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Strategy for developing the Active Pharmaceutical Ingredients (api) industry in order to improve the resilience and competitiveness of the country's pharmaceutical industry

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CITATION

Siregar P, Ma'arif M S, Jahroh S et al. (2025). Strategy for developing the Active Pharmaceutical Ingredients (api) industry in order to improve the resilience and competitiveness of the country's pharmaceutical industry. *Journal of Infrastructure, Policy and Development*. 9(4): 10297. <https://doi.org/10.24294/jipd10297>

ARTICLE INFO

Received: 13 November 2024

Accepted: 27 December 2024

Available online: 17 November 2025

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Abstract: The study aims to determine the development strategy of the Active Pharmaceutical Ingredients (API) industry in Indonesia to improve the resilience and competitiveness of the national pharmaceutical industry. The independence of the Indonesian pharmaceutical industry is low because the dependence on API imports is high, reaching 90-95%, thus threatening public health services and resilience. The method used is the Analytic Hierarchy Process (AHP), involving 13 experts from various sectors. The results of the study indicate that government involvement is the main priority in the development of the API industry, followed by the selection of API molecules and the development of partnerships. The proposed strategy is expected to accelerate the development of the local API industry to improve health resilience and reduce dependence on imports in the short term, while increasing the competitiveness of the Indonesian pharmaceutical industry in the medium to long term.

Keywords: API industry; government; resilience; strategy

1. Introduction

The world is highly dependent on API supplies from China and India (Cherian et al., 2019). The impact of a country's health vulnerability is very pronounced when facing the COVID-19 pandemic. In addition, various issues, such as the potential for a future pandemic, geopolitics, and geoeconomics, are increasingly creating anxiety about the vulnerability of API supplies and drug availability in the country (Shukar et al., 2021). Suarez (2024) explains that fears of future problems related to the availability of drugs and API drug raw materials have made the government try to manage the supply chain in various ways.

Chemical drugs are still the main choice in health services, with a portion reaching more than 70% (EvaluatePharma, May 2019). High dependence on chemical API imports threatens the pharmaceutical industry and can potentially disrupt public health's safety and resilience (Cherian et al., 2021; Executive Order 14001 2021; Executive Order 14017 2021; Korean Health Industry Development Institute 2021). API independence is very important, especially when or will be in an emergency such as a pandemic, war, or other extraordinary conditions that can cause health vulnerabilities (Zanoletti, 2021; Ruskar et al., 2021; Fernandes et al., 2021; Pylaeva et al., 2022).

API industry has the characteristics of low profits “2%-12% Gross Profit Margin”, is an upstream industry in the pharmaceutical industry supply chain so that it plays an important role in ensuring the availability of drugs (Chodankar & Kale, 2022). The high dependence on API imports, reaching 90%, causes Indonesia, as a country with a population of 280 million, the 4th largest in the world, to consider it important to build and develop a local API industry to reduce dependence and increase health resilience (CNBC, 2024).

Dependence on imports can pose a risk to the stability of drug supply, which in turn has the potential to disrupt public health services. With a strong raw material industry, Indonesia can be more independent and responsive in dealing with health crises. Security of drug supply is an integral part of national resilience, enabling the government to manage and respond to public health needs more effectively (Doroudi et al., 2018; Tucker et al., 2019; Li et al., 2020). As an upstream industry, the development of the API industry has the potential to significantly contribute to the national economy through multiplier effects by creating new jobs, encouraging investment, and increasing domestic pharmaceutical research and development capacity. Local API production will help Indonesia reduce import spending and increase state revenues. In addition, this industry can be a driving force for other sectors, such as research, technology development, and education (Wu & Liu, 2021). Investment in infrastructure and technology in this sector will also create opportunities to develop supporting industries, ultimately strengthening the overall industrial ecosystem (Dovletmurzaeva, 2023). Considering the importance of developing the API industry, strategy formulation is an important part that must be done. This is intended so that there is a scientific basis and by the needs for development according to conditions in Indonesia.

