

# CHALLENGES AND POLICY SUPPORTS IN INDONESIAN PHARMACEUTICAL RAW MATERIALS INDUSTRY

## Tantangan dan Dukungan Kebijakan Industri Bahan Baku Obat di Indonesia

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### Abstract

**Background:** Indonesian pharmaceutical industry is experiencing many challenges, specifically their raw materials mostly are imported products. Several factors that cause the pharmaceutical raw materials industry to be challenging are lack of mastery of technology, lack of government support, low budget for R&D, high costs of development and time consuming, and low innovation incentives.

**Aims:** The aim of this study is to conduct a study on the strategies for developing the pharmaceutical raw material industry in Indonesia

**Methods:** This study employed a qualitative method, the data triangulation gathered from interviews and discussions with several industries and institutions. The study was conducted for six months in 2022.

**Results:** The policies that require to be implemented in order to make the pharmaceutical raw materials industry thrive are (i) the presence of a clear grand strategy, (ii) determining the priority of pharmaceutical raw materials based on industrial needs, (iii) protecting domestic products, (iv) increasing health spending, (v) strengthening basic chemical product, and (vi) increasing the budget for R&D.

**Conclusion:** Some policies that can be enhanced include providing incentives and policies that favor the local pharmaceutical raw material industry, ranging from regulated prices, put an end to dependence on imported products, tax incentives, domestic products protection through import tariff policies, energy subsidies, technology transfers, et cetera.

**Keywords:** pharmaceutical raw materials, policy, pharmaceutical

### Abstrak

**Latar Belakang:** Industri bahan baku farmasi di Indonesia mengalami banyak permasalahan, terutama ketergantungan terhadap produk impor. Beberapa faktor yang menyebabkan industri bahan baku obat memiliki tantangan tersendiri seperti kurangnya penguasaan teknologi, dukungan pemerintah, anggaran riset rendah, tingginya biaya pengembangan bahan baku, dan insentif untuk inovasi masih rendah.

**Tujuan:** Tujuan dilakukan kajian ini adalah untuk menentukan kebijakan strategi pengembangan industri bahan baku obat Indonesia.

**Metode:** Studi ini menggunakan metode kualitatif, data triangulasi diperoleh dari proses interview dan diskusi dengan beberapa institusi dan industri. Penelitian ini dilakukan selama enam bulan di tahun 2022.

**Hasil:** Kebijakan yang perlu ditingkatkan mulai dari (i) adanya grand strategy yang jelas, (ii) menentukan prioritas bahan baku obat berdasarkan kebutuhan industri, (iii) melindungi produk domestik, (iv) meningkatkan health spending, (v) penguatan industri kimia dasar, dan (vi) meningkatkan anggaran untuk R&D.

**Kesimpulan:** Beberapa kebijakan yang dapat ditingkatkan mulai dari pemberian insentif terhadap industri bahan baku obat mulai dari penetapan harga, berhenti ketergantungan terhadap produk impor, insentif pajak, perlindungan produk domestik melalui kebijakan tarif impor, subsidi energi, transfer teknologi, dll.

**Kata kunci:** bahan baku obat, kebijakan, farmasi



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## Introduction

The COVID-19 pandemic gives us many lessons. Several sectors experienced a decline in their business, but the pharmaceutical industry still survive and has grown significantly (Esparcia and López, 2022; Lim and Rokhim, 2021). Furthermore, Indonesian pharmaceutical sector has experienced rapid growth since the implementation of the Indonesian National Health Insurance (JKN) program in 2014 (Theodore *et al.*, 2022). In 2019, the number of people participating in this program reached 215 million or 83% of the total population. Meanwhile, JKN has gained 86.7% of the total population (Anggriani *et al.*, 2020; Binekasri, 2022). It indicates that the pharmaceutical industry will develop even more rapidly in line with the massive rise of JKN program.

Strategic planning to strengthen the national pharmaceutical industry is needed to improve the resilience of the national drug supply in the JKN program. However, the reality is that the pharmaceutical industry in Indonesia still needs to be more sustainable. The number of industries continues to increase; in 2021, there were 241 pharmaceutical companies (Ministry of Industry Republic of Indonesia, 2021; Ministry of Investment Republic of Indonesia, 2022). Based on National Agency of Drug and Food Control (2022), 86% of pharmaceutical company were concentrated on the finished chemical products, and only 2.9% focused on raw material medicine. Raw material or Active Pharmaceutical Ingredients (API) are primary active ingredients that elicit pharmacological responses. The dependence of the pharmaceutical industry on imported pharmaceutical raw materials reaches 90% (Ministry of Health Republic of Indonesia, 2022; The Jakarta Post, 2022). As such, Indonesia is vulnerable to external disturbances if the government does not obtain a supply of raw materials. As we can see now, Indonesia's pharmaceutical raw material rely heavily on imported products.

Based on previous research by Lim and Rokhim (2021) and Siagian *et al.*

(2020), several factors that cause challenges in the pharmaceutical raw material industry are lack of technology expertise, lack of government support, low budget for R&D, high cost of development and time-consuming in the R&D process, and low innovation incentives. An appropriate development strategy is needed to overcome these problems so the Indonesian pharmaceutical raw material industry can develop or sustain. Although there have been studies on the appropriate drug development policies in Indonesia (Siagian *et al.*, 2020) and the impact of drug pricing in Indonesia (Anggriani *et al.*, 2020), these studies have yet to discuss the strategy for developing pharmaceutical raw materials in Indonesia. From those studies, it needs to map the current situation in Indonesia based on challenge and policy aspects. So, this study aims to map the problems in the pharmaceutical raw material industry and to formulate policy recommendations.

## Method

This study employed a qualitative method. To obtain policy recommendation and information about the current condition of the pharmaceutical industry, interviews and discussions were conducted with several industries and institutions. The study was conducted for four months in 2022-2024. The institutions involved in this study were several related ministries (Ministry of Health, National Agency of Drug and Food Control, Ministry of Industry, Coordinating Ministry for Economic Affairs), Indonesia's state-owned enterprise (PT. Kimia Farma Sungwun Pharmacopia), and experts from the University of Indonesia and Bandung Institute of Technology.

Figure 1 shows the research flowchart. The data triangulation was gathered from discussion and literature study. We invite and discuss with each of the six stakeholders related to the pharmaceutical industry issues to understand the current situation and policy implementation. In regulator, several questions were inquired, such as the current policy to support pharmaceutical raw material industry, pharmaceutical raw

material roadmap, and overview of current challenge. The information from industry are needed to explore their current business, policy needed for industry, and obstacle in their business. The information from college is gathered to give us the perspective from academican in describing the problem based on a public policy approach.

