

**Indonesia**

**Preparatory Survey on BOP Business for  
Halal Pharmaceutical Products  
in Indonesia**

**Final Report**

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**Eisai CO., Ltd.**

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## List of abbreviations

Abbreviation	English
JICA	Japan International Cooperation Agency
BOP	Base of the Economic Pyramid
OTC	Over the Counter
MoH	Ministry of Health
IPMG	International Pharmaceutical Manufacturer Group
HAS	Halal Assurance System

Abbreviation	Indonesian	English translation
BPJS	Badan Penyelenggara Jaminan Sosial	Indonesian Social Security Organization
LPPOM MUI	Lembaga Pengkajian Pangan Obat-Obatan dan Kosmetika Majelis Ulama Indonesia	Assessment Institute for Foods, Drugs and Cosmetics, the Indonesian Council of Ulama
BPJPH	Badan Penyelenggra Jaminan Produk Halal	Halal Product Certification Agency

## Executive Summary

### 1. Outline of the survey and consistency with the development issues

#### 1) Overview of the survey

Item	Survey on pharmaceutical products markets, distribution, regulations, raw materials related to Halal assurance
Objectives	To supply Halal pharmaceutical products <sup>*1</sup> for the BOP class <sup>*2</sup> , surveys are to be implemented regarding Halal assurance for market needs, distribution, regulations and raw materials to be used.
Duration	April 2017-March 2019
Region of activity	Indonesia, Malaysia
Business outline targeting commercialization	Supply of Halal pharmaceutical products for the BOP class in Indonesia
Targeting development effect and beneficiaries	Improvement of access to medicine in the BOP class in Indonesia
Contents of activity	Survey on markets and distribution regarding Halal pharmaceutical products; Survey on Halal regulations; Survey on Halal assurance of raw materials for pharmaceutical products

<sup>\*1</sup>: As stipulated in Article 1, Paragraph 2 of the Pharmaceuticals and Medical Devices Law, “Pharmaceutical products” means substances which are intended for use in the diagnosis, treatment or prevention of disease in humans or animals, excluding medical devices, dental materials, medical supplies and sanitary materials (other than quasi-drugs). In this survey, pharmaceutical products are divided into two categories; OTC drugs (no prescription required) and prescription drugs (prescription required).

<sup>\*2</sup>: The BOP class in this survey means the poor whose monthly household expenditure is less than 1,500,000 IDR (approximately 111 USD). It is difficult to grasp incomes accurately because there are cases such as hiring a maid or a driver directly, and the tax management system is insufficient in Indonesia. Therefore, in this survey, based on the approach that major consulting companies adopt in Indonesia, the economic class was classified by the monthly household expenditure including food, electricity, utility payment, tuition fee, luxury items such as cigarettes, and housekeeper cost. With regard to the expenditure above, irregular expenditures such as the cost of household appliances, traveling or recreation are excluded. As for the exchange rate of the above items, the average exchange rate of Bank Indonesia (Indonesian central bank) in December 2017 was applied (1 USD = 13556.68 IDR).

#### 2) Background of the survey

Although about 90% of the people in Indonesia are Muslims, pharmaceutical products certified as Halal are limited to traditional medicines, vaccines and part of OTC drugs. As Halal pharmaceutical products require the installation of an additional production line separated from existing lines, and a review for the change of raw materials to the ones with Halal Certification, Halal pharmaceutical products are generally expensive and limited in terms of choice. Consequently, the access to the Halal pharmaceutical products for devoted Muslims, especially people in the BOP class has become an issue. At the same time, the needs for Halal pharmaceutical products have been increasing every year. “Law No. 33 of 2014: Government Must Establish Halal Product Guarantee Agency” (hereinafter referred to as the “Halal Product Assurance Law”) was established in 2014, and it is under discussion in the government to obligate sellers to obtain Halal

Certification for their pharmaceutical products by October 2019.

The word “Halal” means “permissible” in the principles of Islamic religion (word origin: Arabic), while “Haram” means “forbidden (sinful).” There is another word “Shubha” meaning “doubtful (unclear whether it is Halal or Haram)”. Sometimes Haram and Shubha are called “non-Halal” overall. Basically, the code of conduct of Muslims is defined to be Halal.