2. Method

The research design uses an exploratory approach to investigate problems and gain understanding. The research was conducted in Indonesia, focusing on the API industry, especially chemicals, from January 2023 to February 2024. The data collection process used interviews assisted by the Analytic Hierarchy Process (AHP) questionnaire. In this study, there were 13 experts from 3 groups, namely four respondents from the government, six from pharmaceutical and API industry practitioners, and three from academics and researchers.

Eriyatno (2012) stated that clarifying understanding of the problem being studied requires a hierarchical system structure. Depending on how the concept is used, there is a different understanding and view of the level. In the formulation of modern levels, Rosser (1994) defines *structure* as the arrangement of several sublevels about each other, assuming it is a regular structure.

Analytic Hierarchy Process (AHP) is a structured technique based on mathematics and psychology used to organize and analyze complex decisions. AHP was introduced in 1970 by Saaty (2010) and has been extensively studied and refined. The concept developed when a hierarchy is established is that the decision-maker systematically evaluates the different elements, comparing them individually according to their impact on the elements above them in the hierarchy. In contrast,

decision-makers may use concrete information about related elements, but they usually use their judgments about their meaning and importance. Essence of AHP is that human judgment can be used in the evaluation, not just the underlying information.

Saaty (2010) converts these judgments into numerical values that can be processed and compared across the problem domain. Numerical weights or priorities are assigned to each hierarchical element, making it possible to compare different and often dissimilar elements in an acceptable and consistent manner. The first step in AHP is to model the problem as a hierarchy. Madurika and Hemakumara (2015) state that participants examine aspects of the problem from a general level to a detailed level and then articulate them in the multilevel manner required by AHP. When building a hierarchy, it is required to broaden the understanding of the problem, its context, and the thoughts and feelings of each.

The AHP hierarchy is a structured way to model the decision at hand. It consists of a general goal, a set of options or alternatives, and factors or criteria that relate the options to the goal. The criteria can be further divided into sub-criteria at different levels if the problem requires it. The criteria do not have to apply equally, but differences may exist. The design of the AHP hierarchy depends not only on the type of problem being faced but also on the knowledge, judgment, values, opinions, needs, desires, etc., of those involved in the decision-making process. Building a hierarchy usually involves meaningful discussion, research, and discovery. Even after the initial design, it can be modified to meet new criteria or previously considered irrelevant criteria. The AHP decision hierarchy is built on a literature review and information from literature sources collected in fieldwork during the research phase, interview results, and a systematic and patterned methodological process.

3. Result and Discussion

Implementing a competitive API industry development model must be systematic, desirable, and feasible. In this case, it is necessary to develop an implementable strategy. Lopes et al. (2022) and Quaye and Mensah (2019) explain that strategy is an important step in developing an industry because there is a process to make the industry competitive and sustainable. This condition further explains that industrial development requires a clear and effective strategy to achieve long-term growth and success. Doeleman et al. (2021) explain that a clear and effective strategy requires details and details to consider resource limitations in implementing the strategy.

On the other hand, this is part of accommodating the model developed to be appropriate and based on recommendations. The strategy must be formulated in an implementable manner in order to make the plan a reality (Tawse & Tabesh, 2021). A strategy needs to be based on a decision to take action. Checkland (1985) explains that the decision made is a recommendation, so it must be feasible to be carried out in the situation. Recommendations state what changes need to be made, how to implement the changes, and a follow-up plan to implement and monitor the changes and evaluate the results. Recommendations for making a decision can be made in various ways, such as brainwriting, nominal group technique, Delphi method, and weighted matrices (Bono, 1970; Van and Delbecq, 1974; Helmer & Dalkey, 1963; Saaty, 2008).

The use of weighted matrices has the following advantages: 1) structured and systematic in analyzing various criteria and their importance, 2) quantitative scoring so that it is more objective than voting or discussion, 3) taking into account various views and preferences from various perspectives and 4) the final result is a clear priority for the selected alternatives. Weighted matrices have advantages but cannot yet accommodate each related part and cannot provide a complex picture. Saaty (2008) updated it to the Analytical Hierarchy Process (AHP), which has advantages including 1) organized hierarchical structure, 2) paired comparison, 3) consistency, and 4) sensitivity.