A literature study was carried out to gain information from several countries such as China, Bangladesh, India, and United States (US). We propose these countries because they mostly rely on pharmaceutical sector, high market share of pharmaceutical product, has succeeded in developing pharmaceutical sector, and has increased trend in pharmaceutical sector. These countries can be called the developed hi-tech in pharmaceutical sectors. Bangladesh has made a strong baseline and is moving towards self-sufficiency for pharmaceutical sector. Bangladesh succeeds in manufacturing

API products to become raw materials in medicine. Their pharmaceutical industry is projected to grow 12% annually and surpass USD 6 billion in 2019 – 2025 (Castle, 2022). While China is the highest producer and exporter of more than 1500 API products. The total market size accounts for up to one-third of the global API production (Liu, 2021). Now, China is the second largest pharmaceutical market in the world behind the US (Kanavos *et al.*, 2019). In India, the pharmaceutical industry is expected to grow up to USD 130 billion in 2030. Different from China, India could produce API products at lower cost while maintaining quality (Neshith Desai Associates, 2023). Although the US API products supplied mostly from China and India, the US is widely recognized as a generic medicine producer (Sardella, 2023). As much as 64% of sales of new medicine during 2016-2021 was originated from US (EFPIA, 2022).

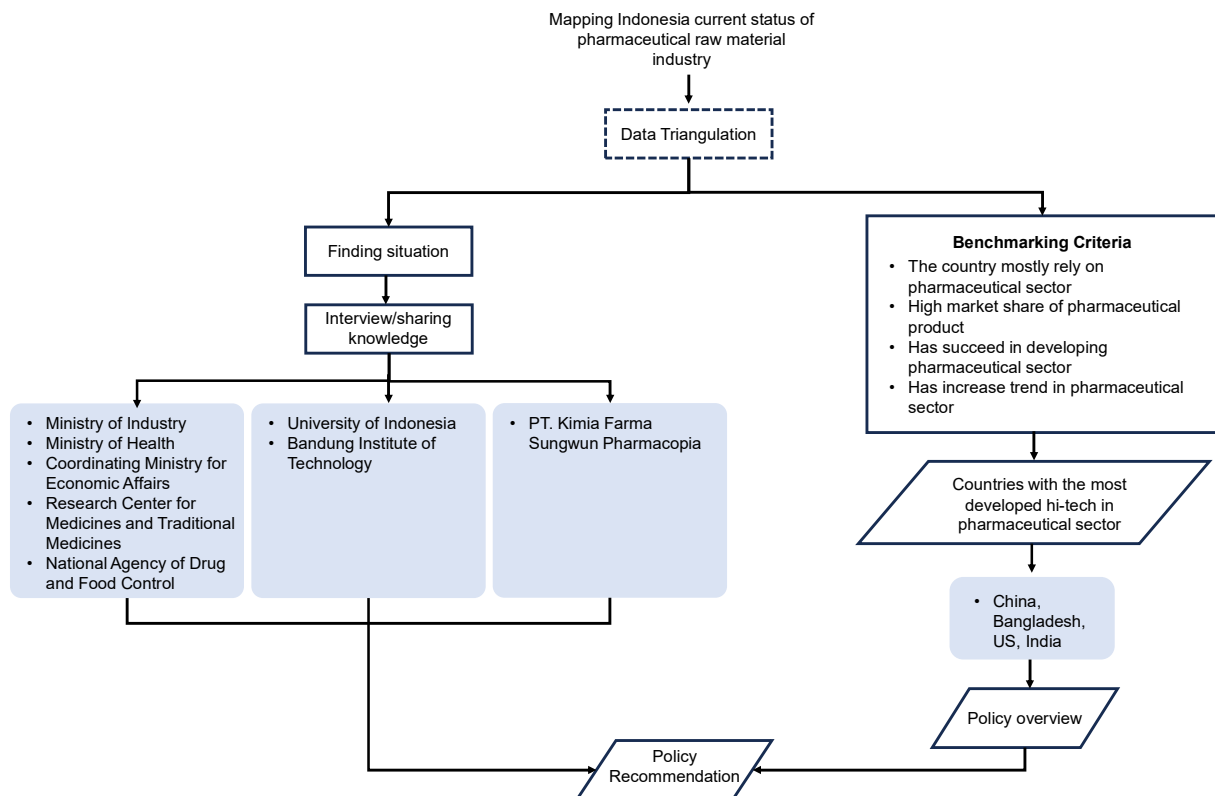


Figure 1. Research flowchart

## Result and Discussion

### Current Status of Indonesian Pharmaceutical Raw Material

Based on the Indonesia National Agency of Drug and Food Control (BPOM), in 2022, 143 pharmaceutical companies already had Good Manufacturing Practice (GMP) certificates. Most of these companies produced medicinal products. Meanwhile, only nine companies produce pharmaceutical raw materials or 3.7% of the total companies. Based on the distribution of industries, several industries are concentrated in western Indonesia (Warsito, 2022). The pharmaceutical raw material industry only exists in Lampung, West Java, and East Java provinces. Most of the pharmaceutical raw materials are supplied from imported products. As of May 2022, imports of auxiliary raw materials, which included chemicals, reached 78% (Ministry of Trade Republic of Indonesia, 2022). The five main pharmaceutical raw materials imported in 2021 reached USD 147,917,018 (IDR 2.1 trillion) (BPS, 2022).

The Ministry of Health reported that the API molecule that has the highest value in Indonesia is clopidogrel, with a total sales value of IDR 4.52 trillion, followed by paracetamol with IDR 4.48 trillion (Ministry of Health Republic of Indonesia, 2022). Further, it is also reported that from the 20 main molecules of drugs, Indonesia can produce only three molecules: clopidogrel, paracetamol, and atorvastatin (Ministry of Health Republic of Indonesia, 2022).

### Current Policy for Supporting Pharmaceutical Raw Material Industry

Through the Ministry of Health, the government continues to encourage the development of drug molecules that are widely used in terms of volume and value. The raw medicinal roadmap made until 2024 includes the development of six drug molecules (candesartan and bisoprolol in 2022, amlodipine and lansoprazole in 2023, and cefixime and ceftriaxone in 2024). The Ministry of Health has several policies to support this; first, developed a mid-term roadmap to determine the main molecules to be developed in the next few years. Second, it is necessary to have a task force

to maintain the R&D ecosystem so that research and development activities can run according to what has been planned on the roadmap. Third, the Ministry of Health also facilitates the transfer of technology change sources to optimize domestic potential.

Other policies protect local industries through Presidential Decree No. 12/2021; the government requires local content on domestic products to be at least 40%. Furthermore, the pharmaceutical raw material industry is regulated through the Minister of Industry No. 16/2020, where the composition of local content for raw materials is 50%, R&D 30%, production processes 15%, and packaging processes 5%. These policies are issued to encourage the growth of the domestic drug raw material industry and will impact the resilience of the Indonesian pharmaceutical industry.

