Flanders
State of the Art

HEALTHCARE & MEDICAL SECTOR IN INDONESIA

FLANDERS INVESTMENT & TRADE MARKET SURVEY

FLANDERS
INVESTMENT
& TRADE

Market Study

//

HEALTHCARE & MEDICAL SECTOR IN INDONESIA

Publication date / September 2023

//

Flanders Investment & Trade Jakarta

T +62 21 316 2036
jakarta@fitagency.com

Flanders
State of the Art

CONTENTS

1. OVERVIEW OF HEALTHCARE SYSTEM

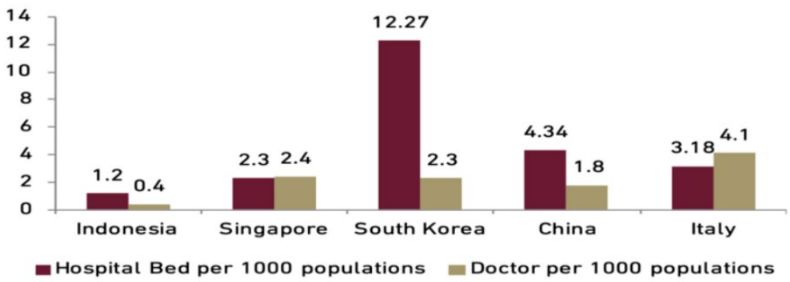
Indonesia introduced its universal healthcare program, the JKN, in 2014, which has since grown into the world's largest, covering over 200 million people. The program is run by the Social Security Administrator for Health (BPJS) agency, and every citizen as well as expats working in the country are mandated to join the program. All companies in the country are responsible for registering their employees and paying a percentage of their premiums. Those registered with the BPJS program are eligible to receive free health services ranging from simple dental check-ups to serious procedures, such as organ transplant.

Roughly 20 million Indonesians are covered by private health insurance, although this is dwarfed by the number covered by the JKN program. Additionally, as businesses in the country are obliged to enroll their employees in the program, many have chosen not to participate in private health insurance schemes. The ranks of those that can afford private insurance are, however, increasing as the middle and affluent class demand faster and a better-quality service. Private insurers will play an important role as an add-on to public coverage like the JKN which, although providing a free service, will only pay up to patient limits.

In the private sector, the employer must pay four percent and the employee the remaining one percent. For civil servants, the government contributes three percent while the employees contribute two percent. In addition to the employee, the premium also covers their spouse and up to three dependent children up to the age of 21. Starting from June 2020, the government has been doubling premiums for the program, hoping this can reduce the program's deficit which reached US$2.3 billion in 2019.

The Health Ministry aims to expand and standardize the country's thousands of integrated health services posts (Posyandu) and community health centers (Puskesmas) so that it can provide primary healthcare to all ages and conduct lab testing as well as screen for deadly illnesses, such as cancer, strokes and tuberculosis.

According to world bank data, the ratio of hospital beds in Indonesia for every 1000 populations is only 1.2, lower than Singapore with 2.3, or South Korea with 12.27. The doctor ratio for every 1000 population is only 0.4, lower compared to other countries. In terms of spending, healthcare spending is still low, at 2.9% of GDP, lower than the average of countries with low-income level 6.1% of GDP, and also lower than the average of East Asia Pacific countries with 7.4% of GDP. Even with the currently low healthcare spending, most private hospitals are already overcrowded and profitable, which implies a huge growth opportunity. Hence, there is still much room for improvement on Indonesia's Healthcare sector.



Source: WDI World Bank, Ciptadana Sekuritas Asia

Also, approximately 40% of Indonesia's 275 million citizens are living on less than USD$ 3.10 per day. The archipelago geography poses a significant challenge to providing accessible healthcare throughout the nation. Vital infrastructures, such as roads, are poorly available especially in the eastern part of Indonesia. Furthermore, healthcare currently takes up only 5 -6% of Indonesia's state budget and a small fraction of this is made available to regional governments. This data alone indicates the difficult effort to provide equal healthcare services to all.

Consequently, individuals residing in Indonesia's rural and distant regions frequently encounter the following problems:

- Weak primary healthcare services
- Almost non-existent secondary specialized care
- 62.9% of population lack access to hospitals
- 60.8% of population lack access to primary healthcare facilities (Puskesmas, Pustu, Midwife)

Even though the infrastructure is in place, significant numbers of primary healthcare facilities have no doctors; mostly in Papua (45.2%), Maluku (44.9%), Papua Barat (40%), Sulawesi Tenggara (29.5%), and NTT (20.5%).

