

## POLICY IMPLEMENTATION OF HALAL PRODUCT ASSURANCE FOR PHARMACEUTICAL PRODUCTS IN INDONESIA

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**Abstract.** After the implementation of halal product assurance (HPA) became a public policy, the assurance for halal pharmaceutical products is a must. However, the implementation has been relaxed for several years. This shows that the policy implementation is complicated. This study aimed to analyze and evaluate the implementation process of the HPA policy for pharmaceutical products in Indonesia. We applied Van Meter Van Horn's theory using the qualitative method through in-depth interviews with eight informants and a review ten documents. The result shows that the implementation is going well but is still not optimal, especially from the point of view regarding halal certification for pharmaceutical products. The main obstacle for business actors in this implementation is obtaining halal raw materials because most of them are still imported. Moreover, a lack of massive socialization and education have also appeared. All stakeholders involved should improve performance according to their respective duties to implement better when the obligation has begun.

**Keywords:** Halal Product Assurance, Pharmaceutical Products, Policy Implementation

**Abstrak.** Pasca ditetapkannya penyelenggaraan jaminan produk halal menjadi kebijakan publik, maka termasuk sediaan farmasi diberlakukan jaminan halal. Namun, pemberlakuan kewajiban sertifikasi halal produk farmasi mendapatkan relaksasi beberapa tahun, hal ini menunjukkan implementasi kebijakan yang dinilai tidak konsisten dan rumit. Penelitian ini bertujuan untuk mengetahui dan mengevaluasi proses implementasi kebijakan jaminan produk halal untuk produk sediaan farmasi di Indonesia. Penelitian ini menerapkan Van Meter dan Van Horn dengan metode kualitatif melalui wawancara mendalam kepada 8 informan dan telaah dokumen sebanyak 10 dokumen. Hasil penelitian menunjukkan implementasi berjalan dengan baik namun masih belum optimal terutama dilihat dari capaian sertifikasi halal untuk produk farmasi yang masih terbilang rendah. Hambatan utama bagi pelaku usaha dalam implementasi ini terletak pada persoalan sulitnya mendapatkan bahan baku yang halal karena sebagian besar masih impor dan sosialisasi informasi dan edukasi mengenai kebijakan yang penyebarannya belum optimal. Semua pemangku kepentingan yang terlibat diharapkan dapat memperbaiki dan meningkatkan kinerja sesuai dengan tupoksi masing-masing agar implementasi kebijakan pada masa kewajiban sertifikasi halal telah dimulai menjadi semakin baik.

**Kata Kunci:** Jaminan Produk Halal, Produk Sediaan Farmasi, Implementasi Kebijakan

### INTRODUCTION

To carry out health efforts, resources are needed. One of the resources in the health sector is a pharmaceutical product. It must meet the requirements stipulated in Article 98 paragraph 1 of the Health Law, which must be safe, efficacious/useful, quality, and affordable. However, this requirement is not sufficient considering that Indonesia is a country with a large Muslim population, around 86.6% (1). In Islam, there are mandatory rules for consuming halal goods or products just stated in the Quran (Al-Baqarah verse: 168): "O people! Eat of (food) that is halal and good that is on earth."

Since the issuance of Law Number 33 of 2014

concerning Halal Product Assurance, hereinafter referred to as the HPA, halal requirements have become mandatory and have legal force in Indonesia, including for pharmaceutical products. Unlike other halal campaigners in Southeast Asia, Malaysia, and Singapore, halal certification in these countries is voluntary (2, 3). However, halal regulations in Malaysia were issued in 2011 through the Trade Description Act 2011 (which replaced the Trade Description Act 1972) (4). For Singapore, it has been regulated in the Administration of Muslim Law Act (AMLA) which was first issued in 1968 and has undergone several revisions (5). In addition, although Malaysia does not yet have specific national regulations regarding halal, the Halal Pharmaceuticals General Guidelines were published in 2012 through Malaysian Standard (MS) 2424,

issued by the Department of Standards Malaysia (6).