The government also provides incentives for priority sector industries. In Presidential Regulation No. 10/2021, two incentives can be used for priority sectors: fiscal and non-fiscal. In addition, through the Ministry of Finance, the government also issued Minister of Finance Regulation No. 130/2020 regarding tax reduction (Coordinating Ministry for Maritime Affairs and Investment, 2021). Incentives related to COVID-19 are also provided based on the Ministry of Finance Regulation No. 9/2021, where the government bears income tax. Tax reductions can also be made through Ministry of Finance Regulation No. 153/2020, which states that industries that carry out R&D activities could receive a tax deduction of up to 300% of the total cost.

### Lesson Learned from Pharmaceutical Industry Success Story: China, Bangladesh, and India

Table 1 illustrates the differences in policies implemented in China, India, and Bangladesh. India has been successful in developing the local pharmaceutical industry. The Indian government provides a small portion of the budget for health care. Additionally, the Indian government has a role in encouraging the local manufacturing.



Table 1. Best practice policies from several countries to encourage pharmaceutical raw materials industry

	India	Bangladesh	China	Indonesia
Domestic product protection	<ul style="list-style-type: none"> <li>Implementing price control system.</li> <li>Stop dependence on pharmaceutical raw materials from China.</li> </ul>	<ul style="list-style-type: none"> <li>Implementing a 7.5% export levy (flat rate) for all materials, but a lower rate is applied for pharmaceutical raw materials.</li> <li>Import facilities are subject to a "block list". The block list provides a description of the material.</li> </ul>	Limiting foreign investment with a maximum share ownership of 49%.	Implementing domestic local content policy; 50% for raw materials, 30% for development, 15% for production processes, and 5% for packaging.
Strategy to create pharmaceutical resilience	Focus on the export and domestic markets.	The government provides cash incentives of 10%.	<ul style="list-style-type: none"> <li>Focus on mass-production.</li> <li>Switching from API production to FFPs.</li> </ul>	<ul style="list-style-type: none"> <li>The Ministry of Health has a roadmap of raw materials to be substituted.</li> <li>National Research and Innovation Agency (BRIN) has National Research Master Plan (RIRN) that include pharmaceutical raw materials.</li> <li>The Ministry of Industry creates a national Industrial Master Plan for the pharmaceutical raw material Industry.</li> </ul>
Energy subsidy policy for pharmaceutical raw materials industry	-	-	Energy subsidies to produce cheaper API product.	

Parameters	India	Bangladesh	China	Indonesia
Ease of invest	<ul style="list-style-type: none"> <li>Establishment of special economic zone (SEZs)</li> <li>100% automatic approval for foreign investment.</li> </ul>	<ul style="list-style-type: none"> <li>Bangladesh promotes investment opportunity through Export Processing Zone Authority (BEPZA).</li> <li>Build 100 economic zone.</li> </ul>	<ul style="list-style-type: none"> <li>Developing special economic zone.</li> <li>No import fee for production utilities.</li> </ul>	<ul style="list-style-type: none"> <li>Build industrial estates for integrated pharmaceutical raw materials in Batang.</li> <li>Issuing the law abolishes minimum wage by sector (Omnibus Law)</li> </ul>
Tax incentives to encourage competitiveness	<ul style="list-style-type: none"> <li>Financial cost exemption.</li> <li>Value added tax exemption.</li> <li>100% tax reduction in the first of five year and 50% for the next year.</li> </ul>	<ul style="list-style-type: none"> <li>Tax holiday 5-7%.</li> <li>Refunding value added tax for 10% of finished pharmaceutical formulations product and 20% for API product.</li> </ul>	<ul style="list-style-type: none"> <li>Income tax reduction from 15% to 25%.</li> <li>Income tax reduction up to 50% in special economic zone.</li> </ul>	<p>Provide tax incentives in the form of 100% tax holiday for investments of more than IDR 500 billion (5-20 years) and 50% for investment of IDR 100 – 500 billion (5 years).</p>
Push R&D intensity	<ul style="list-style-type: none"> <li>200% tax deduction from income for R&amp;D.</li> <li>Establishment of API-specific manufacturing clusters</li> </ul>	Technology transfer	<ul style="list-style-type: none"> <li>Increase R&amp;D budget.</li> <li>Tax and import duty exemption incentives for certain materials (15% income tax deduction, 150% "super deduction tax" for R&amp;D).</li> <li>81% of R&amp;D expenditure provided by government and 5.41% from private company.</li> </ul>	<ul style="list-style-type: none"> <li>Super deduction tax for R&amp;D (up to 300%).</li> <li>Joint venture with the company that master the technology of pharmaceutical raw materials (e.g., Kimia Farma Sungwun Pharmacopia).</li> </ul>
References	(Reddy and Gupta, 2013; World Health Organization, 2017)	(Sampath, 2019)	(Atkinson, 2020; Ni <i>et al.</i> , 2017; PWC, 2009; World Health Organization, 2017)	(Coordinating Minister for Maritime Affairs and Investment Republic of Indonesia, 2021; Ministry of Industry Republic of Indonesia, 2021)

India has started the development of the pharmaceutical raw materials industry since 1970. The government mandates the development of API products with schemes of 100% domestic company ownership, foreign investors partially owning the company, and 100% owned by foreign investors (World Health Organization, 2017).

Apart from India, Bangladesh also has an excellent pharmaceutical industry structure. Bangladesh has a similar vision as India; they are not dependent on imported API products. Currently, the Bangladesh drug market is divided into two: generic, with a share of about 92% of the total local production and 8% of patents, Local companies meet 97% of national demand, while imports meet the remaining 3%. Bangladesh has produced 19 API products (Sampath, 2019).

Bangladesh also provides many incentives for domestic pharmaceutical raw material industries, ranging from lower export levies for the pharmaceutical raw material industry, tax breaks, technology transfer, and a "block list" system. Bangladesh has a good development plan for the drug industry. The technology transfer process is carried out properly so the local pharmaceutical industry can develop rapidly. An exciting policy is the application of a "block list" system. In this system, imports of raw materials must go through the approval of the Directorate General of Drug Administration (DGDA) (United Nations, 2012). This system provides information regarding pharmaceutical production plans so that the supply of pharmaceutical raw materials will be recorded and well-known.

China is one of the countries with a rapidly growing pharmaceutical industry (Peña *et al.*, 2021). China has a different strategy from India and Bangladesh. China is a densely populated country, so the strategy to encourage its pharmaceutical industry is to mass-produce low-level generic drugs and API products (Ni *et al.*, 2017). China has 6,807 pharmaceutical companies that produce 2,000 API products with an annual capacity of 2 million tons. China's current strategy is to start shifting from producing API products

to producing finished pharmaceutical products (FFPs). China focuses on FFPs because FFPs have a higher level of profitability (Fang, 2017; World Health Organization, 2017). In addition, China tends to maximize domestic use by limiting pharmaceutical industry investment to a maximum foreign shareholding of 49%.

