Primum Non Nocere: A Policy Approach for Pharmaceutical Investment in Indonesia

ASIA’S PATH FORWARD

By Andree Surianta | 1 September 2020
COVID-19 has thrown international trade and investment into disarray; however, it is first and foremost a global health crisis. With Global Value Chains (GVCs) receiving heightened scrutiny, no other industry has been so prominently featured in the discussions of anxious governments as the pharmaceutical industry. Many are looking to internalize the pharmaceutical supply chain to ensure access to a critical arsenal in fighting a pandemic. However, it should be noted that this is an industry with a particularly volatile mix: an immense drive for cost efficiency coupled with enormous health and environmental liabilities.

Like other GVCs, the globalization of pharmaceutical manufacturing is driven by the pursuit of cost effectiveness. A long research and development process usually leaves less than 10 years of patent protection to recoup the USD $1.5 – 2.6 billion spent to discover a single medicine.¹ Thus, the drive to lower manufacturing cost is particularly acute in this industry. This has led to an offshoring and outsourcing trend by US and EU firms to contract manufacturers (CDMOs) in China and India for the last 20 years, attracted by economies of scale, availability of low-cost skilled labour, and relatively lenient environmental regulations.² Keeping in mind these specific characteristics, careful consideration should be taken by any governments attempting to rapidly expand pharmaceutical manufacturing capacity.

BREAKING UP THE PHARMA CHAIN

According to the US Food and Drug Administration (FDA)’s database, China and India host 31% of the world’s manufacturing sites for pharmaceutical core ingredients (API).³ Their production volume is quite formidable, supplying as much as 80 - 95% of medicinal ingredients in the US, EU, and Indonesia.⁴


On top of that, both still have spare API manufacturing capacity, with China running at 70% and India at 30-40%. Interestingly, India, which supplies 40% of the world’s generics (off-patent medicines), depends on China for its API needs. Such dominance by a single country in the upstream links of the pharmaceutical supply chain has become a shared concern of both developed and developing countries alike in facing this global health crisis.

It should be noted, however, that the calls to reduce dependence on China for pharmaceutical raw ingredients began much earlier. Quality issues in 2008 and 2018 sparked a debate on the trade-off between low cost and safety. In 2017, Chinese authorities shuttered hundreds of API plants due to pollution issues. These repeated disruptions culminated in warnings for reshoring issued by the FDA and the European Fine Chemicals Group (EFCG) in late 2019, right before the pandemic struck. In light of the outbreak, the US government is pouring in financial support to boost the domestic pharmaceutical industry, as well as establishing a network of partner countries for its corporations to move to as an alternative.

The result of the latter is the Economic Prosperity Network, an initiative to unite like-minded countries, companies, and civil societies operating under the same set of values in critical industries. These “values” are yet to be clarified, however GVC restructuring talks are underway between the US with Australia, India, Japan, New Zealand, South Korea, and Vietnam. Since the crisis that birthed this initiative is one of public health, it is reasonable to expect that the pharmaceutical industry will be one of these “critical industries”.

---


6 Mulin, “Drug Chemical Makers Brace”; Lorin, “Europe’s Suicidal Reliance on”.


With the US stepping up efforts to uproot GVCs from China, Indonesia is keen to benefit from any potential relocation of US pharmaceutical firms to boost its own manufacturing capacity and increase drug availability. This excitement could be seen in recent local media news flows following a phone call between President Jokowi and President Trump, which allegedly included a discussion on US pharmaceutical firms in China relocating to Indonesia.\textsuperscript{12} In fact, the phone call became a subject of inquiry during the same briefing in which the Economic Prosperity Network was announced.\textsuperscript{13}

The Indonesian pharmaceutical industry’s enthusiasm for foreign direct investment (FDI) is understandable as it signifies a fortuitous wedding of longstanding developmental dreams with the contemporary health crisis. A pandemic naturally brings healthcare into focus. Improving this sector aligns very well with the President’s second-and-final term promise of improving human resources quality.\textsuperscript{14} If such improvement can be supported by foreign capital, then all the better. However, Indonesia will need to carefully rethink its regulatory approach to both attract pharmaceutical FDI and safeguard against its liabilities at the same time.

**INDONESIAN PHARMA PRE-COVID-19: DOMESTIC AND DISCONNECTED**

Indonesia is generally known for its overbearing regulatory system that makes starting a business difficult, enforcing contracts tough, and trading across border arduous.\textsuperscript{15} These challenges are magnified in the pharmaceutical industry as it is one of the most regulated industries in Indonesia.\textsuperscript{16} Foreign ownership threshold of 75\% was specified for the first time in 2007. This was followed soon after by Ministry of Health (MOH) Regulation No. 1010/2008, which stipulates that all medications registered for sale in Indonesia must be produced locally. These factors have contributed to the


\textsuperscript{13} “Special Briefing with Keith Krach, Under Secretary of State for Economic Growth, Energy, and the Environment; Cordell Hull, Acting Under Secretary of Commerce for Industry and Security; Dr. Christopher Ford, Assistant Secretary of State for International.” May 20, 2020.


