Interview with Eisah A. Rahman, Senior Director, Pharmaceutical Services Division Malaysia

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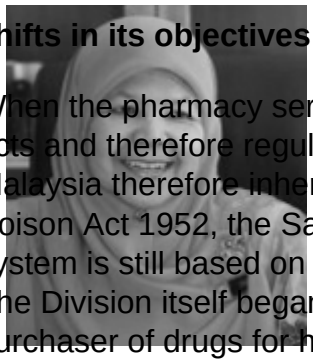
Pharmaceutical Services Division Malaysia



vices Division has been around since 1951, what have been the major shifts in its objectives since then?

When the pharmacy service came into existence in this country it operated under British law and the acts and therefore regulations have been in place since before Malaysiaâ??s independence. Malaysia therefore inherited this foundation including the Registration of Pharmacist Act 1951, the Poison Act 1952, the Sales of Drugs Act 1952, and the Dangerous Drugs Act 1952. The Malaysian system is still based on these acts.
The Division itself began very humbly. Fifty years ago people considered the pharmacist as simply a purchaser of drugs for hospitals. Over time this perception changed. Initially the Division was engaged only in procurement and this was done mostly through the crownâ??s agent, that is to say by the British.

The complex we are currently in came into existence in the early 1960s. In fact, the building we are now in was originally government medical stores and laboratories for medicines. Then in the 1990s when the government embarked on a privatization campaign this complex was privatized and was actually bought out by Pharmaniaga.

The name when the Division started officially was Pharmaceutical Chemistry Division. As it grew, the organization became known as Pharmaceutical Services Division in 1974. When I graduated my registration number with the Pharmacy Board was 543 and now the numbers are more like eight thousand. So there are many more pharmacists today. Personally, I graduated from Australia and the situation was so different from that in Malaysia. In Australia the focus was retail pharmacy and on arrival in Malaysia I had to undergo training at production facilities and hospitals. Over the last five decades the industry has really changed a great deal.

What are the main functions and responsibilities of the Pharmaceutical Services Division today?

The division is split into four principal parts. The largest part is the pharmacy practice and development sub-division. department. This department controls logistics, including budget, procurement, and distribution, of drugs, and clinical and technical aspects of practices. The Division also has a significant focus on the education of professionals, consumers and patients. Pharmacists are today less product-focused and more patient-focused.

Many pharmacists are now placed in hospitals. Before if you looked for a pharmacy in the hospital you would probably find the kitchen. The pharmacies would be at the back because of the convenience of loading and unloading supplies. Everything has now changed. If you walk into a hospital now the first thing you encounter is the pharmacy. I am pleased to see this landscape changing. Pharmacists now enjoy a more prominent role collaborating with doctors, nurses and paramedics in a team.

The other big division is the regulatory department. It operates quasi-autonomously. This body, known as the National Pharmaceutical Control Bureau (NPCB) has grown from the late 1970s and their major activity is product registration. Products need to be shown to be efficacious, safe and of good quality. The NPCB also has a GMP section with inspectors who travel around inspecting both local and international companies. They carry out post-registration work which guarantees that after a product is registered its quality remains the same. Aside from surveillance and monitoring, there is also a mechanism whereby stakeholders particularly healthcare professionals can report to the MADRAC in case of any adverse events. Another section under the NPCB is the laboratory regulation. This was the section which began the NPCB and was created to help the government in the quality control process of procuring of drugs.

Another department is that of enforcement to ensure that all activities are in accordance with the law. This section performs raids and seizures of drugs where it finds illegal activities. The Pharmaceutical Services Division has actually encouraged pharmacists to study law in order to become prosecutors and stand in court. Before this the Division depended too heavily on external public prosecutors.

Under the 10th Malaysia plan the government is attempting to set up a favourable environment for growth. With the Pharmaceutical Services Division involved in so many different aspects of the industry how has the division been able to encourage growth in the industry?

Under the 10th Malaysia plan the focus is on capacity building and the challenge is major. In order to execute this aim to enhance capacity there is the Pharmacy Management sub-division. This department drives the National Medicines Policy and consolidates the governmentâ??s efforts in capacity building, training, identifying new talent and strategic positioning. This department is in line with the healthcare reforms such as 1Care for 1Malaysia. The Pharmaceutical Services Division is therefore heavily involved in the governmentâ??s efforts to promote the pharmaceutical industry.

