Interview with Leonard Ariff Abdul Shatar, President, Malaysian Organisation of Pharmaceutical Industries (MOPI)

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The pharmaceutical industry has been targeted as one of the key growth sectors for the Malaysian economy under the 10th Malaysia Plan, how successful in your opinion have the government been in creating an environment for growth in this industry?

Malaysia stands out from the other ASEAN countries in terms of its operating environment. Within ASEAN the markets differ substantially in terms of tariff barriers and the openness of the markets. Malaysia and Singapore have been at the forefront of promoting harmonization within ASEAN and this is based on the desire to develop their local Pharma markets. Hopefully Malaysia’s steps to achieve harmonization within ASEAN will usher in a single-point registration system facilitating trade across the region. The key obstacle so far has been the protectionist stand-point of other ASEAN members in the pharmaceutical industry.

The priorities for the Ministry of Health have always been the quality of manufacture, the efficacy of the product and the lowest possible price. This explains why the majority of contracts for the government are done on an open-tender basis. Therefore in terms of access to the Malaysian market it is, along with Singapore, the most lucrative per-capita market for Innovators because of the absence of price controls and an open market. The management of pharmaceutical pricing is achieved through tenders for generics and direct negotiations for patented products.

The environment for patent protection is relatively strong in Malaysia, although the MNCs may perceive some problems regarding counterfeit medication. The government has created a framework for patent protection, whilst at the same time allowing for a competitive generics market through open-tenders. Penetration of generics has been more successful in the government market compared to the private sector.
Generics have strong potential for the Malaysian market. The rough size of the Pharma market in Malaysia is approximately $1 billion. Roughly one third of this figure is accounted for by generics but in terms of units the penetration of generics increases to around 60%-70%.
There are also some government initiatives parallel to the 10th Malaysia plan such as the Economic Transformation Programme (ETP) during growth of Pharma market. Pharmaceuticals are central to both plans although it is currently unclear how the ETP will affect the industry.
To sum up the market is open, protected by patent recognition and the Ministry of Health has an active generics policy driven primarily by the rising cost of healthcare.

In terms of growth rates 10.5% is actually an inflated figure. The MNCs tend to increase prices on an annual basis by around 5%. Therefore the real increase in consumption spending is around 5-6%. The government also drives this consumption. Based on value the government purchases around 35% and in terms of volume the government consumes around 70% of pharmaceuticals in Malaysia.

The government has tried to encourage the local pharmaceutical companies to grow beyond Malaysia. The small population of around 26 million people limits what can be achieved cost-effectively. It is therefore difficult to invest in certain assets for such a small market unless companies also engage in exports.

Despite its small size there are a number of drivers fuelling growth in the domestic market including an emerging middle-class, an ageing population and increasing health expenditure. What would you say were the key factors in expanding the home market?

Growth has been shared across both the export and domestic markets. From a manufacturing perspective, exports have been the strong growth factor. The export growth for domestic companies is around 10% per year driven primarily by exports outside of ASEAN. For the domestic market, there has also been consumption growth from an increasingly affluent middle-class, better diagnosis and medical care. These would be the some of the key factors creating domestic growth in my opinion.

One of the biggest growth drivers for generics is the pricing differential. Generics manufacturers can market their products at around 50% of the original patented product thus driving their growth. The growth of the generics market tends not to be straight line. There are growth bumps occurring when products go off-patent.

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Many patented products are due to expire within the next two years. To what extent does this represent an opportunity for local generics companies?

From a revenue perspective, products going off-patent does represent a significant opportunity. However from a market-share perspective, all the main players will end up making these products thus reducing the price through severe competition. It will therefore be necessary to find more niche products.

Currently there are large products such as plavix® or lipitor® which are $50-60 million products and every manufacturer will therefore be seeking an equivalent generic.

Having discussed the openness of the Malaysian market and opportunities for emerging generics, what are the primary challenges for the industry in Malaysia?

Protectionism within ASEAN would be the main challenge in terms of exports. In fact, Malaysian companies struggle to export within ASEAN and find it much easier to gain registration for their products outside of ASEAN. Naturally this greatly reduces the ASEAN countries as a potential market for Malaysian companies. The $500 million potential export market of ASEAN is therefore reduced to a much smaller figure.

In terms of Malaysian growth, the major challenge is the replication of assets. There is little differentiation in assets or dosage forms between companies which would not be the case in a larger market. Once one company begins with pallet technology another one will follow and the same with other technologies. This inhibits the domestic market from developing, however it does force companies to find markets outside of Malaysia which presents another opportunity.

Malaysia is a member of the PIC/S which gives Malaysian products a respected GMP qualification allowing for exports. There is also no differentiation in terms of product standards and the GMP standards adopted are the highest in the industry. Therefore whilst Malaysia is not as competitive as some countries with more lax regulatory environments, its products enjoy global acceptance in terms of standards.

As well as standards, what would you say were some of the potential advantages of the Malaysian export market?

Quality standards are certainly the primary advantage for Malaysian products. An emerging niche is Halal medicine although the Ministry of Health is cautious in promoting such products. The ministry is concerned over contamination by non-Halal products and is therefore promoting this niche cautiously using only obvious Halal products. For example, Gelatine needs to be clearly identified as either bovine or porcine. This is clearly a sensitive area and the Ministry is understandably cautious. Nonetheless, Halal is potentially a good market for Malaysia as it has the manufacturing infrastructure and the expertise to determine whether a product is Halal or not.

Malaysia is obviously well placed to produce Halal medicine, but how easy will it be to penetrate other Islamic countries and become a hub for Halal medicine?