Comparison of Number of Healthcare Providers in Jakarta vs. Eastern Indonesia

Low Doctor-to-Patient Ratio:

Jakarta: 1 Doctor vs. 350 People

Maluku + Papua: 1 Doctor vs. 4000 People

Jakarta: ~27,000 Registered Doctors vs. 10.3m People

Maluku + Papua: ~1,700 Registered Doctors vs. 6.5m People

Stunting, a consequence of inadequate nutrition during both the prenatal period and early childhood, leads to irreversible and debilitating growth impairment. Children affected by stunting will never reach their full potential height and experience restricted brain development, consequently affecting their cognitive capabilities. According to global malnutrition standards, Indonesia falls into the category of having a high prevalence of malnutrition.

- 1/3 Children (under 5yo) Are Malnourished
- 30% Stunting (Low Height for Age)
- 16.6% Wasting (Low Weight for Height)
- 17.5% Under Weight (Low Weight for Age)
- Infant Mortality Rate 60/1000

2. MEDICAL DEVICES AND HEALTH TECH MARKET

The Indonesian medical device and lab equipment industry continues to grow significantly. According to data, provided by the International Trade Administration at the US Dept. of Commerce, the market size of the Indonesian medical device and lab equipment reached some US$3.85 billion in 2022, up from $2.85 billion in 2019. The International Trade Administration determines market size by adding the amount of imported medical devices with the number of devices produced locally, and then subtracting the total with the number of devices that are exported.

That estimate finds further supported in the data from the Ministry of Investment, also known as the Indonesian Investment Coordinating Agency or BKPM. Their records highlight a significant upsurge in the number of medical devices and equipment production facilities, rising from 193 in 2015 to 891 in 2021—a remarkable 361.6% increase in just five years.

One of the catalysts behind this progress is the implementation of a national health insurance scheme known as Jaminan Kesehatan Nasional, or JKN.

In tandem with this, Indonesia aspires to develop its own cutting-edge medical technologies. Historically, the nation has heavily relied on imported medical technologies such as dental x-ray machines, CT scanners, and ventilators. A 2020 Ministry of Health report revealed that approximately 94 percent of medical devices in the country are imported. In 2021 alone, Indonesia imported medical devices and equipment worth Rp 12.5 trillion. Local production predominantly focuses on disposable items such as surgical masks, gloves, and hospital beds.

While imported products dominate the market, primarily encompassing sophisticated medical instruments, exports of medical devices amounted to less than US$267 million in 2019. These exports were largely composed of low added-value products like masks, surgical gloves, and hospital furniture.

These imports predominantly consist of technologically advanced medical instruments and infrastructure, including diagnostic tools, medical lasers, CT scans, and other diagnostic equipment. However, even basic medical devices such as tweezers and scissors for eye surgery are part of this landscape. Several high-tech medical devices, like units for radiotherapy, cardiotocography, electrical mucus suction, mobile X-rays, mammography, digital panoramic imaging, dental X-rays, cryosurgery equipment, and dental elevators, among others, are yet to be manufactured within Indonesia.

Given this, the Indonesian government continues to drive the development of the local medical device industry. The issuance of Presidential Instruction (Inpres) No. 2/2022 on accelerating the utilization of domestically produced goods for government tenders is the latest move in this direction. Through this instruction, the government anticipates local medical device manufacturers will eventually produce middle-class medical technology and healthcare devices by 2035 to fulfill domestic demand. Although domestic medical device producers already manufacture basic items such as surgical gloves, bandages, orthopedic aids, hospital furniture (e.g. patient beds and drawers), wheelchairs, portable sterilizers, disposable gowns, anesthesia machines, coronary stents, medical needles, and surgical thread. Data from the Ministry of Health indicates that the national medical equipment industry displayed growth trends in early 2018.

For the foreseeable future, the Indonesian market will continue to grow with comparatively low competition from local manufacturers, and the country will remain highly dependent on imports for its medical devices. On the other hand, medical device manufacturers/distributors, pharmaceutical companies, and medical technology firms can tap into a large market while helping Indonesia to improve its medical facilities.

The demand for medical devices will be propelled by the expansion of private and government hospitals and clinics, as well as enhancements to existing facilities. Another driving factor behind this anticipated demand is the surge in non-communicable diseases, for the diagnosis of which advanced and high-tech equipment is required.

