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Position Paper

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Table of Contents

1. Economic Relations 2

1.1 Introduction 2

1.2 The Global Pharmaceuticals Market 2

1.3 The Indonesian Pharmaceuticals Market 3

1.4 EU in Indonesia 5

1.5 The European Pharmaceuticals Market 6

1.6 Indonesia in EU 7

2. Potentials for enhanced cooperation 7

2.1 General Opportunities 7

2.1 Indonesian Health Care Sector 8

2.3 Indonesia in the Region 11

3. Issues and Challenges 12

3.1 Current Situation 12

3.2 Regulatory Framework Indonesia 13

3.3 Regulatory Framework EU 15

1. Economic Relations

1.1 Introduction

Indonesia is important to the EU: it is fast becoming a middle income country with an impressive growth record (positive throughout the economic crisis). Indonesia is the largest market in ASEAN with an economic growth target of 7.7%. Even though Indonesia only represents 0.5% of EU exports – less than smaller countries such as Malaysia and Thailand - the EU is very interested in Indonesia, not the least because of its potential. Indonesia has gained an important role in G-20 and its potential inclusion in the list of BRI[I]C countries.

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.

In 2008, Indonesia exported EUR 13 billion worth of goods to the EU, making the EU its biggest export destination of non-oil and gas exports. Indonesia imported goods from the EU worth EUR 6 billion. Trade grew by an annual average of 6% and remained strong even during the global crisis (EUR 17 billion in 2009). The EU is the third largest source of Foreign Direct Investment in Indonesia and EU companies have a strong and longstanding presence in Indonesia with a significant economic presence. 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 Global Pharmaceuticals Market

From 2000 to 2008, global pharmaceutical sales have more than doubled. With about 37%, the United States remains the largest individual market worldwide. Over the past three years, the growth of this market, which always was above average until the first few years of the new millennium, now has more in common with the moderate dynamics of the European markets. The strongest growth was exhibited by the Eastern European, Latin American and Asian markets. In 2008, Europe's share of the world market grew to 32% (2003: 26%) primarily due to the strength of the Euro against the US Dollar. Germany's share of the global market remained nominally (i.e. at the current USD exchange rate) at about 4.5%. This represents a real decrease to 3.5%.

1.3 The Indonesian Pharmaceuticals Market

The market size of pharmaceutical products in Indonesia is estimated to be around IDR 37.5 trillion (US$ 3.9 billion, 2010), with an impressive average annual growth in the last five years of 10%.

Indonesian Pharmaceutical Market 2005 – 2010						
	2005	2006	2007	2008	2009	F2010
Total Market (IDR bn)	23,589	23,047	25,708	29,981	33,969	37,531
Growth (%)	13.6	- 2.3	11.5	16.6	13.3	10.5
Ethical (IDR bn)	14,622	14,033	14,837	16,969	19,225	21,142
Ethical Growth (%)	15.5	- 4.0	5.7	14.4	13.3	10.0
OTC (IDR bn)	8,967	9,014	10,871	13,012	14,744	16,389
OTC Growth (%)	10.8	5.4	15.0	19.6	13.3	11.2
Source: PT Kalbe Farma, Market Overview Q1/2010						

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 pharmaceuticals companies operating in Indonesia, there are an estimated 20 European companies with an active presence.

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

The Indonesian pharmaceutical industry consists of chemical-pharmaceutical and non-chemical traditional (herbal) medicine manufacturers. There are around 232 chemical and pharmaceutical companies. Local companies account for around 90% of sales, mostly these are "formulators" of medicines that import basic (active) materials/ingredients, also explaining the increased demand for pharmaceutical basis materials (90% growth in imports since 2003 to US$ 338 billion in 2008).