Malaysian Halal standards should be accepted in other Islamic countries. The only potential problem is the fact that these products could be easy to replicate. If Malaysia is to use Halal as a differentiator for exports overseas then Malaysian manufacturers must realize that this is a short-term niche.

If API manufacturers come to understand the demand for Halal they will develop their own products and will do this from countries with larger domestic markets e.g. India, Indonesia or even the Middle East and Malaysia will lose its status as the hub for these products. The reasoning behind exploration of Halal medicine was not so much determined by a desire to export as by sensitivity to the need to give domestic consumers a choice.

Malaysia took on the commitment to develop Halal standards when it chaired the OIC. The Halal standard was based on EMEA regulations. PIC/S standards must be met first before Halal standards meaning that the supply chain must meet the highest standards of manufacturing before even considering Halal.

This said, Malaysia is well placed for exports given its geographic location in the centre of South-East Asia. Singapore could take on this role but the cost of labour and land is prohibitive. Malaysia therefore appears as a better distribution point for Halal medicine in the region and offers a good transport hub for distribution.

In terms of large-scale manufacture what is the potential of Malaysia to expand manufacture and meet domestic and international demand?

Malaysia's small population prohibits large scale projects. However, this depends on how entrepreneurial companies are. For example, there is unlikely to be a green-field site set up to cater for Halal medicine in Malaysia. However, over the last ten years there has been a degree of consolidation of companies and reinvestment by existing players in increasing standards. Future growth in this niche sector will most likely be driven by existing players rather than new specialist companies.

Many companies with products going off-patent do not wish to carry the same number of manufacturing assets on their balance sheet and therefore they are looking at contract manufacturing in Malaysia. Malaysia stands in a good position for outsourcing because of its high capacity and standards. However, Malaysia needs to brand itself better. In terms of PIC/S membership among ASEAN members there is only Malaysia and Singapore. Singapore does not try to brand itself because no generics company can survive there due to the size of the market. However, Malaysia does have both the potential and the facilities.

After the financial crisis, many of the MNCs have been looking for places where they can profit from low-cost manufacture. What has been the scale of outsourcing in Malaysia so far?

The trouble is that Malaysia is not really low-cost in comparison to several of its regional neighbours. Compared to Australia or Taiwan land prices are relatively cheap, but compared to Burma or Viet Nam they are much more expensive.

However, as a package for outsourcing work, Malaysia could be very competitive despite its lack of an API industry and the necessity to import raw materials from India and China (the two largest API producers globally). Malaysia carries out quality control, finishes the Pharma products and re-exports to other countries in the region under international standards.

In terms of investment in biotech, we see a similar scenario. Biotech does not show much growth in Malaysia because the scale of growth is determined by the ability to register the products domestically. The Ministry of Health is therefore the prime mover or otherwise of the biotech industry and unless the Ministry is satisfied with the standards of biotech they will not approve these products.

In Korea, the Ministry of Health relaxed many of the rules for biotech registration allowing for the development of a sizeable domestic market. In Malaysia companies are still grappling with the standards required for biotech products and the cost of development of a product for a 26 million domestic population base is expensive.

At the same, the Ministry is trying to promote biotech in Malaysia with initiatives such as the Malaysian Biotech Corporation and tax breaks for BioNexus companies. Is the government supportive of biotech healthcare?

At the moment most of the developments in Biotech are being driven by agriculture rather than pharmaceuticals. The level of development in BioHealthcare is still relatively small. The combination of the cost of registration and clinical trials means that the returns will not be substantial.
The Malaysian Biotech Corporation has been set up as a means to develop the biotech industry in Malaysia, however only around 10% of its investment actually goes to the pharmaceutical industry. The majority goes to palm oil and nutritional products.

To address the association (MOPI) itself, it started in 1981 and evolved from eight to thirty-four members. How has the role of the association changed in this time and what does it stand for now?

The association provides a voice for its members to government pertaining to domestic manufacture. MOPI is first and foremost a representative of manufacturers in the Malaysian pharmaceutical industry. The primary objective of the association was therefore to create a level-playing field among all the manufacturers. This prevented differences in standards which would have created problems for companies operating against backyard manufacturers. Therefore the association provides a voice for its members with government and twice a year the association conducts formal discussions with the Ministry of Health concerning the industry.

The growth of the association from 8 to 34 members has been driven by the growth in the pharmaceutical market. The association has captured around 80% of the generic industry in Malaysia. These companies are all chasing the one third of the one billion dollar pharmaceutical industry. The $1bn industry will grow however. The demographics in Malaysia are similar in size to Australia and Taiwan and in both cases the domestic pharmaceutical market represents around $4-6billion. Therefore if Malaysia continues to develop its middle income base and GDP per capita then the industry will follow suit. The eventual potential for the Malaysian market is five times what it is today.

Success or failure will depend on continuing growth in income per capita, and awareness of healthcare. The question at the moment is still whether or not the government has a blueprint for growth. MOPI is currently urging the government to look at the Australian and Taiwanese models to see if similar gains can be achieved in Malaysia.

All MOPI members have the capacity to meet future demand. However, this capacity will obviously be diminished if these companies prioritize the export market. The key question for local companies at the moment is whether to emphasize the domestic or the international markets.

What would be your final message to Pharmaceutical Executive as the representative of MOPI members on the future of local companies in Malaysia?

The main asset of Malaysia for the large MNCs is an excellent contract manufacturing environment thanks to high standards. Malaysia may not be as cheap as a facility in Indonesia or an unregulated factory in India, but the assets of local companies in Malaysia have all been audited by international authorities. Malaysia is therefore the best manufacturing centre in South East Asia if not the whole of Asia. Malaysia offers the best combination of quality and cost relative to the other countries of the region.

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