The pharmaceutical policy in developed countries, such as the US, has a massive concern for the health sector. In 2001, the US experienced an anthrax virus attack, considered as bioterrorism. The US then needed the antibiotic ciprofloxacin more broadly to deal with bioterrorist attacks. The US government provides a 50% discount on antibiotics to enable access to people at a low price. The government can procure and produce drugs at low prices (Kesselheim *et al.*, 2019; Morgan and Sterling, 2019). In 2001, the US spent USD 6 billion in response to bioterrorism attacks, showing the public health system improvement. An excellent public health education program, good clinicians, epidemiological skills, and adequate health infrastructure become the instruments for anticipating outbreaks. Further, they can also minimize casualties and the broader economic impact (Franz, 2009).

### Challenges in Developing Pharmaceutical Raw Material Industry in Indonesia

The challenge of the Indonesian pharmaceutical raw material industry is low health expenditure. One indicator related to economic growth is healthcare expenditure (Yang *et al.*, 2021). Based on several studies, healthcare expenditure and economic growth have a relationship (Chaabouni and Saidi, 2017; Raghupathi and Raghupathi, 2020). The increase in healthcare expenditure indicates increased economic growth. Figure 2 shows the plot between health expenditure per capita and GDP. Indonesia is included in the top 20 countries with the largest GDP in the world. However, Indonesia's health expenditure per capita is very low, which is only 3.1% of the total GDP. Indonesia's health expenditure per capita value is still below other ASEAN countries, such as Malaysia

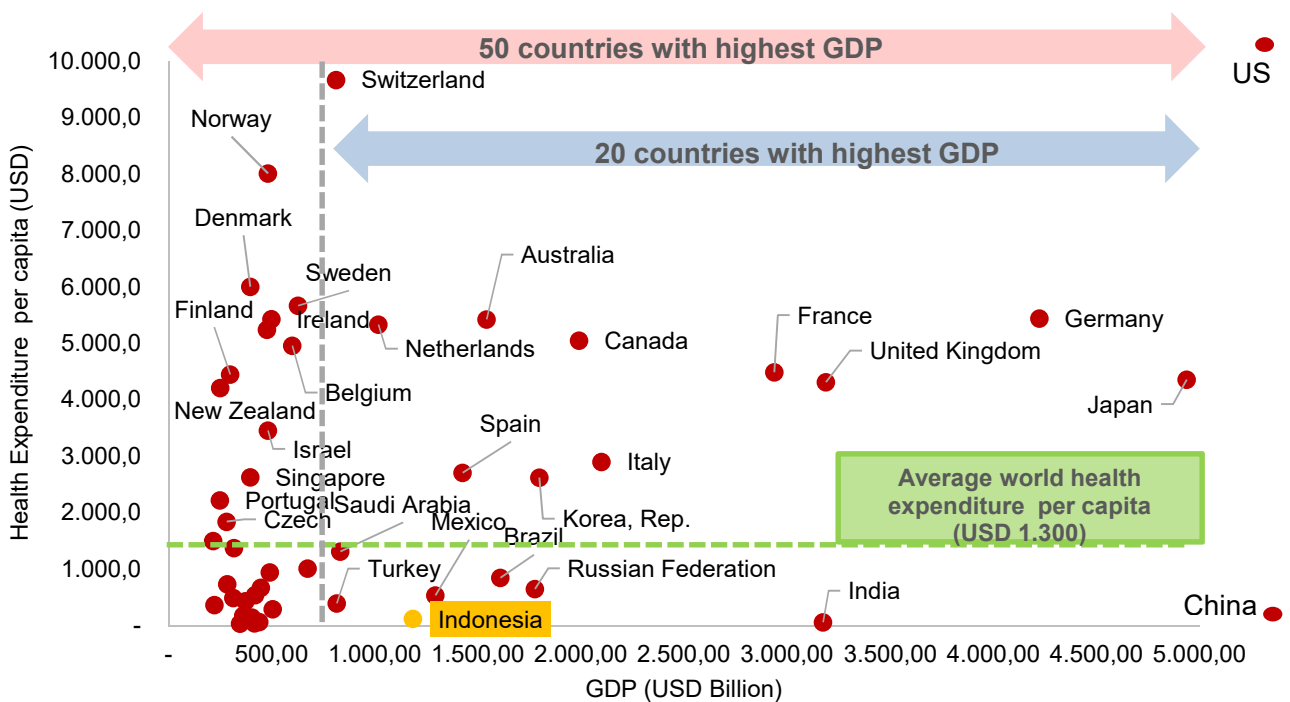


(USD 361), Vietnam (USD 36), Singapore (USD 1,804), and Thailand (USD 111) (Suwantika *et al.*, 2020). Health expenditure is still considered a luxury item, so people tend to be low in spending their income on health needs (Shaikh and Gandjour, 2019).

Another challenge is R&D activities. The financial burden incurred from R&D will not necessarily produce products that can be directly sold to the public. This event is often interpreted as a "valley of death", where it takes a high cost to develop drug molecules with a development period of 15-20 years and a failure rate of up to 95% (Gamo *et al.*, 2017; Scherer, 2014). Industries with a low market share will undoubtedly find it difficult to carry out the R&D process with high-cost requirements and the uncertainty of the developed product. Due to the high cost and uncertainty, pharmaceutical companies in countries such as India tend to develop and manufacture drug molecules that have been proven to be mass-produced and sold. However, the pharmaceutical industry relies heavily on innovation to produce high-value new molecular entities (NMEs)

(Schuhmacher *et al.*, 2021). The R&D budget is an important element for developing the pharmaceutical raw material in terms of competitiveness, technology, efficiency, new products, and services (Rahman and Howlader, 2022). The pharmaceutical sector relies heavily on innovations to produce new molecules (Schuhmacher *et al.*, 2021). The established companies will allocate around 40-50% of their revenue on R&D activities (Rahman and Howlader, 2022). In Indonesia, one of the state-owned companies with a large pharmaceutical market share, PT. Kimia Farma, issued a budget of USD 2 million or 0.2% of total sales in 2021 for R&D (Ayubi, 2022; Kimia Farma, 2021).

Prices of local products tend to be less competitive compared to imported products. On the other hand, the price gap of imported pharmaceutical raw materials varies widely. For example, clopidogrel's lowest price is USD 150 per kg, while the highest is USD 1,392 per kg. The price of local clopidogrel is around USD 210 per kg,



Source: World Bank (2022)

Figure 2. Mapping of health expenditure in 50 countries with highest GDP– reprocessed data



but the price of imported clopidogrel is still lower than local products (Ministry of Industry Republic of Indonesia, 2022). Similarly, amoxicillin made in a small laboratory plant in Indonesia has an estimated price of USD 30-50, which is higher than amoxicillin imported from India and China with a price of USD 20 (Agency for the Assessment and Application of Technology, 2020).

