Tares Krassanairawiwong â?? Secretary-General, Thai FDA

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Dr Tares Krassanairawiwong, secretary-general of the Thai FDA shares the recent reforms carried out in the hope of facilitating greater patient access to both domestic and internationally-produced treatments. Dr Krassanairawiwong also highlights the institutionâ??s current priorities, including medical cannabis, positioning Thailand as a clinical trials hub, and further developing the countryâ??s biopharmaceutical industry.

What is the Thai FDAâ??s remit and what are the strategic priorities you have established since taking over as secretary general?

The Thai FDA is a government agency under the Ministry of Public Health, which is responsible for protecting the health of Thai citizens by ensuring the quality, safety, and efficacy of health products.

We also have the mandate to encourage citizens to adopt appropriate consumptive behaviour through the dissemination of proper health product information. I was appointed secretary-general last year and have set our priorities as protecting consumer health and creating more competition for both Thai and international health products.

To keep pace with what is a disruptive world, the Thai FDA has had to update and evaluate its strategic plan. Our current strategic plan (2019-2022) consists of five main strategic priorities. We are working on smart regulations to be able to deliver the laws and policies which will bring the largest possible benefits to both the public and to the industry. We are trying to create â??smart consumersâ?? with improved health and media literacy.

We are also investing in risk management systems and using digitalization to inform our consumers. Thailand is currently on its 12th National Economic and Social Development Plan, one of the key focuses of which is the Thailand 4.0 policy, which focuses on digitalization. In response to â??Thailand 4.0â??, our smart service strategy has been established to unlock the country from several economic challenges related to health product regulations. While the creation of smart information and smart organization aims to be responsive to the emerging disruptive trends, we have learned to lead the Thai FDA to be adaptable and reinvent ourselves to stay ahead.

In the past few years, we have conducted reforms in areas such as a one-stop service complex, a consultation system, and the application of Good Registration Management to improve our performance. In terms of the regulatory processes, the Thai FDA has facilitated our industryâ??s growth by implementing electronic submission (eCTD) and proactive consultation for new research and innovative drugs to meet the requirements for product registration. This will accelerate rapid access to innovations for patients.

Furthermore, we have been collaborating with public and private networks to establish the Medical Product Cooperation Council of Thailand (MPCT) to promote Thai medical products which are compliant with international standards to enhance the efficiency of the process. The 5 â??smartsâ?• are our main strategic priorities to achieve our goal, which is â??safe consumers, prosperous entrepreneur,s and a sustainable Thai health system.â?•

What are the main strengths of the Thai pharmaceutical and life science industries?

The Thai FDA became a PIC/s Participation Authority in 2016, which was a great recognition. It helps to promote and drive our pharmaceutical products to be more acceptable for export markets, not only in the ASEAN region but also globally. Another strength of Thailand is that we have a lot of competent manufacturers which produce a wide range of chemical products, biologicals, vaccines, and biosimilars. Our government institutes and universities have strong research and development capabilities and work collaboratively with the local pharmaceutical industry to develop and manufacture innovative medicines.

Nowadays, researchers are developing new treatments not only in small molecule drugs, but also in biopharmaceuticals, gene therapy, and regenerative medicines. They are working on unmet medical needs. The scale of future regenerative medicines will increase, which will likely attract investment in this new area.

Along with the PIC/s membership, our registered pharmaceutical products are recognized for their high manufacturing standards and this will potentially pave the way for access to the international market.

What are the most significant opportunities for the Thai pharmaceutical industry?

First of all, Thailand has lots of room for medical product developers to develop their products and put them on the market with supportive policies from the government. Biopharmaceuticals and vaccines are the areas which the government and the Thai FDA are focused on. To encourage the domestic industry to unite in R&D to develop products, the Thai FDA has created and announced: â??The list of targeted medicinal productsâ?• which includes medicinal products that impact the public health system in Thailand and may support the sustainable growth of the economy.

Another major topic for Thailand and the Thai FDA is clinical trials. The number of clinical trials in Thailand has been continuously increasing over the past few years, with a variety of medicinal product innovations and technologies developed from both the domestic and overseas industries. Within the Thai FDA, we believe that this phenomenon is occurring due to supportive medical infrastructures for the conduct of clinical trials in the country. Thailand has competent physicians and staff, modern medical technology and equipment, and patients. The Thai FDA has promoted and supported clinical research for health product innovations, particularly medicinal products. Thailand has recently successfully amended a new Drug Act to add regulation for scientific and ethics and standards related to clinical trials known as â??Good Clinical Practiceâ?• (GCP). Compliance with the GCP standard assures the public that the rights, safety, and well-being of trial subjects are protected and that clinical data generated is credible.

Additionally, the government and the Thai FDA is looking carefully at the legalization of medical marijuana. Thailand is the first country in Asia to legalize the utilization of cannabis for medical purposes. Early this year, the Thai FDA amended the Narcotics Act to permit the use of cannabis for medical and research purposes under the supervision of a licensed physician who has been trained under specific courses approved by the Ministry of Public Health. The government has also supported potential agencies to cultivate quality cannabis for domestic medical uses.

What is your long-term vision and expectations for the Thai pharmaceutical industry?

I am expecting Thailand to position itself as an industry hub thanks to our medical hub policy. The domestic production of active pharmaceutical ingredients and products is essential, not only to ensure national drug security but also to provide quality products to the world. Additionally, the Thai pharmaceutical industry is now moving forward to more complex molecules, such as biologicals, biosimilars, and vaccines. This is in line with the government project, â??Genomic Thailandâ??, which requires intensive research and investment. I hope that it will be realized in the next few years.

We have prioritized the abilities to research, develop, and manufacture generic products to substitute costly patented drug products, and new drug products derived from previously approved chemicals, vaccines, and biosimilars. As Thailand is an ageing society, the additional expectation is the contribution to the creation of healthy longevity and supporting the healthcare system.

The Thai FDA has facilitated the development of new drug innovations throughout the whole process from research discovery to registration using advancing regulatory science to create stable and sustainable access to innovative medicine. We also aim to collaborate with all stakeholders to develop the ecosystem that promotes clinical trials in the country and develop our human capital concerning all challenges.

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