EIBD
EU-INDONESIA BUSINESS DIALOGUE

POSITION PAPER

PHARMACEUTICAL-COSMETIC SECTOR

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SECTOR

PHARMACEUTICAL-COSMETIC

EU-INDONESIA RELATIONS

The European Union 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. As the world's fourth-most populous country with a fast growing economy, Indonesia is turning into an important market for pharmaceutical and cosmetic products. EU investment in Indonesia is mostly allocated to infrastructure and manufacturing, especially chemical, pharmaceutical and food industries, which have benefitted from European modern technologies and know-how.

Over the last two decades, EU-Indonesia trade and investment flows have grown significantly. The EU's total trade with Indonesia has increased from USD 7.6 billion in 1990 to USD 30 billion in 2013. However, in 2013, Indonesia ranked only as the EU's 31st trading partner (Eurostat). The export of goods from Indonesia to the EU has also increased 8-fold in the last decade, amounting to USD 16,674 million in 2013. Essentially, trade flows between Indonesia and the EU complement each other.

The EU is the second largest investor in the Indonesian economy. However, in 2004-2010 Indonesia received only 2% of EU investments to Asia and 6% of those to ASEAN. The majority of the EU's outward FDI to Asia goes to Hong Kong, Japan, China and Singapore. In Q2 of 2014, the EU's value of investment in Indonesia amounted to USD 9,508.7 Million[1] . The EU and Indonesia are currently working towards an ambitious Comprehensive Economic Partnership Agreement covering trade, investment and services.

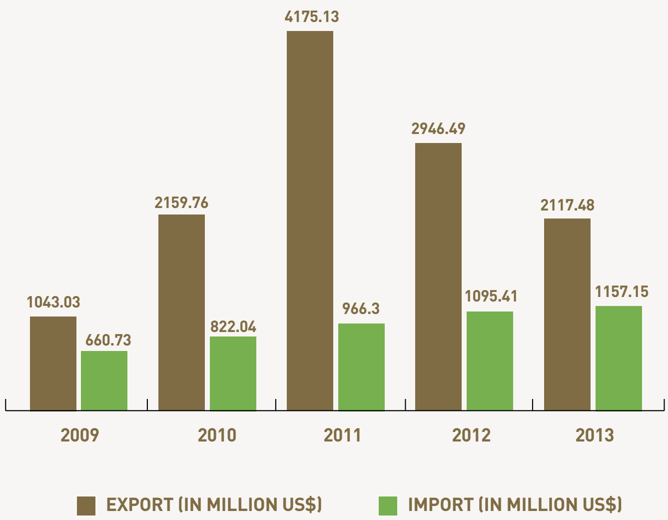
Pharmaceutical

Indonesian pharmaceutical actors consist of 170 local companies (including four state-owned) and 32 foreign companies. Foreign companies have a 40% market share. Out of the estimated 32 multinational pharmaceutical companies operating in Indonesia, about 20 European companies have an active presence. European pharmaceutical global players are drawn to Indonesia for its large potential, and numerous multinationals also maintain facilities in the country, including Sanofi, Bayer, Novartis and Merck.

1 BKPM Statistic Report of Foreign Direct Investment Realization Based On Capital Investment Activity by Country, 30 September 2014 (excluding Oil & Gas, Banking, Non-Bank Financial Institution, Insurance, Leasing, Investment which licenses issued by technical/sectoral agency, Porto Folio as well as Household Investment

Indonesia's pharmaceutical sector has grown by 12.5% annually over the past several years expanding by 85% from 2007-2013 (Pacific Bridge Medical). This is expected to continue until 2018. It is clear that universal healthcare coverage, implemented in January 2014, will boost the generic medicine market. The trade balance between the EU and Indonesia for pharmaceutical products, chemicals, rubber and plastic reached USD 7740.26 million in 2013, with total import of USD 4701.63 million, and total export of USD 12,441.89 million (Information and Data Center, Ministry of Industry).

CHEMICAL PRODUCTS, PLASTICS, RUBBER AND PHARMACEUTICAL PRODUCTS



Cosmetics

The beauty and cosmetics market in Indonesia is growing fast with a 14% growth in cosmetics sales in 2012 totalling USD 1.01 billion (Euromonitor). Sales of cosmetics in Indonesia's urban areas for the first half of 2013 increased by 9.4% to USD 53.8 million compared to the same period in 2012 (Nielsen Indonesia 2013 Survey). Rural areas in Java may constitute huge potential in cosmetics sales, as cosmetics sales in rural areas of Java jumped by 27.5% year-on-year to USD 7.3 million in the first half of the year. The spread of retail outlets throughout Indonesia also increases options for sales into regions. Modern supermarkets, department stores, convenience stores and pharmacies generally usher in a wider product range, making global brands available to new customers.

