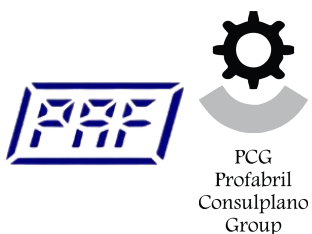




PHARMACEUTICAL IN INDONESIA

FACT SHEET



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TABLE OF CONTENT

1. Industry overview in Indonesia	3
2. Entry into the Indonesian Market: How to	5
a. Regulatory Compliance	6
b. Local Partnership	6
c. Trade and logistical aspects	7
d. Post-Market Surveillance	8
3. Market Analysis: Opportunities and Threats	9
a. Big Players / Market Share in Indonesia	10
b. Trends and Opportunities	15
c. Threats and challenges	18
4. Other relevant information	20
a. Official institutions	21
b. Business associations	22
c. Main exhibitions, fairs, trade shows or expos	23
Bibliography.	24



1. INDUSTRY OVERVIEW IN INDONESIA

Indonesia is one of the fastest-growing pharmaceutical markets in Asia and is home to 270 million people. With a market value of around USD 10.11 billion in 2021, this makes Indonesia the largest pharmaceutical market in the ASEAN region [1]. In 2021, the Ministry of Health also shared that there are 241 companies engaged in the pharmaceutical manufacturing industry, 17 companies in the pharmaceutical raw material industry, 132 companies in the traditional medicine industry, and 18 companies in the natural product extraction industry. The industry also saw an increase in the number of companies producing medical equipment – from 193 to 891 between 2015 and 2021 [2]. Pharmaceutical industry is one of the fastest growing industry in Indonesia. Even though the revenue of this industry is seeing a decline post pandemic, its growth is still relatively higher compared to other industries in Indonesia which is around 7%.

In addition, the Indonesian government has been implementing various initiatives to improve healthcare access and affordability, which has positively impacted the pharmaceutical market. These initiatives include the implementation of the National Health Insurance program (JKN) to provide coverage for the population. The Indonesian government also encourages the use of generic drugs to reduce healthcare costs. This has led to an increase in the consumption and production of generic medications.

[1] [HTTPS://I3L.AC.ID/INDONESIAS-ROLE-IN-PHARMACEUTICAL-MARKET/](https://i3l.ac.id/indonesias-role-in-pharmaceutical-market/)

[2] [HTTPS://VISIGLOBAL.CO.ID/CANTINGQIND/CONSTRUCTION-SECTOR/2630/2022/04/](https://visiglobal.co.id/cantingqind/construction-sector/2630/2022/04/)

HERE ARE SOME KEY POINTS ABOUT THE PHARMACEUTICAL INDUSTRY IN INDONESIA:



DOMESTIC PRODUCTION

Indonesia has a well-established pharmaceutical manufacturing sector, producing a wide range of pharmaceutical products, including generic drugs, over-the-counter (OTC) medicines, and traditional herbal medicines.

REGULATION

The pharmaceutical industry in Indonesia is highly regulated by the Indonesian Food and Drug Authority (BPOM - Badan Pengawas Obat dan Makanan). BPOM oversees the registration, production, and distribution of pharmaceutical products in the country.



IMPORT DEPENDENCY

While Indonesia has a strong pharmaceutical manufacturing sector, it still relies on imports for some specialized drugs and active pharmaceutical ingredients (APIs). This import dependency poses challenges for the industry's self-sufficiency.

TRADITIONAL MEDICINE

Traditional herbal medicine plays a significant role in Indonesia's healthcare system. The country has a long tradition of using herbs and traditional remedies, and many companies produce herbal products alongside conventional pharmaceuticals.



COUNTERFEIT MEDICINES

The pharmaceutical industry in Indonesia faces issues related to counterfeit medicines. This poses risks to public health and affects the reputation of both domestic and foreign pharmaceutical companies.

