Kim Ribbink

Pharma Doors Begin to Open in INDONESIA

Though many challenges continue for pharma companies bringing products to market in Indonesia, a growing middle class and improving healthcare access make it a desirable market.

Indonesia is the world's fourth largest country in terms of population, with 247 million people, and the largest economy in Southeast Asia. According to Statistics Indonesia, the GDP annual growth rate has averaged 5.43% between 2000 and 2013.

An archipelago comprising more than 17,000 islands, Indonesia has a burgeoning middle class, however, according to the World Bank data from 2012 shows that Indonesia has 26 deaths from every 1,000 live births (as compared with the Singapore where infant mortality is two per 1,000 births).

Indonesia is also doing poorly in a number of health and infrastructure related indicators; for example, data from 2009 show that Indonesia still suffers 307 deaths for every 100,000 live births.

However, according to Vince Grillo, Ph.D., general manager, Kantar Health Singapore and Malaysia, as per capita income grows so will spending on healthcare, which will result in continuing healthcare reforms, investment in healthcare infrastructure, and improved access to care.

The healthcare market in Indonesia is valued at $23.9 billion, and by 2016 could reach $30 billion, says Ames Gross, president of Pacific Bridge Medical.

"Next year Indonesians are expected to spend $145 per capita on healthcare, up from $34 a decade ago," he says. "Currently, the country spends 2.9% of its GDP on healthcare, however this percentage is expected to grow quickly over the next decade."

Pharma Opportunities

The Indonesian pharmaceutical market is worth $6.4 billion and is growing annually at a rate of 12.8%, Mr. Gross says, adding that this high rate of growth is likely to be maintained through 2018.

"Over the past seven years, the pharmaceutical market in Indonesia expanded 86%," he says.

According to Dr. Ken Lee, VP and regional general manager, South East Asia, Quintiles, most of the large global pharmaceutical companies have a presence in Indonesia and according to the International Pharmaceutical Manufacturers Group (IPMG), have invested some $900 million in R&D.

The Indonesian pharmaceutical market presents foreign drug firms with a variety of challenges, Mr. Gross says.

"The local pharmaceutical sector is protected from foreign competition through several national laws," Mr. Gross says, in particular Decree 1010.

"Decree 1010 was issued by the Ministry of Health in 2008, on the Registration of Drugs and requires foreign companies to either manufacture drugs locally or form partnerships with local manufacturers in order to register their own drug," Dr. Grillo says.

In 2010, the definition of "local manufacturing" was expanded to also mean packaging and labeling, Mr. Gross says.

In response to Decree 1010, Mr. Gross says foreign pharmaceutical firms have increasingly forged partnerships with other international companies or domestic drug producers to build up their Indonesian manufacturing capabilities.

Dr. Grillo says there is also a cap of 75% of foreign ownership of a domestic drug company.

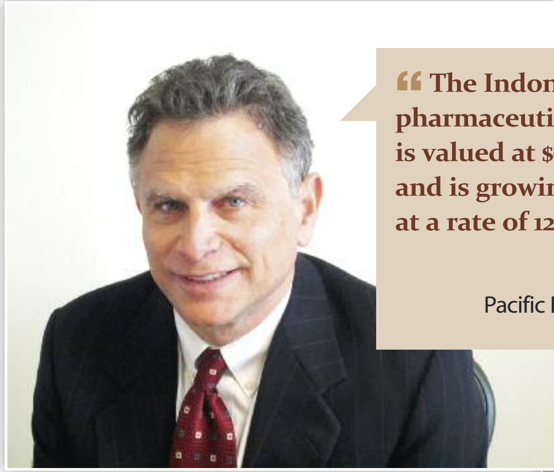
"So global pharmaceutical companies have either invested in manufacturing, licensed products to local companies, or taken on partial ownership of local companies," he says.

Ash Kuchel, global group president, Publicis Healthcare Communications Group, says that further complicating entry into the mar-

Indonesia at a Glance

Total population:	247,000,000
Gross national income per capita (PPP international $):	4,730
Life expectancy at birth m/f (years):	68/71
Probability of dying under five (per 1,000 live births):	31
Probability of dying between 15 and 60 years m/f (per 1,000 population):	200/166
Total expenditure on health per capita (Intl $, 2011):	127
Total expenditure on health as % of GDP (2011):	2.7

Source: Global Health Observatory
Figures are for 2011 and 2012



“The Indonesian pharmaceutical market is valued at $6.4 billion and is growing annually at a rate of 12.8%.”

AMES GROSS
Pacific Bridge Medical

“There is a strong interest from research-based global biopharma companies to conduct clinical research in Indonesia because of the large concentrated patient populations and disease profiles.”