3) Objectives of the survey

Under the circumstances of 2) above, this survey was conducted to construct a business model that contributes to the improvement of access to medicine through the supply of Halal pharmaceutical products that Muslims in the BOP class can also take with ease.

4) Outline of the business model

The outline of the business model is making Halal pharmaceutical products manufactured in Indonesia available to patients in the upper class who are medically well-equipped private hospitals or clinics at normal pharmaceutical prices. It is aimed in particular to improve access to medicine for the patients in the BOP class under the system of medical treatment at the patient’s own expense, while also selling them to public hospitals and clinics that covers most area of Indonesia at official pharmaceutical prices, in other words at lower prices. At the same time, the model also aims to increase the total sales quantity and reduce the cost by exporting and marketing Halal products manufactured in the same manner in Indonesia to Malaysia, a neighboring country with a large Muslim population.

5) Consistency with the development issues

✧ Survey on Halal pharmaceutical product market

As mentioned above, the majority of the population of Indonesia is Muslim, however the purchasing trend, method of access to pharmaceutical products and needs may differ based on income and other reasons. In this survey, prior to the concrete commercialization of Halal pharmaceutical product supply, interviews to the local citizens were carried out regarding the method of access, ability to pay and needs for Halal pharmaceutical products to clarify the issues. The results of the interviews are considered as the basic information for the realization of the Halal pharmaceutical product supplying business.

✧ Survey on issues related to distribution of Halal pharmaceutical products

With regard to the marketing/distribution of pharmaceutical products, various stakeholders such as hospitals, distributors and pharmaceutical manufacturing organizations exist; therefore, the opinions and thoughts of stakeholders regarding Halal pharmaceutical product supply should be considered when starting commercialization. IMS (current company name is IQVIA, changed from Quintiles IMS), a consulting company specializing in the healthcare field, has conducted the interviews to each stakeholder and summarized the issues in each process from the marketing to the distribution of pharmaceutical products.

✧ Survey on Halal regulations

Currently, although the Indonesian government made it mandatory in October 2014 to obtain Halal certification by October 2019, documents such as guidelines that define the standards for Halal pharmaceutical products have not been issued. Unlike foods or other products, regulatory-approved manufacturing methods or raw materials of pharmaceutical products cannot be changed easily; therefore,

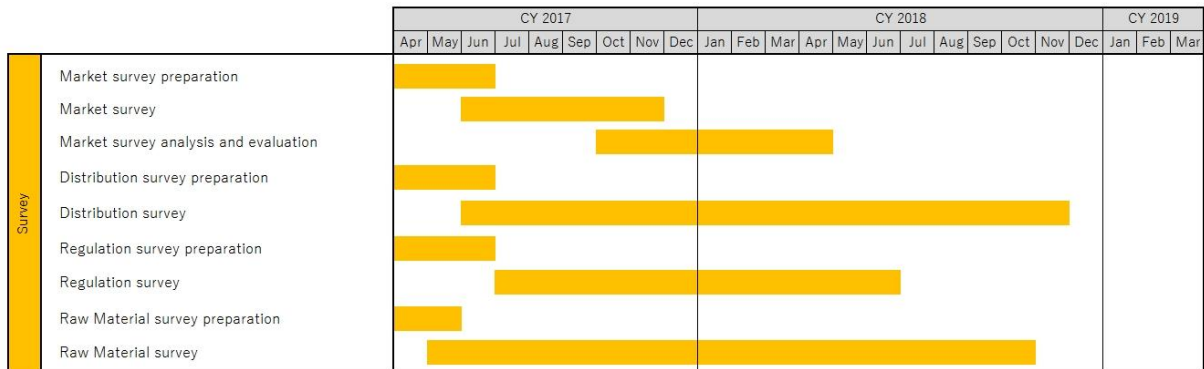
in order to assure they are Halal, it is necessary to establish the criteria for Halal assurance which considers manufacturing processes and raw materials for pharmaceutical products. For that purpose, a re-consignment contract concerning a survey on Halal regulations was concluded with Bogor Agricultural University regarding obtaining Halal certification for pharmaceutical products. At the start of the survey, this university had the only public Halal research institute that provided advice on Halal to the Halal certification body in Indonesia, the Halal Science Center. Based on the results of the survey, processes and issues necessary to obtain Halal certification for pharmaceutical products were summarized.