INVESTMENT OPPORTUNITIES

The Indonesian government has been encouraging foreign investment in the pharmaceutical sector to improve healthcare access and promote innovation. Joint ventures and partnerships with local companies are common avenues for foreign pharmaceutical firms to enter the market.

2. ENTRY INTO THE INDONESIAN MARKET: HOW TO

Entering the pharmaceutical market in Indonesia can be a complex process, but here are some important aspects to consider:



A. REGULATORY COMPLIANCE



Familiarize yourself with the regulatory framework governing the pharmaceutical industry in Indonesia. To enter the Indonesian market, the drugs must fulfil all safety requirements. The registration of the product is regulated under Indonesian National Agency of Drug and Food Control (BPOM). This includes obtaining necessary approvals, permits, and certifications. The registration must be done by the local company, local agent, or distributor before the products cleared to Indonesian customs. To import drug and food, the importer must apply Letter of Import (Surat Keterangan Impor or SKI) to the Head of BPOM [3]. It is essential to consult with legal, regulatory, and business experts familiar with the Indonesian pharmaceutical market to ensure compliance and maximize your chances of success.

B. LOCAL PARTNERSHIPS



Consider establishing partnerships or collaborations with local companies, distributors, or agents who have knowledge of the Indonesian market. They can provide valuable insights, distribution channels, and assist in navigating the local business landscape. If you plan to manufacture pharmaceutical products locally, ensure compliance with Good Manufacturing Practices (GMP) standards. Quality assurance is crucial to gain the trust of healthcare professionals, regulators, and consumers.

C. TRADE AND LOGISTICAL ASPECTS



Imported medicines must first register to get BPOM's distribution permit in Indonesia and must also have an import certificate or paper called Surat Keterangan Impor, abbreviated as SKI. The registration of imported medicines is carried out by the domestic pharmaceutical industry, which obtains written approval from the overseas pharmaceutical industry (localization). The written approval must include a technology transfer agreement with the provision that within a period of 5 (five) years, it must be produced domestically. In addition, foreign corporations operating in the pharmaceutical sector must meet the requirements as evidenced by the appropriate documents or, if necessary, a local inspection is carried out by the authorized officer [4].

The distribution network in Indonesia can be challenging due to the country's vast geography and archipelagic nature. However, efforts have been made to improve infrastructure, logistics, and supply chain management to enhance the availability of pharmaceutical products across the country. Develop a robust distribution and supply chain strategy to ensure efficient and timely delivery of your products. Work with reputable logistics providers and distributors who have experience in the Indonesian market. Consider the archipelagic nature of the country and design a network that can reach both urban and rural areas effectively.

D. POST-MARKET SURVEILLANCE (PMS)



Once your products are in the market, monitor their performance and address any feedback or concerns promptly. Maintain compliance with post-market surveillance (PMS) requirements, including adverse event reporting and product recalls if necessary.

PMS is crucial in the pharmaceutical industry in Indonesia, as in any other country, for several important reasons:

1. **Safety Monitoring:** PMS helps ensure the ongoing safety of pharmaceutical products once they are on the market. It allows regulatory authorities like the Indonesian Food and Drug Authority (BPOM) to detect and investigate adverse events, side effects, or safety concerns associated with drugs. This helps protect the health and well-being of patients.
2. **Quality Assurance:** It helps maintain the quality and efficacy of pharmaceutical products. Monitoring the post-market performance of drugs allows for the identification of quality issues or manufacturing defects that may not have been apparent during pre-market testing.
3. **Early Detection of Issues:** PMS can detect issues such as product contamination, substandard manufacturing practices, or unexpected side effects early on. Addressing these issues promptly can prevent widespread harm and product recalls.
4. **Pharmacovigilance:** Pharmacovigilance is a subset of PMS that focuses on monitoring and evaluating the safety of drugs. It involves the collection, analysis, and reporting of adverse drug reactions (ADRs). In Indonesia, as in other countries, pharmacovigilance activities are essential for assessing the risks and benefits of drugs and making informed decisions about their continued use.
5. **Building Trust:** Effective PMS and pharmacovigilance efforts build trust between the pharmaceutical industry, healthcare professionals, and the public. When people trust that their medications are closely monitored for safety, they are more likely to have confidence in the healthcare system.