## Discussion and Policy Support

Based on interviewing experts and benchmarking several countries such as India, Bangladesh, and China, there are several important lessons learned in formulating recommendations for developing the pharmaceutical raw material industry in Indonesia, which are as follows:

### Indonesia still needs to have a clear and integrated grand strategy for developing pharmaceutical raw material

The appropriate policy framework still needs to be formulated based on Table 1. It is obvious that several Ministries or agencies organizing the implementation of policies in Indonesia often have different policy philosophies, occasionally reflecting their individual sectoral egos. According to Nugroho (2015), policymaking does not only look at the problems faced, but it is also necessary to determine the expected ideal conditions as a milestone in describing the policy planning that will be pursued (Nugroho, 2015). Handing over to the market to produce pharmaceutical raw materials is impossible because it is less profitable for the private sector. In this situation, the government has to take a major role in fixing the market and giving direction to the stakeholders (Mazzucato, 2017).

### The research goals for pharmaceutical raw materials should be aligned with the national demand

To achieve national resilience in health care, the government must ensure the availability of pharmaceutical raw materials at all times. Priority is an essential

factor that should be stated. This priority is a part of the consensus as previously stated. As we learn from Bangladesh, in 1982, they had 150 essential drugs, but in 2016 there were 285 drugs became the priority (Murshid and Haque, 2019).

At this time, Indonesia has ten drug priorities based on the highest value in the local economy. This should be compared with the technology availability and the basic chemical that already produced in Indonesia by local industry. This priority will keep our strategy on track. After formulating priority drug molecules, further research must be in line with the priority of developing these molecules. It must be clear, understood, and approved by all stakeholders.

### Market protection of local drug prices

Market protection is the main strategy used to maintain the viability of indigenous enterprises, as we can learn from India and Bangladesh. According to Ederington and McCalman (2011) and Melitz (2005), protecting the infant industry from foreign products is vital to close the technology gap with such items. The imposition of import taxes and quotas, along with production subsidies, can provide protection. However, this support is only temporary because the infant industry will eventually mature. As a result, it is exceedingly challenging for the infant industry to compete with established rivals. According to the learning curve principle, in this instance, the unit cost will fall as output rises (Qiu *et al.*, 2019).

Policies such as price control, tax incentives, import duties, etc., should be implemented. As the country with the world's largest economy, The US also applies a policy of protecting local products. In 2018, the US imposed an import tariff of 12%. This policy aimed to preserve the intermediate products of local traders (Barattieri and Cacciotore, 2023). Consequently, the import tariffs in the US could reduce imported products, especially those imported from China, and increase exports to non-Chinese countries (Cheng *et al.*, 2021).

The current approach of the government entails the implementation of a

local content policy for pharmaceutical products as a means to protect the market for indigenous pharmaceutical raw material. In accordance with the Ministry of Health's 2020-2024 Action Plan, it is projected that by the year 2024, the local content of the top 10 medicines listed in the National Formulary (FORMAS) will surpass the threshold of 50% (Ministry of Health Republic of Indonesia, 2020). In pricing mechanism, the government use e-catalogues which is facilitated by the National Public Procurement Agency, wherein the necessary pharmaceuticals are subjected to auctions and negotiations to secure the most favorable rates (Winda, 2018).

### **Increase health expenditure to boost up local market industry**

The low health expenditure in Indonesia is the main issue that causes typically low common market share in Indonesia. The large population of Indonesia makes the increase in health expenditure an important variable in increasing the local market. The growth of pharmaceutical market will help reducing the marginal costs, which will impact strengthening competitiveness. Health expenditure is a crucial factor; higher health expenditure will boost economic performance by increasing human capital productivity (Raghupathi and Raghupathi, 2020). Increased health expenditure can be done through public education, improving health insurance performance, and so on.

One of the contributing factors to the limited allocation of funds towards healthcare is the presence of low income levels (Raghupathi, 2020). According to a study conducted by (Ke *et al.*, 2011), there is a positive correlation between the utilization of health insurance mechanisms and the levels of health expenditure in various nations, as indicated by the research conducted by the World Health Organization (WHO). Hence, enhancing the efficacy of Indonesia Social Health Insurance (BPJS) services holds significant importance in promoting individuals' inclination towards seeking medical treatment when afflicted with illness.

### **Strengthening basic chemical industry**

The basic chemical industry is a part of the upstream sector of the pharmaceutical industry. For example, petrochemical products, benzene and propylene, are processed into para-aminophenol (PAF) as a raw material for pharmaceutical products such as paracetamol. Currently the government through Ministry of Industrial is developing Medicine Industrial Area in Batang. This action will accelerate the industry because the area will also integrate among pharmaceutical supply chain. Another action is a paracetamol factory with a 3,800-ton annual capacity was built in partnership between Kimia Farma and Pertamina. The existing local content policy is deemed suitable for fostering growth in the pharmaceutical raw material business. However, it is important to note that the absence of incentives may hinder the industry's progress and expansion. Policy support was also issued by Ministry of Finance, tax holiday and allowance provided to help industry growth. Another policy needs such us ease of licensing, certificate issuance, and support finished good development. The incentive policy will enhance the economic viability of pharmaceutical raw material manufacturing facilities.

### **Increase R&D budget allocation**

The intensity of pharmaceutical R&D, especially for pharmaceutical raw materials, must be increased. In addition, the budget for R&D also needs to be improved. Countries with leading industries in R&D activities (pharmaceutical, engineering, and biotech) tend to be more intense in carrying out R&D. In contrast, countries with industries that mostly depend on natural resources, tourism, finance, and transportation tend to have lower R&D activities (Sandra, 2021). The industrial structure in Indonesia is characterized by a relatively low-intensity R&D activity. The solution to this issue should be found in the mid-term plan

