EIBD
EU-INDONESIA
BUSINESS
DIALOGUE

EIBD Position Paper Pharmaceutical

8 November 2012

ACTIVE

1. Economic Relations

1.1 Introduction

The relationship between the European Union (EU) and Indonesia is at an all-time high with strong and positive trade relations, taking advantage of the complementing structures of the two economies. In terms of foreign direct investment to Indonesia in 2011, EU is the second largest contributor with USD 2.7 billion according to BKPM. However, on a regional basis, direct EU investment to Indonesia is still relatively small, accounting for 1.6% of EU's direct investment in Asia.

Indonesia has continuously reported a strong surplus in its trade with the EU, and it was more than USD 8 billion in 2011. Total value of EU-Indonesia trade for the same period was USD 33 billion. The main categories of EU imports from Indonesia are in agricultural products, mainly palm oil, fuels and mining products, textiles and furniture. EU exports to Indonesia consist primarily of machinery and transport equipment, chemicals and various manufactured goods.

Indonesia is a very attractive market for EU pharmaceutical industry while EU companies would be able to help transform Indonesian industry to become a major supplier and exporter of drugs as well as potential new herbal medicine *(jamu)* products. Combining vast natural and human resources of Indonesia with the know-how and technology of European investors would result in an increase in the competitiveness of Indonesian pharmaceutical companies as well as the supply of medical services in Indonesia. EU pharmaceutical market is the world's second largest after the USA. The EU market (extra EU imports) has substantially grown, 2 times during the last 10 years. Around 80% of pharmaceutical imports to the EU come from Switzerland and the USA. Indonesia only provided 0.02% of EU imports in 2010.

The EU, on the other hand, constitutes a large and important market for Indonesia with its 500 million citizens. It is also the source of investment and trade giving rise to fair employment conditions, sustainable development and innovative technological solutions. The total stock of EU foreign direct investment in Indonesia amounts to approximately EUR 50 billion. Over 700 EU companies are established in Indonesia.

1.2 The Indonesian Pharmaceutical Market

The market size of pharmaceutical products in Indonesia is estimated to be around IDR 43.16 trillion (US$ 4.58 billion, 2011) (Source: ITMA Q4 2011, IMS Data), with an impressive average annual growth in the last five years of 10%.

Indonesian Pharmaceutical Market 2008-2015

	2008	2009	2010	2011	2012F	2013F	2014F	2015F
Total Market (USDbn)	2.76	3.15	4	4.58	4.85	5.88	6.61	7.40
Growth (%)	3.99	14.37	26.92	14.41	5.88	21.45	12.32	11.91
Ethical (USDbn)	1.6	1.9	2.5	2.72	2.9	3.56	4	4.54
Ethical Growth (%)	5.23	14.45	30.54	9.4	6.68	22.36	13.14	12.72
OTC (USDbn)	1.1	1.24	1.6	1.85	1.94	2.33	2.6	2.86
OTC Growth (%)	2.15	14.23	28.8	15.6	4.7	20.1	11	10.64

Source: GP Farmasi Indonesia

Medicines are classified in two groups based on how they are distributed: ethical (prescribed by doctors: patented & generic drugs) and non-ethical (over the counter) medicines

The market consists of 170 local companies including four state owned companies and 32 foreign companies. The foreign companies have a 40% market share. Out of the estimated 32 multinational pharmaceutical companies operating in Indonesia, there are an estimated 20 European companies with an active presence. The Indonesian pharmaceutical industry consists of chemical-pharmaceutical and non-chemical traditional (herbal) medicine manufacturers. There are around 232 chemical and pharmaceutical companies.

The distribution of pharmaceuticals is through 11,000 pharmacies, 7,000 registered outlets and 1,900,000 retail outlets. The Indonesian market does not have any price control on pharmaceutical, something that makes it potentially very profitable.