This makes AHP worthy of use for implementing strategy formulation recommendations. In this research, the AHP structure has four levels to develop the domestic API industry, each obtained from developing the sixth stage of the soft system method. At level 1, it focuses on stakeholder groups (actors) involved and playing a role in developing the domestic API industry. At Level 2 it focuses on important factors that are needed and must be owned in developing the domestic API industry. Level 3 focuses on criteria, namely the goals to be achieved in developing the domestic API industry, and level 4 focuses on alternative strategies that can be used to develop the domestic API industry. Expert information is processed using super decision software. The processing process requires Consistency Ratio (CR) conditions with a maximum limit of 0.10. Saaty (1994) stated that if the CR value exceeds 0.10, it indicates an inconsistency in the choice of comparison of each element. The inconsistency level value below 10% or 0.1 indicates that 13 expert respondents have appropriate answers and can be accepted as true. The description of each level and description of each element is as follows:

1. Actor
 - a. Government: The government is an organization that has the power to create and implement laws together with the Law and the authority to regulate communities in a certain area, which is generally a country.
 - b. Business Actors: Every individual or business entity, whether in the form of a legal entity or not a legal entity that is established and domiciled or carries out activities within the jurisdiction of the Republic of Indonesia, either alone or together through an agreement to carry out business activities in various economic fields. In this case, the focus is on API manufacturing companies.
 - c. Academics and Researchers: A person or group of people who are highly educated or someone who is pursuing a profession as a teacher, researcher, and professor at a university or research institution.
 - d. Association: An organization or association established and funded by a company operating in a particular industry to strengthen and togetherness of the sector. In this case, it is the pharmaceutical industry association and the API industry association.
2. Factors
 - a. Economic: Consideration of the establishment and operation of a company/industry based on economic or business feasibility calculations.
 - b. Technology: A part in the form of techniques, inventions, or tools intended to help accelerate the achievement of business goals.

- c. Human Resources: People who have the ability, skills, knowledge, and experience to assist in industrial development activities and the added value therein.
 - d. Raw Materials: The main components used in the production process to produce a product.
 - e. Government Policy: A series of actions or decisions taken by the government and government agencies to achieve certain goals.
3. Criteria
- a. Pharmaceutical resilience: Resilience and ability to guarantee and meet the needs of pharmaceutical preparations in the appropriate quantity, quality, and efficacy in all conditions.
 - b. Pharmaceutical independence: Own ability to guarantee and meet pharmaceutical preparations' needs in the appropriate quantity, quality, and efficacy in all conditions.
 - c. Competitiveness: The ability to produce pharmaceutical preparations that are superior to competitors in price, quality, and service to attract and retain consumers.
4. Alternatives
- a. Strengthening R&D: Activities carried out by the industry to innovate, develop, and improve new products, services, or processes.
 - b. Government Involvement: The active role of the government in making policies, providing fiscal and non-fiscal facilities, and being directly involved in producing API to develop the API industry.
 - c. Global Market Penetration: Activities carried out by industry to expand its reach and presence in the international market. In this case, it aims to increase the company's market share, sales, and profits by reaching consumers abroad.
 - d. API Molecule Selection: Selection of API molecules to be produced domestically
 - e. Supporting Industry Development: Development of industries involved and playing a role in API production, especially upstream industries of the API industry, namely the petrochemical industry, chemical industry, and intermediate API.
 - f. Building Partnerships: Seeking cooperation partners, especially in obtaining the technology and capabilities needed to develop the API industry and market development.
 - g. API Industry Human Resources Development: Systematic and planned efforts to ensure the availability of competent human resources who can support the operation of the API industry, as well as effective development to improve the knowledge, skills, and competencies of employees working in the API industry.