It is anticipated that the ability of foreign manufacturers to import medical devices will become less cumbersome, particularly as the government persists in reforming regulations to improve the ease of doing business. Moreover, Indonesia is a member of the ASEAN Medical Device Directive (AMDD), a set of directives designed to harmonize regulations across the region. This necessitates medical device manufacturers to register their devices in any member state where they conduct production.

Prominent foreign firms already established in the country include Siemens, GE Healthcare, and Pfizer. These companies have greatly benefited from the implementation of the JKN program, particularly for equipment such as MRI machines, PET-CT scanners, and ICU equipment, among others.

Indonesia's strategy in integrating digital technology into health care services propels the development of digital health care. COVID-19 contact tracing, vaccination, and even telemedicine is served under the digital healthcare umbrella. Despite these feats, questions arise: *to what extend have Indonesia's digital health services helped consumers? How confident are medical practitioners with the accuracy of diagnosis via digital consultation? What challenges and opportunities await the digital healthcare sector in Indonesia? What will be the future of traditional hospitals?* Further understanding from sector stakeholders' perspectives will be beneficial for the future of Indonesia's health care.

In a country with only 0.4 doctors per 1,000 population, coupled with the challenge of its geography spanning over 17,000 islands, telemedicine emerges to provide healthcare access to even the remotest regions while alleviating the strain on the existing healthcare system.

The incorporation of information and communication technology (ICT) into healthcare will also expedite reforms in Indonesia's healthcare sector. The utilization of healthcare apps, for example, holds the potential to revolutionize how hospitals and doctors manage their records, gather, and exchange patient data.

The COVID-19 pandemic has accelerated the growth of digital healthcare and will likely become the new standard in the region post-COVID-19. The local healthcare app, Alodokter, has witnessed over 30 million active users since March 2020 (one and a half times higher than pre-COVID-19 levels). Another telemedicine app, Halodoc, along with the ride-hailing giant GoJek, has collaborated with the Ministry of Health to provide COVID-19 diagnostics in remote areas.

To enhance connectivity across the archipelago, the government has undertaken the Palapa Ring Project, which endeavors to offer access to 4G internet services to more than 500 regencies across the country. This extensive project, costing US$1.5 billion, involves the installation of 35,000km (21,747 miles) of undersea fiber-optic cables and 21,000km (13,000 miles) of land cables, spanning from the westernmost city in Indonesia, Sabang, to the easternmost town, Merauke. Additionally, these cables traverse every district from the northernmost island, Mianagas, to the southernmost island, Rote.

3. PHARMACEUTICAL MARKET

According to a report by Indonesia's Drug and Food Supervisory Body (BPOM), the current count of active pharmaceutical manufacturers in Indonesia stands at approximately 208. These manufacturers encompass 4 state-owned corporations, 35 multinational corporations, and 169 Indonesian national private corporations. Furthermore, the Indonesian Ministry of Health's data from 2021 indicates the presence of approximately 200 drug manufacturing industries, 17 pharmaceutical raw drug industries, 132 traditional medicine industries, and 18 natural product extract industries.

Given that the majority of these corporations are primarily engaged in drug formulation or manufacturing, it's important to recognize that this focus results in a considerable demand for imported pharmaceutical raw materials (APIs). Indonesia continues to heavily rely on imported pharmaceutical raw materials. At the ASEAN level, for instance, the Indonesian pharmaceutical market accounts for 27% of the total ASEAN pharmaceutical market.

Indonesia's pharmaceutical industry has witnessed annual growth ranging between 10-13 percent, largely propelled by the implementation of national health insurance. This policy has significantly benefited the industry, which stands as the largest within ASEAN. Notably, the industry's sales surpassed US$9 billion in 2019 and reached US$10 billion in 2021.