Strong demand is attracting global players to Indonesia for its large potential, as well as increasing imports of cosmetics, especially for premium products. Global cosmetic firms, such as Unilever or L'Oréal are expanding their presence in Indonesia. Unilever has used its longstanding local presence and established a local brand Citra. L'Oréal sees so much potential in Indonesia that in 2012 it picked Indonesia to build its largest factory worldwide.

The regulatory and administrative compliance rules for the cosmetic industry have significantly improved since 2010, as Indonesia has now moved to a Notification process instead of Registration for cosmetic products. This aligns Indonesia with the rest of ASEAN member countries in implementing the ASEAN Cosmetic Directive (ACD).

POTENTIAL MARKET IN INDONESIA

Pharmaceutical

Opportunities for the pharmaceutical and cosmetic industries will likely arise from the growing middle class, progressive growth in GDP, increasing health awareness, strong economic growth, and a shift in spending patterns of the Government. Today, Indonesia has 74 million middle-class and affluent consumers, comprising 30% of the population; in 2020, this is projected to rise to 141 million, comprising 54% of the population[2]. This expanding middle class and the increased public health spending through the implementation of Universal Health Coverage (JKN/KIS) contribute to a rising demand for healthcare services in general and pharmaceuticals in particular. It is expected that Indonesia's healthcare market should more than double from 2012 to 2018.

With limitations placed on foreign ownership of companies in Indonesia and with restrictions placed on the import of certain goods into the market, investment in the pharmaceutical market remains relatively untapped and the potential to expand and develop the sector is plentiful.

Cosmetics

Apart from Indonesia's robust economic growth, current beauty trends encourage the use of personal care products. While sales of cosmetics have grown fast over the past years, there still remains significant untapped potential as Indonesia's population grows in numbers and in affluence. Notwithstanding the allure of the domestic market, Indonesia is also a significant exporter of cosmetics. Increasingly expensive tastes and rising affluence in urban centres make Indonesia a highly attractive market, while the prospects of expanding into ASEAN afford local producers the opportunity to reach millions of additional consumers.

Because of its proximity to abundant natural cosmetic ingredients, Indonesia is likely to have a cost-advantage when compared to all the large natural cosmetic producing countries. Beauty and personal care are still expected to perform respectably over the forecast period. The potential for growth is still good, as the geographical penetration of many products has yet to reach an optimum level over the review period, given the vast size of the country. Improved distribution networks in rural areas will give rural consumers better access to beauty and personal care, although urban consumers will remain the main engines of growth.

POTENTIALS FOR ENHANCED COOPERATION

Indonesia is attractive for investors for a vast array of reasons: Indonesia is the largest and considered the most stable democracy in Southeast Asia; it is one of the largest economies in a dynamic ASEAN region, posting progressive domestic growth in consumer market (especially within middle income market segments). Furthermore, Indonesia has a wealth of natural resources and a large, young labour force in addition to a growing and solid industry.

Overseeing all the conditions that make Indonesia a very attractive investment destination, the Government of Indonesia could harness this momentum to further attract foreign investors that could accelerate the country's economic growth. Furthermore, the Government of Indonesia inherits the responsibility to craft and manage the execution strategy around Indonesia's resilience and competitiveness in welcoming the ASEAN Economic Community (AEC) 2015.

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2 Boston Consulting Group Study: Indonesia's Middle Class and Affluent Consumers, March 2013

However there are several challenges that Indonesia needs to overcome to unleash its economic potential to the fullest. Among others, Indonesia's inadequate infrastructure remains a major roadblock. Infrastructure development over the past decade has not maintained pace, alongside expectations. The World Bank stated that total infrastructure investment from the past decade by the central government, sub-national governments, state-owned enterprises and the private sector, is less than 4% of GDP – about half of what is needed[3]. In addition, while the size of the working-age population is attractive, a large part of that labour force will need upgraded training to become fully effective. Both of these issues require significant investment, from public and private entities, in order to enhance and sustain the country's long-term economic growth.

Cosmetics is a highly dynamic and competitive industry and always pushes for new innovations including environmental innovations. European cosmetic research-and-development companies bring not only knowledge and technology but also innovation breakthroughs which lead to and are used as cosmetic trend reference, as well as offering developed innovation strategies which are beneficial for global competitive advantage.

Multinational research-based pharmaceutical presence brings the innovation or latest invention in medication and treatment to Indonesia, as well as increasing the capacity of healthcare professionals towards the latest innovation and invention for the benefit of Indonesian patients.

