Interview: Kenneth Y Hartigan-Go, Acting Director General, Food and Drug Administration Philippines (FDA)

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Kenneth Y Hartigan-Go, Acting Director General of the Food and Drug Administration Philippines (FDA) discusses the current state of regulations processes, strategies that the FDA are applying to the major challenges being presented, and further elaborates on the affect that the universal healthcare would have on the Filipino market.

One of the FDA's main concerns is to protect the quality of medicines in the market. Both the MNCs and the local Philippine manufacturers are required to adhere to very strict standards in this regard. Many of them, however, have expressed their concerns over the quality of imported products. From an FDA perspective, do you see this as a challenge? If so, how can this challenge be addressed?

As a brief introduction, it is worth mentioning that I have taken up my position only eleven months ago, with the task to reform a 50-year-old agency. There is a lot of resistance to making things move. More than ensuring public safety and health, the FDA's task also carries elements of trade facilitation as well as national competitiveness. Also, we need to regionally align with the economy and within ASEAN. Another important task that rests upon our shoulders is national security, as we have to deal with smuggling, counterfeiting, and so forth. It is a problem that we are only being recognized as a public health and safety agency, which foregoes the other tasks that lie ahead of

us. In a way, we are misunderstood as an agency. Moreover, we are experiencing interference from non-regulators, which prevents us from doing our work properly. We have to be seen as credible, neutral and independent to do what we are supposed to do.

We are concerned over the quality of many generic medicines that are currently being marketed and sold in the Philippines. A 2006 survey indicated that only 20 out of 70 local pharmaceutical manufacturers surveyed were following cGMP guidelines.

Since then, the number has improved. In one way or the other, all companies are now compliant with good manufacturing practice. However, our audits remain nothing but a snapshot of the company. There are limited guarantees to the robustness of the quality and methods according to which these manufacturers operate. We have been assured that more than 60 local companies are cGMP compliant. However, this does not mean that the quality of their products is good. This requires other continuous surveillance.

For the overseas importers of finished products, we will soon inspect their supplier's cGMP compliance. At the moment, registration for those companies is based on paper certificates. As a regulatory agency, we validate these documents.

What are some of the strategies you have outlined to address several of the aforementioned issues?

The first step is the application of the ASEAN common technical document (ACTD). Up until recently, if companies could not comply with the document, we would create a national simplified regulatory route within the country. As from August 1, 2013, this ACTD process has been adopted.

Second step, the Philippine FDA now requires its inspectors to inspect the overseas manufacturing facilities of companies that export finished products to the Philippines.

Our third strategy is for generic products, especially those belonging to category four (indicating low permeability and low solubility), to undergo bioequivalent testing as a mandatory requirement for license renewals. Anything new would also require bioequivalence data from now on. At the moment, we only have three bioequivalence testing centers in the country. They were charging PHP 1 million (USD 25,000) per product to be tested. Because these are private industry centers, we as the regulatory body have no legal ground to gain access to their data. Although the government has accredited these three centers, we had never thought of imposing data transparency. This will now change. In fairness, we also need to bring down the prices of bioequivalence testing. As part of our strategy, we also intend to create more bioequivalence

testing centers around the country.

The fourth strategy is the imposition of product stewardship by the industry. Unlike big pharma, generic companies rarely engage in post-marketing surveillance of their own products. This will also change since we will start implementing Risk Management Planning (RMP). RMP is enshrined in Law RA9502, which is a law from 2008 requiring companies to invest in product monitoring. Though signed in 2008, this law has not yet been implemented. As an operational manager, it is my task to implement this law. From now on, we will be requiring registration dossiers to include RMP. Aspects to be considered are, for instance: 'How are you going to monitor your product? How are you going to issue dear doctor letters? What are the timelines to inform the FDA and the medical community about problems with the product or serious adverse events? When and how do you submit product label edits? When and how should you voluntarily withdraw products? Etc.'

To further level the playing field, a fifth strategy is the application of a 2010 document called the 'Asia Pacific Economic Cooperation (APEC) Declaration of Ethical Marketing Practices for Biopharmaceuticals'. This document was signed by APAC member countries in Hawaii but not implemented in the Philippines yet. Just six weeks ago, we at the FDA created a marketing communications unit to prepare an FDA guideline on what is ethical or unethical in terms of marketing practices. The Philippine Pharmaceutical and Healthcare Association of the Philippines (PHAP), has pushed through an ethical code of practice for the MNCs in the Philippines that is aligned with the IFPMA guidelines. Local companies, however, have not yet adopted such guidelines on a voluntary basis. To address this disparity, FDA will in time implement the APEC guidelines for all players in the market.