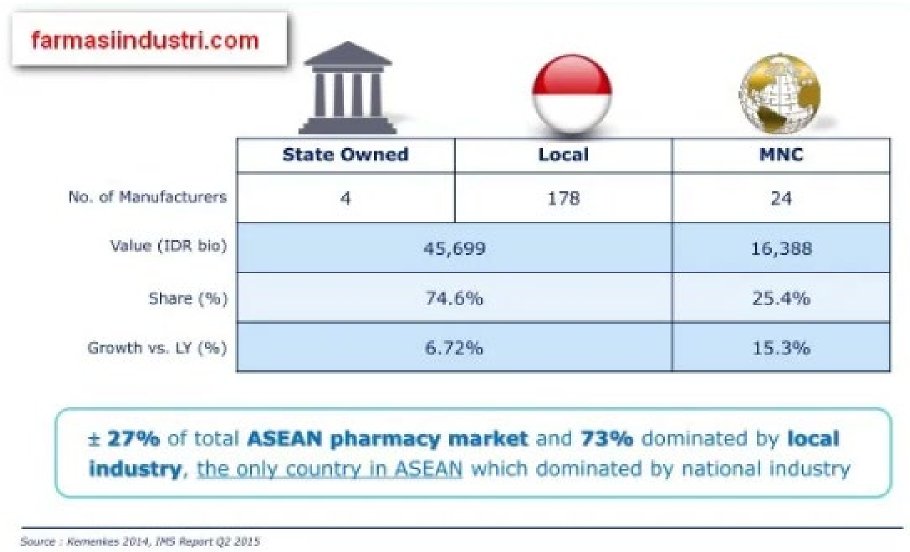
Around 60 percent of the market consists of prescription medicines, while 40 percent comes from over the counter (OTC) drugs. However, a significant portion of both categories comprises generic drugs, constituting the largest segment of the pharmaceutical market. These generics make up approximately 70 percent of the local drug market by volume, amounting to approximately US$700 million.

The JKN program has particularly boosted the sales of the country's generic drug products. The BPJS agency has stipulated that up to 90 percent of the drugs listed in the Essential Medicines List must be generics. Local producers dominate this sector, including industry leaders like Kalbe Farma (the largest private pharmaceutical company in the region), as well as state-owned enterprises Kimia Farma and Biofarma, which together account for approximately 75 percent of the market share.

Around 90 percent of the raw materials employed in drug production, however, are imported. This has prompted the government to revise the Negative Investment List (NIL) to allow foreign investors 100 percent ownership of factories engaged in producing these crucial raw materials.

Despite the government's encouragement of generic drug use to manage costs, these types of medications yield a very low-profit margin, approximately 20 percent compared to 60 percent for branded medications. The industry is also not conducive for innovative drug manufacturers in the near term due to limited spending on research and development, a shortage of qualified scientists, and challenges in enforcing patents and other forms of intellectual property protection.

- Growth in the pharmaceutical industry is expected to reach 12-13 per cent per annum.
- The pharmaceutical market is worth IDR 84 trillion (USD 6 billion) and is claimed to reach $10.11 billion by 2021.
- Over the counter (OTC) pharmaceuticals amount to IDR 48.8 trillion (USD 3,483 million) in 2018. It is expected to grow by 1.3 per cent per year (CAGR 2018-2021).
- For OTC pharmaceutical, per person revenues of IDR 183,250 (USD 13.08) are generated, in relation to total population figures.
- The Indonesian Pharmacists Association reported that about 95 per cent of raw material for medicine is imported.
- Foreign ownership of pharmaceutical firms has increased from 75 to 100 per cent.
- Indonesia is home to more than 30,000 medicinal plants out of the 40,000 globally known medicinal plants.



	State Owned	Local	MNC
No. of Manufacturers	4	178	24
Value (IDR bio)	45,699		16,388
Share (%)	74.6%		25.4%
Growth vs. LY (%)	6.72%		15.3%

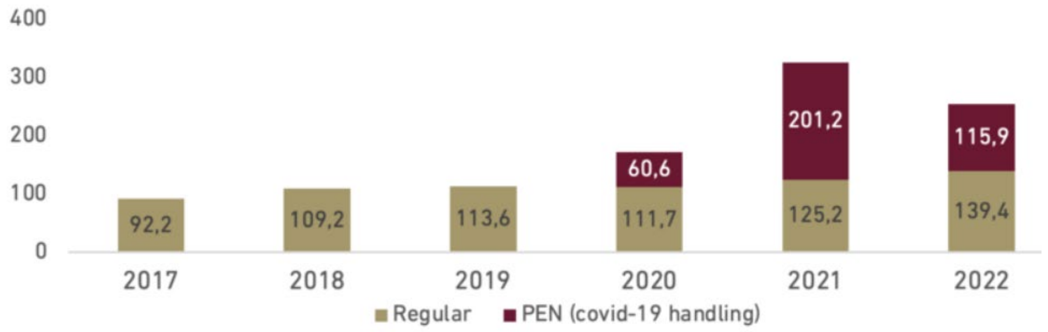
4. MARKET TRENDS

There's the country's lack of hospitals and medical professionals, especially specialist doctors, as issues that would have to be addressed. To this end, the Health Ministry plans to equip each of the country's 514 regencies and cities with a hospital that can accommodate moderate-level surgical operations, such as heart stent operations or tumor removals, while each province will have its own advanced hospital. The Health Ministry also aims to address the country's lack of doctors by increasing the quota for medical students and lecturers, on top of providing more scholarship opportunities.