Indonesia is a very attractive market for EU pharmaceutical and cosmetic industry where EU companies would be able to help transform the Indonesian industry into a major supplier and exporter of drugs and cosmetic. 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 the Indonesian pharmaceutical and cosmetic industries. It is important to look at how opportunities in the pharmaceutical and cosmetic sectors can be developed, and how a 'win-win' situation can be created for both Indonesia and the EU in an agreement on investment and cooperation in technology and knowledge transfers.

ENHANCING ACCESS TO INDONESIA MARKET

As Indonesia moves closer to the establishment of the AEC 2015, the freer flow of capital, goods, services, investment and people may substantially change the way business and interaction are carried out with Indonesia's neighbouring countries. To achieve the AEC's objectives, barriers such as the countries' specific laws, rules, regulations and standards governing goods and services need to be harmonized. An integrated ASEAN market, particularly in the pharmaceutical, cosmetic and healthcare industry, with harmonized standards, registration and evaluation, mutual recognition of qualifications and cross-border cooperation, will boost the sectors to become more prominent players in the global landscape.

3 The World Bank Report: Indonesia: Avoiding the Trap, July 2014

Foreign direct investment limitation

Yet, due to the prevailing regulatory framework, Indonesia has seen limited foreign investment in the pharmaceutical sector since 2007. The considerable number of significant, restrictive laws and regulations that industries are subject to is hampering the development of the sectors.

The Government of Indonesia issued the Presidential Decree No. 39/2014 on the List of Business Fields Closed and Business Fields Open with Conditions to Investment ("Presidential Decree No. 39/2014") effective as of 24 April 2014. This Decree now limits the foreign ownership in a distributor to 33%. The term "distributor" used in the Decree has been broadly interpreted. One of the interpretations is that imported goods of a foreign company operating in Indonesia should be handled by a distributor (where foreign equity ownership is limited to 33%). This interpretation also applies to sales from a wholesaler to retail companies. Another interpretation is that even locally produced goods by a foreign company within its own factory in Indonesia, still need to be handled by a distributor subject to foreign investment limitations. This restriction could potentially affect cosmetics distributor companies in the implementation.

The same Presidential Decree No. 39/2014 raises foreign shareholding in pharmaceutical manufacturers to 85% but still closes pharmaceutical distribution entirely to foreign investment. In addition to the fact that the underlying necessity to limit foreign shareholding in these sectors remains hidden, these limitations carry the following risks:

- Cosmetic distribution:
  Limitation of foreign ownership in cosmetic distributors will potentially affect the growth of distributors. Under this scheme, the principal company is required to disclose its formula to its local distributor partner(s), which is subject to confidentiality and IP protection. Distribution of imported cosmetic products will not develop effectively, which will in turn affect the distribution of imported cosmetic products.

- Pharmaceutical manufacturing:
  - Capital intensive pharmaceutical manufacturing and research requires high investment amounts. Any potential partner would have to contribute at least 15%, significantly limiting the number of potential, sufficiently financially strong partners in Indonesia
  - Any growth requiring additional funds for investment and/or working capital will only be possible if the local partner is able and willing to contribute according to his share
  - The Indonesian partner automatically benefits from intellectual property registered by the foreign investor, without contributing to the development cost of such IP
- Pharmaceutical distribution:
  - Any partially foreign-owned distributor which existed before 2007 cannot significantly grow his business if the local partner is not willing or able to contribute funds according to his share
  - The absence of foreign distributors prohibits regional/global distribution contracts between multinational companies at attractive rates and conditions
  - Both of the above effects will ensure that distribution costs will remain high in the future, at the expense of the patient/consumer

Improving communications in policy making process

European pharmaceutical and cosmetic industries support the strengthening of communications with the Government of Indonesia and are well-placed to be involved in the policy making process as one of the stakeholders from the early development of the formulation of draft regulations/laws.

By enhancing an effective, two-way communication between the Government of Indonesia and the European pharmaceutical and cosmetic industries, it is expected that the investment climate and business environment can be improved towards facilitating the growth and development of the Indonesian economy.

Non-tariff measures

Non-tariff measures, which include a variety of regulations on imports and exports, such as technical requirements, quotas and rules of origin, have become a major impediment to international trade as companies strive to comply with an increasingly complex web of policies and technical standards.

Currently the Government of Indonesia is still using layered processes for import licenses and procedures as a way to limit legal or illegal imports, as well as to protect the market from illegal products and/or counterfeit products by preventing smuggling. While these measures are to a certain extent manageable, they are also time consuming, costly and keep potential smaller companies (traders) out of the market due to regulatory uncertainty. In the cosmetic and pharmaceutical industry, BPOM has implemented a strict control process on imported cosmetic and pharmaceutical products through its SKI (Import Information Letter); yet, the Ministry of Trade is now implementing an additional mandatory submission of Surveyor Report, applicable for cosmetic products. BPOM has implemented the online submission of documents in SKI application, which reduces a significant amount of time. This is in contrast with the implementation of the Surveyor Report, where the process is still largely manual, contributing to longer import dwell times and extra administrative cost.