\textsuperscript{16} “Pharmaceutical and Medical Technology - EuroCham Position Paper 2018” EuroCham, 2018 http://www.eurocham.id/publications
creation of an industry dominated by local manufacturers which are focused almost exclusively on the domestic market.\(^{17}\)

Figure 1 shows that new FDI in the Indonesian pharmaceutical industry dropped right after the introduction of the 2008 regulation. Interestingly, the ruling seems to spur domestic direct investment only briefly, as it also declines beyond 2009.\(^{19}\) However, following the implementation of the National Health Insurance (JKN) scheme, one of the largest government-run single-payer healthcare programs in the world, investment spiked.\(^{20}\) In a relatively isolated market like Indonesia, the sudden influx of 133 million customers is an especially strong investment catalyst.

![Figure 1: FDI Realization in Pharmaceutical Industry in Indonesia (USD million)](image.png)


\(^{18}\) BKPM via CEIC database

\(^{19}\) Data for 2010 domestic direct investment is unavailable

Subsequent policy developments show increasing tension between welcoming FDI and building local capacity. FDI restrictions were partially relaxed in May 2016 by allowing 100% foreign ownership in pharmaceutical raw materials manufacturing. However, soon after that the President tasked 12 ministries and agencies to develop the industry by “going local,” i.e. prioritizing domestic products in public procurement, issuing local content policies, encouraging foreign-domestic joint ventures, and implementing local certification. This has led to multiple regulations trying to further enforce localization at the opposite ends of the sector.

One of these is Law No. 13/2016 on Patent. It requires patented products to be produced in Indonesia, else the patent can be revoked. A flanking policy at the other end is the public procurement system. With JKN now the largest buyer of medicines, the government is using price setting and procurement priority lists as policy levers to direct development in the industry. Once again, these developments seem to deter foreign investors, as Figure 1 shows another decline in pharmaceutical FDI in recent years despite possible relocations due to pollution-crackdowns in China.

When talking about FDI, Indonesian officials usually refer to the allure of a large domestic market, apparently believing that it will be enough to outweigh any restrictions imposed on foreign investors. The brief history above shows that, indeed, market opportunities encourage investment. However, history also demonstrates that the various localization requirements were followed by multiple years of new investment decline. It seems that for the pharmaceutical sector, Indonesia's market size is insufficient to outweigh the restrictions.

Realistically, Indonesia is a small pharmaceutical market, valuing just over 1% of the top two markets worldwide: the US and China. Furthermore, it barely has a raw material industry. Without serious efforts to improve linkages with the global market, foreign investors will continue to view Indonesia as a market with limited opportunities and prefer to operate in bigger markets with readily available production capacity.

21 Foreign ownership is still capped at 85% for finished products
FACING THE PANDEMIC WITH A MIXED BAG OF POLICIES

Nevertheless, the tug-of-war between outward- and inward-looking policies in the pharmaceutical sector continues even during this health crisis. The Indonesian Ministry of Industry (MOI) is the latest to join the localization ranks through its Regulation No. 16/2020 on Local Content Calculation for Pharmaceutical Products. As Figure 2 shows, pharmaceutical companies self-declare their local contents, but the calculations must be verified by independent assessors which are registered with MOI. Herein lies the problem: extra licenses mean extra cost and new opportunities for rent-seeking behaviours. This will certainly work against ensuring the availability of medicines for all.

Figure 2: Local content certification process for pharmaceutical products (Note: LC stands for local content).

SSEK Legal Consultants (Eddymurthy and Raharja 2020)
Furthermore, although this regulation does not specify a minimum level required, foreign businesses believe that this will eventually be specified under the public procurement system.\textsuperscript{26} Given that Indonesia imports most of its pharmaceutical raw materials, this policy may further limit drug availability for patients using the JKN. This behavior seems to ignore past lessons that localization policies were ineffective and current fact that bigger producers are still operating below capacity.

On the other hand, the flagship Omnibus Bill on Job Creation currently under Parliamentary debate contains changes that are long-awaited by investors but also alarming when viewed using the pharmaceutical lens. The first positive is that it revokes the local production requirement in the Patent Law. Secondly, it seems to finally do away with foreign ownership restrictions. Another positive is that it streamlines import-export licensing which would encourage linkages with GVCs and the global market.

However, the World Bank highlights that in streamlining the licensing requirements, this Bill relaxes environmental protection requirements and no longer classifies medicine as a high-risk product.\textsuperscript{27} As a matter of fact, this is of special concerns for the pharmaceutical industry, as experience in China shows. Perhaps this was to be regulated more specifically in the Omnibus Bill on Pharmacy, but this legislation has now been dropped from the national legislation program due to the pandemic.\textsuperscript{28} While manufacturing may be important for economic recovery post-COVID-19, a lack of safeguards – especially for pharmaceutical manufacturing – may well result in serious damage to the environment and human lives.