According to world bank data, the ratio of hospital's bed in Indonesia for every 1000 populations is only 1.2, lower than Singapore with 2.3, and South Korea with 12.27. The doctor ratio for every 1000 populations is only 0.4, lower compared to other countries. In terms of spending, healthcare spending is still low, at 2.9% of GDP, lower than the average of countries with low-income level 6.1% of GDP, and also lower than the average of East Asia Pacific countries with 7.4% of GDP. Even with the currently low healthcare spending, most private hospitals are already overcrowded and profitable, which implies a huge growth opportunity. Hence, there is still much room for improvement on Indonesia Healthcare sector.

Another aspect of the transformation would be the development of a "big-data" record keeping system, called Satu Sehat (one health), that would integrate patient health data across all health sectors. Close to 3,000 health centers in Java and Bali, or around 70 percent of the total health centers there, and 370 hospitals on the two islands, or around 30 percent of the total, have been integrated into the Satu Sehat system.

5. INDONESIA'S HEALTHCARE BUDGET



Source: Finance Ministry, Ciptadana Sekuritas Asia

Indonesia's current healthcare crisis presents an opportunity for reform, translated into six major areas:

1. Primary care: Routine immunization and screening
2. Secondary care: Optimizing the national hospital distribution
3. Health systems resilience: Form reserve health personnel and increase capability for emergency countermeasures
4. Healthcare financing: Allocate investments in the healthcare sector
5. Healthcare human resources: Implement a scholarship roadmap and open up academic training across the country
6. Healthcare technology: Data collection and integration into the Biomedical & Genome Science Initiative (BGSi) with support from East Ventures

Parallel to the significant reforms, the ministry is also reinvigorating the structure and network of primary health services and public health laboratories, ensuring that each transformation reaches every corner of Indonesia. This encompasses measures such as standardizing services in Posyandu, enforcing digitalization standards, and incorporating preventive care.

Among these reforms are changes to the "Posyandu Prima" program, aimed at revitalizing the numerous integrated health services posts (Posyandu) dispersed across the country. There's also a restructuring of the National Health Insurance (JKN) program and the provision of scholarship opportunities for numerous medical students. These reforms work in tandem with the revitalization efforts to create a comprehensive health service structure that ensures every Indonesian benefits. This involves standardizing services at Posyandu, enforcing digitalization standards, and incorporating preventive care.

It would be misleading to suggest that the pandemic has solely revealed vulnerabilities in the health system. Long-standing issues in Indonesia's health system, such as gaps in health infrastructure, the availability and quality of health workers, and inequities in healthcare access, have been apparent for a considerable time.

In a broader sense, Indonesia continues to struggle with poor sanitation. Clean water access is challenging outside major cities, leading to the prevalence of illnesses like diarrhea, gastroenteritis, and contagious diseases such as typhoid, paratyphoid fever, dengue fever, and malaria. Additionally, as per the World Trade Organization, about 70% of men over the age of 20 in Indonesia are smokers. This contributes to an increase in non-communicable diseases like cancer, stroke, heart disease, and diabetes, necessitating products for chronic disease management.

The country's health sector has consistently received insufficient investment, with only about three percent of GDP allocated to healthcare. The decentralization in 2001 shifted much of the control of public health expenditure and service delivery to local governments, which in turn led to debates about geographical disparities in health infrastructure and services. Persistent gender disparities in health are also evident.

In the years following 2001, the health sector underwent a series of reforms, including efforts to enhance the quality of health workers in 2013, and most notably the implementation of universal healthcare in 2014. Nonetheless, experts contend that further reforms are necessary to address the challenges posed by the country's evolving demographic and epidemiological landscape.

Indonesian hospitals are additionally burdened with outdated and obsolete equipment, causing the healthcare rating of Indonesia to rank lower than its ASEAN peers. These issues have compelled affluent Indonesians to spend around $600 million to seek medical treatment in Singapore, Malaysia, and Australia. It's noteworthy that 69 percent of all medical tourists in Malaysia originate from Indonesia.

6. MARKET OUTLOOK AND OPPORTUNITIES

For the foreseeable future, the Indonesian market will continue to grow with relatively low competition from local manufacturers and the country will remain heavily reliant on imports for its medical devices. On the other hand, medical device manufacturers/distributors, pharmaceutical companies, and medical technology firms can tap into a large market while helping Indonesia to improve its medical facilities.

