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FOSTERING FOREIGN DIRECT INVESTMENT IN THE PHARMACEUTICAL SECTOR

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Main Points:

- *Despite being designated as a priority sector (Presidential Instruction No.6/2016) and being excluded from the foreign ownership restriction list (Presidential Regulation No. 44/2016), the Indonesian pharmaceutical industry experiencing lower (FDI) growth than before 2009.*
- *The urgency to increase domestic production of active pharmaceutical ingredients (API) in order to reduce dependency on imports (over 90%) of raw medicine materials.*
- *Important reforms, particularly by reviewing mandatory local production as a precondition to market access (Health Minister Regulation 1010/2008) could attract more FDI and increase patient access to medicine.*
- *Recommend fostering the enabling-environment through non-discriminatory incentives and policies to strengthen Presidential Regulation No.44/2016 and promote Indonesia's competitiveness in ASEAN.*

PHARMACEUTICAL INDUSTRY IN INDONESIA

The pharmaceutical industry is one of the five priority industries in the 2015-2035 National Industrial Development Master Plan, as stated in the Government Regulation 14/2015. As the fourth largest non-oil and gas contributor to the economy and with its strong potentials as the engine of growth, the pharmaceutical sector has a significant role in the country's industrial landscape.

However, as shown in Figure 1, the growth of pharmaceutical and chemical industries has been declining since 2012. From 2003 to 2018, the average growth of the pharmaceutical and chemical sectors was lower than Gross Domestic Product (GDP) and non-oil and gas manufacturing industry growth. Last year the sector's growth dropped to an unprecedentedly low level of 1.42%. The sluggish growth is a paradox given Indonesia is the home to 40 % population of Southeast Asian with a market value estimated at Rp90 trillion (US$6.4 billion) (Global Data, 2018).

This market figure will continue to rise as the middle-class population grows, along with the high rate of urbanization. Furthermore, a state health insurance program called BPJS Kesehatan, as part of the National Health Insurance (JKN) which was launched in January 2014, has covered 217,549,455 beneficiaries or 89.6% of the total population as of December 2019.

Figure 2 shows the average growth of foreign direct investment (FDI) during the five years before and after the issuance of Permenkes 1010. In the 2003-2008 period, the average FDI growth was reached 212% while in 2009-2013 was only 57.1%. On the other hand, however, it can also be seen that the growth of domestic direct investment (DDI) rose from 51% in the 2003-2008 period

