Ewe Kheng Huat – Executive Director, PhAMA, Malaysia

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Ewe Kheng Huat, executive director of PhAMA, the Malaysian association for innovative companies, describes the current market environment for innovative medicines in Malaysia, from the difficulties to enter the Malaysian market to the great opportunities the country can offer in terms of clinical research and shared services.

What are the main opportunities and challenges in the Malaysian pharmaceutical industry?

Malaysia is a very diverse country with a population of around 32 million multilingual people. The cost of research is also relatively lower than other ASEAN countries and we have high-quality healthcare professionals taking care of a good pool of patients. Therefore, we believe the country can be an attractive hub for clinical trials in the region and the government should focus its efforts on bringing more innovation, technology transfers and technology applications to foster better investments and partnerships.

Another attractive area for Malaysia is the development of shared service centres. Indeed, multinationals are choosing Malaysia to develop their finance, IT or human resources services. Some are even bringing their medical services in the country to support the ASEAN region. Bearing in mind that companies only establish two or three shared service centres in the world, they have truly perceived the value of Malaysia for their businesses.

However, the country is currently experiencing challenges in introducing a national health insurance. The current public healthcare system lacks funding and especially for innovative medicine. A better funding will reduce out-of-pocket payments in the private sector for Malaysian patients. The new government has provided some good directions regarding the financing of the system by announcing their aim to double the budget spending in healthcare. However, while it is still too early to witness tangible actions to reach this goal, the Ministry of Health has introduced the Patient Assisted Programs (PAPs) to support access of innovative medicines.

In what way can PhAMA participate in shaping the Malaysian health ecosystem?

PhAMA is planning to engage in further discussions to see how the government can provide more funding for innovative medicines. It is important for us to establish early engagement with different stakeholders. We want to work on bringing more innovative medicines to patients and that is an industry and policymakers' efforts.

The government is now looking at different models from other countries. We are looking at a system that would be applicable to the specificities of the Malaysian market by making sure there is value in the innovation brought to patients. Value comes with cost-effectiveness and its comparison with other similar treatments. That is why the association is also educating our members on the Health Economics aspect of the industry. We have developed partnerships and collaborations in this area to ensure the proper knowledge is being delivered to our members.

How would you assess the market access for innovative products in Malaysia?

The market access for innovative medicines starts from clinical research and in this area, Malaysia has seen a growth of investments in industry-sponsored research. For example, our members have been investing quite a lot in phase II clinical trials in needed therapeutic areas such as oncology, diabetes and hypertension, and there is a rising interest for phase I trials. We are also excited to see the government supporting clinical research by promoting the country to attract more investments, but they should establish a better link between welcoming clinical trials and bringing the solution to patients afterwards.

Indeed, after clinical trials comes the registration and from a regulatory standpoint, Malaysia is facing challenges in terms of timelines as product registration takes around 18 months. Therefore, National Pharmaceutical Regulatory Agency (NPRA) has recently introduced online submissions for

registration dossiers. The system experienced some technical issues, making the process less efficient but it has been under review to strive for the better. It is good that PhAMA have constant dialogues with NPRA to help improve the regulatory process. As we have two separate markets, the private and public sector, one of the biggest issues for innovative companies in the public sector is the process to include their medicines into the National Formulary. The new submission process imposes criteria like 12 months of use and registration. This submission also asks for budget impact analysis. Considering that we are not able to get a good access to the public market, we are now working with the government to have a better understanding of how submissions should be made.

With the new government, what can be expected for the future of innovative products in Malaysia?

Considering that health is a very important asset for a country, the pharmaceutical industry has been named as one of the key focus areas by the new government. They have been trying to develop the industry with a specific focus on generic manufacturing, but it is a challenging segment as we are competing against major Indian and Chinese competitors.

The Ministry of Health under the new government is taking some time to understand the current ecosystem and challenges to be solved. However, its work is made difficult by the different disruptions appearing in the areas of procurement. Last year’s issue on compulsory licensing of one of the innovative medicines also shocked the industry. More recently there was a call to control medicine pricing. We would like to see more transparency and early engagement with the Industry before new policies and regulations are introduced.

What are PhAMA’s top priorities for the upcoming years?

Up to now, PhAMA has developed very strong position papers on market access, IP protection, reference pricing, and biosimilars. We have built a very good reputation by driving good ethical practices in the country, our members are increasing, and we established a good network of partners. PhAMA wants to expand the collaboration further with all stakeholders such as the government for regulatory purposes and clinical research. There are also great opportunities for medical tourism. We also want people to understand how the investment cycle works in research and how it brings value to patients.

As access is our main priority, we want to help the government create incentives to bring more innovation in the country. We want to and increase stakeholders' engagement to understand and appreciate the value in innovative medicines in improving patients' outcome. The Malaysian market has one of the lowest prices in the region as our members are making an effort to make it accessible, but some regulations discussed would go against our effort. Our members are also strongly involved in prevention with many programs to patients and doctors focused on specific areas such as diabetes, hypertension, mental health and vaccines.

Thanks to its growing market, Malaysia will become a high-income country with an ageing population in the upcoming years. Companies should invest in Malaysia as we have a good pool of talents and good support with the establishment of shared services centres. It is also a very exciting country to invest in with a strategic location at the centre of the ASEAN region.

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