Of course the spirit of 1Care for 1Malaysia is integration. The division is working very closely with the Malaysian Pharmaceutical Society, with the Malaysian Organization of Pharmaceutical Industries and with research-based MNCs in the context of PhAMA.

Malaysia is a multi-ethnic country allowing the Division to have a focus on traditional medicines. There are a great number of different associations operating under the umbrella of traditional medicines. There is also a strong supplements industry in Malaysia. This represents a whole spectrum of associations that the Division works with. In the past, many problems were generated by the lack of communication with stakeholders. Increasingly the Division has come to recognize that communication is necessary.

After 20 years experience with Boehringer Ingelheim, what would you say are the main specificities of the Indonesian pharmaceutical industry?

Indonesia differs some what from other Asian countries, starting from being a non reimbursement market with a very large population, to people having a small disposable income. Indonesia also has a gap in infrastructure as compared to other Asian countries like Malaysia or Taiwan. There is a need to put a proper infrastructure in place, roads, railways, ports and telecommunications amongst

others as this all adds to the cost of doing business.As far as healthcare is concerned, GDP spending from the government is small and declining. Moreover, this year Indonesia will have elections and government is increasing the level of subsidies for fuel and such like commodities which could be better spent. Even if that money were not used for the healthcare sector it could be used to develop infrastructure, which in turn could create more jobs and increase levels of income. As the majority of medicines are paid out of pocket and research based companies price their products at a higher level than local generics, it is challenging for us to find the right target customers. Moreover, many people that can afford our medicines are not treated locally but visit neighboring countries like Singapore, where up to 60% of the patients in some hospitals can be Indonesian.

Consequently, it is difficult to sell products to people that cannot afford them or to people who can afford them but are treated elsewhere which means that MNCs have a far smaller market share than local companies.How does Boehringer Ingelheim adapt its strategy to the Indonesian scenario?

We provide an opportunity for the Indonesian population to access the best international medicines and update the doctors in term of diseases and latest treatments that are available to give them a choice.Besides the production plant, Boehringer Ingelheim has three business lines covering: animal health, consumer health and prescription medicines. Consumer health care is definitely a good opportunity here while at the same time prescription medicines is still growing well.

Animal health is a new business we are developing with a good scope for poultry and swine vaccines.Considering the low IP protection and the high level of counterfeit drugs, what are the challenges of promoting innovative products in Indonesia?

I believe the level of counterfeit drugs is around 20%, which is very high. Our strategy is different from other subsidiaries worldwide as we do not have patented products in Indonesia and some of our products already have over 50 generic copies. On the other hand, these products are still performing very well in the market, and we certainly make the most of our older products, promoting them for a longer time as compared to other countries. Patients still buy our products because their efficacy and safety is well proven and know they can trust the product.Boehringer Ingelheim has been one of the first believers in the Indonesian pharmaceutical market and established a state of the art manufacturing plant in Bogor that complies with ASEAN GMP certification. Considering the increasing competition in the region what are still the advantages of having a manufacturing plant in Indonesia rather than say China? First of all, a country like China is so vast and its growth rate is so high that having a manufacturing plant in China to serve both the domestic market and the rest of Asia is extremely challenging. Additionally, in China and to a lesser extent in India, the cost of employment is rising and those countries will no longer be an inexpensive production base. In Indonesia we have just made a significant additional investment to enlarge our production facility to meet the growing needs of our local copmany and other multinationals for whom we toll manufacture, and cost wise we are comparable to India. We therefore provide value to our own company, to other Boehringer Ingelheim operating units to whom we export and also to other multinational companies who toll-manufacturing with us.

How will the 10/10 decree impact your strategy?