Imported products dominate the market and largely consist of sophisticated medical instruments, such as diagnostic tools and medical lasers, CT scanners and other diagnostic equipment. Indeed, many high-tech medical devices such as units for radiotherapy, cardiotocography, electrical mucus suction, mobile X-ray, mammography, digital panoramic, dental X-ray, cryosurgery, dental elevator.

Aside from being an importer of high-tech equipment, Indonesia is also an importer of basic medical devices such as tweezers and scissors for surgery. However, domestic medical device producers do already manufacture many basic items such as surgical gloves, bandages, orthopedic aids, hospital furniture (e.g. patient beds and drawers), wheelchairs, portable sterilizers, disposable gowns, anesthesia machines, coronary stents, medical needles and surgical thread.

It is expected that the ability of foreign manufacturers to import medical devices will become less cumbersome, especially as the government continues to reform regulations on ease of doing business. Further, Indonesia is also a member of the ASEAN Medical Device Directive (AMDD), a set of directives that aim to harmonize regulations across the region and require medical device manufacturers to register their devices in any member state where they have production.

Established foreign firms who already have a foothold in the country are Siemens, GE Healthcare, and Pfizer. These companies have greatly benefited from the rollout of the JKN program for equipment such as MRI machines, PET-CT scanners, and ICU equipment, among others.

6.1 MARKET OPPORTUNITIES FOR HOSPITALS AND HEALTHCARE FACILITIES

Indonesia has 2,925 hospitals providing just over 318,000 beds, or 1.17 beds per thousand population – the lowest rate in ASEAN.

Approximately 63 percent of the country's hospitals are privately managed, and the low number of hospital beds reflects the growing opportunity for foreign investors to fill the shortfall. There is an increasing demand for new hospitals in second-tier cities such as Surabaya and Bandung as more of the population engage with the universal healthcare program.

The government has allowed foreign investors to have 67 percent ownership in private hospitals and 70 percent ownership for investors from ASEAN. This is also the case for private health clinics, although foreign investors are limited to specialized medical services and not basic medical clinic services.

The main challenges for hospital operators will be recruiting doctors (the country only has 0.4 doctors per 1,000 population) in addition to choosing the right location to build the hospitals. The opportunity lies in second-tier cities as bed occupancy is still low and thus there is potential for growth. Furthermore, second tier cities offer lower property prices and hence profitability is usually higher than in first tier areas such as Jakarta.

7. MARKET APPROACH AND DISTRIBUTION CHANNELS

7.1 INVESTMENT OPPORTUNITIES IN INDONESIA

The New Investment List contains significant changes to foreign direct investment (FDI) in Indonesia. These changes were foreshadowed by the enactment in November 2020 of Law No. 11 of 2020 regarding Job Creation (the Omnibus Law) and include liberalization of certain aspects of the healthcare and pharmaceutical sectors.

In the healthcare and pharmaceutical sectors, the Omnibus Law has amended the following laws:

- Law No. 36 of 2009 regarding Health (Health Law);
- Law No. 44 of 2009 regarding Hospitals (Hospital Law);
- Law No. 5 of 1997 regarding Psychotropics; and
- Law No. 35 of 2009 regarding Narcotics.

Further government regulations are expected to be issued to implement these changes, one of which has already been issued – Government Regulation No. 47 of 2021 on Administration of the Hospitals Sector (the Hospitals GR).

7.2 DISTRIBUTION OF PHARMACEUTICAL PRODUCTS AND RAW MATERIALS

Foreign ownership restriction in the wholesale distribution business, including in the pharmaceutical sector, has been the subject of numerous changes over the last few decades, primarily because protectionist sentiment has generally favored distribution by local companies.

The New Investment List has eliminated the foreign ownership restriction pertaining to the distribution of raw materials for pharmaceutical products, as specified in the 2016 Negative List.

The New Investment List is silent on the distribution of finished pharmaceutical products. In theory, that should make this line of business open to 100 percent foreign ownership. However, in the past, unwritten policies of the MOH and Indonesia's Food and Drug Administration (BPOM) have made it difficult for foreign investors to establish foreign-owned distributors of finished pharmaceutical products in Indonesia, even though this business line was not expressly restricted under the 2016 Negative List.

Yet, it may take some time to determine how the new regulations and policies of relevant regulators will interface with these new FDI rules. We will continue to monitor developments in this area.