Over the Counter (OTC)

Indonesian OTC market has a double-digit growth rate according to some estimates. This can also be linked to a long history of self-medication in the country. Another factor that will help the OTC market grow is the fast-growing pharmacy sector. The success of pharmacy companies such as Apotek K-24 with franchising has forced the state-owned company, Kimia Farma, to follow suit. This is likely to increase sales of OTC products throughout Indonesia, making it an attractive market.

Generics

Indonesia is a major generic market with the generics market estimated to make up 75% of the total pharmaceutical market in Indonesia. But, despite the country possessing huge manufacturing capabilities, the lack of R&D in domestic companies could cause the market to stagnate, especially if IPR regulations are not tightened.

For generics, Indonesia cannot yet compete with India or China. Those two countries have sufficient raw materials for manufacturing available on the local market. For Indonesian producers to produce, they have to import and the main challenge is the high import duties for the raw material, which makes production in Indonesia relatively uncompetitive.

The competitiveness of Indonesian generics pharmaceuticals manufacturing is also limited by the weak infrastructure in the country and expensive financing, making products more expensive. Additional issues hampering the development of the pharmaceutical sector in Indonesia is the lack of skilled labor.

Furthermore, there is a perception that Indonesian products do not have the sufficient level of quality and the country is not yet export driven enough. The support from the Government to exporting companies in the pharmaceutical sector is still very weak. The future growth of the generics industry in Indonesia is uncertain, and is dependent on a number of factors. The first of these is the value of the Rupiah against the US Dollar as the market is heavily reliant on imported raw materials. Another factor is government price cuts of branded generics, which are intended to give poor citizens access to branded drugs. However, the cuts could also be viewed as biased towards the government, which owns most of the non-branded drugs (Source: worldpharmaoutlook.com).

Raw Materials

Indonesia still imports over 90% of the pharmaceutical raw materials it needs, showing that its dependence on overseas industries is very high - with about 70% of the imported raw materials coming from China. Dependency to imported raw materials potentially may lead to national drugs supply being unstable which can hinder the health service performance as almost all health facilities require drugs. Inconsistency of Government's policies in the protection of raw materials industry is one of the factors why local raw materials industry is not well-developed. Raw material manufacturing is an industry with high technology research and development. This should present opportunities for investment in raw material manufacturing industry, providing technology transfer, capital and human resources.

Herbal medicine

Herbal medicine *(jamu)* is one area where Indonesia could create a competitive advantage in the EU market, following increased interest in 'alternative medicines' in EU (and growing imports of related products), along with a well-developed industry in Indonesia, availability of resources and that Ministry of Health ensures jamu is safe and backed by research, also to ensure efficacy. Typical ingredients for common recipes include varieties of ginger; spices such as nutmeg, cardamom, cumin and cloves; certain chilies; and fruits like papaya and banana. Jamu treats especially health-complaints like fatigue, muscle and joint pain, infertility, high cholesterol, skin problems, and indigestion.

The availability of raw materials to make traditional herbal medicine is relatively abundant in Indonesia. The results of studies conducted by the Indonesian Institute of Science showed that 30,000 of the 40,000 available species of world medicinal plants are found in Indonesia.

Indonesia has 1,243 jamu producers and over 10% are large-scale operations and the rest are small and medium-sized firms. The herbal medicine sales revenue in Indonesia is significantly increased by 140% from USD 520 million in 2006 to USD 1,250 million in 2011. In 2012, the sales revenue is expected to reach USD 1,350 million. Herbal medicine potential sales up to 2015 is expected to reach USD 2 billion locally, and USD 1,660 million through export. (Source: GP Jamu Indonesia)

The distribution of herbal medicine to EU countries faces many challenges. Among these are the registration process, uncompetitive price compared to products coming from China or India, Indonesian technology and production capabilities are not yet up to EU's standard, as are the quality control standards - which fall short of the EU's minimum requirement. Further to this, the delivery cost of herbal medicine products from Indonesia to the EU is high due to the necessity in maintaining the quality of the product, meaning air delivery air delivery is the only option, thus pushing costs up even higher. It should also need to be underlined that the EU has different standard from Indonesia for raw materials than those originating from Indonesia which may lead to obstacles in the provision of raw materials.