For Boehringer Ingelheim and for other research based companies in Indonesia with factories and spare capacity, the decree provides an opportunity. In this respect, MNCs coming to Boehringer Ingelheim will find a trusted company that produces according to GMP at a competitive price. For MNCs without a manufacturing plant it is tough and although it seems like a final decision has been made, there are still considerable efforts been made to reverse or at least modify the decree to

exclude pharma companies. How is being a family owned company an advantage in a period of crisis? Being a privately owned company is one of the key differentiators of Boehringer Ingelheim. This status is reflected in the fact that we do not have pressure on dividends and earnings and that we can take a longer term view to develop and implement proper strategies. Boehringer Ingelheim has positioned itself as a well respected family owned company with high quality manufacturing standards and medicines with a strong research and development culture. When it comes to marketing practices we are probably a little bit more conservative than other companies on how we promote our products. This gives a different feeling and the patients, the doctors and all our partners know that we deliver what we promise. In addition to that, Boehringer Ingelheim has a strong respect for its employees and for their professionalism. We have a high level of autonomy in the decision process and,

within boundaries, the business is driven by the countries, not by a region or corporate body with minimal understanding of the complexities of the country on the ground. Final message about what our readers can find in Boerhinger Ingelheim Indonesia?

In Boehringer Ingelheim Indonesia they can find a professional company that has been in Indonesia for many years and which has the aim of providing the best available medicines to the Indonesian population. We have recently reinvested in our plant and have increased our workforce, including contracted workforce, to more than 700 people. We continue to invest in CSR projects from such projects as HIV Aids education to free medical check and medicines for the poor. Boehringer Ingelheim will continue to invest in Indonesia and its employees as well as providing the latest updates on treatments for the local medical community. We are here to stay for the long term.

This growth rate has been steady. Malaysia is moving with the aspiration of its leaders to become a developed country by 2020 with barely ten years to go. For the Division, the domestic industry initially did not exist. The industry instead represented family-run businesses â?? a type of cottage industry.

However, since Malaysia became a member of the PIC/S, the Geneva based organization; the industry has had to comply with industry standards. This process has required the involvement of the industry and the government in a close dialogue. As regulators and law enforcers the Division has a role to play. However, one key point is that the Division cannot compromise on public safety for the benefit of the industry. Patient safety must come first and international standards must be met.

Malaysia being a small country with just 27 million people compared to Indonesia which has close to 250 million. In fact, the whole of ASEAN is around 600 million and along with Brunei and Singapore, Malaysia is one of the smallest countries.

For the local industry in terms of availability and sustainability, it cannot depend on the local market. There are so many other emerging countries including Korea, China, and India who are also competing for the world market. They need to explore international markets to remain competitive.

Would you briefly outline the market share between MNCs and local companies?

The local industry is progressing although there are a number of high-end products which local companies cannot cater for including biologics, vaccines etc. For those categories Malaysia still depends on imports. Although in terms of volume local manufacturing surpasses that from MNCs, in terms of value products from innovator companies exceed those of local manufacturers. The ratio is around 65%:35% in favour of MNCS in value terms.

Biotechnology is an emerging field that the government want to expand. Other countries such as Korea have made it easier for companies to register their products to promote their

biotechnology industry. Is there potential for the same in Malaysia?

I am afraid not. The division has just adopted its guidelines for biosimilars and these guidelines are very close to those of the EMEA. The Division strongly believes it is necessary to benchmark against internationally recognized standards.

Looking at ASEAN as a region there are efforts to harmonize regulation and Malaysia is honoured to take the lead in these efforts and has been chair of harmonization since 1999. By default, in my position I am now chairing this group. Even the documents developed for ASEAN are based on US FDA, ICH, WHO etc. The process is one of adoption and adaptation.

Malaysia has committed itself to healthcare integration and economic integration. Whatever is adopted at the ASEAN level is included in our national system. Malaysia is really looking abroad in terms of its pharmaceutical industry.

PIC/S standards are very useful for exporting to North America, Europe and Australia but can pose problems when exporting to countries with fewer regulations because it can make products higher cost and less competitive. How advanced is the process of harmonization to get rid of these disparities in regulatory standards within ASEAN?

ASEAN cannot be compared to the EU. The EU has a strong political will pulling it together. ASEAN does not have such a strong history being established in 1967.

There is an ASEAN document pertaining to pharmaceuticals stating that any drug submitted in an ASEAN country has to conform to the regulations of that document. You could well ask how to ensure that different countries interpret these regulations in the same way. We are addressing these problems and are having regular seminars and workshops to address this.

In terms of GMP another step has been that Malaysia legally bound itself by signing up to an mutual recognition agreement (MRA) on GMP inspection. This currently only involves Malaysia and Singapore as the only two members of PIC/S. There is mutual recognition of standards between these countries meaning that inspections are unnecessary. The enforcement date for the other countries is the 1st January 2011 whilst any product coming from non-PIC/S countries will be subjected to inspection. Encouragingly, Thailand, Philippines and Indonesia have submitted their application to PIC/S. We hope that more members of ASEAN will do the same.

