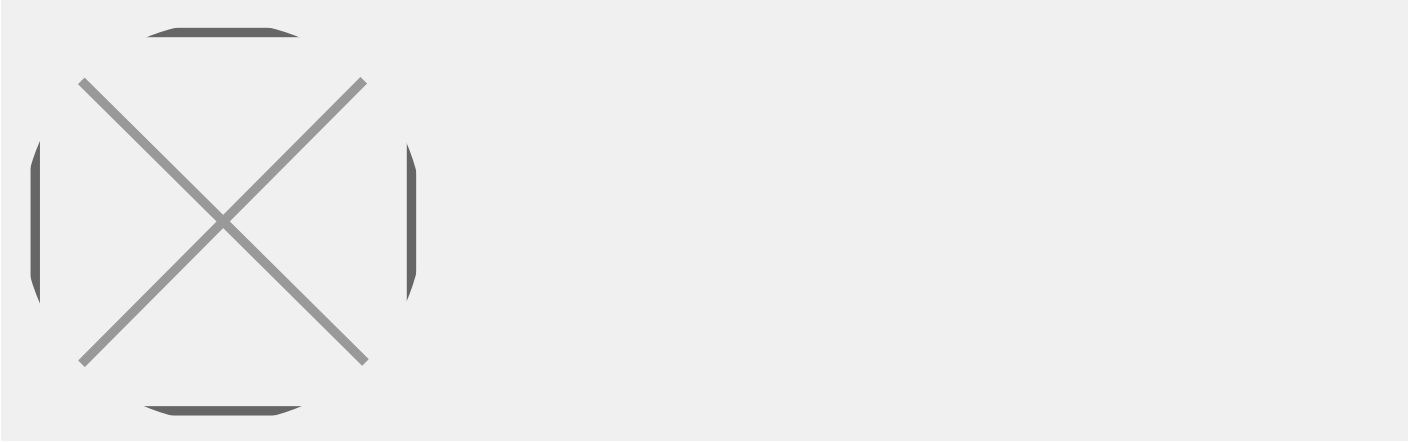
Interview with Nazarita Tacandong, Acting Director IV, Food and Drug Administration (FDA) Philippines



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Ms. Tacandong, you assumed office as Director of the Bureau of Food and Drugs (BFAD) in June 2009, and two months later the BFAD became Food and Drug Administration (FDA) following the Food and Drug Administration Act of 2009. What have been the main changes between the BFAD and the FDA and what has been your personal involvement in the Bureau?

To give you my background, I have been in the Bureau for 29 years and then I went on leave for one year to join the World Health Organization (WHO) in the Western Pacific Region, which is based in Manila. The civil service would allow us to go on leave without pay only for a year, after which you either opt for retirement or resignation, and since I have been in the FDA for 29 years I opted for an early retirement. After a year, I was appointed as the Acting Director here at the FDA.

Regarding the changes of the BFAD to FDA, the Republic Act (RA) 9711 otherwise known as Food and Drug Administration Act of 2009 has really strengthened the Bureau of Food and Drugs. Firstly, the Republic Act 9711 provides that there will be four centers of the major products that we regulate, namely the Center for Drugs, the Center for Food, the Center for Cosmetics and the Center for Devices and Technology and Radiation, which is under the Department of Health (DOH), but with the new law BHDT will be under the FDA.

In addition to that, the law also provides that FDA can retain its income so we are not totally dependent on the Government appropriation. This way we will be able to hire more people, train

our staff, and upgrade our facilities especially in the laboratories.

Another aspect of the RA is that, in addition to the head of the agency which is named as the Director General, there will be two Deputy Directors General, one will take charge of the admin and the finance, while the other one will take charge of the regional offices.

The law provides that we will also have satellite laboratories, one of which is already operating in Tagum City, Davao, catering for samples for the Mindanao region. The second one will be operational in Cebu soon, maybe end of July, because they are still doing some finalization of the laboratories, mainly the placement of some equipment. We are also planning to put up one in Subic but I think that it will not happen in the near future. In the regional offices we have Food Drug Regulatory Officers (FDROs) who are under the Department of Health – Center for Health Development. With the new law, they will now be directly under the Food and Drug Administration.

One of the objectives that led the creation of the FDA was to strengthen the BFAD. Former Secretary of Health Duque stated that the FDA was a dream come true, as the industry wanted this reinforcement for a long time. After ten months, do you feel that this objective has been reached and that the FDA now is stronger than before?

I would say that the FDA is stronger than before but what has been prioritized by the law has not been totally achieved, because it has been only ten months after the passing of the law. We still have to hire more people, to get the approval of the National Economic Development Agency and the Department of Budget and Management (DBM) as well so that we will be able to fully utilize the retained income.

As a part of the RA 9711, the FDA will open new centers and establish new testing facilities as well – you have also recently obtained the ISO certification. Do you think this has helped with the fight against counterfeit medicines?

Definitely, yes. The Philippines has been very active in trying to curve the proliferation of counterfeit drugs in the past years. When I was with the inspection division of the BFAD, we had many activities to inform the public on how they could detect suspected counterfeit drugs. We were also able to train people from other countries to detect counterfeit drugs using our laboratory facilities.