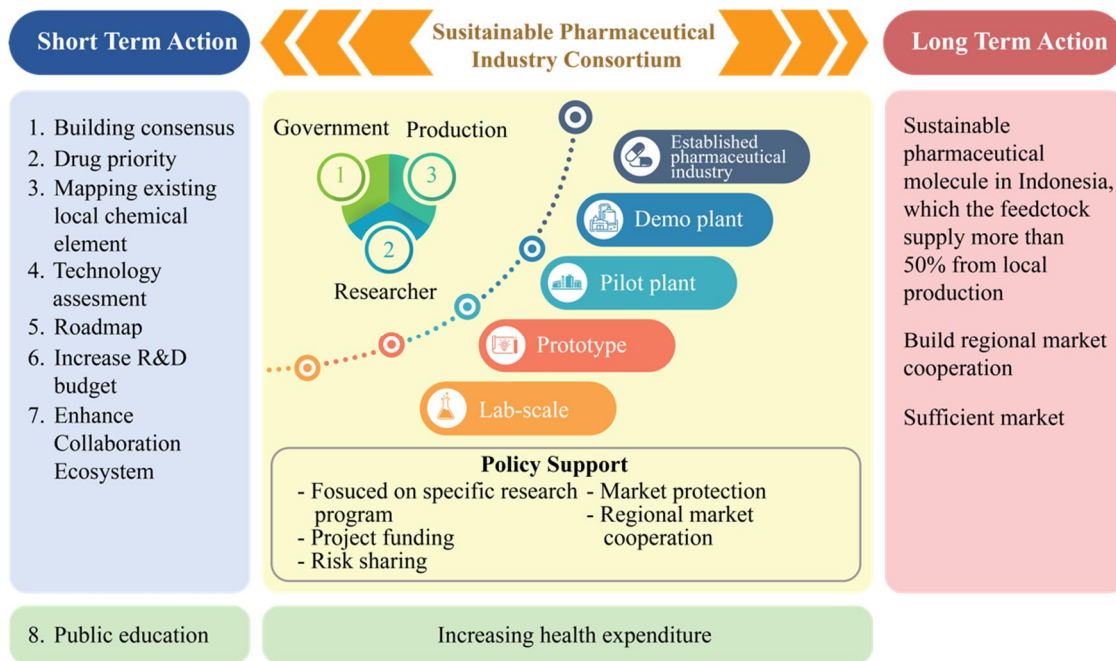


Figure 3. Summary policy recommendations that can be taken as an effort to grow the domestic drug raw material industry (author's concept)

(Figure 3). The mid-term strategy could be a form of improving research collaboration between institutions. By improving R&D intensities, firm innovation will emerge. One indicator that a company is considered to be innovative is if the ratio between R&D spending and revenue is above 3% (Park *et al.*, 2021).

## Conclusion

The pharmaceutical industry has a vital role in supporting the Indonesian economy. To support the current policy, there are several barriers that need to be addressed, starting from Indonesia's low health expenditure, low budget allocation for R&D activities, and price competition against imported pharmaceutical raw material products. Based on benchmarks from several countries that have been at the forefront in developing their pharmaceutical raw material industries, such as India, Bangladesh, and China, of course, providing many incentives and policies favor the local drug raw material companies, ranging from regulated prices, stopping dependence on imported

products, tax incentives, domestic protection products through import tariff policies, energy subsidies, to technology transfers. Several policies carried out by the government to encourage the national pharmaceutical raw material industry are the synchronization between the government and stakeholders that have an interest in the pharmaceutical raw material industry, determining pharmaceutical raw material research priorities following industry needs, protecting the local market, increasing health expenditure, strengthening basic chemical industry, and increasing the budget for R&D.

## Abbreviation

GDP: Gross Domestic Product; RIPIN: National Industrial Development Master Plan; JKN: Jaminan Kesehatan Nasional; GMP: Good Manufacturing Practice; API: Active Pharmaceutical Ingredients; DGDA: Directorate General of Drug Administration; FFPs: finished pharmaceutical products; PAF: para-aminophenol; NMEs: new molecular entities.

## Declaration

### Ethics Approval and Consent Participant

This study has been approved by the National Research and Innovation Agency (BRIN). This research does not display data that is confidential. Most of the data obtained is general information and is contained in the literature.

### Conflict of Interest

The authors state that there were no substantial conflicting financial, professional, or personal interests that could have influenced the performance

### Availability of Data and Materials

The data used to support the findings of this study are included within the article.

### Authors' Contribution

EH conceptualized, analyzed and wrote the study, EDS and NAH analyzed the result, AA and DH reviewed the manuscript, SZ collected the data, AW review policy recommendation, and HAR review country benchmarking and wrote the study.

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## References

Agency for the Assessment and Application of Technology (2020) *Health Technology Outlook 2020*. Jakarta-Indonesia.

Anggriani, Y. *et al.* (2020) 'The Impact of Pharmaceutical Policies on Medicine Procurement Pricing in Indonesia Under the Implementation of Indonesia's Social Health Insurance System', *Value in Health Regional Issues*, 21, pp. 1–8. Available at: <https://doi.org/10.1016/j.vhri.2019.05.005>.

Atkinson, R.D. (2020) *The Impact of China's Policies on Global*

*Biopharmaceutical Industry Innovation*. Information Technology & Innovation Foundation. Available at: <https://itif.org/publications/2020/09/08/impact-chinas-policies-global-biopharmaceutical-industry-innovation/> (Accessed: 5 November 2023).

Ayubi, S. (2022) 'The Role of SOE Healthcare Holding Company in Indonesia Healthcare Ecosystem'.

Barattieri, A. and Cacciatore, M. (2023) 'Self-Harming Trade Policy? Protectionism and Production Networks', *American Economic Journal: Macroeconomics*, 15(2), pp. 97–128. Available at: <https://doi.org/10.1257/mac.20190445>.

Binekasri, R. (2022) '86,7% of Indonesian Population has Already join JKN Program'. Available at: <https://www.cnbcindonesia.com/market/20220630130849-17-351778/867-penduduk-ri-sudah-jadi-peserta-jkn> (Accessed: 9 May 2022).

BPS (2022) *Indonesian GDP 2021*. Badan Pusat Statistik. Available at: <https://www.bps.go.id/indicator/11/106/2/-seri-2010-distribusi-pdb-triwulanan-seri-2010-atas-dasar-harga-berlaku.html> (Accessed: 9 May 2022).

Castle, L. (2022) 'Active Pharmaceutical Ingredient (API) Manufacturing: The Next Growth Driver of The Bangladesh Pharmaceutical Industry'. Available at: <https://www.lightcastlebd.com/insights/2021/08/active-pharmaceutical-ingredient-api-manufacturing-the-next-growth-driver-of-the-bangladesh-pharmaceutical-industry/> (Accessed: 8 October 2022).

Chaabouni, S. and Saidi, K. (2017) 'The dynamic links between carbon dioxide (CO<sub>2</sub>) emissions, health spending and GDP growth: A case study for 51 countries', *Environmental Research*, 158, pp. 137–144. Available at: <https://doi.org/10.1016/j.envres.2017.05.041>.