Semajit Singh of Frost and Sullivan said that one of the barriers for companies investing in Malaysia is the large number of counterfeit drugs within the market. What is your take on this assessment?

In my opinion, we are primarily dealing with a perception. There are of course reports of counterfeit medicines from time to time, but this is a very small percentage. As far as healthcare products are concerned it is always an issue. We cannot allow even one defective or counterfeit product.

Criticisms could be raised over the lack of IPR protection in Malaysia. However, this is not under the purview of the Ministry of Health but under the Ministry of Domestic Trade, Co-operatives and Consumerism.

Around 5 years ago, the Division introduced the mandatory security hologram. It is now an important enforcement tool. The enforcement department of the Division, and even the public, can use this tool to determine whether or not a product is counterfeit. There is a list of licensed manufacturers and only they can purchase these holographic labels.

In terms of the logistics of regulating this market, there are due to be many innovative drugs going off-patent in the next few years. This offers huge potential to generics companies. Are there any logistical problems in regulating the generics market or potential log-jams in obtaining bioequivalence studies?

Generics companies sometimes complain of the speed of taking a product to the production lines. Products coming from abroad need to be checked and verified and often the type of information required by one regulator differs to what is required in Malaysia. This is why certain companies can be surprised when registering drugs in Malaysia. For example there are certain products that are not allowed in Malaysia but acceptable in other countries.

Certification can also vary when in Malaysia a product might be categorized as a traditional product and therefore falls under the purview of the Division whereas in another country traditional medicine might be left to the industry to self-regulate.

For generics the target time for registration is between nine and twelve months which takes into account bioequivalence studies. For innovative drugs, the dossiers submitted are usually high quality and the division has 7-8 reference countries to allow for faster registration time. There is also a panel of experts in various medical disciplines.

In Malaysia, the markets are very open in comparison to other countries. In some countries, they only register products which they feel are necessary. As a result the authorities have fewer regulatory cases to oversee. In Malaysia, all products must be examined by the Division representing a much greater workload. Malaysia does not have this type of protectionism and the choice is left to the consumer.

However, MNCs still have to register a Marketing Authorization Holder. Does this place restrictions on the freedoms of MNCs to operate in Malaysia?

This measure is simply for liability reasons. If there are any problems and these companies need to be pursued there needs to be a local based company of MAH to bear responsibility.

The Medicine Advertisement Board (MAB) has been the body in charge of regulating the 1956 Medicines (Advertisement and Sale) Act. These regulations have recently been reviewed, what is the extent of this liberalization?

The Division does not allow for products to be advertised for twenty diseases. It is not possible to advertise a product for diabetes for example. However, as you mentioned, the Division has become more flexible regarding advertising. Previously there were huge delays in registering to advertise. Now there is a fast-track scheme where permission is given within three days. There is also greater freedom for companies to use different media to advertise such as the internet.

The Division does not just oversee product advertising but also the advertising of practices. The Division works very closely with the Malaysian Medical Council (MMC) which has its own guidelines pertaining to ethics.

In terms of the relationship between allopathic and traditional medicine, is there a difference in the time required to register a product and does this skew the market in favour of traditional medicines?

It is true that Malaysia has a strong herbal industry. Looking at the ratio between local and imported traditional medicines, local firms are dominant. Customers expect traditional medicine to be more indigenous. The diverse ethnic background of Malaysia helps fuel the traditional medicine industry.

To an extent it is easier to register a traditional medicine product. With traditional medicine the Division is now mainly focusing on quality and safety, although efficacy is still important. Claims made for traditional medicine must be substantiated just as much as for any other type of drug.

On a personal side, for readers who do not know Malaysia it might be surprising to see a woman in charge of the Division. What has been your experience in the industry and are women well represented in the pharmaceutical industry?

Readers should not be surprised to see a woman in charge of the division. Even looking at the number of women in the pharmaceuticals faculties at universities the ratio is around 70-80% female. Pharmacy is more of a feminine profession in Malaysia. Although in the past men would dominate enforcement in the industry. However now women are taking charge and standing up in court to prosecute cases of wrongdoing. In terms of top management in the Division there is a 50:50 split but in middle management women are mainly in charge.

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