DR. KEN LEE / Quintiles

ket is the attitude that generic medications are equivalent to brand-name medications, a thought held by the government, insurance companies, and Indonesian people themselves.

Indonesian-produced drugs make up about 90% of the total pharmaceutical market, Mr. Kuchel says. According to the International Pharmaceutical Manufacturers Group, national companies control about a 75% market share.

“Because of Indonesia’s desire for self-sufficiency, about three-quarters of the country’s medicines are developed and manufactured by Indonesian companies, with more than 240 pharmaceutical manufacturers on the ground,” Mr. Kuchel says. “Large pharmaceutical companies such as Pfizer, AstraZeneca, Roche, and Merck Sharp & Dohme, among others have already begun to make inroads in the market through licensing agreements, manufacturing partnerships, or breaking ground on new facilities.”

Dr. Grillo says generics make up about 70% of the market and generic drug sales are expected to grow by 15% in 2014.

“We also have observed the rise in share prices for some of the main players of generics in Indonesia,” Dr. Grillo says.

Even with these barriers to market access, there is still considerable presence of international pharmaceutical companies in Indonesia, including Sanofi, Takeda, Novartis, Bayer, Pfizer, and Merck, Dr. Grillo says.

There are some strong incentives for entering the Indonesian market, Dr. Lee says. Of the country’s 247 million people, half live in urban areas and changing healthcare insurance will increase the percentage of insured people.

Dr. Lee notes that lifestyle-related diseases — smoking, inactivity, high blood pressure, cholesterol, and obesity — are expected to increase.

“In addition, Indonesia’s regulatory body, which now allows parallel EC submissions, has issued GCP guidelines that follow those of the ICH,” Dr. Lee says.

Dr. Grillo says it remains uncertain whether the government will ease barriers of trade, such as ownership rules, to attract more investment from international pharmaceutical companies.

“The tradeoff would be more competition for the local generic manufacturing, whose strong growth has been a result of these barriers,” Dr. Grillo says.

For foreign companies wishing to register their pharmaceutical products in Indonesia, drugs are classified in four categories, Mr. Gross says. Product registration applications are submitted to the Indonesian National Agency of Drug and Food Control (NADFC). Pharmaceutical companies should adhere to Association of Southeast Asian Nations (ASEAN) standards and must submit their applications in the ASEAN Common Technical Documents (CTD) format. Drug product registration can take as long as three years.

One of the big challenges for the domestic drug manufacturing industry is high inflation rates, because imports account for about 93% of the raw materials used in pharmaceutical manufacturing, Mr. Gross says.

“PT Kalbe Farma, a domestic drug giant, reported that in the first half of 2013 it experienced a 19% increase in its costs of goods sold,” he says. “PT Kimia Farma, another large domestic Indonesian drug manufacturer, also reported sales increasing more slowly than its costs of goods sold.”

Healthcare Access

Until recently, Indonesia had in place a decentralized healthcare process that was implemented in 2001 where healthcare provision is largely in the hands of regional governments, Dr. Lee says.

“Private healthcare services are primarily financed by individuals, with some insurance and employer reimbursement,” Dr. Lee says. “Publicly provided healthcare services are financed by a mix of public budgets and user fees, which in turn are financed by a mix of household, employers, and insurers.”

At present, about 60% of Indonesia’s 247 million citizens are covered under some form of health insurance, accepted at community healthcare practices and clinics where people most often access medicine, Mr. Kuchel says.

“Those who do not have insurance are left to either pay out of pocket, some choosing to ignore medical conditions because their low incomes cannot afford them, or rely on the government,” he says.

To help close this gap, in January this year, Indonesia’s Ministry of Health unveiled a program known locally as Sistem Jaminan Sosial Nasional (SJSN), to provide free or government-subsidized healthcare to every citizen by 2019, Mr. Kuchel says.

The media in Indonesia have described the program as the world’s largest healthcare scheme and will have about 120 million subscribers — previously uninsured — to begin with. The system will gradually cover all Indonesians over the next five years.

Designed as a cross-subsidy program, those with higher incomes will pay higher premiums for health insurance while lower income individuals will be pay less for the same medical benefit or get it for free.

A new government agency called the Social

Security Organizing Body will manage the program.

However, the program has been met with some scepticism, Mr. Kuchel says.

“Part of the challenge with the current healthcare system in Indonesia comes from the country’s topography, with clinics and specialists disproportionally dispersed among cities, rural areas, and tiny islands,” he says. “Another challenge is the number of healthcare practitioners available. Recent estimates show the country only has 85,000 general practitioners and 25,000 specialist doctors to service a rapidly growing population.”