2. Potentials for enhanced cooperation

The advantages of Indonesia for investors are; Indonesia being the largest and is considered to be the most stable democracy in Southeast Asia, one of the largest economies in a dynamic ASEAN and Asian region, strong growth within the Indonesian consumer market (especially within middle income market segments), and the current internal market production networks and FTAs. Further to this, Indonesia has the availability of natural resources and large labour force of which a large proportion are still at an especially young age. All these points should be taken into consideration when discussing Indonesia's potential with regard to the pharmaceutical industry.

General Opportunities

- How can we enlarge trade and investment opportunities in these sectors benefiting both - Indonesia as well as the EU?
- Based on statistics, Indonesia spends very little on drugs. This is an opportunity for EU businesses. EU pharmaceutical exports to Indonesia have been increasing over the past 5 years and can be improved on by solving technical issues.
- Indonesia's level of export to the EU is low, how can we increase Indonesia export to the EU in a way which will benefit both parties?
- Out of 40 thousand of types of jamu, 30 thousand types are found in Indonesia. It is an area of interest to the EU that will also be beneficial to Indonesia.
- Indonesia has great potential in the exportation of locally produced pharmaceuticals to the EU. However, mobilisation from both business groups and Government is required.

Health Care in Indonesia

Indonesia has made improvements in the health sector during the last ten years, health delivery capacity has expanded and important indicators such as child mortality are declining. However, more than half the population lacks health insurance coverage. In 2009, the National Board of Social Security (DJSN) was established in accordance with Law No. 40 of 2004 on National Social Security System. Following the legislation, Law No. 24 of 2011 was issued and mandated the establishment of the Social Security Implementation Agency (BPJS).

Starting 2014, ASKES and JAMSOSTEK are no longer private limited companies under the Limited Liability Companies Law No. 40 of 2007 and the State-Owned Enterprise Law No. 19 of 2003. ASKES and JAMSOSTEK will be in the form of entirely government owned agencies and are no longer under Ministry of State-Owned Enterprise. Social security services must be based on non-profit orientation, portable, have compulsory contributions, mutuality, and prioritise the benefits for their clients. The private sector is playing an increasingly important role in the provision of health care in Indonesia, especially in big cities, with wide variations in quality of care. Furthermore, as there is no regulation on pricing or quality of service in place, users are vulnerable to excessive treatment and expenses. The National Social Security System foresees support for the poor via JAMKESMAS (Public Health Insurance Scheme). Therefore, opportunities in Indonesia to enlarge the market (quantity and quality) are abundant, especially considering scope for increased income levels and insurance coverage.

Regulatory Issues

1. **Drugs Registration**

   Minister of Health Regulation No. 1010/2008 on Drugs Registration ("MOH Regulation No. 1010") and BPOM Regulation No. HK.03.1.23.10.11.08481 of 2011 on the Criteria and Procedures for Drug Registration ("Brown Book")

   MOH Regulation No. 1010 stipulates the technology transfer requirements, which requires local manufacturing facility for off-patent products. In 2011, Head of BPOM issued the Brown Book, for public protection against drugs that do not meet drug safety, quality and the use requirements. The Brown Book acts as the implementing regulation of MOH Regulation No. 1010, and is effective since 12 October 2011.

   Based on the Brown Book, it was concluded that this regulation has provided the industry with more room to negotiate with the Government (BPOM and the Ministry of Health) despite the requirement to localize several simple products in Indonesia. Further, it is also concluded that the industry does not have to perform the whole manufacturing stages for every product marketed in Indonesia.

   Recommendation

   We applaud the issuance of the Brown Book. However, there is always a risk of different interpretations of the MOH Regulation No. 1010 by government agencies officials, which still needs to be managed accordingly. This requires dialogues and consultations between pharmaceutical companies, associations, and National Agency of Drug and Food Control (BPOM) with the Ministry of Health to understand the full implications of the regulations, local manufacturing requirements and how companies should manage their businesses to comply with the regulations.

