

## Billy Urudra - President, MOPI, Malaysia

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*Billy Urudra, president of the Malaysian Organisation of Pharmaceutical Industries, highlights the major trends and challenges in the Malaysian pharmaceutical industry, especially for generics players and touches upon the potential changes that will arise from the new government.*

### **Can you provide our readers with an overview of the current healthcare dynamics in Malaysia?**

Like all countries in the world, Malaysia's healthcare costs are rising, and it is a big burden for our government. Right now, the government funds the healthcare system fully. Malaysian citizens going to any public hospital will not be turned away. They will be diagnosed, treated, and given any medication free of charge. Therefore, during an economic crisis where the population's buying power decreases, patients will all go to the public hospitals. This year, a bill of MYR four billion or about USD one billion, was approved to procure medicines and consumables for all government hospitals. After adding other costs such as the development of hospitals and buying new equipment, it runs to approximately MYR 26 billion.

Then, of course, there are primary health care providers and private institutions, which are considered more convenient despite patients needing to pay out-of-pocket for the treatments. These services are usually paid either through insurance schemes that are usually a benefit of working for a company or by private insurance paid for directly by individuals. However, the portion

of the population paying for private insurance is relatively lower. Most of the population continues to rely on public healthcare. In general, unlike many other countries in Asia where most of the healthcare expenditure is out of pocket, Malaysian medical costs are covered by the government or insurance.

The recent general election which saw a new government be elected after 60 years, was a pleasant surprise and a welcomed change by most Malaysians. At this juncture, the new government is settling in to understand the current healthcare issues in Malaysia. The new government has offered many reforms but will need time to study a lot in the next few months before introducing any new changes.

**There was a recent discussion on the Malaysian procurement system and its possible misuse by the industry. How is the government currently handling the procurement system in the country?**

Indeed, recent news made accusations regarding the false monopolization of supplies to the government and manipulation of medical supply costs. In reality, the procurement system in our country is structured to be very transparent and professional. All procedures are done online with minimal human interactions in the transaction process. The government procurement is done via two main systems. The first system is the Ministry of Health (MoH) open tender, representing 40 to 50 percent of the procurement process, where the government will publish a list of medicines to be procured in major newspapers, inviting any company registered in Malaysia to participate. The results are published online through the MoH website awarding to the lowest bidder. However, under the current policy, local producers are given a slight advantage. It is not a mandatory policy, but a measure to help support Malaysian companies as it helps in creating jobs, paying taxes, and reducing the need to rely on foreign imports. MOPI hopes this policy will be maintained with the new government.

The second system, about 30 -40 percent of the procurement process is done through the concessionary via the Approved Pharmaceutical Product List (APPL). The total procurement of medicines and consumables is approximately of around MYR 1.3 billion or USD 300 million and the concession has been given to Pharmaniaga Berhad Logistics until November 2019. In this context, Pharmaniaga is solely providing the administration with the logistics, warehouses, and supply chain systems to connect all hospitals in Malaysia. The procurement is not done by Pharmaniaga itself but by the MoH. Therefore, there is a similar open tender done every three years in which

companies meeting the same criteria as in the MoH tender process go through a similar submission procedure and the results are decided by the MoH. Any company, foreign or local can participate as long as their products are registered and approved in the Malaysian market. The concession will continue until the end of 2019.

**MOPI represents mainly generics suppliers in the country. What trends have you identified in the generic segment?**

As the cost of healthcare rises, people want cheaper and affordable drugs. We see the demand trend for generics rising. The volumes of these drugs have increased considerably and there are various chronic illness drugs which are going off patent soon giving opportunities to generic companies to launch some of their products. The new government is also supporting the cause of genericizing medicines with strong controls of quality and safety and our pharmaceutical regulatory authority does a crucial job of ensuring that our products comply with one of the highest standards in the world. Malaysia is a member of the Pharmaceutical Inspection Co-operation Scheme, so we must ensure that we comply with those strict standards.

Therefore, we will see the trends of generics continuing to increase in Malaysia. Going back ten years, 80 percent of the Malaysian market was supplied by Innovators' products. However, generics have shifted to about 40 to 50 percent of the drug supply in the country.

MOPI members contribute quite significantly in the Malaysian economy. Employment wise, our members have over 8,000 employees and we are constantly investing and expanding. Up to 2014 there was nearly MYR four billion invested into the local pharmaceutical industry by our members. On a yearly basis, we pay MYR 100 million in taxes collectively. In 2011, under the previous government, the pharmaceutical industry was recognized as a key economic area for development in Malaysia which brought in investment and growth to the industry. With the change of government, MOPI hopes that the pharmaceutical industry will still be regarded as a strategic industry for the country.

**What are the challenges being faced by the local generics industry in Malaysia?**

The Malaysian market is a very small market compared to the rest of Asia. The investment of pharmaceutical companies become very expensive if only relying on the local market. Our market is only about MYR seven billion, hardly even USD two billion. Now there are many players within

such a small market which makes it difficult for any business to succeed.

Adding to this are the rising regulatory and compliance requirements. Over the years, NPRA has been upgrading its regulatory and compliance standards to be in line with international requirements. NPRA's aim is to make the Malaysian pharmaceutical industry as a leader in the regulatory field in ASEAN. This is good for our members because when we export our products, it will be seen as high-quality products which gives us a competitive advantage.

These are constant challenges for our members, and as an association, we constantly have dialogues with the NPRA. They have been very open to listening to our views and they are trying to balance the improving standards versus cost implications.

### **What international success has been seen by local Malaysian pharmaceutical companies?**

One very important company, Biocon Malaysia, has been a success in the attraction of foreign investment to the country. Biocon Malaysia is a wholly owned subsidiary of Biocon Ltd India and one of the fastest growing biosimilar companies in the world, partnering with companies like Mylan for the USA and European markets. In 2010, Biocon was looking to invest in a new biologic plant outside of India. With the government offering several incentives, Biocon decided to invest in a USD 200 million factory in Johor Malaysia. It is the first and biggest biological investment in Asia, which is also built to FDA and EMA requirements. We are proud that Biocon is a member of MOPI.

### **Moving forward, where would you like to see the industry go?**

Like in the past ten years, we are going to see many more changes in the coming decade. I am confident these changes will be favorable for all our members. The generics industry will grow and there will be more opportunities for development. Alongside this, I see the market opening to foreign access and collaboration across Asia. As the standard and regulatory challenges increase, there will be dropouts in the industry. Perhaps companies will merge together to become stronger, but this will be good for the industry in the end. Malaysia stands a very strong position because we are accustomed to the very high standards of quality and we are leading in areas like technology. If our members make the right strategic decisions, through investment and partnerships, they will be able to springboard into the Asian market as key players in the global market.

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