3. MARKET ANALYSIS: OPPORTUNITIES AND THREATS



A. BIG PLAYERS / MARKET SHARE IN INDONESIA

Indonesia has a growing pharmaceutical manufacturing sector. The government has been promoting local production to reduce dependence on imported drugs and enhance self-sufficiency.

With 220 companies working in the pharmaceutical industry, the Indonesian market is quite fragmented and there is no dominant player. Although the local companies holds the majority of the market share of ~75%, the biggest market share a single company hold is only 6%. If the market is categorized by the company group, government own companies (BUMN) hold the largest share with close to 9% market share [5].

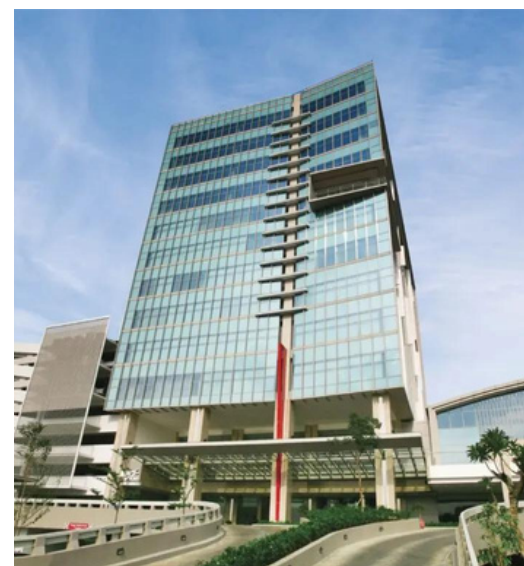
The big market share of pharmaceutical companies in Indonesia can have significant implications for various stakeholders, including consumers, competitors, regulators, and the companies themselves. The dominance of a few companies may limit consumer choice in some cases. This can affect the availability of generic alternatives and may impact healthcare access.

THE BIG PHARMACEUTICAL GROUPS IN INDONESIA (THAT HOLDS AT LEAST 5% OF MARKET SHARE) ARE:



BIO FARMA GROUP (GOVERNMENT OWN / BUMN) - [HTTPS://WWW.BIOFARMA.CO.ID/](https://www.biofarma.co.id/)

PT Bio Farma (Persero) is an Indonesian state-owned enterprise based in Bandung, West Java and the only local vaccine manufacturer in Indonesia, which produces vaccines and sera to support immunization in Indonesia and other countries. Bio Farma vaccine produced vaccines against measles, polio, hepatitis B, and pentavalent vaccine. Bio Farma has supplied vaccines to multiple countries through UNICEF, PAHO and other organizations. Since 2020, it also serves as the holding company for listed state-owned enterprises Kimia Farma and Indofarma.

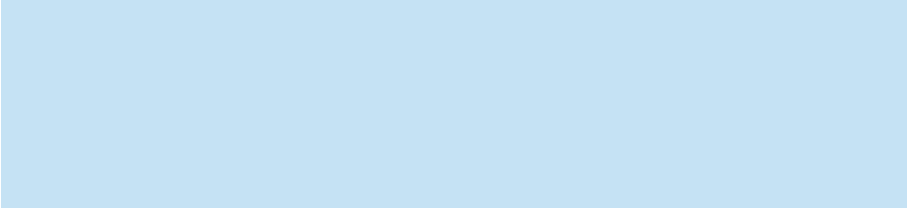


KALBE GROUP - [HTTPS://WWW.KALBE.CO.ID/EN](https://www.kalbe.co.id/en)

PT Kalbe Farma Tbk, or simply known as Kalbe, is an Indonesian pharmaceutical, healthcare and nutrition company established in 1966. Kalbe is the largest publicly listed pharmaceutical company in Southeast Asia with around US\$5 billion in market capitalization and revenues of over Rp 15 trillion. The company has expanded by strategic acquisitions of pharmaceutical companies, becoming an integrated consumer health and nutrition enterprise. The Kalbe Group has brands in the prescription drugs, OTC drugs, energy drink and nutrition products, distribution arm that reaches over 1 million outlets.