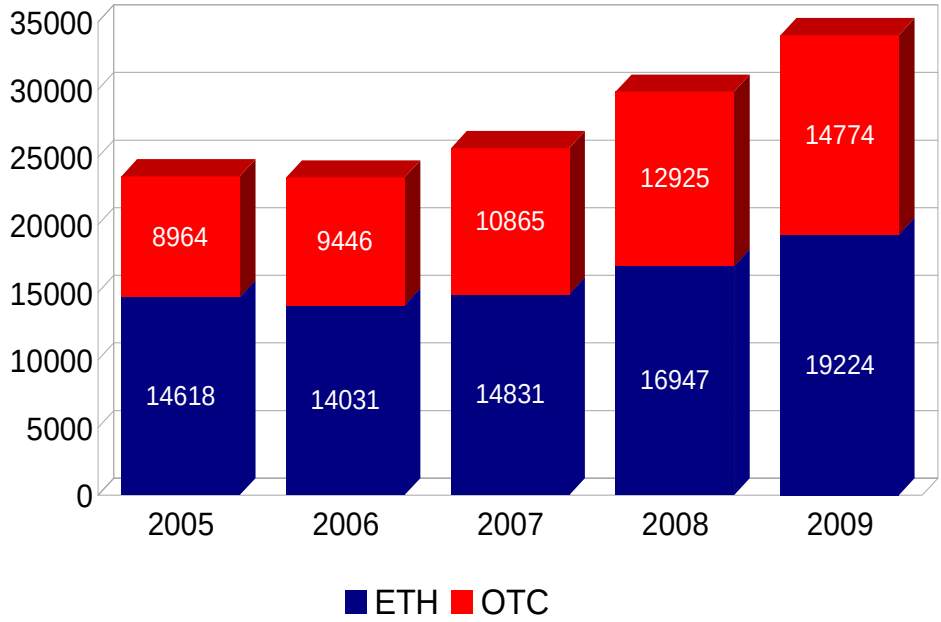
Most of the manufacturers have facilities to produce four types of medicines: tablet, syrup, cream and caplets and some can also produce medicines in the form of drop, powder and granule. Many local companies produce medicines under special production license from overseas manufacturers, particularly for ethical products. These usually hold the exclusivity of production and marketing of those products in Indonesia. Local compa-

nies are responsible to register the products in the DG of Drug and Food and the DG of Patents. Product development, in general, relies on foreign licenses or on expiry of patents to enable mass production. Seven companies occupy 40% of the market. Only one out of these seven is a multinational company (MNC).

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 suffient 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 pharmaceuticals 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 (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.

1.4 EU in Indonesia

Pharmaceutical products (HS 30) are one of the EU's important export products to Indonesia. Exports grew by 72% (value) in 2008 compared to 2005. Among the products, HS 3004 (medicament mixture put in dosage) had a 65% share and grew by 56%. Most of the EU exported products are utilized by Indonesian pharmaceutical producers to formulate final medicines. In terms of overall EU exports, exports to Indonesia is very small, below 0.3%.

Currently 30% of the manufacturers in Indonesia are foreign companies. In a regional comparison this level is remarkably low indicating that there actually should be room for further development of the sector through foreign investment. However due to the pre-

vailing regulatory framework Indonesia has seen no or very limited investment in the sector since 2007.

1.5 The European Pharmaceuticals Market

EU's pharmaceutical sector is substantial. On average approximately EUR 430 was spent on medicines in 2007 for each European and this amount will likely continue to increase as the population in Europe ages. Overall, in 2007, the market for prescription and non-prescription medicines for human use in the EU was worth over EUR 138 billion ex-factory and EUR 214 billion at retail prices.

The drug development costs for a new chemical or biological candidate was estimated at over EUR 1 billion in 2007 and on average it takes 12-13 years to bring a new medicine to the market. Out of every 10,000 substances synthesized in laboratories, only one or two will successfully pass all stages to become marketable medicines. (IMI Press Release, 2008)

In 2008 EFPIA countries' pharmaceutical exports totaled EUR 203,800 million. This amount also includes the trade flows between the EFPIA countries, w hich were estimated to EUR 124,300 million in 2008. Exports to non-EFPIA countries amounted to EUR 86,400 million, i. e. 37.4% of total exports. Pharmaceuticals represented 5.6% of total EU manufacturing exports in 2008 against 2.1% in 1990. The top 15 pharmaceutical companies in EU by 2008 sales were:

Rank	Company	Sales ($M)	Based/Headquartered in
1	Pfizer	43,363	US
2	GlaxoSmithKline	36,506	UK
3	Novartis	36,506	Switzerland
4	Sanofi-Aventis	35,642	France
5	AstraZeneca	32,516	UK/Sweden
6	Hoffmann–La Roche	30,336	Switzerland
7	Johnson & Johnson	29,425	US
8	Merck & Co.	26,191	US

9	Abbott	19,466	US
10	Eli Lilly and Company	19,140	US
11	Amgen	15,794	US
12	Taj Pharmaceuticals	16,234	India
13	Wyeth	15,682	US
14	Teva	15,274	Israel
15	Bayer	15,660	Germany
16	Takeda	13,819	Japan

1.6 Indonesia in EU

Export of Indonesian pharmaceuticals is relatively small, but increased by 166% in 2009 compared to 2005. As percentage of overall EU imports, Indonesia only provides 0.01%, still a doubling compared to 2008. There is a big potential as the EU market (extra EU imports) have been growing substantially, 64% in the last 4 years. Overall growth was 75% (compared to 2005).

2. Potentials for enhanced cooperation

A survey with EU Member States mentioned the following advantages of Indonesia for investors: The largest and considered the most stable democracy in Southeast Asia; on of the largest economies in a dynamic ASEAN and Asian region; Consumer market growing strongly (especially middle income market segments); ASEAN potential – internal market production networks and FTAs; Availability of natural resources; Large labour force, especially young people. All these points should be taken into consideration when discussing Indonesia's potential with regards to the pharmaceutical industry.

2.1 General Opportunities

How can we enlarge trade and investment opportunities in these sectors benefiting both - Indonesia as well as the EU?

- Based on statistics on average spending on drugs, Indonesia has a very low level of spending on drugs. This is an opportunity for EU business.
- EU pharmaceutical exports to Indonesia are increasing in the past 5 years and can be improved, by solving technical issues, and EU can have benefits of this.

- Indonesia's level of export statistics to EU is low, how can we increase Indonesia export to EU? This will be benefiting for Indonesia as well for EU.

- Out of 40 thousand of types of jamu (herbal medicines), 30 thousand types are found in Indonesia. It is an area of interest to EU, and also will be benefiting to Indonesia.

- Indonesia has very big opportunities to export pharmaceuticals to the EU, but a mobilization from both business and Government is required.

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), coupled with a well developed industry in Indonesia and availability of resources. The 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.

2.1 Indonesian Health Care Sector

The Indonesian health care sector has a wide range of problems to tackle that also could be turned in to opportunities, these include:

- Growing and ageing population;
- Inefficiency in pharmaceuticals distribution;
- Shortage of pharmaceuticals;
- Lack of physical resources;
- Non conducive investment climate in pharmaceuticals sector.

Demographics

As a middle income country Indonesia's age distribution is stabilizing and we will see an ageing population as one of the major demographic changes for the country. With an ag-

ing population we will see additional demand for more and more qualified services offered by hospitals, health workers and more sophisticated health care.

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. Since the 1990s, the Government of Indonesia launched programs requiring government health institutions to use generic medicines, also supported by the private sector. The National Social Security System foresees support for the poor via JAMKESMAS (Public Health Insurance Scheme). Still, only 26% of 230 million people was covered in 2007 and per capita medicine consumption is low compared to other countries. Therefore, opportunities in Indonesia to enlarge the market (quantity and quality) are abundant, especially considering scope for increased income levels and insurance coverage.

Human and physical infrastructures are limited and face quality and efficiency problems. Significant improvements in the quality and costs of pharmaceuticals are needed. Indonesia's reform process also needs to address a number of major policy concerns. Health expenditures per capita are low compared to regional neighbors as well as relative to Indonesia's income level, health expenditure as part of GDP is the lowest in the region with 2.2%. Indonesia also has among the lowest ratios of doctors and hospital beds per 1.000 population compared with its regional peers, with 0.98 doctors per 1.000. Furthermore health price levels in Indonesia are highest among its peers, with all health indicators being worse in the poorer eastern provinces of the country.