Furthermore, there are almost 2,400 hospitals and about 9,600 primary care centers in Indonesia.

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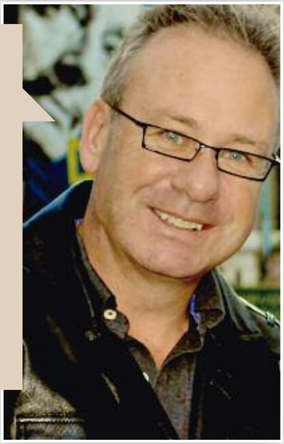
> Publicis Healthcare Communications Group



Reaching Patients and Clinical Studies

The introduction of SJSN presents companies with an opportunity to invest in the market as the demand for healthcare products and services increases, Mr. Kuchel says.

“The program will place more of an emphasis on disease prevention and education, and even disbursement of healthcare infrastructure,” he says. “Forming relationships with on-the-ground manufacturers and distributers, and providing evidence-based facts that differentiate name-brand medications will be critical to ensuring long-standing success in this largely untapped market.”

Dr. Grillo concurs: “We need to be mindful that SJSN offers a very basic package of healthcare and low-cost generics. Despite this, there is growth opportunity for non-generic pharmaceutical companies in Indonesia. With economic growth and increases in personal wealth, more people will be able to afford more extensive insurance coverage and more expensive, non-generic medicine.”

With regard to clinical research, Dr. Lee says Indonesia has participated in a total of about 400 studies, and compared with its Southeast Asian neighbors, Indonesia at present conducts significantly fewer studies.

“Despite having considerably smaller populations, countries like Malaysia, Thailand, and the Philippines conduct six to eight times more clinical trials than Indonesia, based on data from 2011 and 2012,” he says.

There is a strong interest from research-based global biopharma companies to conduct clinical research in Indonesia because of the large concentrated patient populations and disease profiles, Dr. Lee says.

“The barriers to increasing clinical trials in Indonesia are that there are relatively fewer sites experienced in conducting trials and the challenges with regulatory process,” he says.

To date, the main therapy areas studied include diabetes, oncology, and infectious diseases, such as malaria.

From a regulatory perspective, the main challenge to conducting clinical trials is difficulty in obtaining a Material Transfer Agreement (MTA) before biologic samples are allowed to be shipped out of the country, Dr. Lee says. The MTA is governed by the National Institute of Health Research and Development (NIHRD) of Indonesia. In a number of clinical trials, biologic samples need to be shipped for testing in a central laboratory to globally harmonize results.

“In 2012, to help overcome this regulatory challenge, Quintiles signed an agreement with Prodia Clinical Laboratory to set up a CAP-accredited and NGSP-certified harmonized central laboratory to facilitate rapid testing of biologic samples locally,” Dr. Lee says. “The Quintiles-Prodia harmonized central laboratory allowed Quintiles’ biopharma customers to conduct clinical research in Indonesia and help establish the potential benefits of new medicines in the Indonesian population while contributing to global programs.”

> “Beneath the potential and allure of the Indonesian market, international pharmaceutical companies face many challenges.”
>
> **DR. VINCE GRILLO** / Kantar Health

Balancing Risk

According to Dr. Grillo, there is an Indonesian proverb that perhaps best sums up the state of the Indonesian pharmaceutical market: “Calm water does not mean there are no crocodiles.”

He notes that to enter the Indonesian market, companies will need smart strategies to capitalize on the growth, patience to see how the universal coverage will pan out, and understand the barriers of trade until they are potentially lifted.

“And perhaps also a little faith that the crocodiles are not that hungry,” he adds. PV

Vaccines in Indonesia

In August last year, Indonesia officially rolled out a pentavalent vaccine designed to immunize newborns against five diseases: diphtheria, whooping cough, tetanus, hepatitis B, and hemophilia influenza type B. The vaccine was produced by a local vaccines manufacturer Biofarma and has been added to Indonesia’s national immunization program, according to Health Minister Nafsiah Mboi.

Also in 2013, stakeholders in the Jakarta Health Card (KJS) program in Indonesia were reportedly deliberating the introduction of different rates for public and private hospitals registered under the program. Private hospitals are said to be incurring financial losses because of the wide gap between the actual costs and the medical fees covered by the city administration. The stakeholders are evaluating the current rates and still discussing the feasibility of readjusting the rates.

According to Oloan Siregar, assistant to the city secretary for people’s welfare, one thing to consider is that the government subsidizes the public hospitals, while private hospitals do not receive any subsidy.

Source: Indonesia Pharmaceuticals and Healthcare Report, Business Monitor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