DEXA MEDICA GROUP - [HTTPS://WWW.DEXAGROUP.COM/ID/DEXA-MEDICA/](https://www.dexagroup.com/id/dexa-medica/)

Dexa Medica has evolved from a small company established in 1969 to one of Indonesia's largest ethical pharmaceutical companies at the beginning of the 21st century and has become a prominent, well-respected player in the domestic pharmaceutical market. Dexa Group has also developed Original Indonesian Modern Medicines (OMAI) from Indonesia's natural resources. BPOM is a strategic partner of the Dexa Group in developing OMAI which has been clinically tested so that it holds a phytopharmaca certificate and has been exported to foreign countries.



SANBE GROUP - [HTTP://WWW.SANBE-FARMA.COM/](http://www.sanbe-farma.com/)

PT Sanbe Farma is one of the pharmaceutical companies that was established in 1975. The company engages in drug sales, drug production and formulation development. After more than three decades since its inception, the company is the largest pharmaceutical manufacturer in Indonesia and this company is starting to rank highest among all Pharmaceutical Manufacturers in Indonesia including amongst Multinational Companies. PT Sanbe Farma has market coverage in Indonesia covering more than 37,000 doctors, served by 1,000 medical representatives, through a network of partners of 1,100 Sales people, 35 depots, 60 sub-depots and a corporate workforce of 8,000 personnel. The company has eight cGMP approved manufacturing facilities according to International Standards. PT Sanbe Farma conducts international operations in 20 countries, and makes a major contribution to global healthcare. International operations not only cover the export of formulations to various developing and under developed countries, but also seek partnerships and alliances from the market.

DARYA-VARIA - [HTTPS://WWW.DARYA-VARIA.COM/EN](https://www.darya-varia.com/en)

PT Darya-Varia Laboratoria Tbk (Darya-Varia) is a domestic investment pharmaceutical company established in 1976. In November 1994, Darya-Varia listed its shares on the Indonesia Stock Exchange (IDX) with the stock ticker code of DVLA. In 1995, Darya-Varia acquired PT Pradja Pharin (Prafa) and became the parent entity to continue expanding into the health sector in Indonesia. In 2014, the Company merged with Prafa, with Darya-Varia as the sole surviving entity. Currently, Darya-Varia operates two manufacturing plants that have met the international standards of current Good Manufacturing Practice (c-GMP) and standards set by the National Agency of Drug and Food Control (BPOM). Soft gelatin capsule products, liquid preparations, medicinal plasters, ointments, and creams are produced at the Gunung Putri Plant. In producing these products, Gunung Putri Plant implements an Integrated Management System and has obtained ISO 9001:2015, ISO 14001:2015, ISO 45001:2018 and ISO 22000:2018 certificates.



TEMPO SCAN - [HTTPS://WWW.TEMPOSCANGROUP.COM/EN](https://www.temposcangroup.com/en)

PT Tempo Scan Pacific Tbk and its subsidiaries are part of the Tempo Group, a group of companies which commenced its business activities through the establishment of PT PD Tempo on 3 November 1953 in the trading business of pharmaceutical products. The Company was established through the restructuring process in 1991 and originally named PT Sanchemie which in 1970 started its large scale commercial production of pharmaceutical products. With time, the Company through its subsidiaries has also manufactured cosmetics and consumer products since 1977. In 1994 the Company became public company and listed 75,000,000 shares on the Indonesia Stock Exchange/IDX (previously known as Jakarta Stock Exchange/JSX). Its brands & services includes Health Care, Consumer Care, Cosmetic, Prescription, Medical Devices, Distribution Services, and Manufacturing Facilities. The brands under Health Care, Consumer Care and Cosmetic categories are currently available in some countries and prominent in several markets, namely: Thailand (International Beauty Products Ltd. and RT Beauty Care Ltd.), Philippines (Tempo Scan Pacific Philippines Inc.), Malaysia (Tempo Scan Pacific Malaysia Sdn. Bhd.) also Nigeria and other African Countries (Tempo Scan Africa Ltd.).