✧ Survey on Halal assurance of raw materials for pharmaceutical products

Many raw materials are used when pharmaceutical products are manufactured, and these should be verified and demonstrated from a scientific viewpoint whether raw materials have Halal issues. At the same time, considering that Halal is a standard with strong religious aspects, demonstrating Halal assurance should be performed not only from a scientific perspective, but also from a religious one. Therefore, it is very important to confirm Halal assurance with an institute that has a certain level of reliability among authorities that certify Halal products. Therefore, in this survey, we implemented a survey regarding Halal assurance of raw materials generally used as excipients in pharmaceutical products, mainly the specifications of pharmaceutical excipients in Japan, and summarized the processes to confirm Halal assurance of raw materials by cooperating with the Bandung Institute of Technology, a university that supports pharmaceutical authorities scientifically in Indonesia.

## 2. Method of the survey

### 1) Overall survey plan



### 2) Survey period

Included in the chart shown in 1) above.

### 3) Surveyed areas

< Indonesia >

- Jakarta
- Bandung
- Surabaya
- Semarang
- Padang
- Medan
- Makassar



<Target Regions of Survey in Indonesia>

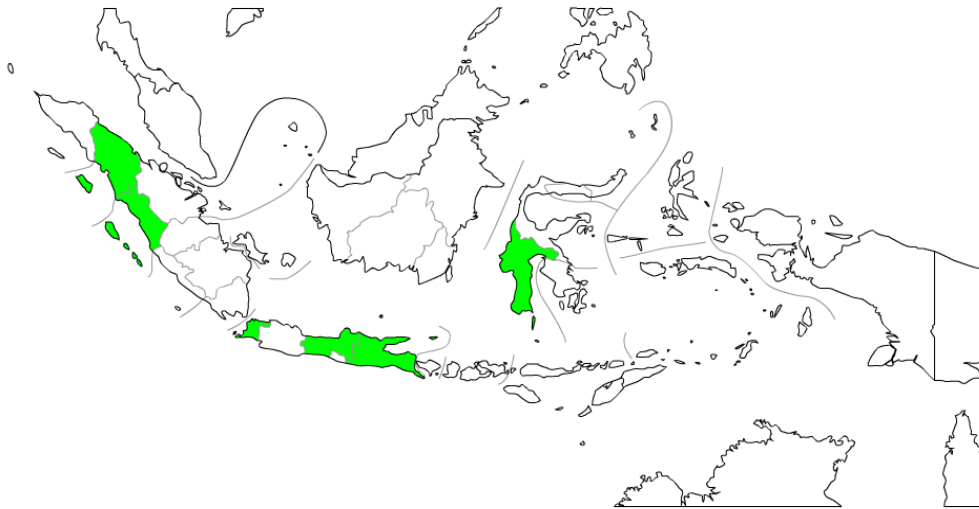
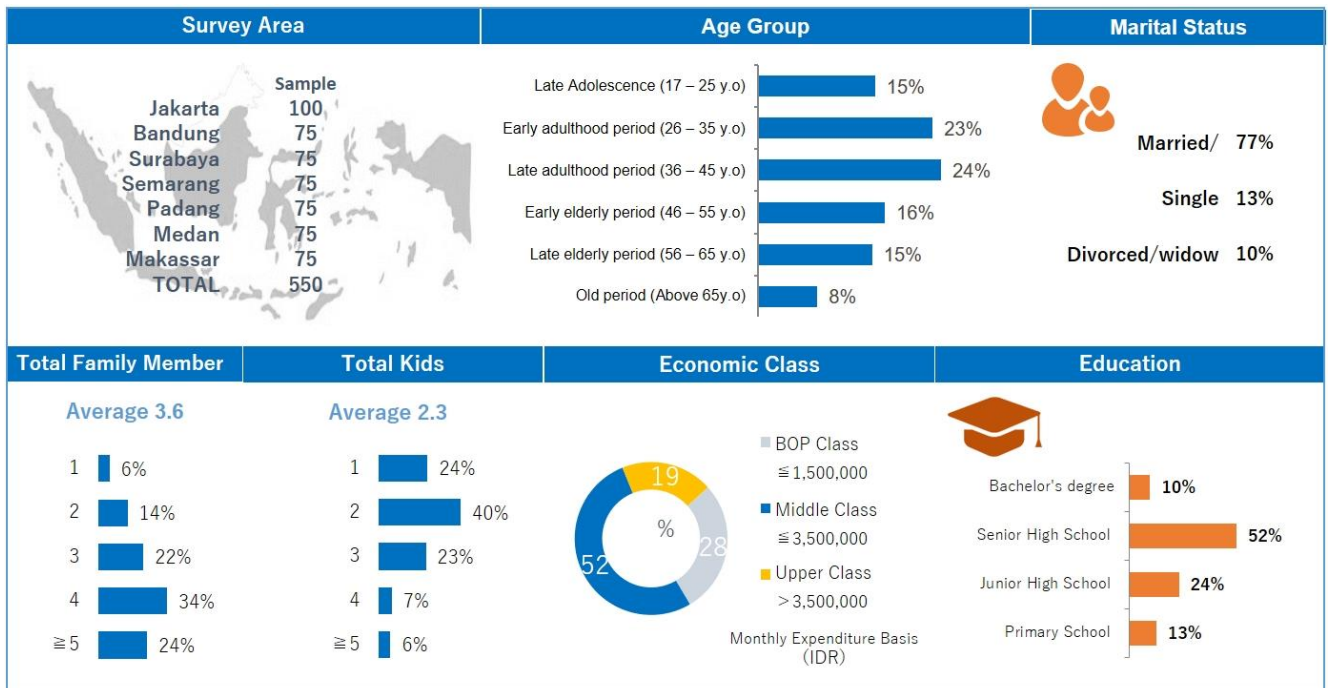