Initially, this policy drew protests from the pharmaceutical industry (7). This disagreement is because about 90% of pharmaceutical raw materials are still imported (8), which means that the halalness of raw materials depends on the policies of the exporters, and whether they pay attention to the halal aspect or not.

Nowadays, halal-related policies are regulated in the HPA Law and its derivatives law, such as Government Regulation Number 39 of 2021 and Minister of Religion Regulation Number 26 of 2019. From those regulations, it is known that the phasing of the halal certification obligation for pharmaceutical preparation products, such as drugs, traditional medicines, cosmetics, health supplements, and quasi-drugs, begins in 2021 with different deadlines depending on the type (9,10). Therefore, this policy has entered the implementation phase. Policy implementation includes actions taken by public and private individuals (or groups) that affect the achievement of goals in previous policy decisions (11).

This study aims to analyze the implementation of the HPA policy for pharmaceutical products by adapting the Van Meter Van Horn's policy implementation model. The model runs linearly with policies, implementation performance, and other variables, consisting of the size and objectives of the policy, resources, characteristics of the implementing agency, inter-organizational communication, and enforcement activities, conditions (economic, social, and political conditions), and the disposition of the implementer that become the liaison between the two, including those related to the implementor (12). In this study, we exclude the size and purpose variable.

## METHODS

This was a qualitative study with a phenomenological approach through in-depth interviews and document reviews that were analyzed descriptively. Data collection was conducted in May – July 2021 after obtaining the ethical clearance letter (Number: Ket-150/UN2.F10.D11/PPM/00/02/2021) from the Commission on Research Ethics and Public Health Service, Faculty of Public Health, University of Indonesia.

The study involved 8 informants who were selected

by purposive sampling from different agencies related to HPA policy and the pharmaceutical sector. The criteria for selecting informants in this study are as follows:

1. Policy makers or regulators who have the authority, understanding, and knowledge related to halal product assurance policies, especially for pharmaceutical preparation products, including HPA Organizing Agency/BPJP (informant no. 1/I1), The Council of Indonesian Ulama/MUI (informant no. 2/I2), National Agency of Drug and Food Control/BPOM (informant no. 3/I3), Ministry of Industry (informant no. 4/I4).
2. Implementers of the policies mentioned in the laws and regulations related to the halal product guarantee policy, including those who feel the direct impact of the policy; including the Pharmaceutical Industry which has a unit in charge of halal certification and is a large-scale pharmaceutical production and sales company/Industry 1 (informant no. 5/I5), the Pharmaceutical Industry which does not have a unit in charge of halal certification and is a medium-scale pharmaceutical production and sales company/Industry 2 (informant no. 6/I6).
3. The public who pays special attention to the policy of guaranteeing halal products, especially for pharmaceutical preparations, including the Association of Indonesian Cosmetics Companies/Perkosmi (informant no. 7/I7) and Indonesia Halal Watch/IHW (informant no. 8/I8).

Informants stated their willingness to involve in this study through an informed consent form.

## RESULTS AND DISCUSSION

### Resources

Resource variables can be viewed from three aspects. First, the financial resources. It is known that costs are an obstacle for Micro, Small, and Medium-Sized Enterprises (MSMEs) and the medium-scale pharmaceutical industry (I3). Meanwhile, the large-scale pharmaceutical industry (I5) admits that it is not hampered by budget problems for implementing this policy. The government has determined the cost of BPJP services as stipulated in the Minister of Finance Regulation (Figure 1).



Figure 1. BPJPH Service Rates (13)

Fortunately, now the government has implemented free certification for micro and small enterprises (MSEs). However, this study has not captured whether the support provided has been optimally absorbed and on target.

Second, the facilities. It is known that the pharmaceutical industry, on a large scale, has distinguished special facilities used to produce products to be certified (I5). On the other hand, the pharmaceutical industry, which has not yet certified its pharmaceutical products, does not yet have supporting facilities.