B. TRENDS AND OPPORTUNITIES

The pharmaceutical market in Indonesia is dynamic and evolving, presenting several trends and opportunities. This strong growth factor of the pharmaceutical industry in Indonesia is supported by several elements such as the National Health Insurance (Jaminan Kesehatan Nasional also known as JKN), Generic Medicines, and drug manufacturing. JKN is a government program that aims to meet the needs of every resident, which ranges from 270 million people to have insurance and access to healthcare. The program, which was carried out starting in 2016, is expected to be evenly distributed in 2019.

The unbranded generic market contributed 10.8% to the growth of the pharmaceutical market. It is estimated at around IDR 8.7 trillion or equivalent to USD 619 million. It is hoped that this growth will keep rising in line with the JKN program. Hence, the main key to the expansion of the pharmaceutical market in Indonesia is an increase in the types of products and generic drugs.

Additionally, the government has eased the ownership restrictions. The government's new regulation on ownership limits states that foreign companies can get 100% ownership, which was previously only 75%.

The next page will tell you about the key trends and opportunities in the pharmaceutical market in Indonesia:



TRENDS

- **Growing Healthcare Demand:** Indonesia's large and increasingly affluent population is driving greater demand for healthcare services and pharmaceuticals. The expanding middle class is more willing to spend on healthcare, leading to increased consumption of pharmaceutical products.
- **Increased Investment:** There is a growing interest from domestic and foreign pharmaceutical companies in investing in Indonesia. Joint ventures, partnerships, and acquisitions are common strategies to tap into the market's potential.
- **Digital Health and Telemedicine:** The COVID-19 pandemic accelerated the adoption of digital health solutions and telemedicine in Indonesia. This trend is likely to continue, offering opportunities for pharmaceutical companies to develop digital health platforms and offer remote healthcare services.
- **Generic Drugs:** The demand for generic drugs is on the rise as they are often more affordable than branded counterparts. This presents an opportunity for companies focusing on generic pharmaceuticals.
- **Biotechnology and Innovation:** The pharmaceutical industry in Indonesia is gradually embracing biotechnology and innovation. Investments in research and development (R&D) are increasing, with a focus on developing novel and biologically derived drugs.
- **Pharmacovigilance:** There is a growing emphasis on pharmacovigilance and post-market surveillance to ensure the safety and efficacy of pharmaceutical products. Companies that can effectively monitor and report adverse events will have a competitive advantage.



OPPORTUNITIES

- **Vaccines:** The COVID-19 pandemic has highlighted the importance of vaccine production and distribution. There are opportunities for pharmaceutical companies to invest in vaccine manufacturing and distribution in Indonesia.
- **Chronic Disease Management:** With the rising prevalence of chronic diseases like diabetes and cardiovascular conditions, there is a growing need for medications and therapies for long-term disease management.
- **Herbal and Traditional Medicine:** Indonesia has a strong tradition of herbal and traditional medicine. Companies that can combine traditional remedies with modern pharmaceutical practices have opportunities in this segment.
- **Export Potential:** Indonesia's strategic location in Southeast Asia makes it a potential hub for pharmaceutical exports to neighboring countries. Companies can leverage this geographical advantage to expand their reach.
- **E-commerce:** The growth of e-commerce in Indonesia offers pharmaceutical companies a platform to reach a wider consumer base. Online pharmacies and medication delivery services are gaining popularity.
- **Biosimilars:** The development and production of biosimilars (biological products that are highly similar to already approved biologics) present opportunities for pharmaceutical companies, as they offer cost-effective alternatives to biologics.
- **Healthcare Access:** Addressing healthcare access challenges in rural and underserved areas presents opportunities for pharmaceutical companies to expand their distribution networks and improve patient reach.



