Ramli Zainal – Director, NPRA, Malaysia

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Dr Ramli Zainal, the director at National Pharmaceutical Regulatory Agency (NPRA), expresses the continuous work of NPRA to build a strong regulatory ecosystem in Malaysia and the important role that the Malaysian regulator has in the ASEAN region. He also takes time to explain the upcoming priorities to further establish the international recognition of NPRA.

Can you introduce yourself as well as your main priorities upon joining the NPRA?

I joined the NPRA in 1991 as a GMP auditor and stayed in the organization until 2004 when I decided to start my post-graduate study in Pharmacoeconomics. After completing my PhD, I moved to the Institute for Health Systems Research as a researcher. In 2017, I came back to the NPRA as the Director.

My main priority was to improve the organization to be on a par with the other regulatory agencies and to strive towards regulatory excellence. We used the WHO Global Benchmarking Tool (GBT) as our reference and our early assessment showed that the Malaysian NPRA is at Performance Maturity Level three, which put us in a rather performant position, considering that Maturity Level four agencies are WHO-listed authorities, more stringent regulatory agencies. To achieve Maturity Level four, National Regulatory Authorities (NRA) must fulfil additional requirements, some of which include autonomy to recruit own staff, mechanisms to promote transparency, accountability and communication, and promotion of Good Regulatory Practice. NPRA is already striving towards that

goal. Only 50 countries are part of the Maturity Level three and four and we are among these countries.

We are a WHO Collaborative Center for Regulatory Control of Pharmaceuticals since 1996 and as such, we can assist member countries in terms of regulatory control of pharmaceuticals. We are also one of the very first ASEAN markets to gain the Pharmaceutical Inspection Co-operation Scheme or PIC/S accession which is the international reference standard for Good Manufacturing Practice (GMP) in the industry. Since obtaining PIC/S accession, we have also been assisting other countries to improve their GMP standards in order to be PIC/S participating authorities.

All regulatory authorities around the world are subject to the same pressure regarding time registration approvals and price regulation. How does NPRA in Malaysia compare on these subjects?

In the context of registration timeline, we have collaborated with the Centre for Innovation and Regulatory services (CIRS) which conducted a survey at NPRA to analyze the timeline for approval. Looking at their early findings, Malaysia is comparable to other countries' time frame and product registration time. One of the initiatives in this segment is the implementation of online registration in 2002 to facilitate the registration process and also to improve transparency. Since the system was introduced in 2002, various enhancements, with input from stakeholders, were made with our latest version, QUEST3+, allowing online payment to be made. With the addition of these features, we are able to process applications more efficiently on top of ensuring greater transparency. Malaysia has also embraced the concept of reliance, which means that we are able to shorten the time of registration by relying on reports established by other recognised regulatory agencies around the world.

NPRA's focus is on determining the quality, safety and efficacy of a product before granting its marketing authorisation. With regards to pricing, it is not a determinant for product placement in the Malaysian market. This pricing issue falls under the hands of another division. Malaysia practices a dual healthcare system which comprises the public and the private sectors. As there is no pricing regulation in Malaysia as yet, the price is determined by pharmaceutical companies in the private sector. In the public sector, the national healthcare system is heavily subsidized by the government, and any product procured by the government needs to go through a process of tendering or contracts through bulk purchasing to procure at the lowest price. This entire process does not involve NPRA.

What do you see as the main pharmaceutical trends in Malaysia?

Malaysia relies heavily on importation with almost 60 percent of pharmaceutical products imported. We have been supportive of the local pharmaceutical industry for the country to be self-sustainable for pharmaceuticals. We are also looking at the vaccine industry and how to attract more products in this segment. Malaysia has been producing generics for the local and export market. As more biosimilars are used to improve treatment accessibility, Malaysia has embarked on biosimilars production under the National Key Economic Area (NKEA) plan. For example, Biocon's factory in Johor the first local manufacturer to produce biosimilars. Other than generics and biosimilars, Malaysia also has started producing inhalers. In response to that, NPRA follows closely the requirements of various notable reference countries, and wish to bring our industry up to international standards.

NPRA is also involved at the ASEAN level to provide support to traditional herbal medicine industry. Moreover, I am proud to say that we were among the first countries to regulate traditional herbal medicines. However, looking at the Malaysian ethnic composition, we have to be very careful when regulating traditional and complementary medicines. For local plants, we have our own herbal monograph, which is a way to promote our local herbs. In terms of consumption, we have noticed that there seems to be an increased uptake of traditional and complementary medicines. It is currently a trend to consume these products to ensure well-being, leading to more than 50 percent out of the 24000 products registered today being traditional and complementary medicines. We also see good opportunities for herbal and Halal products. Indeed, in the Halal segment, we work closely with the Department of Islamic Development of Malaysia or JAKIM, and Malaysia has set up the MS 2424:2012 – Halal Pharmaceuticals which is the first halal standard for pharmaceuticals in the world.

What are the next improvements that you have set for NPRA in Malaysia?

We first want to work on our speed of approval, but there should be a good balance with ensuring safety. Indeed, the industry wants everything fast, but the drug registration has to be well-assessed to avoid any issues with patient's safety in future. Good post marketing surveillance and smart partnerships are vital in ensuring product safety on the market. Nowadays, regulatory agencies are communicating with each other about concerns and risks on certain aspects, which helps in hastening the process of approval. If a product is already registered in a

reference country, we don’t need to spend a lot of time reviewing it in Malaysia. Therefore, I believe that global networking is very important, and with WHO pushing in this direction, NPRA is looking forward to more collaboration with other regulatory authorities.

Secondly, we also want to improve the efficiency of our staff. We already have a strong training programme as we send our people abroad for training and post-graduate studies every year. With rapid advancement in regulatory science, we have to ensure that our staff keep abreast with current developments. Under the Asia Pacific Economic Cooperation (APEC) initiatives with regards to Good Regulatory Management, this comprises Good Submission Practice by the industry and Good Review Practice by the regulators. In line with the international agenda on regulatory system strengthening and capacity building as advocated by the World Health Assembly (WHA), we attended a lot of conferences and programmes as speakers to share our knowledge. As a WHO Collaborating Centre for Regulatory Control for Pharmaceuticals, we continue to impart our knowledge. The goal is to become a reference centre for other regulatory agencies.

Thirdly, we are re-organising our work processes in order to improve our efficiency and the needs of our industry. As a first step, we would like to put a lot more emphasis on post-marketing activities, as pre-marketing only offers limited data. In the future, we will have a lot more market surveillance activities to make sure the safety of products in the market.

What has been your proudest achievement?

We have set up a high standard in our regulatory agency, which is recognised by other countries. As an authority, we make sure that the industry complies to the standards set by international bodies. We became a member of PIC/S and from there, we brought the industry to an internationally accepted level of Good Manufacturing Practice (GMP). Our IT system is continuously enhanced to meet the current need in the digital healthcare era. We have also received many other international recognitions including as a Non-Organisation for Economic and Development (OECD) Member fully compliant to the Good Laboratory Practice (GLP) Mutual Acceptance Data (MAD) System (since 2013) and as an observer in the International Council for Harmonisation (ICH) of Technical Requirements for Pharmaceuticals for Human Use in 2018. Therefore, I am proud to say that both regulators and industry have worked together to make sure that products are of quality, safe and efficacious in Malaysia.

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