The Analytical Hierarchy Process in this study was conducted by collecting data from 13 expert respondents with 123 questions. The data collected from the experts was then checked for consistency to ensure that the data obtained was valid. Data processing using Microsoft Office Excel software, the processing results from each respondent were then combined with the calculation of the average value. Muzaqin

and Cahyadi (2019) explained that to obtain the priority of each level, an average calculation approach can be used from the values obtained in each element or part. The following is an explanation:

1. Actor

Level Determination of the priority of actors in the development of the domestic API industry is based on the determination of stakeholders who play a role, the size of their role, and their influence on the industrial ecosystem. The API industry in Indonesia is an infant industry, so its development is very different from the development of a mature industry. The calculations carried out provide results in **Table 1**.

Table 1. Actor Level Processing Weight.

Actor	Weight	Priority	Inconsistency
Government	50,88%	1	6,58%
Business Actor	26,75%	2	
Academics and Researchers	14,75%	3	
Association	7,59%	4	

Source: Primary Data (2024).

There are 4 actors who have an important role in the development of the domestic API industry. The government is the most important actor, acting as a motor and overseeing the development of the domestic API industry (50.88%). The domestic API industry does not yet have. It has difficulty having comparative and competitive advantage, so if the competition is left to the market mechanism (economic market), it will not be able to compete with the current global API market leaders, namely China and India. The government is an actor who can design and direct competition in an industry according to government needs (Mugo & Macharia, 2021). Respondents stated that business actors are the second priority in developing the domestic API industry (26.75%), considering that business actors will only be interested in entering and investing in the API industry if it is economically and business attractive. Academics and researchers (14.75%) are the third priority, considering that their contribution in the form of human resource development and API R&D to increase the competitive advantage of the API industry takes time. Association (7.59%) is the last priority in developing the domestic BBO industry based on the function of a support system in a business community. However, business decisions are in the hands of company management.

2. Factor

Level Factors are needed elements or resources that play an important role and must be owned to develop the domestic API industry. Five factors have been agreed to play a role in developing the domestic API industry: raw materials, government policies, economics, human resources, and technology. Industrial development, in general, is required to have the strength to compete in the market. However, in terms of the API industry development process, a different driving factor is needed because the API industry is still an infant industry. The calculations that have been transformed are as in **Table 2**.

Table 2. Factor Level Processing Weight.

Description	Raw Materials	Government Policy	Economic	HR	Technology	Inconsistency
Academics and Researchers	5,5%	38,7%	27,3%	6,8%	21,6%	6,7%
Association	5,3%	39,9%	30,3%	9,5%	15,1%	7,4%
Domestic API industry	4,9%	39,5%	30,6%	8,2%	16,7%	8,2%
Government	4,6%	39,7%	30,1%	9,6%	16,0%	7,7%
Final	5,1%	39,5%	29,6%	8,6%	17,3%	7,5%
Priority	5	1	2	4	3	<10%

Source: Primary Data (2024).

Government policy (39.1%) is the most needed factor. It plays an important role in resolving various business challenges, such as low economics, and technical challenges, such as changing source regulations for domestically produced APIs. Economic factors attract business actors to invest in the industry, becoming priority number 2 (29.6%). Although there are challenges in owning API production technology, this factor can still be managed with various approaches, such as cooperation with other parties with the required technology, making it a priority factor number 3 (17.3%). Like technology, partnership cooperation with API manufacturers from China and India will be able to help with the limitations of HR capabilities in API production know-how, making it a priority factor number 4 (8.6%). The fifth priority is raw materials (5.1%), considering that the development of the chemical and intermediate API industry takes a long time (takes time). However, in the near term, it can use global sources such as China, as is done by the API industry in various countries, including India (Huq et al., 2016; Eshoo & Schiff, 2019; Nikkei Asia, 2021c).

3. Criteria Level

Criteria are the goals to be achieved in developing the domestic API industry. As calculated in **Table 3**, there are three criteria or goals for the development of the domestic API industry: resilience, independence, and competitiveness.

Table 3. Criteria Level Processing Weight.