C. THREATS AND CHALLENGES

The pharmaceutical market in Indonesia faces challenges such as price controls, intellectual property rights issues, counterfeiting, and limited healthcare infrastructure in some regions. These challenges can impact market growth and profitability of the companies. Understand the needs and preferences of healthcare professionals, hospitals, pharmacies, and end consumers would increase the success of market penetration in Indonesia.

Here are several key challenges to be considered before entering pharmaceutical market in Indonesia:

- **Regulatory Hurdles:** Indonesia has stringent regulations governing the pharmaceutical industry, overseen by the Indonesian Food and Drug Authority (BPOM - Badan Pengawas Obat dan Makanan). Navigating the complex regulatory environment, including product registration, compliance, and labeling requirements, can be time-consuming and costly.
- **Local Manufacturing Requirements:** To establish a pharmaceutical manufacturing presence in Indonesia, companies may face requirements for local production facilities, which can involve significant capital investment.
- **Import Restrictions:** While Indonesia has a growing pharmaceutical manufacturing sector, it still relies on imports for certain specialized drugs and active pharmaceutical ingredients (APIs). Companies looking to import pharmaceutical products must comply with import regulations and may face competition from local manufacturers.

- **Distribution Challenges:** Indonesia's archipelagic geography presents distribution challenges. Ensuring efficient and reliable distribution of pharmaceutical products across the vast and diverse nation can be logistically demanding.
- **Price Controls:** The government of Indonesia has implemented price controls on certain pharmaceutical products to ensure affordability. These controls can affect profit margins for pharmaceutical companies.
- **Counterfeit Medicines:** Indonesia has had issues with counterfeit medicines. Ensuring the authenticity and quality of pharmaceutical products is critical, and companies need robust anti-counterfeiting measures.
- **Cultural and Language Differences:** Understanding the local culture and language is essential for effective marketing and communication in Indonesia. Companies may need to adapt their marketing and promotional strategies to resonate with the local population.
- **Intellectual Property Protection:** Intellectual property protection can be a concern, and companies must take steps to safeguard their patents, trademarks, and other intellectual property rights.
- **Political and Economic Factors:** Indonesia's political and economic landscape can be dynamic and subject to changes that may impact the pharmaceutical industry. Staying informed about these factors is crucial.
- **Cultural Sensitivity:** Understanding and respecting local customs and cultural sensitivities is essential for building trust and credibility in the Indonesian market.

Companies willing to navigate these challenges can find opportunities for growth and impact in Indonesia's pharmaceutical sector.

4. OTHER RELEVANT INFORMATION



A. OFFICIAL INSTITUTIONS

MINISTRY OF HEALTH - [HTTPS://WWW.KEMKES.GO.ID/](https://www.kemkes.go.id/)

The Ministry of Health (Indonesian: Kementerian Kesehatan) is a government ministry which organize public health affairs within the Indonesian government. It has the Directorate General of Pharmaceutical and Medical Devices who carries out the formulation and implementation of policies, preparation of norms, standards, procedures, and criteria, provision of technical guidance and supervision, evaluation, and reporting in the field of pharmaceutical production and distribution.

NATIONAL AGENCY OF DRUG AND FOOD CONTROL (BPOM) - [HTTPS://WWW.POM.GO.ID/](https://www.pom.go.id/)

Badan POM/BPOM or Indonesian FDA, is a government agency of Indonesia responsible for protecting public health through the control and supervision of prescription and over-the-counter pharmaceutical drugs (medication), vaccines, biopharmaceuticals, dietary supplements, food safety, traditional medicine and cosmetics.