One final policy development that is quite exciting but still relatively inward-looking is a proposed super tax deduction for research and development (R&D) activities. Organisations can claim up to 300\% of their R&D cost, as shown in Table 1, provided that all R&D activities are done in Indonesia by Indonesian taxpaying firms. As such, foreign firms can only claim this if they set up a research facility in Indonesia. Furthermore, the effectiveness of this policy may be limited if the Patent Law revision in the Omnibus Bill on Job Creation falls through. Only companies with an internal R&D department can get the

\textsuperscript{26} Mejri, “Local Content Regulation”; Eurocham, “Pharmaceutical and Medical Technology”


maximum benefit, so it may not fit well with the outsourcing model increasingly used in pharmaceutical GVCs.

<table>
<thead>
<tr>
<th>Stages</th>
<th>Claimable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Real Cost</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Additional:</strong></td>
<td></td>
</tr>
<tr>
<td>Commercialization</td>
<td>100%</td>
</tr>
<tr>
<td>Patented in Indonesia</td>
<td>50%</td>
</tr>
<tr>
<td>Patented Overseas</td>
<td>25%</td>
</tr>
<tr>
<td>Research Cooperation with Government R&amp;D</td>
<td>25%</td>
</tr>
</tbody>
</table>

*Table 1: Proposed Super Tax Deduction for Research and Development Activities*

One final consideration for this tax incentive is the strain it puts on the state budget. If the “real cost” covers all drug discovery expenses, full utilization for a single drug will mean US$4.5 – 7.8 billion less tax revenue. Compare this to the entire tax incentives that the Indonesian government extended to all businesses during COVID-19: USD $8.67 billion.\(^{30}\) It seems that even a single full claim from a pharmaceutical company could deprive the state of much needed revenue post-COVID-19.

---

\(^{29}\) Coordinating Ministry of Economic Affairs

PRIMUM NON NOCERE AS A POLICY PRINCIPLE

“First, do no harm” is one of the primary principles of decision making in the healthcare profession. It not only embodies the goal of making patients better but also acknowledge that any intervention may cause harm; thus, care must be exercised when making decisions. This principle can provide a useful guideline for the Indonesian government when mulling policy options for the pharmaceutical sector, as outlined in the recommendations below:

1. Do no harm to availability

While developing domestic capacity is a commendable goal, the President should always remind his ministers that the ultimate goal is medicine availability for all citizens. History shows that local production rules deters investment while increasing market size encourages it, so the Omnibus Bill’s revision to Patent Law and import-export licensing is very welcome. However, there are other localization rules that should also be reviewed, such as MOH Regulation 1010/2008 and MOI Regulation No. 16/2020. The latter is of special concern as it not only affects businesses but also customers. While for businesses this means more cost and uncertainty, for customers this could mean directly restricting supply. Before determining a minimum local content for JKN procurement, a thorough review must be conducted in collaboration with the industry to identify potential shortages due to exclusion, especially for medicines with no substitutes.

2. Do no harm to people and the environment

At the moment, the criteria for risk-based licensing in the Omnibus Bill on Job Creation is not yet clear and is delegated to an implementing regulation. When designing the formula for the implementing regulation, the Coordinating Ministry for Economic Affairs should seek input from a broad range of stakeholders, including the patient community, industry and civil society, to capture as many risk factors as possible. Streamlining business licensing is indeed key to the reform process, but any changes to licensing should be commensurate with the damage a business may impose on the population’s health and environment.

3. Do no harm to innovation

A tax incentive for R&D is an excellent initiative but it presents a dilemma. Too small, and it will be ineffective. Too big, and it drains state revenue. Before implementing this, the Ministry of Finance should do a thorough review of what costs will form the basis of the calculation. Input from various industrial sectors will be useful to realistically estimate the potential impact to state revenue. When
finally implemented, claims evaluation should not only consider cost magnitude but also knowledge content. This is to avoid knowledge-intensive-but-costly innovations being sidelined by cheaper-but-low-impact innovations. At the end of the day, incentives are not good long-term investment attraction tools and should not replace efforts to improve the broader investment policy framework.

This Asia’s Path Forward paper addresses **Diversifying Supply Chains**. Visit [CIPE.org](http://CIPE.org) for further Asia's Path Forward papers on the six essential themes for an economic recovery roadmap:

- Restarting Economies
- Diversifying Supply Chains
- Combating Corruption
- Authoritarianism and Challenges to Democracies
- Economic Challenges for Women and Marginalized Groups
- Chamber and Association Responses and Strategies

**AUTHOR**

**Andree Surianta**

Andree Surianta is an Australia Awards PhD Scholar in the Policy & Governance Program at the Crawford School of Public Policy in Canberra, as well as an Associate Researcher with the Center for Indonesian Policy Studies in Jakarta. His articles have been published in The Interpreter, East Asia Forum, and LinkedIn Pulse and can be found at ORCiD ID 0000-0002-2009-541X. With fifteen years of working experience in the private and public sector, he has developed a strong interest in how socio-economic policies can affect a country’s performance in attracting foreign direct investment and its participation in the global value chains.