Description	National Pharmaceutical Competitiveness	Pharmaceutical Independence	Pharmaceutical Resilience	Inconsistency
Raw Materials	12,5%	25,1%	62,4%	4,5%
Government Policy	11,1%	30,8%	58,1%	2,8%
Economic	12,9%	35,6%	51,5%	5,0%
HR	11,6%	31,8%	56,7%	4,5%
Technology	12,9%	32,4%	54,7%	4,8%
Final	12,2%	31,1%	56,7%	4,3%
Priority	3	2	1	<10%

Source: Primary Data (2024).

The impact of the COVID-19 pandemic, concerns about the threat of the next pandemic, and various geopolitical and economic issues have encouraged the government to develop the domestic API industry to increase health resilience through

API independence. National resilience and health resilience are the ultimate goals that require pharmaceutical independence through API independence to increase sustainability, so resilience is the priority, and independence is the second priority. Resilience is an increase in the ability to absorb problems, recover from problems, adapt to new situations, and learn to anticipate if similar problems or other potential forms occur. Meanwhile, independence is an effort to increase operational capabilities for domestic production to reduce dependence on imports significantly. In the medium to long term, the existence of the domestic API industry is expected to increase the competitiveness of the domestic pharmaceutical industry so that it can compete in the global market.

4. Alternative Strategy

Level 7 alternative strategies are important to achieve the criteria or objectives of developing the domestic API industry, the calculations of which have been transformed as in **Table 4**.

Table 4. Alternative Strategy Level Processing Weight.

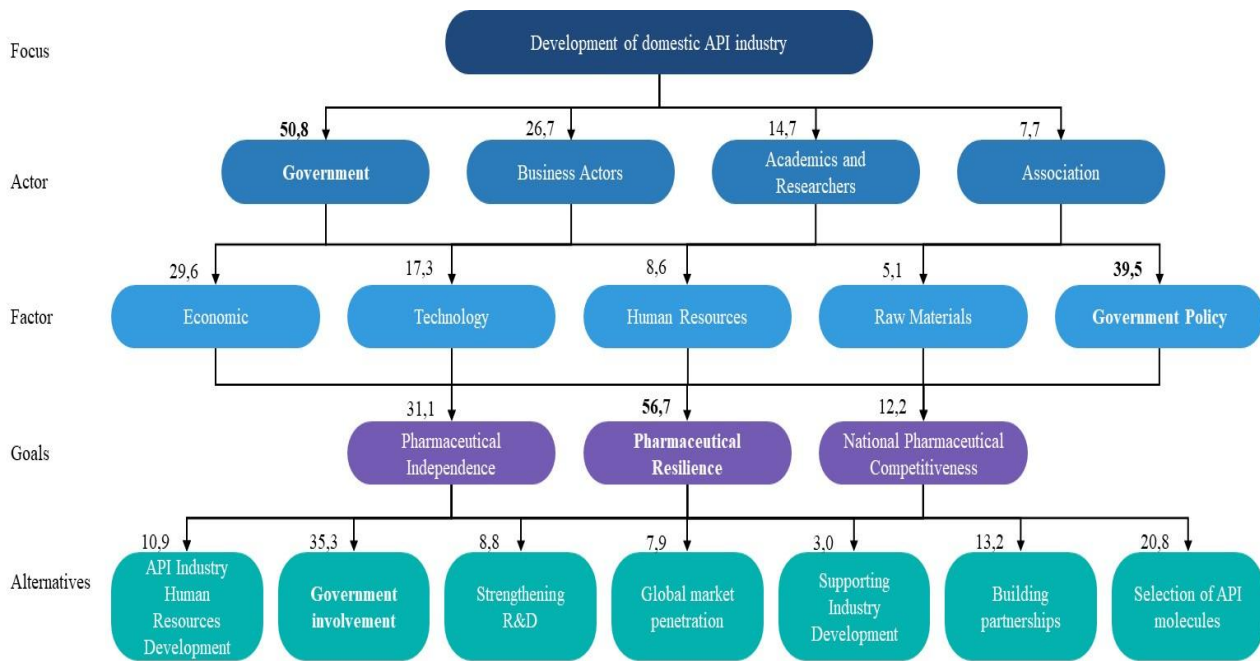
Description	National Pharmaceutical Competitiveness	Pharmaceutical Independence	Pharmaceutical Resilience	Average	Priority
Government involvement	34,6%	38,2%	33,1%	35,3%	1
Selection of API molecules	22,0%	21,4%	18,9%	20,8%	2
Building partnerships	11,2%	15,0%	13,5%	13,2%	3
API Industry Human Resources Development	12,0%	8,9%	11,9%	10,9%	4
Strengthening R&D	8,7%	8,4%	9,3%	8,8%	5
Global market penetration	9,0%	5,1%	9,7%	7,9%	6
Supporting Industry Development	2,4%	2,9%	3,6%	3,0%	7
Inconsistency	9,2%	8,6%	8,7%	8,8%	<10%