According to a 2009 report by the World Bank physical access to health services in Indonesia is considered adequate, however there are shortages in the number and distribution of health professionals. Most significantly there are too few doctors, especially specialists where the availability is extremely low, there are also major quality concerns of the existing work force due to lack of medical training facilities, lecturers and investment in medical education. Even though these problems are evident, foreign doctors are not allowed to practice in Indonesia. Currently Indonesia has high distribution costs with even the cheapest generic drugs being prices above international reference price. The lack in both human

and physical infrastructure in the health sector makes the sector inefficient, hence it results in high cost of healthcare for the Indonesian general public.
The burden of 'high cost of healthcare in Indonesia' will be partly alleviated if the social health insurance system as mandated in the Law No. 40/2004 will be implemented. It is vital that the law gets implemented, and the industry is ready to support the government of Indonesia in their effort to provide better access to healthcare for the Indonesian people.
The insurance system has to be improved, as per today poor people cannot afford hospital treatment. This fact results in the strange contradiction of Indonesia statistically having an insufficient amount of hospital beds, but not fully occupied hospitals.

International pharmaceutical companies are ready to help Indonesia to improve the health system. The foreign pharmaceutical sector is willing and able to assist the Indonesian Government in improvements of the healthcare sector. Closing out know-how of the leading pharmaceutical companies in the world is counterproductive and will damage the Indonesian health sector in the long run. Ideally this challenge could be converted to an opportunity if partnerships could be entered between the potential EU investors in the sector and existing local players. However, the regulatory framework would have to be improved, for example with regards to data exclusivity and general IPR related issues, including encorcement.

If these issues are resolved, increased investment in the Pharmaceutical sector would in time lead to increased knowledge transfer to the domestic industry as well as positive competition which in turn contributes to the development and competitiveness of the domestic companies in the pharmaceutical industry.

Indonesia currently has a rare window of opportunity to catch up with its neighbors, which earlier have been more successful in the health sector. This requires a reformed regulatory framework supporting the development of the health/pharmaceuticals sector. ASEAN implementation in 2011 would be an opportunity for utilizing Indonesia as a country to invest and use as the source of products to the cluster, the markets will have to accept products from Indonesian manufacturing facilities. Therefore, Indonesia should rather attract them than ending up importing products from neighboring countries only.

To facilitate the development of the health and pharmaceuticals sector in Indonesia there should also be increased collaboration between the government and the private sector to provide better access to quality healthcare and development of the pharmaceutical sector.

2.3 Indonesia in the Region

Indonesia offers the potential to reach a vibrant economic region of almost 2 billion consumers, strengthened by several FTAs in the region. By functioning as a stepping stone to the region including China, Indonesia could reemerge as a potential investment destination.

Indonesia is building an economic community with the ASEAN-countries. Through ASEAN Indonesia has an FTA with China, and FTAs with India and Australia are next in line. Several companies have already chosen Indonesia as their hub to access the markets in the region. The role of Singapore as a R&D hub also has to be taken into consideration. Lessons can be learnt from Singapore, with regards to how investors and foreign researchers and doctors are attracted. The spill-over effects to the industry, academia and ultimately the society can not be denied.

The Singapore example is outlined as follows:

- Economic & Political Stability
- Economic Incentive : Companies Investing
- Regulatory Framework
    - IP : Laws were drawn up to protect foreign investors.
    - Clear Bioethics code : Stemcell, Human Tissue, Genetic Research
- Personnel and Infrastructure
    - Personnel training, 276 postgraduates were awarded scholarships to pursue biomedical doctoral degrees, costing USD 0.6 million/scholarship. Liberal immigration policy for biomedical experts.
    - Infrastructure
        - Tuas Biomedical Park: USD 331 million investment for bulk actives.
        - Biopolis: USD 301 investment (phase 1) for R&D hub in Asia.
    - Singapore Brand.

If Indonesia could try to become an integral part of this multibillion industry, either as the part of a regional network as a manufacturing hub, or as a part of the supply chain it

would benefit the Indonesian pharmaceutical industry. To try to emulate the actions that have been taken by Singapore would not be advisable since this would require significant upgrades in fields where Indonesia is lacking, such as trained staff (PhD level), world class infrastructure, strong IP laws (including enforcement) protecting investors. Furthermore the restrictions on foreign doctors to practice in Indonesia, halts the potential development of any significant R&D facilities in the country.

