Interview with Parulian Simanjuntak, Executvie Director, International Pharmaceutical Manufacturing Group

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Although Indonesia in the last ten years had the second highest growth in ASIA in terms of drugs' production and consumption, the market share of research based companies has dropped from 50% to 25%. What have been the main drivers leading to the current scenario?

The share of international companies presently represents 25% of the total market share in Indonesia. The main reason of the dropping in market share is due to the country's economic conditions, in particular the poverty, which causes an increasing approach to self medication and OTC consumption. The latter is growing much faster than the prescription market also because in Indonesia OTC, produced by local companies, substitute ethical products. Poverty also reveals that there is not health insurance in Indonesia. On the prescription market, we have only recognized the patent protection since 2001, so not even ten years ago. Prior to that, it was used to happen that copied drugs were already sold in the market before the producing company had launched the product. Similarly, the transparency of registration time has only been introduced officially in 2003, and although the registration seems transparent, it is a reality that companies can get a faster registration process only if they have good connections.Another reason of the market share drop for MNCs has been caused by the governmental policy oriented to promote and to protect the local

industry. We can see it from the number of the drugs registered from national companies compared to the one registered by international ones. This ”discrimination” against multinational companies is also visible in the regulation of generics. In fact, since 1998 the Government is promoting the use of generics, however, because of confusion in terminology, when we refer to generics we mean non-branded generics, which are priced from 70% to 80% of the originators’ price, with some cases of generics products priced higher than the originals. So all these factors have contributed to the decline, or better, the growth of the local companies, which is much faster than the one of the multinationals.

With lenient policies toward innovators, the Government support for non ?

branded generics, and the new ministerial decree that obliges MNC to have a manufacturing plant to market their products, what are the perspectives for research based companies in Indonesia? It is not very clear of what is the real intention of the Government in issuing the decree 10/10. The original idea was to remove the rights of distributors to register products and consequently obtain the licence to sell them. This idea, based on the argument that distributors are not responsible for the products was actually very good and IGMP supported it.However, because in Indonesia, distributors and agents are not differentiated, they are bond together as distributors and they can register products. The mistake was made in 1991 in the reformation era. Since 1991 distributors were allowed to register products, importing and selling without being responsible for potential liabilities. Moreover, as becoming a distributor is relatively simple and does not require high capital investments, according to the statistics provided by the Ministry of Health, presently there are over 2,000 registered distributors selling to 8000 pharmacies. However, the 2,000 distributors is also explained by the decentralization process begun in 2001, when the district governments required the wholesaler or companies participating in the local tenders to be local companies. Hence, distributors with the head office in Jakarta have to register an additional legal subsidiary in another region to meet the local requirement and gain the permission to market their products, which in turns had led to the multiplication of distributors. That was the good intention of the government. However, I have to go back in history to make sure there is a better understanding of the underpinning reasons leading to the current confusion of the decree 10/10. In the 1970s, I was here already starting as a young man coming back from Germany, 90% of the market belonged to foreign companies, as at that time there were no national investments in the pharmaceutical industry. At that time the Government required MNCs operating in Indonesia to have manufacturing facilities, and as the country was a virgin land for the pharmaceutical industry every company was willing to enter the Indonesian market.Since 1991 the Government oriented its policy toward the creation of a stronger local industry and to promote the consumption of generics, which

together with the drying-up of the pipelines for research based companies, has contributed to the downsize of the international companies' market share. Indonesia started to re-open its market after the financial crises of 1998, allowing distributors to register products without having a manufacturing plant; therefore some of the companies that had previously withdrawn from the market came back.

The R&D based companies without a manufacturing plant; called PBF – pharmaceutical wholesalers ?

were wrongly classified as distributors. This has created the confusion in the legislation. Recently the Government gave a nomenclature where there are only three types of pharmaceutical companies: manufacturer, distributors and retailers. I challenge this argumentation and I have presented the fact as PBF should be classified as manufacturers rather than distributors, even though this definition is also incorrect since PBF have manufacturing facilities but not in Indonesia.

Besides a large market what will be the advantage for PBF companies to maintain their presence in Indonesia and decide to invest in a manufacturing plant?

Most of the factories, as far as I know, are working under capacity and as the efficiency is the name of the game I don't think they will establish production facilities. Secondly, the necessity of having centres of excellence and the entire business model built on exploiting comparative advantages worldwide, will not allow them to establish manufacturing facilities in every country. As in the last five years research based companies have introduced more than 250 new medicines in the domestic market.

What will be the impact on the Indonesian healthcare sector if those companies will withdraw from the market?