Source: Primary Data (2024).

Government involvement is the priority strategic alternative in developing the domestic API industry. The major challenge of developing the domestic API industry using a business approach requires high government involvement through government policies and direct API production through assignments to relevant government institutions such as the TNI (Military) Pharmaceutical Institute or BUMN. Selection of API molecules that are a priority for domestic production must be carried out because the number of chemical API molecules is large while the resources available are limited. The selection of API molecules is the second priority alternative strategy that can be carried out by setting selection criteria, such as those urgently needed to support the national health insurance program and a roadmap for developing API molecules. Building partnerships with other parties that, in the short term, can help develop technology and HR capabilities to produce API are the third and fourth strategic priorities.

In the medium to long term, domestic universities and research institutions can prepare competitive API technology and HR. The fifth strategic priority is strengthening research and development, the main capital used to produce and increase the competitive advantage of the domestic API industry. Global market penetration to

increase economies of scale is the sixth strategy, which can be carried out by increasing the competitive advantage of the domestic API industry. The last alternative strategy is the development of supporting industries, especially upstream industries of the API industry, namely the chemical industry and intermediate API. The development of this upstream industry is also an important part of efforts to improve the competitiveness of the domestic API industry. The description and final results of the Analytical Hierarchy Process in the research on the development of the domestic API industry are presented in **Figure 1**.



Source: Transformation of Primary Data Processing (2024)

Figure 1. Analytical Hierarchy Process of Domestic API Industry Development.

The API industry in Indonesia is an infant industry that, with an economy market approach, will compete directly in global competition against the global API market leaders, namely the Chinese and Indian API industries. The competitive and comparative advantages possessed by the Chinese and Indian API industries make the development of the API industry in several countries face major challenges if carried out with a business approach. The success story of the government's active role in the development of infant industries has occurred in several countries, such as South Korea, which developed the electronics and automotive industries starting in 1960 (Al-Shamsi, 2022), Taiwan which developed the textile and semiconductor industries with support in the form of incentives, subsidies and cheap funding (Auty, 1997), China which issued a breakthrough policy by opening a special economic zone in 1980 (Lu et al., 2019; Riccardi, 2022). The development of the domestic API industry requires the main driver, namely the government.

Government policy is an important thing that plays a role in the development process of an industry that is mature or infant. In general, government policy is very important for the industry because the government has a role in creating a conducive and attractive regulatory framework (Fazlagic & Szczepankiewicz, 2020), providing

supporting infrastructure that can encourage efficiency in the industry (Foster et al., 2023), protection and promotion of products that have been produced domestically to maintain trade stability (Maswood, 2018; Osabuohien et al., 2018).

The development of the infant industry requires different support from mature industries. According to Thaker (2018), Jankowska et al. (2021), and Bencheckroun and Long (2018), the infant industry requires several government policies such as 1) Market protection through the imposition of tariffs and import quota restrictions, this is intended to protect the entry of products from countries that are competitive. Implementation is carried out by setting higher import tariffs to protect local products from competition with imported products and implementing import quotas to limit the entry of foreign products and provide market space for domestic industries. 2) Provision of subsidies and fiscal incentives for the domestic API industry; this is intended so that the industry's cost production from the industry is better. Implementation can be done by providing incentives for production and tax reductions, and 3) Use in the local market, intended so that domestic BBO products can be absorbed in the domestic market so that it can increase economies of scale.