Table 1. Summary of Targets of Market Survey in Indonesia



Base : All Respondents ( N =550)

Table 2. Definition of Economic Class in Market Survey in Indonesia

Economic Class	Monthly Expenditure (IDR)
BOP Class	E : $\leq 1,000,000$
	D : 1,000,001 ~ 1,500,000
Middle Class	C : 1,500,001 ~ 2,500,000
	B : 2,500,001 ~ 3,500,000
Upper Class	A : 3,500,001 ~

Source : IQVIA

The BOP class that is the target of this survey is applicable to the BOP Class shown in Table 2 above.

<Malaysia>

- Klang Valley
- Penang
- Johor
- Sarawak

<Target Regions of Survey in Malaysia>

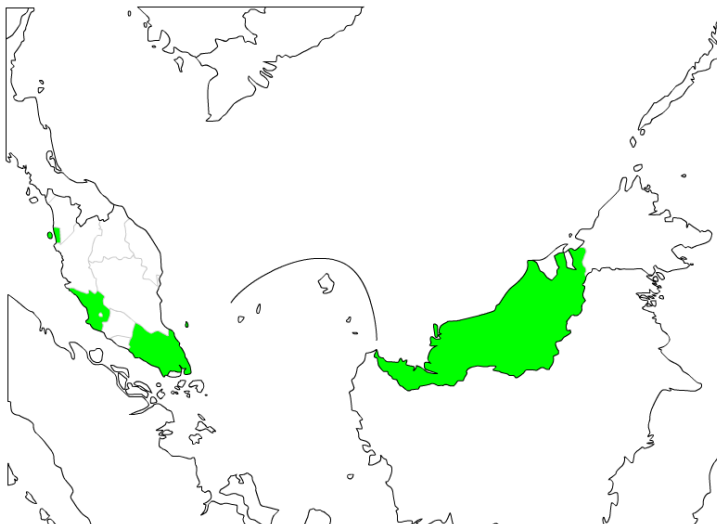
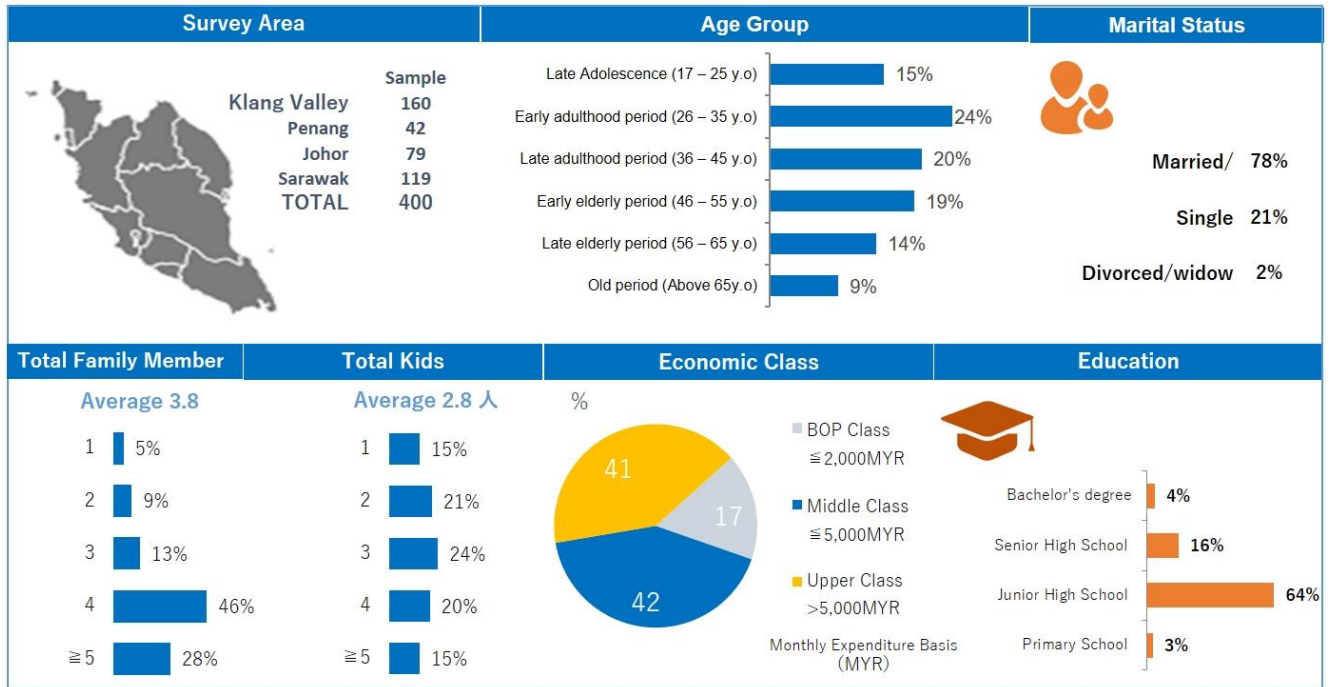


Table 3. Summary of Targets of Market Survey in Malaysia



Base : All Respondents ( N =400)

Table 4. Definition of Economic Class in Market Survey in Malaysia

Economic Class	Monthly Expenditure (MYR)
BOP Class	F : ≦2,000
Middle Class	E : 2,001 ~ 3,000
	D : 3,001 ~ 5,000
Upper Class	C : 5,001 ~ 8,000
	B : 8,001 ~ 10,000
	A : 10,001 ~

Source : IQVIA

#### 4) Survey structure and responsibilities

- Proposing company: Eisai Co., Ltd.  
The company that proposed this survey, and implemented the preparation of the plan/implementation/report of the surveys on markets, the trend of Halal regulations, Halal assurance of raw materials for pharmaceutical products, targeting the supply of Halal pharmaceutical products to the BOP class in Indonesia.
- Partner: PT Eisai Indonesia  
A local subsidiary of Eisai Co., Ltd, who jointly proposed this survey. Some of the employees were members of the survey. The main task was supporting the overall operations of the survey at actual sites based on the instructions of Eisai Co., Ltd.
- Re-consigned contractor: Bogor Agricultural University  
Responsible for collecting information related to Halal regulations in this survey. Mainly the university implemented the survey of the critical items and acceptance criteria to obtain Halal certification of pharmaceutical products.
- External resources: PT IMS Health Indonesia (currently IQVIA)  
Responsible for executing the market survey and collecting information in this survey. In the market survey, the company confirmed the contents of the survey with the proposing company, Eisai Co., Ltd., after summarizing the secondary information, and implemented actual interviews with stakeholders related to the approval/manufacture/distribution of pharmaceutical products, as well as opinion polls of the general public in Indonesia and Malaysia.
- External resources: Bandung Institute of Technology  
Responsible for confirming Halal assurance of raw materials for pharmaceutical products in this survey. The institution implemented verification and confirmation of Halal assurance of raw materials that Eisai Co., Ltd. selected and frequently uses for pharmaceuticals from a scientific viewpoint.