If research based companies go away, they will have to face higher entry barriers and it will be difficult for them not to lose market presence. In the end companies will eventually find another way to sell their products in Indonesia and the Government is well aware of that. Therefore, if PBFs will not have a direct presence in the market they will license local companies, having joint venture or toll manufacturing agreements, which will allow them to overcome the legislation. At the end of the day, the first day I could imagine they will not be inclined to share dossiers and know-how, especially for sophisticated drugs, because of technology spillover fear; hence they will evaluate very prudently the risks and benefits of having or not a direct presence in the local market. Additionally, for some drugs the current level of consumption will not left to have a local production facility. Presently 10% of the drugs are imported to Indonesia, and the Government should

seriously think about the consequences on the domestic healthcare sector if those drugs will be retired from the market. I met the Minister last December, presenting the individual market share of international companies, the reasons why Indonesia imports some medicines, the commercial feasibility of each drug and the fact that there is basically no negative impact for MNCs in closing down some of their local operations. In fact, closing down some operations will mean that existing factories will be sold to other multinational companies, which in turn will create additional undercapacity problems. Similarly, workers will be minimal effected and the workforce downsizing, due to the redundancy in operations, will be minimal and tolerable. What has to be understood is that research based companies have been operating in Indonesia for the last 30 years, their contribution to the Indonesian health care system has been extensive. According to the development of the market their business model has changed over the years and MNCs will change their position again as the game will be reshaped because they are here for business. Therefore, in IPMG we believe the Government will analyze the different outcome of this policy and we are confident they will change this all-or-nothing proposition. Beside the decree 10/10, the Government continuous pressure on prices and the lack of IP protection reduce the appeal of the domestic market for foreign drugmakers.

As representative of the international research based companies what would you suggest the Government to take as an immediate action to increase the attractiveness of the country to pharmaceutical MNCs?

Business certainty. Indonesia is competing against other countries, and Indonesia has been left behind, even lower in health indicator than Vietnam. The market is still attractive, if you look at this statistics, the customer population of foreign drug manufacturers is 10% of the population, which means at least 22 million people and can be compared to the size of the entire Malaysian market. Therefore, multinational companies will think twice before withdrawing from the country. The other reason is that since there is no reimbursement policy, from 80% to 85% of health care expenditures as paid out of pocket. However, since 2004 there is a law on social security that includes the possibility to create a health insurance. Coming through it will be a boost for the market. I told everybody since the 70’s that the market is potential and last year, 2008, I said the same: Indonesia is a potential market.

Those potentials are only referred to sales or also to upstream processes such as R&D, clinical trials and molecules/API productions?

No, the potentials are exclusively referred to the market as there is a critical lack of human resources and there is also no effort to increase the awareness of living a healthier life or making

Indonesia an innovator player. The Government has to do something to spur the local industry since we have less than 3% of the GDP expenditure for health, the drug consumption per-capita is the lowest in the region, even lower than Vietnam. Furthermore, Indonesia has been surpassed by Thailand in terms of market size, losing the leadership in the region and the $2billion of the market represents less than 1% of the global selling.Despite the TRIP agreement and extensive legal reforms on intellectual property laws, with at least 20% of the total market shares represented by counterfeit drugs, Indonesia still occupies one of the world's lowest ranking for intellectual property protection.

Can we translate the poor enforcement of Indonesia IP into the low commitment of the country to enhance innovation?

Well, if speaking with the Minister of Heath, she will probably reply that in Africa the market for counterfeit drugs is maybe 40%. Given the risks of counterfeit drugs and the negative impact on originals, both in terms of sales and negative branding, IPMG is very active in the anti-counterfeit campaign. As we started the campaign giving explanation to the media, the local associations and the Ministry of Health started to challenge our figure based on the 10% average of counterfeit drugs given by the WHO, assessing that the market of counterfeit drugs is probably much lower than we expect. Indonesia consist of so many Islands, so many ports which make drug smuggling easy. Therefore I can say that the level of counterfeit drugs ranges from 4% to 40%. However, the Government has not taken serious initiatives to face this problem and even though a series of reforms and memorandum of understanding have been signed, not much has changed and the number of patent registrations keeps falling.

Speaking with the MNCs worldwide what advice would you give them to successfully operate in Indonesia?

As every country has different culture, in order to be successful in Indonesia, international companies have to understand the local costumes. IPMG role is to help those companies to provide a better service to the people and to support the country by presenting the different benefits local companies cannot bring to the domestic healthcare system on their own. The national Government is trying to protect the local industry, but since domestic producers have already 75% of the market share there is nothing left to protect. Policy makers should implement a better and a more transparent regulation and try to meet the interest of all the stakeholders without penalizing research based companies.

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