Third, human resources. Essentially, the halal certification process is carried out by three main parties, including Halal Audit Agency (LPH) for the products, MUI to give the fatwa of the products, and BPJPH to issue the halal certification of the products. All of them need to have qualified human resources. As executor, the pharmaceutical industry must also have qualified human resources, and it's known that the pharmaceutical industry already has human resources that specifically handle halal matters, which mainly have a pharmaceutical background (I5), while BPJPH is still looking for human resources who have competence in the pharmaceutical sector (I1). Meanwhile, BPJPH admits that although there are still insufficient human resources, the current certification process can still be handled.

### Inter-organizational Communication

This variable highlight two things. First, from the transmission aspect, it is known that the socialization of the obligation of halal certification to business actors in the pharmaceutical sector has not been optimal (I1, I8). The problem is very much felt by business actors from the MSMEs. In socialization regarding halal certificates for MSMEs

organized by the informant's agency, the informants found that none of them came from traditional medicine MSMEs (I3). Second, although the transmission of information was considered not optimal, in terms of clarity, the information submitted by the authorized institution regarding JPH was considered clear by several informants (I4, I5).

The low intensity of information dissemination can be made possible by at least two things, namely: first, the dissemination of information to food and beverage business actors is prioritized because the obligation for halal certification for food and beverage products has started in 2019 rather than the initial limit for halal certification obligations for pharmaceutical products; two, COVID-19 pandemics that took place from the middle of early 2020 were enough to grab the attention of stakeholders from both the government and the industrial sector, so the focus shifted to emergency and production sustainability instead of focusing on the implementation of HPA.

### Characteristics of Implementing Agencies

Based on interview's results, it was classified into three. First, some informant agencies have paid great attention to halal issues marked by the existence of a special section that handles halal, such as Industry 1 and the Ministry of Industry. Second, others have not paid much attention to halal issues for pharmaceutical preparation products, such as Industry 2 and BPOM. Third, non-governmental organizations (NGO) like Perkosmi and IHW are the two institutions that always advocate and participate in socializing HPA policies. While from the document review regarding the organizational structure of each informant agency, the researcher considers that, in general, those agencies are ready

to implement HPA, especially for pharmaceutical products.

### Economic, Social, and Politics Condition

HPA's policies, in general and specifically for pharmaceutical products, are related to economic, social, and political aspects. In the economic aspect, halal certificates are considered to provide added value for business actors so that products are increasingly in demand in markets dominated by Muslim consumers (I3). At consumers' request, business actors try to provide halal-certified products so as not to lose consumers. On the other hand, producers of raw materials are very likely to increase prices because raw materials need to be certified, which will impact the price of the finished products (I7).

In the social aspect, the presence of the HPA policy was motivated by the needs and awareness of the community. The result of the interviews showed that, in general, public awareness of halal assurance began to increase (I5, I8). Other studies also state that the increasing awareness of halal in the community has led to the development of halal certification in Indonesia (I4). However, for pharmaceutical products, specifically drugs, some people still prioritize efficacy and do not place too much importance on their halal status (I4, I6). Even so, the halal status of vaccines has been widely discussed lately, as a study stated that halal certification of vaccines is one of the topics of public discussion on Twitter social media ahead of the emergence of the COVID-19 vaccine (I5).

Third, from the political aspect, HPA's policies are considered good for trade politics (I1, I8). However, the challenge is the possibility of changing political patterns if business actors are close to the authorities. Also, the growth of the halal inspection industry can be rolled into politics (I5).

### The Disposition of Implementers

The attitude or tendency (disposition) of the implementer towards a policy, whether to accept or reject it, will affect the success or failure of the implementation of public policy (I6). We interpret from interviews that, in general, the informants tend to be positive, agree, and accept this policy. This preference for support is possible because the informants position themselves as consumers with individual Muslim backgrounds.

