Interview: Dr. Boonchai Somboonsook, Secretary General of the Thai FDA and Mrs. Yuppadee Javroongrit, Senior Expert on Pharmaceuticals Standard, Food & Drug Administration, Thailand

21.09.2015

Tags:

government, FDA, pharmaceuticals, healthcare, regulation, Thailand, medical devices, government, biopharmaceuticals, policy, research, intellectual property

PharmaBoardroom met the Secretary General of the Thai FDA and the Senior Expert on Pharmaceutical Standards at the FDA. They explained the FDAâ??s role in Thailandâ??s pharma market, what the organization is doing for Thai copyright rights, how it is promoting international investment and integration within the ASEAN Economic Community.

Please introduce the Thai FDAâ??s roles and what current projects the organization has in the pipeline?

Dr. Boonchai Somboonsook (BS): The Thai FDA is part of the Public Health Service Support under the Ministry of Public Health. The organization plays a vital role in promoting efficiency and effectiveness among the various industries we regulate, such as health product control, drug control, food control and narcotics control, among others. During my time here, I have worked on improving the various departments in both the pharmaceutical industry alongside the Thai Regulatory Board to develop new regulations, which facilitate growth. As a result of our encouraging policies for local players, we have quite a lot of local pharmaceutical companies that can compete with other exporting countries. The amount of pharmaceuticals products sold abroad has increased significantly in recent years because of the policies we have put in place. The economic bridge we have developed with our neighbors in the region also put us at an advantage to work competitively at an international level. The bridging of the Association of Southeast Asian Nations (ASEAN) Economic Community will ensure that Thailand, and our neighboring countries, are able to work more cohesively with regards to products in the pharmaceutical industry, medical devices and cosmetics

industry.

What are your biggest priorities at the moment?

BS: The first priority for me is to educate the masses about the work we are doing and help sway policies to promote growth within Thailand. We want to respectfully compete with our regional neighbors with regards to production, but in order to do so we need to see a change in the way our regulatory processes function because we need faster results for domestic and international investors. Moreover, we need more internal experts within our organization to understand new products, such as biopharmaceuticals. We have already begun to make some changes within the organization and working towards creating a more structured institution and create new regulatory bodies, such as one specifically for cosmetics.

The organization has six subdivisions and each division is an expert in their respective fields: drugs, food, cosmetics, narcotics, psychotropic substances and medical devices, respectively. What are you currently doing to prepare for the upcoming cooperation between ASEAN Member States on a local and international level?

BS: All these subdivisions are in the process of reorganization because the ASEAN Economic Cooperation will officially launch next year and we need to improve our standard procedures to have more global procedures that work hand-in-hand with the other 10 ASEAN Member States. Moreover, we are working with the Pharmaceutical Research and Manufacturerâ??s Association (PReMA) to improve dialogue between international players in Thailand who might have business affairs in other Southeast Asian (SEA) markets. We are also about to start using e-submissions for pharmaceutical products to facilitate an easier way for business members in Thailand to register their products and hopefully this will lead to a smoother transition with other markets in SEA. Furthermore, we are working on getting policies instituted that will further facilitate the registering of products on a local and eventually regional level.

Mrs. Yuppadee Javroongrit (YJ): The Thai FDA is not the main player in the ASEAN harmonization, but is helping promote pharmaceutical harmonization because we are well organized in various sectors. Geographically, Thailand is centrally located and we seek to become an influential power in the harmonization process. For example, our e-submission will be the first of its kind in the ASEAN.

The main role of the Thai FDA is to protect consumerâ??s health, especially, to ensure safety, quality, and efficacy of health products within its remit. What shift in policy would most benefit the Thai FDA?

BS: Some of the policies we have instituted at the FDA are outdated regulations. For example, submission of documents for registration of a product is free in Thailand and we cannot change this procedure by law. Consequently, this leads to unnecessary products being registered, but the process is lengthy because of the unnecessary policies in place that allow for all products to be registered for free. If you place a fee, or hire more workers to approve products the turnaround period will be reduced dramatically. Improving the length of time it takes to get a product approved is of great interest for the Thai FDA because we receive complaints from government organizations and industry players alike asking us to reduce the time it takes to get a product approved. However, we are working on a solution where we would have a new office under the Minister of Health, but separate from the Thai FDA, to help expedite the process.

What is the organization doing to support the governmentâ??s objective to move Thailand from the â??middle income trapâ?• into a knowledge economy where R&D can flourish?

BS: The governmentâ??s policy is clear: they want to increase revenue in Thailand by granting organizations incentives to invest in Thailand. As an organization, the Thai FDA believes in our capacity to push the agenda forward to help ensure that the industries we serve are well represented and can economically thrive in our business climate.

What is the Thai FDA doing to advocate for protection of intellectual property rights?

BS: The Thai FDA has been working with the National Research Council of Thailand, which promotes research of national products and we are helping promote the intellectual property rights of national pharmaceutical products by advising industry players about first step registration.

YJ: If we take into consideration the chain of life science products, there are four parts: the first one is R&D, the second one is the development stage, which involves a lot of clinical studies, the third one is about manufacturing and last there are services. We are assisting the Secretary General create regulatory processes, mainly in development and manufacturing because we have been given the green light to assist in the creation of national standard regulations. As the Thai FDA, we are ready to support the development of products in Thailand by improving transparency and provide consultation services for companies wishing to register new products.

Do you believe international investment will increase if intellectual property policies are improved?

YJ: The Pharmaceutical and Medical Device Agency (PMDA) has demonstrated that the regulatory signs between corporations, regulators and academics needs to be well instituted to protect intellectual property rights and promote innovation. Corporations, along with academic institutions are already promoting regulations under the public sector, the private sector and academic sector. As regulations become more transparent I believe it will further promote innovation in Thailand.

BS: Moreover, we are working with regulatory agencies in Singapore to help bridge policies amongst nations in Southeast Asia.

What impact will the bridging together of the ASEAN Economic Community have on the Thai FDA?

BS: The bridging of the ASEAN Economic Community in December 2015 will create many positive changes for the region, although it will take some time to develop uniformed policies. I believe that trade amongst the Southeast Asian region will be improved in various sectors, such as technology and pharmaceuticals. It is my personal belief that Thailand will play a larger role in the coming years because of its geographic location and production capacity. Moreover, the harmonization of the region will enable nations to work together, create and produce medicine. Global pharmaceutical research teams already see the value in the region because many clinical trials are done here for new and innovative vaccines.

Where do you hope to see the organization and the pharmaceutical industry in five years?

BS: We have many aspirations for the organization that will promote growth in the pharmaceutical industry. For example, we strive to collaborate more with ASEAN member nations in various sectors. Moreover, we would like to work alongside other international regulatory bodies, such as the Chinese FDA and the Pharmaceutical and Medical Device Law (PMDL) in Japan. Working alongside other international players will attract investment to Thailand and will facilitate more streamlined methods of bringing new products to the market!

Click here to read more articles and interviews from Thailand, and to download the latest free pharma report on the country.

See more interviews