7.3 MANUFACTURING AND DISTRIBUTION OF HEALTH EQUIPMENT

The manufacturing of Class A health equipment, encompassing medical diagnosis equipment, is now permissible with 100 percent foreign ownership if undertaken in collaboration with cooperatives or micro, small, and medium enterprises (CMSMEs). This stands in contrast to the previous constraint of a maximum 33 percent foreign ownership stipulated in the 2016 Negative List.

Manufacturing of Classes B, C and D – covering more sophisticated health equipment – remains open to 100 percent foreign ownership. The previous "special licence" from MOH seems to have been removed by the New Investment List.

Distribution of health equipment (all types), previously capped at 49 percent under the 2016 Negative List, is now also open to 100 percent foreign ownership.

7.4 PRIVATE HOSPITALS AND MAIN (SPECIALIST) CLINICS

Private hospitals, encompassing both general and specialist facilities, alongside main (specialist) clinics, are experiencing a significant shift toward liberalization. Previously subject to a 67 percent foreign ownership limit (or 70 percent for ASEAN investors), these restrictions have been eliminated by the New Investment List. Notably, this removal of foreign ownership and location constraints extends to regions that were previously excluded, including locales like Makassar and Manado.

However, foreign investors should exercise caution and awareness of existing sectoral requirements that remain applicable. Among these is adherence to the Hospitals GR, which mandates foreign-owned hospitals to fall within Class A or B designations. Moreover, MOH Regulation No. 26 of 2018 on Electronically Integrated Licensing Service in the Healthcare Sector (amended by sub-sector regulations on hospital classification and licensing) necessitates that foreign-owned main clinics be situated adjacent to or in proximity with a Class A or Class B hospital. Additionally, these clinics are obligated to integrate their information management systems with the nearby hospital, as stipulated by the MOH 26 Reg.

In essence, although significant relaxation measures have been put in place, foreign investors should still be aware of the existing sector-specific requirements that hold importance in the regulatory framework.

7.5 MEDICAL LABORATORY CLINICS

Medical laboratory clinics were not expressly covered by the 2016 Negative List, suggesting that they were 100 percent open for foreign investment. However, in practice, unwritten policies of the MOH and BKPM in some circumstances imposed a foreign ownership cap of 67 percent, matching the restrictions for main clinics under the 2016 Negative List.

Under the New Investment List, it appears that medical laboratory clinics remain 100 percent open to foreign investment but now require local partnership with a CMSME. We will continue to monitor developments in this area as well.

Meanwhile, primary healthcare facilities such as primary clinics (klinik pratama) – including general medical services clinics, private maternity facilities, residential health services, and basic healthcare service facilities – remain off-limits for foreign investment.

Business Line	**Previous Regulation**	**Positive Investment List**
Hospital	67% foreign ownership (70% for ASEAN investors)	Open for 100% foreign ownership for the hospital with a minimum number of 200 beds
Medical Device Distributor	Maximum 49% foreign ownership	Open for 100% foreign ownership
Medical Device Testing	Maximum 67% foreign ownership	Open for 100% foreign ownership

7.6 EXPORTING TO INDONESIA

In Indonesia, the exclusive authorization of medical device registration and distribution lies with medical device distributor companies. This presents a significant hurdle for foreign entities and investors aiming to enter the industry.

Indonesia's medical device industry was worth US$4.5 billion in 2019 with the majority (US$2.8 billion) coming from imported medical devices like diagnostic tools and medical lasers. On the contrary, the export of the same plunged to US$267 million.

Following are some of the factors expected to further stimulate the demand for importing medical devices in Indonesia:

- Expansion of private and government hospitals and clinics
- Enhancements to the existing medical facilities
- Use of diagnosing devices for the rise in non-communicable diseases
- Liberalizing of government regulations
- Seamless process of importing medical devices for foreign manufacturers.

