

# INVESTOR UPDATE: WHAT MAKES VACCINES AND MEDICINE BUSINESSES HOT IN INDONESIA?

The COVID-19 pandemic has completely changed people's lifestyle and needs. Post pandemic, people will be taking much better care of their health, adopting active lifestyles, taking more vitamins and health supplements to maintain their health, taking more vaccines and boosters to prevent disease, and feeling a need for medicines and drugs to the point that there will be a sense of urgency in stocking medicines at home for a peace of mind.

When we talk about COVID-19, we directly think about the associated vaccines and relevant medicines. This article will focus on investment opportunities in Indonesia for vaccines and medicines. Two significant examples of the COVID-19 impact are (i) the acceleration of vaccine manufacturing, as conducted by Pfizer and Moderna, and (ii) the rising demand for medicines, drugs, and vitamins. Due to the rising awareness of healthcare in the pandemic era, the post pandemic era will be a time where the healthcare industry will thrive. Both domestic and foreign investors can see this as an amazing opportunity moving forward.

## Investment and Establishment

Generally, there are three possible mechanisms in the establishment of a vaccine and/or drug business in Indonesia:

- Vaccine and/or drug manufacturer;
- Vaccine and/or drug distributor; and
- Vaccine and/or drug retail seller.

In terms of commencing the establishment of the abovementioned business activities, the foregoing three establishment mechanisms have separate classifications in the Indonesian Standard Industrial Classification (*Klasifikasi Baku Lapangan Usaha Indonesia* -"KBLI") according to Government Regulation No. 5 of 2021 regarding the Organization of Risk-Based Business Licensing ("GR 5/2021").<sup>1</sup> The relevant KBLI numbers for the above mentioned business activities as regulated in Presidential Regulation No. 49 of 2021 regarding Amendment of Presidential Regulation No. 10 of 2021 regarding Investment Business Fields ("PR 49/2021")<sup>2</sup> are as described in the table below:<sup>3</sup>

Type of Business Activity	KLBI Number	KLBI Heading	Description	Scale and Risk
Manufacturer	21012	Pharmaceutical Industry Products for Humans	Includes business of manufacturing and processing: a. Medicines b. Health/food supplements	Large Scale and Medium to Low Risk
Distributor	46441	Wholesaling of Pharmaceutical Drugs for Humans	Includes wholesale trading of pharmaceutical drugs for household use	Large Scale and High Risk

<sup>1</sup>Article 4 of GR 5/2021

<sup>2</sup>Annex III of PR 49/2021

<sup>3</sup>Annex I of GR 5/2021

Retail Seller	47721	Retail Trade in Pharmacies of Pharmaceutical Goods and Drugs for Humans	Includes retail trade for pharmaceutical goods and medicines in finished form in pharmacies.	Large Scale and High Risk
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The complete information on the KLBI classifications can be viewed on the OSS website for more information.

Large scale business referred above is defined as a business having capital of over Rp 10 billion according to Government Regulation No. 7 of 2021 regarding Ease, Protection, and Empowerment of Cooperatives and Micro, Small and Medium Enterprises.

It is worth noting that the abovementioned KLBI business activities are open 100% for both domestic and foreign investment according to PR 49/2021.<sup>4</sup> Furthermore, the investment required for foreign investors to participate in establishing a foreign investment company in Indonesia (“**PMA Company**”) pursuant to Capital Investment Coordinating Board Regulation No. 4 of 2021 (“**BKPM Reg 4/2021**”)<sup>5</sup> is as follows (i) the PMA Company must have a minimum of IDR 10,000,000,000.00 (ten billion Rupiah) (around USD 700,000 depending on the exchange rate at the time of investment) issued and paid-up capital and (ii) the PMA Company must have an investment value equal to or higher than IDR 10,000,000,000.00 (ten billion Rupiah) for each KLBI number (line of business), excluding land and building.

## Licenses

### 1. General OSS License

GR 5/2021 introduced a risk-based licensing approach, which establishes four risk levels, from low, medium-low, medium-high, to high, each with its own licensing requirement. In the preparation stage prior to commencing its business, a PMA Company must obtain licenses from OSS starting with the issuance of a Business Identification Number (“**NIB**”) through the Online Single Submission (“**OSS**”) platform. KLBI 21012 is considered a medium to low-risk activity for foreign investment and requires an NIB and Standard Certificate as regulated in Article 13 of GR 5/2021. On the other hand, KLBI 46441 and 47721 are considered high-risk activities for foreign investment and require an NIB, business license issued by the central government, and Standard Certificate as regulated in Article 15 of GR 5/2021. An NIB, under

the current regulatory framework, also serves as an Importer Identification Number, as well as a Customs Access Right.