2. **Draft Law on Monitoring of Pharmaceutical Supply, Medical Devices and Household Health Products ("Draft Law on Pharmaceutical Supply")**

   The Draft Law on Pharmaceutical Supply was originally titled Draft Law on Pharmaceutical Supply, Medical Devices, Household Health Products and Processed Food. The Parliament has already circulated internally the latest Draft Law on Pharmaceutical Supply in which the provisions regulating the roles of Minister of State-Owned Enterprise and processed food have been removed.

   According to the Draft Law, all standards, requirements and responsibilities do not refer to and/or are contradicting existing regulations. The Draft Law does not provide transition period for companies to adjust to the requirements in the on Draft Law, and until the implementing regulations is issued. Further, it stipulates direct obligation of companies to compensate consumers for product complaints with no requirement for the consumers to provide evidence for the complaint. This creates a potential moral hazard on the part of the consumers. The Draft Law also stipulates obligation for companies to allow Government inspectors to take pictures at company facilities. This poses a risk to companies' ability to protect its confidential information.

   Recommendation

   - To harmonize the Draft Law with the existing regulations to avoid overlap and inconsistency.
   - To provide a transition period for companies to comply with the new regulations.
   - Remove the direct obligation of companies to compensate consumers' product complaints in order to avoid moral hazard.
   - Revise the article on obligation of companies to allow inspectors to take pictures at company facilities with a provision "only when there is an indication of a violation".

3. Draft Law on Halal Product Guarantee ("Halal Law")

Halal Law is currently being finalized by the Indonesian Parliament, and is included in the 2012 National Legislation Programme *(Prolegnas)*. The purpose of this Law is to make halal certification mandatory for food and beverages, medicines, cosmetics, chemical products, biological products and genetically-engineered products. It is also understood that the halal assessment will be applied to both product ingredients and equipment used in the production process. Categorising certain pharmaceutical products as 'non-halal' will not assist with public health objectives. It will hinder a patient's access to the best healthcare available and work against disease prevention. The mandatory halal certification may also prolong the time that patients have to wait in gaining access to certain medicines. Medicines which may harm patient more than do good. The impact this will have on the industry will be quite significant in terms of additional cost considering that the Halal Law makes the requirement to physically separate premises and equipment used for processing halal pharmaceutical products from those used for processing non-halal products compulsory.

Recommendation

- To make halal certification voluntary.
- The removal of pharmaceutical products from the definition of products that are subject to halal certification on the basis of public health. Pharmaceutical products are consumed and/or administered not out of preference but of necessity, and in general there is no halal alternative to a specific substance because similar products are produced using the same key substances and similar production processes. Putting halal label on pharmaceutical products will potentially develop patients' resistance against certain treatments or medical interventions which will have an adverse impact on public health.

4. Health insurance system in Indonesia

In 2004, the Government of Indonesia issued Law No. 40 of 2004 on National Social Security System, and National Board of Social Security (DJSN) was established in 2009. Following the legislation, Law No. 24 of 2011 was issued and mandated the establishment of Social Security Implementation Agency (BPJS). Starting 2014, ASKES and JAMSOSTEK are no longer private limited companies under the Limited Liability Companies Law No. 40 of 2007 and the State-Owned Enterprise Law No. 19 of 2003. ASKES and JAMSOSTEK will be in the form of entirely government owned agencies and are no longer under Ministry of State-Owned Enterprise. Social security services must be based on non-profit orientation, portable, have compulsory contributions, mutuality, and prioritise the benefits for their clients.

Recommendation

- Changes must be made in the way the upcoming Social Security programme will be executed. It must be thought of as a social insurance principle and social investment to be borne by all of related stakeholders.
- To acknowledge the private sectors role in health care services. The National Social Security System Law does not distinguish between public sector and private sector health care facilities. We are aware that public sector health care facilities are very limited, and that the private sector will participate based on the regional distribution policy in terms of health care access as long as there is a proportional funding scheme from BPJS.
- To accelerate the process of formulating the "Roadmap for Universal Health Coverage".