The disposition of implementers, especially from the government sector, towards halal issues has been shown at least from the formation of the National Committee on Sharia Finance/ KNEKS, increasing the number of sharia hospital establishments, and the promotion of halal tourism. From the business side, the positive disposition is motivated by people's preferences in consuming halal products at this time. It was mentioned that the pharmaceutical and cosmetic market share will continue to rise, with an estimated 7.1 percent for pharmaceuticals and 6.9 percent for cosmetics in 2023 (I7).

### Implementation Performance

Policy implementation is considered effective when the policy objectives can be met; people act in accordance with what the policy intent wants, the policy subject uses the method determined by the policy, or even if the policy subject continues to do what is determined (I6). HPA is legal certainty regarding the halal status of a product, as evidenced by a halal certificate. In simple terms, the objective of the HPA policy can be seen from how the certification is achieved. Previous studies stated that the number of halal-certified drugs in 2014 was only 28 items and reached 100 items in early 2018 (I8). Furthermore, in 2019 there was a significant spike, so the total number of pharmaceutical products that have been certified halal reached around 1,504 from 77 pharmaceutical companies (I9). Until 2021, there were 2,806 halal-certified drugs out of 19,935 that have received distribution permits from BPOM (Table 1). This shows the trend of halal certification increasing from year to year.

Table 1. Achievement of Pharmaceutical Product Certification as of July 2021

Product Type Category		Number of registered (BPOM)	Number of certified (LPPOM MUI)	Percentage (%)
BPOM	LPPOM MUI			
Drugs	Drugs and Vaccine	19,935	2,806	14.08
Traditional Medicine	Herbs (Jamu and Traditional Medicine)	13,668	3,657	26.76
	Cosmetics	262,753	33,169	12.62
Health Supplement	Supplements and supplement materials	5,164	1,191	23.06



-	Enzyme	-	731	-
-	Vitamin, mineral, dan other nutrients	-	727	-
-	Group of protein, amino acids, nucleotides, nucleic acid	-	472	-

Source: BPPOM and LPPOM MUI, 2021

However, there is a sharp decline in these matters during 2019-2020, as shown in Figure 2. This was made possible due to the coronavirus disease-2019 (COVID-19) pandemic, which began to spread widely in Indonesia in 2020. This assumption was

supported by Nurani et al: the information obtained from the Head of the BPJPH Halal Registration and Certification Center showed that the application for halal certification from business actors in this pandemic situation there is decreasing (20).

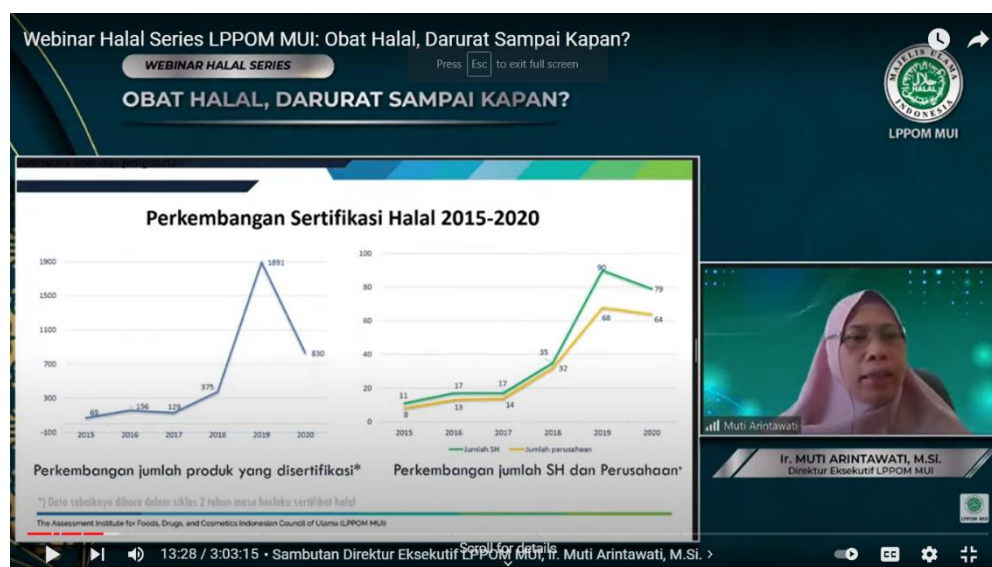


Figure 2. Development of Halal Certification 2015-2020 (21)