To import medical devices, a local company must acquire a distribution license known as Izin Penyalur Alat Kesehatan (IPAK) issued by the Ministry of Health Republic of Indonesia (MOH RI). This procedure can be initiated through an e-registration online system, rendering the process both straightforward and efficient. The requisite documents that need to be prepared for medical device registration with MOH RI include:

- Executive Summary with a brief on marketing history, Intended uses and indications, regulatory clearances and pending approvals in other countries, and important safety or performance information

- Essential Principles Checklist
- Declaration of Conformity
- Device Description
- Design Verification and Validation
- Device Labeling
- Risk Analysis
- Manufacturer Information

8. LEGISLATION

Specific regulations oversee healthcare assets, contingent upon the nature of the products or services provided. The Ministry of Health (MOH) assumes authority over healthcare service licenses, encompassing establishments such as hospitals, pharmacies, medical clinics, clinical laboratories, and optical and other healthcare facilities. Licenses for each healthcare service provider are issued by the MOH. The MOH also holds the mandate for overseeing medical devices, necessitating that any such devices possess marketing authorization from the MOH prior to distribution. In alignment with these regulatory roles, the MOH introduced MOH Regulation 14 of 2021 addressing the Standards of the Licensing System in the Healthcare Sector.

Additionally, the Drugs and Food Monitoring Agency (BPOM) has established specific regulations tailored to the category of food and drugs. For instance, BPOM Regulation No. 27 of 2020 delineates the Criteria and Procedure for Health Supplements Registration, while BPOM Regulation No. 11 of 2020 outlines the Criteria and Procedure for Health Supplements Registration. Under the aegis of BPOM regulations, all food and drug products are mandated to secure marketing authorization from BPOM before distribution within Indonesia.

During the process of business combination, the transfer of these licenses and marketing authorizations isn't directly accommodated, as Indonesia does not recognize automatic transfers of licenses. Such 'transfers' of marketing authorizations or licenses transpire through a two-step sequence:

- de-registration of previous marketing authorizations or licences; and
- reapplication for new marketing authorizations or licences by the new entity at the relevant government authority.

8.1 INVESTMENT REGULATION

Manufacturing of pharmaceutical products and raw materials

The New Investment List no longer contains any foreign ownership restriction for the manufacturing of finished pharmaceutical products, which is now open to 100 percent foreign ownership. Under the 2016 Investment List, foreign ownership in this business segment was capped at 85 percent.

Raw materials manufacturing remains open to 100 percent foreign ownership. The 2016 Negative List had already removed the previous 85 percent foreign ownership cap because the domestic pharmaceutical industry still lacks the capacity to develop raw materials. A very high percentage of the raw materials used in manufacturing pharmaceutical products in Indonesia is still being imported, mainly from China and India.

9. TRADE SHOWS

Indonesia Hospital Expo
https://hospital-expo.com/

Indo Health Care Expo
https://indohealthcareexpo.com/

Further information can be obtained by contacting FIT Jakarta, who have more details available on import data and import regulations as well as on importers / distributors of medical equipment.

10. SOURCES

Healthcare costs leave Indonesians out-of-pocket | East Asia Forum

Digitising Indonesia's Health Care Sector | Deloitte Indonesia | Life Sciences & Health Care

The Republic of Indonesia health system review (who.int)

Indonesian Health System Transformation - East Ventures

Doubts linger over Indonesia's healthcare system transformation | The Star

id-lshc-digitising-indonesia-health-care-sector.pdf

Diagnosing Indonesia's health challenges | Lowy Institute

Frontiers | The Capacity of the Indonesian Healthcare System to Respond to COVID-19 (frontiersin.org)

Why It Matters - Lack of Healthcare Services in Indonesia's Remote Areas (doctorshare.org)

Indonesia's Failing Healthcare Industry and How Medical Tourism Can Help

Indonesia's Key Health Problems (unair.ac.id)

In brief: regulation of healthcare M&A in Indonesia - Lexology

New Foreign Investment Rules in Indonesia's Healthcare and Pharmaceutical Sectors | Indonesia notes (hsfnotes.com)

Indonesia - Healthcare (Medical Devices & Equipment) (trade.gov)

Indonesia's medical device industry continues to expand (ahk.de)

Indonesia's Healthcare Industry: Growing Opportunities for Foreign Investors (aseanbriefing.com)

Indonesia's Healthcare Industry: Growing Opportunities for Foreign Investors (aseanbriefing.com)

Medical Equipment & Devices | Business Indonesia (business-indonesia.org)

Investment Potential in Pharmaceutical Industry in Indonesia | BKPM

Disclaimer

The information in this publication is provided for background information that should enable you to get a picture of the subject treated in this document. It is collected with the greatest care based on all data and documentation available at the moment of publication. Thus this publication was never intended to be the perfect and correct answer to your specific situation. Consequently it can never be considered a legal, financial or other specialized advice. Flanders Investment & Trade (FIT) accepts no liability for any errors, omissions or incompleteness, and no warranty is given or responsibility accepted as to the standing of any individual, firm, company or other organization mentioned.

Date of publication: September 2023