How do you look at the speed of the product registration process in the Philippines?

We have seen some improvements with the consistency of our registration procedures and have observed that the timelines are now better respected than before. The FDA is 400-people strong, one third of which sit in administration and have no direct involvement in technical procedures. Among the rest, there are roughly 80 people who are contractual workers. All in all, we do not have sufficient technical officers to cover the more than 80,000 establishments beyond pharma, i.e. in food, cosmetics, toys and devices. We cannot keep up with the growing progress of technology and innovations, which are bringing more products and companies into the market. In my view, by strengthening our talent pool and IT systems we could do a better job at creating a faster registration process. For this, however, we need the approval from the Department of Budget and Management. From our own calculations, we would need 1,200 people to do our job properly. But in principle, we can increase the speed of the product registration process.

In addition to that, we still hear stories of papers and documents getting lost within the organization. At present, we are organized as a pyramid, where the top director needs to clear everything. Proper management techniques need to make everyone in the organization, including the back office staff, accountable for their actions. To avoid the loss of paperwork, we have already implemented a bar code document tracking system. This will make us faster, more transparent and less susceptible to corruption. FDA is devolving management decisions to centers and decrease bureaucracy.

As an organization, we have had issues of credibility in the past. For instance, we used to make use of yahoo or gmail accounts when it came to official emailing. For many entities and people, especially from overseas, this did not come across as very trustworthy. Therefore, all of our staff are now using our official 'fda.gov.ph' email extension. They are now required to use their work emails to represent themselves externally.

Further to that, we have also cut down on a number of redundant work processes. This measure was part of our '4 R plan': 'Review, Remove Redundant Regulation'. We have been working on simplifying our laws and clarifying our rules so that even laymen can understand them. These measures or codes are now under review by the University of the Philippines Law Center, for proper verification.

At the end of the day, we want to provide a set of FDA rules that are easy to comprehend by everyone.

Because of our regulatory ambiguity, and inconsistency, a middle layer of so-called 'consultants' erupted. On behalf of smaller to medium-sized enterprises, they guide companies through the labyrinth of the FDA registration process. Even though our regulation does not allow 'fixers', they do exist. We are taking a number of measures to address these problems.

First, we want to minimize face-to-face transactions between our evaluators and industry officers. Second, we have introduced Qualified Persons Regulatory Affairs (QPRA) training. This sets the basic information and procedure that quality officers need to know to minimize the application deficiency during the submission of requirements.

We took note of the FDA's intentions to raise registration fees. Can you elaborate?

In our view, we feel that no Filipino taxpayer should be subsidizing product registrations of individual companies. At PHP 20,000 (USD 500) our fees for three to five years of registration are still very low, especially taking into account that other countries charge up to PHP 480,000 (USD

12,000). In principle, we do not view this as raising fees but as correcting and restructuring our fees.

From an FDA perspective, what is your take on what universal healthcare will do to this market?

Universal healthcare coverage is a political promise that should follow or come in parallel with an upgrading of the country's health systems.

It is a step forward for the country, but should also require operational managers to support the six building blocks for health systems as articulated by the World Health Organization (WHO) in 2007: health governance, health financing, information & communication technology applications in health, human resource management in health, health service delivery between clinical and public health, and access to products.

At present, our approach to achieving the WHO building blocks is still very fragmented and inefficient. Without the support of these building blocks, our country will never achieve universal healthcare coverage. More than financing alone, universal healthcare coverage is about having the right services ready, clear and consistent regulations, good corporate governance, communication flow between local and national governments, and so forth.

An important topic currently on the regional agenda is ASEAN harmonization. From a regulatory point of view, what impact do you foresee?

Although it is certain that the ASEAN harmonization will happen, the way it will be implemented is still subject to further discussion and debate. There is still a gap between the policy that is being developed and specific operational actions. Some of the ASEAN countries seem to have questions around the quality of the registration process.

We would like to see someone taking a lead role, perhaps two or three countries, to start the harmonization process. We are also looking for a company that is willing to test the new system. It is to my understanding that such a 'volunteer' has not yet been found. Perhaps bilateral projects by neighboring nations could be a pilot to try out.

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