- Cheng, L. *et al.* (2021) 'Destruction and Deflection: Evidence from American Antidumping Actions against China', *Structural Change and Economic Dynamics*, 57, pp. 203–213. Available at: <https://doi.org/10.1016/j.strueco.2021.03.009>.
- Coordinating Minister for Maritime Affairs and Investment (2021) 'Investment Policy and Development of Integrated Industrial Estates for Pharmaceutical Industry'. Bali.
- Ederington, J. and McCalman, P. (2011) 'Infant industry protection and industrial dynamics', *Journal of International Economics*, 84(1), pp. 37–47. Available at: <https://doi.org/10.1016/j.jinteco.2011.01.002>.
- EFPIA (2022) *The Pharmaceutical Industry in Figures*. Belgium: The European Federation of Pharmaceutical Industries and Associations.
- Esparcia, C. and López, R. (2022) 'Outperformance of the pharmaceutical sector during the COVID-19 pandemic: Global time-varying screening rule development', *Information Sciences*, 609, pp. 1181–1203. Available at: <https://doi.org/10.1016/j.ins.2022.07.146>.
- Fang, Y. (2017) 'Pharmaceutical Policy in China', in Z.-U.-D. Babar (ed.) *Pharmaceutical Policy in Countries with Developing Healthcare Systems*. Cham: Springer International Publishing, pp. 169–191. Available at: [https://doi.org/10.1007/978-3-319-51673-8\\_9](https://doi.org/10.1007/978-3-319-51673-8_9).
- Franz, D.R. (2009) 'Preparedness for an anthrax attack', *Molecular Aspects of Medicine*, 30(6), pp. 503–510. Available at: <https://doi.org/10.1016/j.mam.2009.07.002>.
- Gamo, N.J. *et al.* (2017) 'Valley of death: A proposal to build a "translational bridge" for the next generation', *Neuroscience Research*, 115, pp. 1–4. Available at: <https://doi.org/10.1016/j.neures.2016.11.003>.
- Kanavos, P., Mills, M. and Zhang, A. (2019) *Pharmaceutical policy in China* [PDF]. LSE Consulting. Available at: <https://doi.org/10.21953/LSE.FG2T522B8R1X>.
- Ke, X., Saksena, P. and Holly, A. (2011) *The Determinants of Health Expenditure: A Country-Level Panel Data Analysis*. World Health Organization, p. 4. Available at: [https://www.r4d.org/wp-content/uploads/TransitionsInHealthFinancing\\_DeterminantsofExpenditures.pdf](https://www.r4d.org/wp-content/uploads/TransitionsInHealthFinancing_DeterminantsofExpenditures.pdf).
- Kesselheim, A.S. *et al.* (2019) 'Pharmaceutical Policy in the United States in 2019: An Overview of the Landscape and a Venues for Improvement', in *Stanford Law & Policy Review*. England: University of Stanford, pp. 421–481.
- Kimia Farma (2021) *Annual Report: Kimia Farma to The Next level for Global Healthcare Company*. Jakarta: PT. Kimia Farma, Tbk. Available at: [https://www.kimiafarma.co.id/files/Lap\\_Tahunan/Laporan\\_Tahunan-2021.pdf](https://www.kimiafarma.co.id/files/Lap_Tahunan/Laporan_Tahunan-2021.pdf).
- Lim, H. and Rokhim, R. (2021) 'Factors affecting profitability of pharmaceutical company: an Indonesian evidence', *Journal of Economic Studies*, 48(5), pp. 981–995. Available at: <https://doi.org/10.1108/JES-01-2020-0021>.
- Liu, H. (2021) 'The Impact of the Coronavirus on Chinese Pharmaceutical Industry', in *6th International Conference on Financial Innovation and Economic Development (ICFIED 2021)*, Sanya, China. Available at: <https://doi.org/10.2991/aebmr.k.210319.010>.
- Mazzucato, M. (2018) 'Mission-oriented innovation policies: challenges and opportunities', *Industrial and Corporate Change*, 27(5), pp. 803–815. Available at: <https://doi.org/10.1093/icc/dty034>.
- Melitz, M.J. (2005) 'When and how should infant industries be protected?', *Journal of International Economics*, 66(1), pp. 177–196. Available at:

- <https://doi.org/10.1016/j.jinteco.2004.07.001>.
- Ministry of Health Republic of Indonesia (2022) 'Indonesia Pharmaceutical Policy'. Jakarta, Indonesia.
- Ministry of Health Republic of Indonesia, M. of (2020) *Action Plan Directorate of Pharmaceutical Production and Distribution 2020-2024*. Jakarta.
- Ministry of Industry Republic of Indonesia (2021) 'Increasing the use of domestic products through the Domestic Content policy'. Bali.
- Ministry of Investment Republic of Indonesia (2022) 'Promising Potential in Indonesia's Pharmaceutical and Health Industry'. Available at: <https://www.bkpm.go.id/id/publikasi/detail/berita/potensi-menjanjikan-di-industri-farmasi-dan-kesehatan-indonesia#:~:text=Menurut%20data%20dari%20Kementerian%20Kesehatan,18%20industri%20ekstraksi%20produk%20alami.&text=menjadi%20891%20perusahaan>. (Accessed: 9 May 2022).
- Ministry of Trade Republic of Indonesia (2022) 'Indonesia Trade Balance May 2022'. Available at: <https://www.kemendag.go.id/id/newsroom/press-release/mendag-zulhasneraca-perdagangan-indonesia-mei-2022-surplus-usd-2-9-miliar-1> (Accessed: 9 June 2022).
- Morgan, J.M. and Sterling, S. (2019) *Lowering Drug Prices: A Blueprint for Reform*. The Great Democracy Initiative. Available at: [https://rooseveltinstitute.org/wp-content/uploads/2021/08/GDI\\_Lowering-Drug-Prices-Blueprint\\_201911.pdf](https://rooseveltinstitute.org/wp-content/uploads/2021/08/GDI_Lowering-Drug-Prices-Blueprint_201911.pdf).
- Murshid, M.E. and Haque, M. (2019) 'Bangladesh National Drug Policy 1982-2016 and Recommendations in Policy Aspects', *Eurasian Journal of Emergency Medicine*, 18(2), pp. 104–109. Available at: <https://doi.org/10.4274/eajem.galenos.2019.43765>.
- National Agency of Drug and Food Control (2022) 'Pharmaceutical Industry data In Indonesia That already had GMP Certificate'. Available at: <https://www.pom.go.id/new/view/direct/industri-farmasi> (Accessed: 9 June 2022).
- Neshith Desai Associates (2023) *The Indian Pharmaceutical Industry: Regulatory, Legal and Tax Overview*. India: Neshith Desai Associates, p. 3. Available at: [https://www.nishithdesai.com/fileadmin/user\\_upload/pdfs/Research\\_Papers/The-Indian-Pharmaceutical-Industry.pdf](https://www.nishithdesai.com/fileadmin/user_upload/pdfs/Research_Papers/The-Indian-Pharmaceutical-Industry.pdf).
- Ni, J. *et al.* (2017) 'Obstacles and opportunities in Chinese pharmaceutical innovation', *Globalization and Health*, 13(1), p. 21. Available at: <https://doi.org/10.1186/s12992-017-0244-6>.
- Nugroho, R. (2015) *Policy Making: Mengubah Negara Biasa Menjadi Negara Berprestasi*. Elex Media Komputindo. Available at: [//10.103.0.43:80%2Findex.php%3Fp%3Dshow\\_detail%26id%3D520%26keywords%3D](http://10.103.0.43:80%2Findex.php%3Fp%3Dshow_detail%26id%3D520%26keywords%3D) (Accessed: 6 November 2023).
- Park, H. *et al.* (2021) 'A Study on the Impact of R&D Intensity on Business Performance: Evidence from South Korea', *Journal of Open Innovation: Technology, Market, and Complexity*, 7(2), p. 135. Available at: <https://doi.org/10.3390/joitmc7020135>.
- Peña, O.I.G., Zavala, M.Á.L. and Ruelas, H.C. (2021) 'Pharmaceuticals Market, Consumption Trends and Disease Incidence Are Not Driving the Pharmaceutical Research on Water and Wastewater', *International Journal of Environmental Research and Public Health*, 18(5), p. 2532. Available at: <https://doi.org/10.3390/ijerph18052532>.
- PWC (2009) *Investing in China's Pharmaceutical Industry*. 2nd edn. PricewaterhouseCoopers. Available at: [https://www.pwc.com/gx/en/pharmalife-sciences/assets/en-pharma\\_03-26-small.pdf](https://www.pwc.com/gx/en/pharmalife-sciences/assets/en-pharma_03-26-small.pdf).

