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Malaysia is ideal for pharma manufacturers

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Mr Leonard Ariff bin Abdul Shatar forayed into the pharmaceutical industry of Malaysia in late 90s and since then he gained wide experience and credibility in the country. In 2008, Mr Shatar was appointed as the director of pharmaceutical division of Chemical Company of Malaysia (CCM) and also as chief executive officer of CCM Duopharma Biotech. In 2010, he took charge of Malaysian Organisation of Pharmaceutical Industries (MOPI) as president.

In this role, Mr Shatar helped MOPI emerge as a prominent regulator and policy maker. He has been ensuring that issues such as patents and regulatory barriers are discussed on a much wider platform and MOPI is able to provide valuable input on matters that have an impact on its members.

Mr Shatar believes that his role as director of CCM's pharmaceutical division is driven by delivering acceptable returns to stakeholders of the organization balanced against needs of being a responsible corporate citizen. However, role as president of MOPI is much more holistic. He believes that looking at the Industry in its totality and charting its future growth involves regular interaction with decision makers within the Malaysian Ministry of Health and other relevant policymaking stakeholders.

During his interview with *BioSpectrum Asia*, Mr Shatar throws light on the evolving phase of Malaysia biopharmaceutical industry and how the industry has pushed itself to global standards amid all the policy barriers. Following are the excerpts:

Recently, Malaysia Ministry of Health raised concerns over adulterated drugs circulating in Malaysia. Is there any role or action that MOPI is taking along with the government to handle the situation?
Issues on adulterated drugs primarily affect the innovator pharmaceutical companies. The Malaysian generic pharmaceutical industry tends to be less susceptible to this due to the lower prices that generics command relative to that of innovators.

MOPI has and will continue in its support of the regulatory agencies to combat any form of unlawful adulterated medicines. The new pharmacy bill intends to increase the penalty on counterfeit medicines as an added deterrent. Counterfeits tend to be in the more popular "over the counter" (OTC) medicines. MOPI estimates that the level of counterfeiting in Malaysia to be less than 2 percent of the total market.

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According to you, what are the biggest challenges in the Malaysian market and how can it be handled?
One of the major challenges facing MOPI members is the increasing cost base. With the advent of the minimum wage legislation, all members will be affected due to the manual component of the industry. Whilst automation is a possibility, in some cases, the size of Malaysian demand does not make automation an economical option. In addition, ever increasing cGMP standards also have an impact on reinvestment levels required in order to comply with the ever-evolving standards.

Another challenge is clarity on patent position. In many cases, it has been noted by industry players that patents on innovator drugs expire much later in Malaysia relative to originating country or even among regional markets. This has led to the inability of Malaysian companies to be first in the market with any generic.

The industry has the potential to not only replace imported high value pharmaceutical products but to also develop a strong position as a major exporter of generic pharmaceuticals with the right support from the Malaysian government. The combination of a knowledgeable workforce, strong regulatory framework and relatively cost competitive infrastructure makes Malaysia an ideal location for current and future pharmaceutical manufacturers to use Malaysia as a manufacturing and export base to cater for the region.

What actions are being taken by MOPI to boost the pharmaceutical industry of Malaysia?
MOPI is representing the industry in engagement with both domestic pharmaceutical regulatory agency (Malaysian Drug Control Authority) and international pharmaceutical regulatory agencies (TGA, US FDA etc).

We are assisting our member companies in meeting PIC/s regulatory changes, provide them platform for cGMP training for member companies and represent the industry in lobbying for government support for the industry. MOPI also represent the industry in regulatory regional meetings e.g. ASEAN Consultative Committee for Standards and Quality (ACCSQ) as member of ASEAN Pharmaceutical Club (APC). The association establishes code of conduct for the industry in line with best practices.

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Local companies in Malaysia are yet to create a strong position in the international market. How do you see the domestic companies rising to global standards?
This is a mistaken perception. The pharmaceutical industry in Malaysia is one of the most open pharmaceutical markets in ASEAN and as a result all industry players have taken it upon themselves to penetrate the export market to different degrees. For example, HOVID, a home-grown Malaysian company already exports to about 40 countries whilst the other pharmaceutical companies in Malaysia export to approximately 25 countries around the world.

Among the impediments to growing the export market has been the lack of a level playing field when competing with our regional competitors. Malaysia celebrated its 10th year anniversary as a member of the Pharmaceutical Inspection Cooperation Scheme (PIC/s) in 2012. The standards required under this scheme have required massive investment by all members of MOPI.

Unfortunately, up to 2011, only Singapore was a member of PIC/s among ASEAN countries leading to a disparity in the manufacturing cost base among ASEAN countries. Regional harmonisation will lead to a more level playing field and should assist the Malaysian pharmaceutical manufacturers in their efforts to penetrate the regional market.

What was the size of Malaysia pharmaceutical industry in 2011-12?
The estimated size of the Malaysian pharmaceutical industry for 2011-12 is approximately $1.4-1.5 billion.

Where is the current focus of the Malaysian pharmaceutical industry? Is it towards innovative drug discovery or generics drugs?
Principal focus of Malaysia industry is in the development of generics and a few on biosimilars. Currently there are two Active Pharmaceutical Ingredients (API) manufacturers in Malaysia. Generic pharmaceutical industry has huge potential to be a major driver in Malaysia's quest to be a high-income nation by 2020.

Development of an active API Industry is also important for MOPI members. Fine Chemical manufacturing in Malaysia is still in it's infancy but as it develops, we would very much like to see more API manufacturers setting up in Malaysia supporting our members in their quest to become major exporters.