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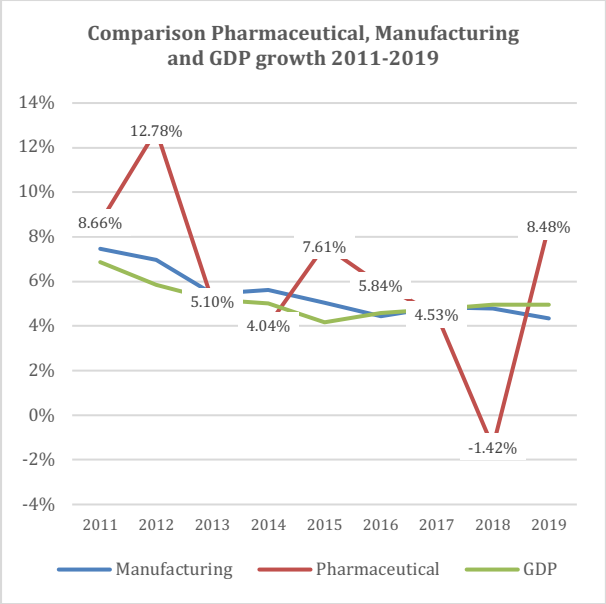
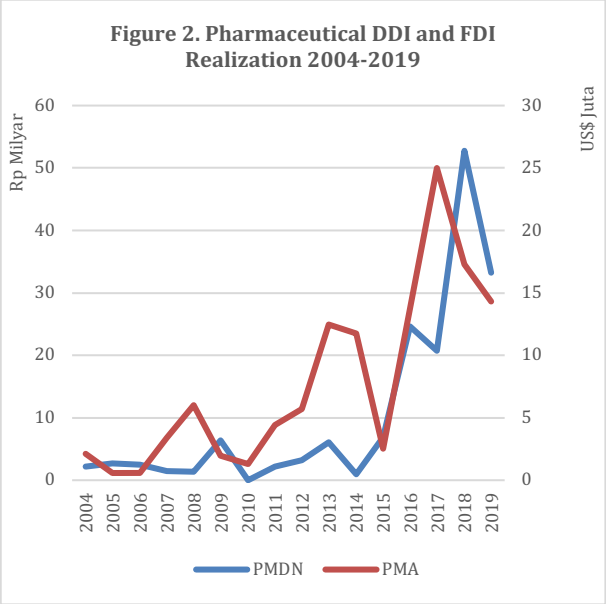
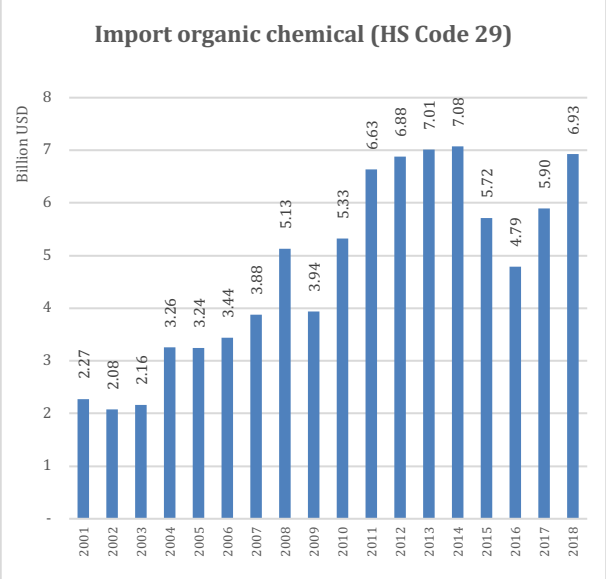
to 82.4% in the 2009-2013 period. The decline in realized foreign investment is a major concern, given that foreign investors contribute to the bulk of the capital invested in this sector.







At least 90% of pharmaceutical raw materials or Active Pharmaceutical Ingredients (API) are imported hence increase trade deficit and weaken rupiah. Presidential Instruction (Inpres) 6/2016 targeted a reduction in API imports and the development of the domestic pharmaceutical industry but not much has changed since the regulation was issued (Figure 3).

However, 92% of the medications covered by BPJS are generic drugs. While cost efficiency is important, the high rate of generic medicine use has raised some concerns about treatment effectiveness. In Malaysia, the proportion of generic drugs is only 53.6% in 2017 (Chow, 2018).

In 2016, at least 85.2% of patients with chronic diseases had to make out-of-pocket payment for innovative drugs that are not listed in the National Formulary (Fornas) and not covered by the National Health Insurance/JKN (Thabrany, 2016). Data from the National Agency of Drug and Food Control (BPOM) showed that the compendium of approved drugs is dominated by generic drugs at a ratio of 7:1 relative to innovative drugs.

In this context, increased adoption and use of a new drug with strict adherence to the principles of innovation and cost-effectiveness would strengthen the national health system while giving the necessary impetus to foster innovation.

Due to the complex interaction of diseases and unique conditions of the patients, the future medical treatment trends will lean towards *tailor-made* treatment rather than a *one-fits-all* approach. This is achieved by incorporating the genetic and genomic makeup of an individual and his or her family medical history, environment, health-related behaviors, culture, and values into a complete health picture that can be used to customize care (Teng, et al., 2012). Generic medicine would no longer be enough.

The goal of drug policy and regulations should be to promote drug access, maintain quality and affordability with strengthening the domestic pharmaceutical industry as optional when possible. Those top three goals should not be sacrificed for the sake of stimulating the domestic pharmaceutical industry.