In October 2014, the Government of Indonesia ratified the Law on Halal Product Assurance, which mandates mandatory halal certification for food and beverages, cosmetics, pharmaceuticals, biological products, chemical products, genetically engineered products, or any products which are applied, used or utilized by people, if such products are manufactured, imported, distributed and/or traded in Indonesia customs area. The Halal Law requires the establishment of separate halal and non-halal manufacturing facilities, reapplication/new application of Halal Certification and Audit, and mandatory affixing of Halal Label/non-halal label, which contributes to huge complexity in managing logistics, administrative cost, and implementation on the field due to the separation of facilities of halal and non-halal commodities.

Counterfeit products

While EU-Indonesia trade relations continue to grow, the registration, protection and enforcement of intellectual property rights (IPR) in Indonesia continues to be an area of concern for European investors. Indonesia still remains on the IPR Priority Watch List issued in February 2014 by International Intellectual Property Alliance, due to Indonesia's non-conformance to international best practices.

Many of the laws passed by the Government of Indonesian on IPR, although welcomed and viewed as positive steps, are difficult to enforce and significant challenges remain. While the intent of these laws is to protect and grow domestic businesses, many international health organizations have voiced concerns about both the violation of international intellectual property standards and the potential dissemination of counterfeit, low-quality drugs and cosmetic products.

The pharmaceutical and cosmetic industries support the enforcement of IPR and are ready to be more proactive in strengthening the IPR enforcement, including conducting inspection and investigation of IP violation affecting their businesses. The protection of IPR in pharmaceutical and cosmetic industries is believed to be more effective with strengthened cooperation and collaboration between the enforcement authorities and the companies.

CONCLUSION AND RECOMMENDATIONS

Indonesia is considered as a major player in ASEAN and therefore needs to accelerate its preparations to face the region`s market integration in 2015. To embrace a smoother implementation of AEC 2015, Indonesia needs to increase its competitive power, improve the competitive edge of its products and services, improve its human resources and harmonize regulations. In this case, Indonesia is well positioned to begin improving the quality, not only of its goods and services, but also of its labour skills, so that it would not serve as a mere market for other countries in the region. Indonesia should also become a production hub for the export of goods as well as a big exporter of skilled workers.

To attract positive sentiment, the reform of bureaucracy in order to accelerate business licenses and permits issuance should also be listed as the new administration's main priorities. A friendly environment to establish a strong, clear and consistent regulatory environment is necessary to attract long-term, value-added investment that benefits the people of Indonesia and supports Indonesia's resiliency strategy.

In this regard, European pharmaceutical and cosmetic industries applaud the positive steps taken by the Government of Indonesia and are ready to support in offering positive recommendations and feedbacks.

RECOMMENDATIONS

- Pharmaceutical and cosmetic production is considered as a high value-added industry which also offers valuable technology transfer. In order to improve the investment climate, the Government of Indonesia should consider providing incentives for manufacturers who invest in Indonesia. Larger production lines will lead to an increased demand for local suppliers of raw materials, and thus will attract investment of raw material providers to supply the demand. We encourage the Government of Indonesia to see the presence of foreign investors as beneficial to both sides and to seize the opportunity and establish firmer cooperation as partners, not competitors to the local businesses, and together improve Indonesia's economy.
- The improvement of trade and investment climate in Indonesia is of importance, considering the overall objective of the EU to support the sustainability of Indonesia's economic growth by improving its trade and investment climate. With this regard, we encourage all industry associations – whether local or foreign - to be part of the policy making process.

- The European pharmaceutical and cosmetic industries welcome the efforts taken by the Government of Indonesia to simplify import procedures and licensing. The multi-layered system of decision making of the Indonesian regulatory authorities often foster an unexpected and frequent policy drift and more can still be done to resolve this situation. We support transparent and efficient import procedures particularly in using online import procedures.
- Developing long-term IPR protection strategies in Indonesia, as well as across the ASEAN region, is essential for Indonesia's continued development and increased integration into the global system. In parallel, we support future opportunities to collaborate with the Government of Indonesia and establish a concrete plan to strengthen IPR protection by conducting internal investigations in the field, in cooperation with the police, BPOM, Directorate General of Customs and Excise, and Directorate General of IPR as the IPR enforcement authorities, as well as by creating public awareness particularly of the danger of counterfeit, low-quality medicines and cosmetic products.

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