The potential Indonesia would have if linking up and drawing from Singapore's standing as a world class research hub would be to benefit from the large and growing population in the country. The cheap labor could also be utilized for basic manufacturing. The wide variety in tropical diseases could make Indonesia suitable for some R&D activities in this field.

3. Issues and Challenges

3.1 Current Situation

Due to a number of reasons Indonesia is no longer attractive as an investment destination for the pharmaceuticals sector. Due to the weak IPR protection and limitations in ownership to 75% for foreign investments as well as regulation 1010/2008 , which forces foreign companies to set up local manufacturing.

During the last couple of years there has been no significant investments in the sector in Indonesia. A number of companies including Johnson & Johnson, Schering Plough and Astra Zeneca have left the country.

The annual growth of the sector is very strong and with a growing middle class of about 35 million the Indonesian market could potentially become increasingly interesting. About 80 million people are currently benefitting from state-driven insurances which will increase consumption in pharmaceuticals.

Entry to EU Market

To enter the EU market remains a major challenge for Indonesian pharmaceutical companies. There is a general lack of knowledge with regards to the structure of the market, the regulations governing the market, furthermore there is very limited support offered to Indonesian companies entering foreign markets by the Indonesian Embassies. Before an Indonesian product can enter the EU market there is also additional expense due to the inspection required, where officials from an EU Government have to visit Indonesia to review the manufacturing facilities. This comes at a minimum cost of USD 15,000,

which in many cases can be a significant amount for some Indonesian pharmaceuticals companies.
The potential the Indonesian exporters could have is in the herbal market. The remaining problem though is that the products are not yet standardized.

The challenges for Indonesian companies entering the EU market can be listed as below:

- Lack of Marketing knowledge & Capability
- Lack of Regulation Knowledge
- Limited Support from Indonesian Embassies
- Product Issue
    - Standardization of Herbal Medicine, Local Heritage
    - Generic products, difficulties to compete with India and China
    - Production
        - 95 % Raw Material imported from China, Eastern Europe, India
        - Import Duties
        - Quality
- Registration
    - File Quality, Registration Cost (EUR 100,000), Inspection Costs (EUR 15,000)
- In general Indonesia can be considered as a more import driven than export driven country.

3.2 Regulatory Framework Indonesia

Registration of Pharmaceuticals in Indonesia

There are improvements in 2010 compared to last year. There are still bottlenecks of registration load because the process is still manual. Previously, the documents can be provided in form of soft copy, but now the documents must be provided in hard copy. Registration is the most important step. Registration process takes a very long time in Indonesia, sometimes up to 12 months, and it is impairing the industry. Many investors want to see this changed. Although there are products from 2009 whose registration numbers have been issued this year, BPOM is requested to speed up the process. Another concern is that in 2011 the government is likely to complicate import procedures. However, starting this year there is a lot of improvement in the registration process, for

example as by now the registration can be done electronically. Also there is no quota in documents anymore, and the evaluation process is now faster than before, however, the bottleneck is still in the issuance of certificate. It is not the queuing to go to the higher level, but the queuing to get the certificates issued, because the company has to be checked again one by one.

Standards and Technical Regulations

Standardization benchmark is the Good Manufacturing Practice (GMP), introduced in 1971. The National Quality Control Laboratory (QC Lab) and the provincial QC Lab were developed with the assistance of WHO. The government controls quality by sampling. At the central level, the regulatory authority for pharmaceuticals is the BPOM (Drug and Food Control Agency). BPOM performs drugs registration, provides licenses for drugs imports and exports, controls drug promotion, monitors and supervises for implementation of GMP, assures the quality of drugs and monitors distribution. GMP includes following assessments: (1) General; (2) Quality Management System; (3) System of Building, Supporting Infrastructure and Equipment; (4) Ingredient Management System; (5) Production System; (6) Packaging and Labeling; and (7) Quality Control System.