DECREE 1010/2008: TEN YEARS DOWN THE ROAD

In 2008, the government issued the Minister of Health Regulation No. 1010/MENKES/PER/XI/2008 (Decree 1010) on Drug Registration is an effort to ensure the medicines meet the safety, quality, and efficacy standard. This policy also serves as a response to some distributors that had not properly maintained supply chain integrity.

Decree 1010 only allows pharmaceutical companies with domestic production operations to register new drugs. The decree allows a transition period of five years when a drug may still be imported before required to be produced in local manufacturing facilities (with certain terms and conditions for special cases such as products under patent protection). The stated goal of regulation was to protect patients from counterfeit and substandard medicines with strengthening the domestic pharmaceutical industry frequently implied.

In consequence, research-based pharmaceutical firms that do not produce domestically—classified as “Pharmaceutical Wholesalers” (PBF)--are required to produce its medicines in Indonesia within two years of the issuance of Decree 1010 as the requirement to register their products. Otherwise, their only option is contracting out the registration of said drugs to another company in order to obtain a distribution permit from BPOM.

However, ten years after the policy was put into effect, 90% of raw medicine materials still reliant on imports, which leads to costly and uncompetitive local generics production. The drug companies that supplying JKN has complained of the increasingly strong price pressures that make it difficult for them to maintain drug quality and erode their profitability. The technology transfer, the investment in research and development as well as in human capital that was expected had not taken place (or at least not at the expected scale). On the other hand, the production of numerous medications could not gain economies of scale even for the Indonesian market, particularly medicines for orphan diseases with a relatively low number of patients.

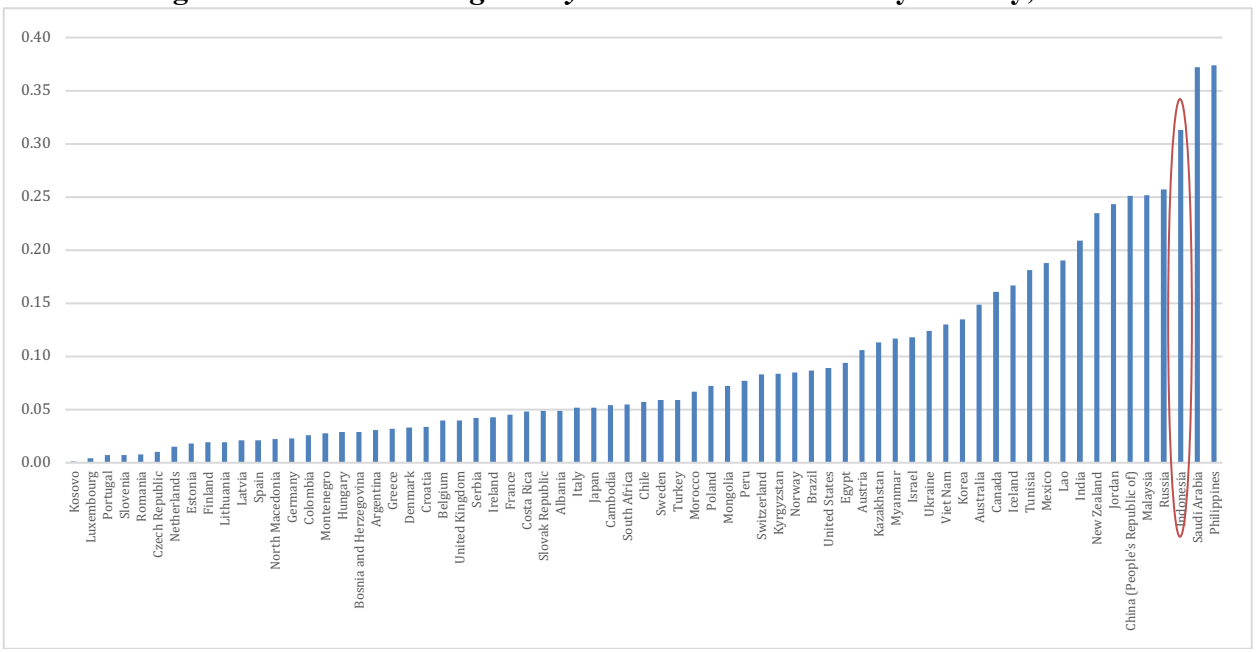
From the patients' perspectives, the restrictions imposed by this legislation have resulted in significant delays in access to or unavailability of lifesaving and life-enhancing drugs. An increasing number of patients have chosen instead to seek medical care and treatment in neighboring ASEAN countries. This led to economic losses of nearly US$ 1.4 billion just from the flight expenses of 600,000 patients in 2017 (Indonesian Ministry of Tourism, 2017) while Wyman (2018) found that Indonesia lost around US$4 billion annually from outbound medical tourism.