- Qiu, L.D., Zhan, C. and Wei, X. (2019) 'An analysis of the China–US trade war through the lens of the trade literature', *Economic and Political Studies*, 7(2), pp. 148–168. Available at: <https://doi.org/10.1080/20954816.2019.1595329>.
- Raghupathi, V. and Raghupathi, W. (2020) 'Healthcare Expenditure and Economic Performance: Insights From the United States Data', *Frontiers in Public Health*, 8, p. 156. Available at: <https://doi.org/10.3389/fpubh.2020.0156>.
- Rahman, Md.M. and Howlader, Md.S. (2022) 'The impact of research and development expenditure on firm performance and firm value: evidence from a South Asian emerging economy', *Journal of Applied Accounting Research*, 23(4), pp. 825–845. Available at: <https://doi.org/10.1108/JAAR-07-2021-0196>.
- Reddy, C.D. and Gupta, N.V. (2013) 'Overview on Contract Research and Manufacturing Services (CRAMs) and Its Present Status in India', *Asian Journal of Pharmaceutical and Clinical Research*, 6(2). Available at: <https://innovareacademics.in/journal/ajpcr/Vol6Suppl2/1781.pdf>.
- Sampath, P.G. (2019) *Pharmaceutical Manufacturing in Bangladesh – A Success Story. What can we learn?* 1. Federation of East African Pharmaceutical Manufacturers (FEAPM), p. 21. Available at: [https://strapi.eacgermany.org/uploads/5fda30fc68f07136175100\\_44e851ba12.pdf](https://strapi.eacgermany.org/uploads/5fda30fc68f07136175100_44e851ba12.pdf).
- Sandra, P.S. (2021) *R&D intensity as a policy target: main takeaways from 11 international case studies*. OECD, p. 36. Available at: <http://www.oecd.org/termsandconditions>.
- Sardella, A. (2023) *US Generic Pharmaceutical Industry Economic Instability*. US: Center for Analytics and Business Insights & Adjunct Lecturer, Olin Business School Washington University in St. Louis, p. 3.
- Scherer, F.M. (2014) 'Research and Development Costs and Productivity in Biopharmaceuticals', in *Encyclopedia of Health Economics*. Elsevier, pp. 249–255. Available at: <https://doi.org/10.1016/B978-0-12-375678-7.01203-7>.
- Schuhmacher, A. et al. (2021) 'R&D efficiency of leading pharmaceutical companies – A 20-year analysis', *Drug Discovery Today*, 26(8), pp. 1784–1789. Available at: <https://doi.org/10.1016/j.drudis.2021.05.005>.
- Shaikh, M. and Gandjour, A. (2019) 'Pharmaceutical expenditure and gross domestic product: Evidence of simultaneous effects using a two-step instrumental variables strategy', *Health Economics*, 28(1), pp. 101–122. Available at: <https://doi.org/10.1002/hec.3832>.
- Siagian, R.C. et al. (2020) 'A policy-making strategy to forecast outcomes of drug development in Indonesia', *International Journal of Health Governance*, 25(2), pp. 137–149. Available at: <https://doi.org/10.1108/IJHG-12-2019-0083>.
- Suwantika, A.A. et al. (2020) 'Cost-Effectiveness Analysis of Spending on Research and Development to Address the Needs for Innovative Therapeutic Products in Indonesia', *Therapeutics and Clinical Risk Management*, Volume 16, pp. 969–977. Available at: <https://doi.org/10.2147/TCRM.S260377>.
- The Jakarta Post (2018) 'Pharma companies still dependent on imported APIs, says ministry', *The Jakarta Post*. Available at: <https://www.thejakartapost.com/news/2018/10/18/pharma-companies-still-dependent-on-imported-apis-says-ministry.html>.
- Theodore, W. et al. (2022) 'The effects of task environment and organizational agility on perceived managerial discretion and strategy

- implementation in a pharmaceutical company', *International Journal of Pharmaceutical and Healthcare Marketing*, 16(2), pp. 204–221. Available at: <https://doi.org/10.1108/IJPHM-11-2021-0116>.
- United Nations (2012) *Local production of pharmaceuticals and related technology transfer in developing countries: a series de case studies*. New York and Geneva: United Nations.
- Warsito, I. (2022) 'Readiness of Upstream and Downstream Industries in Supporting Independence of Pharmaceutical and Medical Devices'.
- Winda, S. (2018) 'Formularium Nasional (FORNAS) dan e-Catalogue Obat Sebagai Upaya Pencegahan Korupsi dalam Tata Kelola Obat Jaminan Kesehatan Nasional (JKN)', *Integritas*, 4(2), pp. 177–207.
- World Bank (2022) 'Current Health Expenditure per Capita'. Available at: <https://data.worldbank.org/indicator/SH.XPD.CHEX.PC.CD?end=2021&start=2021&view=bar> (Accessed: 9 August 2022).
- World Health Organization (2017) *Indian policies to promote local production of pharmaceutical products and protect public health*. Geneva: World Health Organization. Available at: <https://apps.who.int/iris/handle/10665/336750> (Accessed: 19 September 2022).
- Yang, B., Usman, M. and jahanger, A. (2021) 'Do industrialization, economic growth and globalization processes influence the ecological footprint and healthcare expenditures? Fresh insights based on the STIRPAT model for countries with the highest healthcare expenditures', *Sustainable Production and Consumption*, 28, pp. 893–910. Available at: <https://doi.org/10.1016/j.spc.2021.07.020>.