#### 5) Verification

- Verification of market needs for Halal pharmaceutical products
- Verification of issues related to distribution of Halal pharmaceutical products
- Verification of Halal regulations
- Verification of Halal assurance of raw materials

### 3. Results of verification

#### 1) Verification results of acceptance/denial of commercialization

Currently, there are conflicting opinions on Halal pharmaceuticals in Indonesia among the main stakeholders. Specifically, the basic attitude of the Indonesian MoH is to follow the government policy, but the MoH submitted a letter to President stating that since pharmaceutical products are different from food

and beverages, it is difficult to find alternatives; therefore, pharmaceutical products should be excluded from the Halal Product Assurance Law which shows that MoH has an objection regarding Halal. Furthermore, IPMG expressed an objection because to manufacture Halal pharmaceutical products, new investment in facilities and changes of raw materials are required, which increases the pharmaceutical price. Consequently, the cost will increase and that will be a discouraging factor for access to pharmaceutical products. Moreover, the IPMG submitted some requests to the government including the exclusion of pharmaceutical products from the applicable law. With regard to the stakeholders of the largest distributors such as APL, they consider that there are some future issues such as the possibility that inventory control may be more complicated when the quantity of Halal pharmaceutical products increases or the possibility that the separation of control/distribution of Halal products and non-Halal products may be requested. Effectiveness and safety are the priorities of Islamic hospitals, and the priority of Halal is currently not high. On the contrary, the BPJPH and the LPPOM MUI insist strongly to organize Halal pharmaceutical products by October 2019 in accordance with the Halal Product Assurance Law.

When supplying Halal pharmaceutical products broadly to the BOP class, it is necessary to supply pharmaceutical products to hospitals under the public healthcare system, However, currently BPJS which controls this system has not announced a specific policy regarding Halal certification. In order to realize the supply to public hospitals in the current situation, a dramatic reduction of pharmaceutical prices is required. For example, if the price of a pharmaceutical product to a private hospital is 100, it is general that the price of the official insurance system is 30 to 50. In cases where the number of patients is large, it will be about 20, and is necessary to realize a supply price that generates little profit. Therefore, how to reduce the cost to lower the supply price becomes one of the significant factors. However, in general, there is a tendency that the manufacture of Halal pharmaceutical products has high costs, which is a significant dilemma.

From the above, this survey has revealed that, with regard to pharmaceutical product distribution, supplying Halal pharmaceutical products for medical use under the current circumstances will result to more confusion and greater burden on the stakeholders. Also there is a possibility that the supply of Halal pharmaceutical products will discourage the distribution of pharmaceutical products in the market, against the intention of this business.

On the other hand, it was shown based on the survey, that the purchase motivation of consumers for Halal pharmaceutical products is high, and about 75% of consumers are positive about purchasing Halal pharmaceutical products, and 73% of consumers of the BOP class prefer to buy Halal pharmaceutical products. The survey also found that the price rise of up to 10% is acceptable with regard to Halal pharmaceutical products.

With regard to access to pharmaceutical products for medical use, because the main source of information is doctors, it was clear that solving the issues of pharmaceutical distribution mentioned above was significant.

To make pharmaceutical products distributable as Halal, the survey revealed that the possibility of

obtaining Halal certification is high when a relevant manufacturing site is controlled in accordance with the HAS system, provided that the prescription of a pharmaceutical product itself does not contain any suspected Haram substances and there are no packaging/raw materials that are suspected to be Haram in the manufacturing process. However, from the viewpoint of supplying Halal pharmaceutical products continuously in the future, in a situation that the contents and the issuance timing of the new guidelines has been still discussed and not clear, individual pharmaceutical companies cannot make a determination on the range of investment or whether to invest. For that reason, it was also revealed that starting commercialization would be difficult because it is uncertain whether it would be successful.