THE DIRECTORATE GENERAL OF CUSTOMS AND EXCISE - [HTTPS://WWW.BEACUKAI.GO.ID/](https://www.beacukai.go.id/)

The Directorate General of Customs and Excise (Indonesian: Direktorat Jenderal Bea dan Cukai abbreviated Bea Cukai or DJBC) is an Indonesian government agency under Ministry of Finance that serves the community in the field of customs and excise. The Directorate General of Customs and Excise has the duty to organize the formulation and implementation of policies in the field of supervision, law enforcement, service and optimization of state revenue in the field of customs and excise in accordance with the provisions of legislation. The directorate also carry out some basic tasks of the Ministry of Finance in the field of customs and excise, in accordance with policies established by the Minister and securing government policies relating to the traffic of goods entering or leaving the Customs Area and the collection of import duties and excise and other state levies based on legislation apply.

B. BUSINESS ASSOCIATIONS

GP (GABUNGAN PERUSAHAAN) FARMASI INDONESIA - HTTPS://WWW.GPFARMASI.ID/

The Association of Indonesian Pharmaceutical Companies (G.P. PHARMACEUTICAL INDONESIA) was established on August 19, 1969 in Lembang, West Java by delegates representing pharmaceutical businesses from all over Indonesia. The Association of Indonesian Pharmaceutical Companies is a forum for communication and consultation between pharmaceutical entrepreneurs and between entrepreneurs and the government as well as other related parties on matters related to drug production, drug distribution and drug services.

ASOSIASI PENDIDIKAN TINGGI FARMASI INDONESIA - HTTPS://APTFI.OR.ID/

Based on the ideas developed at the Congress of the Indonesian Pharmacy Graduate Association (ISFI) in Jakarta in 2000, and supported by the Communication Forum for State Pharmaceutical Universities throughout Indonesia, it was agreed to form the Association of Indonesian Pharmacy Higher Education that would accommodate all pharmaceutical higher education institutions in Indonesia.

Attended by representatives from higher pharmaceutical education institutions, Airlangga University, Surabaya University, Widya Mandala University, Gajah Mada University, Sanata Dharma University, Ahmad Dahlan University, Pancasila University, Seventeen August 45 University, University of Indonesia, National Institute of Science and Technology, Bandung Institute of Technology, Andalas University, and Hasanuddin University, the Indonesian Pharmaceutical Higher Education Association (APTFI) was formed on August 29, 2000.

C. MAIN EXHIBITIONS, FAIRS, TRADE SHOWS OR EXPOS



- Indonesia Pharmaceutical Expo (IPEX)
- Indo Health Care Expo
- Indonesia International Pharmaceutical (Inapharm)
- Hospital Expo

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AS YOUR TRUSTED PARTNER, WE OFFER A WIDE RANGE OF RESOURCES, NETWORKING OPPORTUNITIES, AND ADVOCACY EFFORTS TAILORED TO MEET YOUR UNIQUE NEEDS. OUR DEDICATED TEAM IS AVAILABLE TO PROVIDE GUIDANCE, CONNECT YOU WITH STRATEGIC PARTNERSHIPS, AND KEEP YOU INFORMED ABOUT THE LATEST INDUSTRY TRENDS AND REGULATORY DEVELOPMENTS IN INDONESIA.

TOGETHER, WE CAN NAVIGATE CHALLENGES, UNLOCK NEW OPPORTUNITIES, AND BUILD A PROSPEROUS FUTURE. WE INVITE YOU TO LEVERAGE THE POWER OF COLLABORATION WITHIN OUR DYNAMIC BUSINESS ECOSYSTEM. JOIN US, AND LET'S SHAPE THE FUTURE OF COMMERCE, DRIVE INNOVATION, AND CREATE LASTING IMPACT.

THANK YOU FOR BEING PART OF OUR VIBRANT BUSINESS COMMUNITY.



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