmetics in this case distribution advice will receive Technical Guidance and Administrative Sanctions based on the critical level of the violations committed by taking into account the sociological aspects contained in the case. Administrative Sanctions in the form of a strong warning to facility owners (illegal cosmetics dealers).

Enforcement (Repressive)

Repressive is one of the characteristics of the social control system. Repressive measures usually take the form of pressure, restraint or oppression. While social control itself is a process or control of the possibility of social deviation

For business actors who have provided guidance but still violate the regulations, the Center of FDA in Makassar will follow up in accordance with applicable laws and regulations. Then sanctions can be imposed as stipulated in the Consumer Protection Act in accordance with the provisions if the business actor violates the prohibitions as stipulated in Article 8 paragraph (1) letter a of the Consumer Protection Act:

"Business actors are prohibited from producing and/or trading goods and/or services that do not meet or do not comply with the required standards and provisions of laws and regulations."

So that if there are business actors who violate the provisions above, they will be subject to criminal sanctions as stipulated in Article 62 of the Consumer Protection Act.

“Business actors who violate the provisions referred to in Article 8, Article 9, Article 10, Article 13 paragraph (2), Article 15, Article 17 paragraph (1) letter a, letter b, letter c, letter e paragraph (2) and Article 18 shall be punished with imprisonment for a maximum of 5 (five) years or a maximum fine of Rp. 2,000,000,000.- (two billion rupiah)

Meanwhile, business actors who produce and then distribute cosmetics containing hazardous chemicals which in the end can cause physical damage to the wearer must be held accountable for their actions on the basis of a mistake that has been made intentionally. As regulated in Article 197 jo. 106 Health Law Number 36 of 2009 which reads:

"Anyone who deliberately produces or distributes pharmaceutical preparations and/or medical devices that do not have a distribution permit as referred to in Article 106 paragraph (1) shall be subject to imprisonment for a maximum of 15 (fifteen) years and a fine of up to Rp. 1,500. 000.000,- (one billion five hundred thousand rupiah).”

If we look at the above article, it can be explained that any person who deliberately produces or distributes pharmaceutical preparations and or medical devices including cosmetics that do not have a distribution permit will be subject to imprisonment for a maximum of 15 (fifteen) years or pay a maximum fine of Rp. 1,500,000,000. (one billion five hundred thousand rupiah).

Imposing sanctions is an effort to enforce community protection. In imposing sanctions on business actors, it must be carried out strictly because there are still business actors distributing illegal cosmetics around us. This is done so that business actors get a deterrent effect and will not repeat their actions again.

So that strict supervision and sanctions are needed by Center of FDA in Makassar so that these business actors no longer distribute these illegal cosmetics in South Sulawesi Province.

After the post-border policy, more comprehensive efforts are needed to control the circulation of cosmetics where after the implementation of this policy there has been an increase in the findings of illegal cosmetic products. FDA continues to make efforts to innovate in increasing the effectiveness of supervision.

Cover

The post-border policy has a significant influence and reduces the effectiveness of supervision carried out by FDA on the distribution of cosmetics in Indonesia. The indicators in this policy cover pre-market and post-market supervision. Pre-market, in this case supervision carried out by FDA before products are circulated on the market by going through the stages in accordance with applicable regulations, while post-market is supervision carried out after goods have been circulated on the market that are not in accordance with applicable laws and regulations. Furthermore, there are legal loopholes at the Customs and Indonesian FDA (Indonesia's Food and Drug Authority) levels, which have led to a rampant influx of goods and/or cosmetics into Indonesia.

The steps taken by FDA in controlling the distribution of illegal cosmetics in Indonesia, especially in the Makassar City area, namely prevention and prosecution. Prevention in this case is carried out in three ways, including accurate supervision, timely supervision, and coordinated supervision with organizational work flow. Meanwhile, enforcement is carried out by imposing sanctions on violators who do not comply with applicable regulations, such as administering administrative sanctions and imposing criminal sanctions on perpetrators of illegal cosmetics distribution.

Efforts to increase control over the distribution of cosmetics can be carried out by terminating the supply chain and terminating the demand chain. Besides that, the use of digitalization of the E-FDA application is in the process of evaluating importers and controlling the distribution of cosmetics.

References

Ali, A. (2017). Achmad Menguak Teori Hukum (Legal Theory) dan Teori Peradilan (Judicial Prudence), (Jakarta: Prenamedia Group), h. 294. *Jakarta: Prenamedia Group*, *213*.

Ali. A., Heryani. Wiwie. (2012) Menjelajahi Kajian Empiris Terhadap Hukum. Kencana

Apriansyah, T., Purwadianto, A., & Hanita, M. (2020). Narrative Policy Analysis: Trade Off Pelayanan Dan Pengawasan Di Era Post Border. *Jurnal Perspektif Bea dan Cukai*, *4*(1).

Apriansyah, T., Imam., & Adis, M. (2019). Kebijakan Kontrol Pasca Perbatasan: Perspektif Analisis Pemangku Kepentingan. Jurnal Riset dan Aplikasi Kepabeanan.

Basuki, S. (2020). Kebijakan Post Border dan Ketidakpastian Regulasi Pemeriksaan Barang Impor di Indonesia. *Kajian Ekonomi dan Keuangan*, *4*(1), 86-102

Indar, H. (2022). Kapita Selekta Administrasi dan Kebijakan Kesehatan.

Irwansyah, I. (2020). Penelitian Hukum: Pilihan Metode & Praktik Penulisan Artikel. *Yogyakarta: Mirra Buana Media*, *8*.

Latif. Birkah. (2020). Integrasi Prinsip Ekonomi dan Lingkungan dalam Perdagangan Bebas (Analisis Terhadap Perjanjian Masyarakat Ekonomi ASEAN (MEA)). Disertasi. Fakultas Hukum Universitas Hasanuddin.

Latifah, F., & Iswari, R. (2013). *Buku Pegangan Ilmu Pengetahuan Kosmetik*. Gramedia Pustaka Utama.

Nurlaila. Nur. M., Tarman. (2020). Laporan Analisis Efektivitas Pelaksanaan Kebijakan Pengawasan Post Border. Pusat Pengkajian Perdagangan Luar Negeri Badan Pengkajian dan Pengembangan Perdagangan Kementrian Perdagangan.

Titis K. L, (2020). *Analisis Efektivitas Kebijakan Pengawasan Post Border,*

Pusat Pengkajian Perdagangan Luar Negeri, Kementrian Perdagangan, 2020,