Furthermore, to see whether policy subjects use the method determined by the policy can be seen from how the cooperation among policy subjects includes the progress of formulation and determination of other related policies as outputs as the result of cooperation. Based on the interviews, cooperation between implementing agencies has already started. However, some other informants doubted this because the form of the results of the collaboration had not yet been seen or had not been published to the wider community even though the halal certification obligation policy will begin soon so that it can be said that cooperation and joint policy determination have not been optimally implemented.

As for whether this HPA policy makes the subject of the policy continue working as mandated in the HPA regulations, it can be seen from the commitment statements of the stakeholders. From the side of the agencies related to halalness, namely BPJPH, MUI, and IHW, they are committed to continuing to disseminate the information so that the HPA policy is understood by business actors and in general by the wider community. In addition, support from

other government institutions, such as BPOM and the Ministry of Industry, shows a positive direction. Likewise, business actors, whether currently certified or not, have shown their desire to start or continue to implement this HPA policy. In other words, this HPA policy can make the subject continue to do what it intended.

In implementing this policy, the main problem faced is dependence on imported raw materials, which the government has also recognized. This is indicated by the tolerance for the commencement of the obligation for halal certification for pharmaceutical products. The key strategy in overcoming this obstacle is the raw material independence policy, as stated by several informants during interviews. In 2016, only four raw materials were produced: Atorvastatin, Simvastatin, Clopidogrel, and Etanercept (22).

Efforts to be independent of pharmaceutical raw materials have several legal bases. The most recent is Presidential Instruction No. 6 of 2016, concerning the Acceleration of the Development of the Pharmaceutical and Medical Devices Industry. The

Director-General of Pharmacy and Medical Devices in the 2016 UNPAD Pharmaceutical Raw Materials Independence Pentahelix Seminar explained that the government plays a role in formulating supporting public policies (stimulating investment, clear policies, public services), funding development, facilitating business, providing guidance and assistance, technical and non-technical and conduct networks, partnerships, and collaborations with other actors (23). To evaluate the progress of the implementation of Presidential Instruction No. 6/2016, particularly by the government, including the roles mentioned above and collaboration with halal-related parties, further research needs to be done. If there is no progress on the independence of medicinal raw materials, then until 2034, the deadline for completing halal obligations may remain the same.

## CONCLUSION

The implementation of HPA for pharmaceutical products in Indonesia can be said to be good but not optimal. It is said to be good because the HPA policy can encourage a) the public to pay attention to the halalness of pharmaceutical products as what policy intent, b) the stakeholders as a policy subject to use the method determined by the policy and continue to do what is determined. On the other hand, the non-optimality of this policy can be seen in the achievement of halal certification and supervision of the use of non-halal labels that are still low. In addition, the lack of human resources who have competence related to the pharmacy at BPJPH, halal facilities in the pharmaceutical industry, and the widespread information about this policy indicates that the implementation of the policy has not been optimal.

## RECOMMENDATIONS

We recommend that all governmental agencies involved in the HPA policy to: a) maintain and improve performance and cross-sectoral cooperation (regulator, businesses, and scientists), as well as update the halal positive list; and b) align the HPA policy with the independence of medicinal raw materials policy and regulations. Besides, the pharmaceutical industry should strive for a commitment to obtain halal raw materials, have halal production facilities, and carry out halal certification continuously. Then, the NGOs, like Perkosmi and IHW, should continue to help the community and business actors by giving socialization and advocating for halal issues to the government.

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