A mapping has been performed by BPOM in 2004 to assess the implementation of GMP in anticipating the ASEAN pharmaceutical harmonization. The mapping grouped the industry into four categories of producers (A, B, C, and D). Category A (29%) manufacturers are eligible to produce in their own facilities; B (29%) to produce in their own facilities if internal improvements are implemented; Category C (26%) are allowed to produce only partly in own facilities and the rest through outside facilities; and D (16%) have to produce through outside facilities (toll manufacturing).

Distribution

Pharmaceutical producers are allowed to manage their own distribution, but they usually outsource – sometimes through subsidiaries - activities for the sake of efficiency. The distributors are called "PBF" (pharmaceutical wholesale companies). In terms of distribution, around 50% of the pharmaceuticals are distributed through pharmacies, 30% through drug stores, and the remaining 20% are distributed directly by physicians and hospitals. Drug stores sell pharmaceuticals at relatively cheaper prices, often 10% to 20%, and generally serve as pharmacies in small towns and rural areas. In addition to OTC drugs, ethical

medicines often also available at the drug stores. The Ministry of Health released regulation Nr. 1010/2008 that does not allow foreign pharmaceutical companies from selling drugs in Indonesia unless they have local production facilities.

According to Decree No. 1010/2008 of the Minister of Health, international research-based pharmaceutical companies operating in Indonesia with no manufacturing facility are not allowed to register their products anymore. They have to appoint an intermediary for this in the form of a local pharmaceutical manufacturing company, which only extends the supply chain and creates additional cost with no benefit to the Indonesian patients. The Ministry of Health Decree on Drug Registration No. 1010/2008 raises concerns regarding the continued import of pharmaceutical products into Indonesia. In effect this decree is forcing the companies that want to stay in Indonesia to start manufacturing (or partner with a manufacturer).
A quick win for the development of the pharmaceutical sector in Indonesia will be to remove regulation 1010/2008, and ensure the foreign invested pharmaceutical sector that they are welcome to contribute to Indonesia's development of the health sector. If the above is not mention it would be advised to create a third type of certification for marketing and sales companies, the affected companies would be granted such certification so that the initial intent of regulation 1010/2008 of cleaning PBFs in Indonesia to ensure the safety of the people is still achieved.

It should be made clear that these distribution companies mentioned above not are "wholesalers" but rather some of the leading pharmaceutical companies in the world that invest significant sums to develop medicines critically needed all over the world. To exclude these companies from the Indonesian market would not only be irrational as the companies supply vital medicines to the Indonesian general public, it is also functioning as a deterrent for future investors. The fact is that it is probable that this results in the Indonesian market having a deficit in critical drugs such as cancer medicines and insulin.

3.3 Regulatory Framework EU

Registration of Pharmaceuticals

When comparing the registration procedures and price for registration there are great discrepancies between EU and Indonesia. To register a new pharmaceutical product in Indonesia would cost in the range IDR 5-20.000.000 (EUR 450 – 1,800), emergency pharmaceu-

ticals could take a short as three months to register. But generally the registration process in Indonesia is long. Issues that still appear as challenges related to the registration process, these include GMP (Good Manufacture Process) and Data Exclusivity. Drug registrations required to be in line with ACTD (ASEAN Common Technical Dossier).
To register pharmaceutical products in EU costs about EUR 100,000 and is a multi-year process. The high cost for registration of pharmaceuticals in EU is one of the major hurdles that keeps Indonesian players out off the market.

REACH Regulation

The new European Chemicals regulation, REACH, was adopted in December, 2006. REACH stands for Registration, Evaluation, Authorization and Restriction of Chemicals. REACH entered into force on June 1, 2007, and will be implemented in phases over an eleven year period. REACH was designed to systematically identify the hazards and risks of chemicals allowing for appropriate risk management measures by industry and, if necessary, provide for further regulatory action by the public authorities.

EU manufacturers and importers are obligated to register substances they produce or import in quantities over one ton per year. This registration requirement applies to substances on their own, in preparations and in articles if they are intentionally released. Timing and other factors affect the required registration date, which could be as early as 1st of June 2008, through as late as 1st of June 2018.