Moreover, we participated in many activities of the World Health Organization on this particular issue to arrest the proliferation of counterfeit drugs. Indeed, Philippines was the first country to have a law that specifically addresses counterfeit drugs. It is the Republic Act 8203 otherwise known as Special Law on Counterfeit Drugs. We were one of the first countries which participated in the WHO’s Rapid Alert System. I have been delegated as a liaison officer for the Philippines in WHO’s program in combating counterfeit drugs.

We are very proud to have been awarded the ISO 17025 certification last April!

The FDA is also involved in the registration of products, a controversial topic after the Bangladesh Pharmaceutical Expo where some representatives complained that the registration process in the Philippines can take up to two years. However, the Food and Drug Administration Act aimed at reducing the registration times from nine to three months. Has this goal been achieved? How long does it take today to register a new product in the Philippines?

You are right, there is a registration issue in the Philippines, and this is something of concern for most of the industries. However, I do not agree when they say that it takes two years. Furthermore we are really trying to speed up the processing of applications for product registration. We issue “automatic renewal” registration for products which have been in the market for years and have no observed defects/problems. We also issue Certificate of Listing of Identical Drug Product (CLIDP) otherwise known as the “baby CPR”. When you already have the Principal Certificate of Product Registration (PCPR) or the so-called “mother CPR” then the distributors can apply for a CPR directly and easily. This process does not take so long, maybe two weeks, while the automatic renewal takes 3 to 5 days and regular registration takes about six months to one year. I think that this is comparable to other neighboring ASEAN member states. The exception is when we deal with a new molecule, which we do not have in the Philippines, because most of these new molecules are coming from developed countries like the US and the UK, and in that case, it takes longer.

Would you be prepared for the registration process if the industry started creating new molecules?

We are prepared. We have sent our people to train in the US, in the UK, or in Australia so I believe we are capable. We also have a pool of experts. They are medical practitioners, experts in each of their fields; for example cardiovascular specialists, who are helping us.

Tomorrow the new administration will take office and President Aquino put a lot of focus on health care during the election campaign. What are your expectations on the new administration and how do you think the Government, together with the FDA, can improve the access to quality medicines for the poor?

Our agency should be able to process applications for registration of products in a speedy manner without compromising the quality and safety of products. There is also the need for increased cooperation with the different industries that we regulate, because there should be self regulation among the industries. We would like President Aquino to recognize FDA as an agency that is really dedicated to achieve our mission to ensure the safety, efficacy and quality of processed foods, drugs, medicines, medical devices and households. The FDA staff is very much committed to deliver efficient service.

An increasing number of Filipino companies are trying to expand into the global pharmaceutical arena and in order to do so it is very important to be at par with international standards. FDA has applied to join the PIC/S scheme. Has the request been approved and what would be the benefits of the membership for the Philippine pharmaceutical industry?

The process of applying for accession to PIC/S started in 2000, when we wanted to have our products internationally recognized. But we were able to launch our official application for PIC/S only last year. There has been an initial assessment supported by the European Commission, trainings have already been conducted, and we are preparing our inspectorates for the PIC/S assessment. The initial assessment was supposed to be done in May but it has been postponed – I am not sure when they will do it, but at least we have already lodged our application.

The major benefit would be that our local manufacturers would be able to export their products to other countries without inspection.

Talking about internationalization, in May 2009 the ASEAN countries came together in an effort to standardize the regulation on the pharmaceutical products. What has been the role of the Philippines FDA in the harmonization process?

FDA has been actively participating in the ASEAN harmonization. We have participated in drafting some of the regulation and in fact there will be a meeting in July in Jakarta again to further discuss issues and concerns on harmonization.

We are glad that our regulations are harmonized with the other ASEAN member states, which means that in the near future if products are registered in the Philippines and will be exported to another ASEAN country they will not go through another registration. In the same way, registered products coming from other countries like Indonesia or Malaysia, need not be registered in the Philippines.

Where would you like to bring the FDA in the next five years?

I would like to see the FDA a stronger entity, internationally recognized, and our staff capacitated in the different fields they are assigned to, like our laboratory analysts, our evaluators and our inspectorates. These are the things that I would like to focus on so that the integrity of FDA will not be challenged. We should also work together with the different stakeholders in the industry and partner with them so that we will be able to effectively and efficiently serve our country and do our tasks.

Having worked in the FDA for 30 years, what would your advice be to people coming into the industry and into the Philippines now?

I think the secret of my long stay here is that I love my job. There were times in which we were rotated in different positions, but I gave my best wherever I was assigned. I always come to the office early so that I can do more work.

For the people in the industries I would say that they should look at the FDA as the regulator, partner, facilitator, not as the police. I would also tell them that we can work together so that both the industry and the FDA will be able to achieve the mission to ensure the safety, efficacy and quality of drugs, processed foods, medical devices and cosmetics.

I learned my management style from my former boss Dr. Kintanar. We started a management style of partnership and consultation. We tried to create technical working groups with the FDA and the other stakeholders for drugs and for foods so that we can work together and review our guidelines and our checklist. I believe that in partnership we can do better – it is easier if they are already part of the regulation. When you involve the industry at the drafting or at the inception of the law, the compliance is higher because they can give their inputs, they know that they were involved in the drafting of the regulation so their compliance is higher, and they also understand better.

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