Based on the above survey results, currently, we did not reach a conclusion to commercialize Halal pharmaceutical product supply business to the BOP class in Indonesia, and considered that it is best to discuss commercialization when the policy of Halal related to pharmaceutical products in Indonesia is clearly disclosed.

The survey results against the verified items shown in 2. 5) above are as follows.

<Verification of the market needs for Halal pharmaceutical products>

Market needs were surveyed through interviews of general consumers that were separated by income classes. As a result of the survey, it was revealed that the number of consumers who prefer to purchase Halal pharmaceutical products was overall large regardless of the income class. The reasons for purchase were not only because of religion, but also because of safety, high quality, or hygiene. In terms of prices, it was found that in cases where the price is in the range of about 5% to 10% higher than normal pharmaceutical products, the number of people who prefer Halal pharmaceutical products is relatively large.

<Verification of issues in distribution of Halal pharmaceutical products>

In the survey, information from the IPMG and the APL, one of the largest pharmaceutical distributors, as well as the Indonesian MoH and Islamic hospitals and doctors, were collected as stakeholders of the distribution of pharmaceutical products for medical use in Indonesia. As a result of the survey, it was revealed that there is a negative intention to make it mandatory to obtain Halal certification of pharmaceutical products for medical use, because currently, there are no specific guidelines regarding how to address the Halal Product Assurance Law. Moreover, it cannot be denied that there is the possibility that making it mandatory to obtain Halal certification of pharmaceutical products for medical use, which are directly connected to the health of the people in the country, might disturb appropriate healthcare. Furthermore, it has been revealed that labeling products as Halal is basically not permitted for distribution of prescription drugs in Malaysia.

<Verification regarding Halal regulations>

In the survey, it was confirmed that doubtful raw materials are not used in original raw materials and manufacturing processes, and it is possible to obtain Halal certification through the current Halal certification process of Indonesia for pharmaceutical products that are considered to have low risk when

obtaining Halal certification. At the same time, with regard to the standards of Halal certification of pharmaceutical products to be issued newly hereafter, discussions are still ongoing in Indonesia, and it could not be clarified within this survey period, but the outline of the system to obtain Halal certification under the new system hereafter was clarified.

<Verification of raw materials related to Halal assurance>

Halal assurance of raw materials was surveyed by selecting raw materials frequently used for pharmaceutical products, mainly the specifications of pharmaceutical excipients to pharmaceutical products in Japan. In the survey, it was clarified what kind of points in terms of the raw materials of the subject materials or the manufacturing process have risks considered to be Haram. Through the survey, it was found that it is necessary to pay careful attention not only to raw materials such as pork, which is considered to be Haram, but also to the type of alcohol used in manufacturing processes or in the culture of microorganisms.

2) Business model aiming for commercialization

The possibility of realizing the business model described in 1. 4) above is to be verified continuously.

3) Remaining issues hereafter and countermeasures

Item	Remaining issue	Countermeasure	Time of action
Macro survey of actual sites	<u>Survey on Halal regulations</u> No specific standards and policies have been finalized by regulatory authorities regarding the acceptance criteria of critical items for the manufacture of pharmaceutical products.	Continuously obtain the information on the trend of application of the Halal Product Assurance Law to pharmaceutical products in Indonesia through the local subsidiary.	Completion time is unknown
Survey on value chain construction	<u>Survey on market needs for Halal pharmaceutical products</u> No remaining issues	Completed	Completed
	<u>Survey on distribution issues of Halal pharmaceutical products</u> The system for pharmaceutical product distribution is not organized in Indonesia because no specific guidelines are issued regarding the enforcement of the Halal Product Assurance Law by the governmental authorities.	Continuously contact with governmental authorities and stakeholders to obtain information on the current state of the construction of a Halal pharmaceutical product supplying system in Indonesia as needed.	Completion time is unknown
	<u>Survey on Halal assurance of raw materials</u> No remaining issues	Completed	Completed