FOREIGN INVESTMENT DRIVES INNOVATIVE MEDICINES

An innovative pharmaceutical industry improves the quality of life and health of populations. A study by Lichtenberg (2017) discovered that innovations by the pharmaceutical sector have been instrumental in increasing the life expectancy and health level of the United States (US) citizens. In addition, Lichtenberg had studied Australia and found that owing to pharmaceutical innovations the mortality rate for people under the age of 75 had dropped by 60% between 1998-2011.

Other studies conducted by Lichtenberg (2019) suggested that innovative drugs had slashed the rate of premature death in nine the Middle East and African countries between 2007 and 2015 to 32%. Lichtenberg's 2018 study in 36 countries suggested that without the introduction of new drugs in the period between 1982 and 2010, the untreated conditions that would otherwise have been eradicated by these medications would have racked up additional 26.3 million disability-adjusted life years by 2015.

Figure 6. ***OECD FDI Regulatory Restrictiveness Index*** **by country, 2018**



Source: ***OECD FDI Regulatory Restrictiveness Index database*** **(2018)**
Notes: Value is varied from 0 (open) to 1 (closed)

FDI is believed to play a key role as an engine of growth and economic development in developing countries. The pharmaceutical sector is no exception. According to Suyanto, Salim, and Bloch (2009), a considerable amount of foreign investment in the subsector of the pharmaceutical industry will create positive spillovers. Foreign investment will increase domestic competition and

drive domestic firms to use their resources more efficiently and therefore boost productivity. In the long run, this technology-intensive subsector stands to gain further benefit from the technology transfer that the investment would have stimulated.

FDI in the pharmaceutical industry could increase public access to the latest, potent and high-quality pharmaceutical products. FDI in the pharmaceutical industry is critical not only to promote economic growth but also to maintain quality of life. However, FDI Regulatory Restrictiveness Index 2018 by the Organization for Economic Cooperation and Development (OECD) put Indonesia as the third most restrictive country among the G20 nations (Figure 6).

FDI in the pharmaceutical sector also faces several restrictions. Decree 1010, despite its initial purpose of regulating drug registration, has morphed into an additional barrier for foreign companies to enter the Indonesian market. An obligation that is not required in Malaysia, Thailand, Singapore, and Vietnam.

The other rationale behind the forced localization mandated by Decree 1010/2008 was patient protection. However, the regulation also has a negative impact on patient access to innovative medicines since it is not allowed producer with production facilities outside Indonesia to obtain the permit to sell their products to Indonesia customers.

POLICY RECOMMENDATIONS

The proposed policy recommendations are:

1. Ministry of Health to issue a regulation that establishes a new category for pharmaceutical companies with production facilities overseas that are currently operating under PBF licenses, to be able to register the drugs in the Indonesian market as long as meeting the standards of National Agency for Drug and Food Control (BPOM).
2. Establish a comprehensive policy of investment incentives (not only tax holiday) with the easy and fast application process to stimulate manufacturing and research (clinical trials) for the pharmaceutical industry in Indonesia to match regional best practices.
3. BPOM to strengthen its monitoring program ensures the quality and effectiveness of medicine sold in Indonesia in close collaboration with law enforcement agencies.

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