To sum up, a PMA Company may only be able to begin its operational/commercial activity upon obtaining an NIB, Standard Certificate, and Permit for KLBI 46441 and 47721 while KLBI 21012 only require an NIB and Standard Certificate. A business license will be granted after the PMA Company has met certain requirements and been verified by the relevant government body.

### 2. Specific Licenses

As a requirement to obtain Standard Certificate and business license from OSS, each of KLBI 21012, KLBI 46441 and KLBI 47721 require specific licenses as regulated by the relevant supervisory ministries and/or authorities. In this matter, the foregoing sectors mentioned are as follows:

- i. Manufacturing by the Ministry of Industry;
- ii. Health by the Ministry of Health; and
- iii. Medicine and Food by the Food and Drug Supervisory Body (“**BPOM**”).

Please find below a list of the specific license/requirements for each KLBI number:

#### i. KLBI 21012

Businesses involved in KLBI 21012 must obtain the following licenses/requirements from the Ministry of Industry, Ministry of Health, and BPOM<sup>6</sup>:

Related Ministry	License/Requirement
Ministry of Industry	Having a National Industrial Information System account (“ <b>SIIN</b> ”)
	Statement of Industrial Estate
Ministry of Health	Pharmacy Industry License requiring:
	a. Run by a Limited Liability Company
	b. Pharmacy Manufacturing Production Plan
	c. Pharmacist data
	d. Location Data
BPOM	e. Payment of non-tax revenue
	Pharmacy Manufacturing License
	Certificate of Proper Method of Making Medicines

<sup>4</sup> Annex III of PR 49/2021

<sup>5</sup> Article 12 of BKPM Reg 4/2021

<sup>6</sup> Article 2 and Annex Ministry of Industry Regulation No. 9 of 2021 (“**MOI Reg 9/2021**”), Article 2 and Annex of MoH Reg 14/2021, Article 2 and Annex of BPOM Reg 10/2021

## ii. KLBI 46441

The following licenses/requirements for businesses involved in KLBI 46441 are obtained from the Ministry of Health and BPOM<sup>7</sup>:

Related Ministry	License/Requirement
Ministry of Health	Pharmacy Trader License requiring:
	a. Run by a Limited Liability Company
	b. Pharmacist data
	c. Location Data
BPOM	d. Payment of non-tax revenue
	Having a Certificate of Proper Method of Distributing Medicines webpage account
	Certificate of Proper Method of Making Medicines
	Statement that the Directors have never been involved in crimes related to medicines
	Certificate of Pharmacy Distribution
	Pharmacist Practice License

## iii. KLBI 47721

The following licenses/requirements for KLBI 47721 are obtained from the Ministry of Health<sup>8</sup>:

Related Ministry	License/Requirement
Ministry of Health	Pharmacy Trader License requiring:
	a. Run by a Limited Liability Company
	b. Pharmacist data
	c. Location Data
	d. Payment of non-tax revenue
	Standard Certificate of Pharmacy
	Certificate of Pharmacy Distribution
	Pharmacy License
	License of Pharmacy Practice

## Conclusion and Things to Consider

There are several things to consider before investing in the vaccine and/or drugs business in Indonesia. First, Government Regulation No. 29 of 2021 regarding the Implementation of the Industrial Sector (“GR 29/2021”)<sup>9</sup> states a manufacturer and distributor are not allowed to sell the products to end consumers by retail.<sup>7</sup> This is important to note when considering the KLBI classification, since one company may not undertake both KLBI No. 46441 (Wholesaling of Pharmaceutical Drugs for Humans) and KLBI No. 47721 (Retail Trade in Pharmacies of Pharmaceutical Goods and Drugs for Humans). Second, for KLBI No. 21021, 46441, and 47721, there is (i) a minimum issued and paid up capital requirement for foreign investment in the PMA Company which must exceed Rp10,000,000,000.00 (ten billion Rupiah) (around USD 700,000 depending on the exchange rate at the time of investment) excluding land and building and (ii) an investment value equal to or higher than IDR 10,000,000,000.00 (ten billion Rupiah) for each KLBI number (line of business) .

In conclusion, the OSS and KLBI system established by Law No. 11 of 2020 regarding Job Creation and further regulated by GR 5/2021 have made vaccine and/or drugs business activity more feasible especially for foreign investment. As the world approaches the post pandemic era, the momentum of the rising awareness of health in society presents new opportunities.

<sup>8</sup>Article 2 and Annex of MoH Reg 14/2021

<sup>9</sup> Article 55 of GR 29/2021

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The article above was prepared by [Nashatra Prita](#) (Partner) and [Christopher Arvanno James Mogot](#) (Associate).

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