Realizing cooperation between government, business, and academia is essential in facing complex challenges. All parties can work effectively and efficiently by identifying common goals, forming collaborative forums, and developing clear action plans. Gu et al. (2023) explained that collaboration between stakeholders can encourage ease in facing the issue's challenges. The concept of government involvement is closely related to active activities; it is known that government involvement in the development of the API industry is a natural thing. The Indian government, through the Ministry of Chemicals and Fertilizers (2021), has actively provided various assistance to increase investment and production, encourage local companies to establish or expand manufacturing units, create many jobs, and reduce dependency. China actively supports the development of mass and rapid industry, including 1) Technology support, 2) Cheap land, 3) availability of raw materials, and 4) support for other industries (Cherian *et al.*, 2019).

Health resilience through pharmaceutical resilience is an important criterion or goal that is a priority in developing the domestic API industry. The basic concept of pharmaceutical resilience is to increase resilience and ability to guarantee and meet the needs of pharmaceutical preparations, which are available in terms of quantity, quality, and efficacy in all conditions. The concept of resilience is a platform that must be prioritized in order to prepare oneself to adapt to all dangerous things that can happen by absorbing problems that may arise, recovering when there is a problem, and anticipating similar incidents from happening again (Pettit et al., 2010; Blackhurst et al., 2011; Wildavsky, 1991; Rice & Caniato, 2003).

The development of the domestic API industry requires a strategy that can solve the challenges and problems of the industry. Government involvement is a strategic priority to achieve the established goal criteria. Policy support indicates the government's support for an issue so that all assistance from the government will be provided in the development process. The impact of government involvement will provide convenience for industry in doing business. Government involvement needs to be further strengthened by being directly involved in API production through assignments to related government institutions such as the Indonesian National Armed

Force Pharmaceutical Institute or BUMN, as well as through government policies that can resolve industrial problems, especially improving low economics. Government policies can be in the form of fiscal and non-fiscal facilities, including:

Table 5. Government Involvement in Fiscal and Non-Fiscal Facility Policies.

Facilities	Form	Description
Fiscal	Tax	Providing tax incentives, such as reducing or exempting income tax, VAT, or import duties, for companies investing in the API industry can encourage investment and expansion.
	Financing schemes	The government can provide financing schemes like credit or grants to help companies finance API development projects. This can reduce the initial investment burden and accelerate industry growth.
	Price subsidies and incentives	The government can provide subsidies or price incentives for API products to compete with fossil fuels. This can increase demand and help the API industry gain a wider market.
Non Fiscal	Infrastructure Support	The government can build or improve infrastructure that supports the API industry, such as production facilities, distribution networks, and access to raw material sources. This can reduce operational costs and increase industry efficiency.
	Regulatory and policy settings	The government can create a regulatory and policy framework that is conducive to the development of the API industry, such as renewable energy mix targets, quality standards, and rules related to land use. This can provide certainty and stability for the API industry.

4. Conclusion

Developing Indonesia's API industry requires a planned and systematic strategic approach. Considering the industry's low competitiveness, government involvement is very important in creating regulations and incentives that support the BBO industry. Increasing competitiveness requires cooperation between the government, business actors, and academics to develop competent human resources, technology, R&D, and supporting industries. The high complexity of the problems means that the domestic API industry development strategy needs to be carried out in stages.

The short-term strategy is to develop and improve the industry's sustainability to increase pharmaceutical independence and national health resilience. This strategy can be achieved by providing support through tax reductions, market protection, and market certainty. The medium- to long-term strategy is directed at increasing the competitiveness of the national pharmaceutical and API industry through developing an industrial ecosystem, which can be done by elaborating on all stakeholders. With the implementation of the right strategy, the API industry is expected to significantly contribute to improving national health resilience and the Indonesian economy. On the other hand, an in-depth analysis of the risks and challenges that may be faced during the policy process is needed. The goal is for the industry to develop competitively and sustainably.

Author contributions: Methodology & writing—PS, MSM, SJ, LT, BMBA. All authors have read and agreed to the published version of the manuscript.

Conflict of interest: The authors declare no conflict of interest.

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