

Busakorn Lerswatanasivalee - CEO, Pharmaceutical Research and Manufacturers Association, Thailand



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Pharmaceutical Research and Manufacturers Association (PReMA) has been a key stakeholder in promoting the value of innovation in Thailand for over 100 years. CEO Dr Busakorn Lerswatanasivalee discusses the changes taking place in the Thai healthcare ecosystem and highlights the key initiatives undertaken by PReMA to widen access to, and awareness of, innovative drugs and solutions. She also explains the crucial role the association will play in making Thailand one of Asia's Top Five destinations for clinical trials by 2024.

What are the main changes that have occurred within the past several years and what are your key objectives currently?

There have been a lot of changes in Thailand since 2014, especially in regard to the regulatory ecosystem. The government has recognized the need for change, and the regulatory issues that the industry has been facing. One of the main achievements is amending Thailand's Drug Act. The drug registration process which previously took more than two or three years, and now takes only 12 months. The industry was very involved in this process and focused on making it more digitalized. It is not perfect yet, and PReMA is very closely collaborating with the industry, and the

Thai FDA to continuously improve those processes for the benefit of the entire Thai healthcare ecosystem, but most of all the patients. Thai FDA is also focused on digitalization to make the processes much faster and more efficient.

Our priority for the moment is to increase awareness of global health challenges. One of the means to do so will be a first-of-its-kind campaign to make noise and educate the Thai population about the different health solutions and treatments that are available to them. Awareness for the value of innovative medicines and solutions must be increased. Thai patients do not realize what prevention programs and or treatments are waiting for them, and this is where PReMA step in. We need to work collaboratively with the Ministry of Public Health, payors, academia, professional councils to inform the general public – that is our mission for this year and the near future.

In what way can PREMA participate in increasing access to healthcare and shaping the Thai health ecosystem?

PReMA is proud to represent the research-based innovative industry. Our members are very involved in bringing the most innovative medicines in the country for the benefits of patient access. They do not only wish to be perceived as merely commercially driven, but as better healthcare solution providers. They are providing lifesaving solutions, increasing patient access to most innovative medicines, and we are very proud to work to enable this to happen. This will require a lot of multi-stakeholder collaboration and understanding of the value of innovation.

Innovative medicines play a crucial role in ensuring that Thai people have access to the best healthcare possible. They do not only help people living longer, healthier and more productive lives, but most importantly they are transforming the incurable in the past diseases into treatable conditions. This is one of the most important parts of our role here at PReMA.

Could you discuss the clinical trials ecosystem in Thailand and why should companies choose Thailand as a clinical trial destination?

In order to increase access to innovation, PReMA is also very involved and committed in collaborations within the area of clinical trials. Thailand is well-equipped to be a potentially strong contender in the international clinical research market. From 2011 to 2016, Thailand conducted a total of 739 clinical trials, the highest number of trials within the Southeast Asian region, followed by Singapore (610 trials) and Malaysia (351 trials). Based on Deloitte Access Economics analysis, it

is estimated that THB 10.4 billion (USD 0.32 billion) was spent on clinical trials in Thailand in 2015. Of this, the majority, or 75 per cent (THB 7.8 billion, USD 240 million) was on Phase 3 research. Phase 1 has the lowest cost; around three per cent of total trial costs. In short, clinical trials bring about economic benefits to the country with a benefit-cost ratio of 2.9:1 in 2015. This means that for every single Thai Baht spent on clinical trials, the return was THB 2.90.

There were over 111,000 Thai trial participants in 2015 and approximately 38 per cent of clinical trials in Thailand had pharmaceutical companies as sponsors. It is estimated that expenditure on trials sponsored by private industry was THB 3.94 billion (USD 120 million).

Thailand is a good location for clinical trials primarily due to its large patient population and lower trial costs per patient compared to developed countries such as the US, the UK and Singapore. Hence Thailand is perceived to be a leading destination for clinical research in Southeast Asia. However, it lags behind other Asian countries such as Korea and Taiwan.

Thailand is in an advantageous position as it possesses a large, concentrated patient pool ideal for the speedy recruitment of trial subjects. Thailand suffers high disease incidence in cancer, cardiovascular disease, stroke and infectious diseases, and attracting multinational companies to conduct clinical trials locally, will enable patients to gain immediate access to some of the most advanced treatments in the world.

A strong infrastructure is required to support a vibrant clinical trials landscape. Capacity building programs is one of the key priorities before Thailand scales up its clinical research businesses. The establishment of various research centres helps support new drug and vaccine discovery and innovation which may potentially be licensed to pharmaceutical companies for further development. Furthermore, it will collaboratively create a regional network of advanced diagnostic technology amongst hospitals to support clinical studies.

The impact of clinical research on Thailand is aligned with the Thailand 4.0 policy, and the establishment of a vibrant clinical research ecosystem plays an important part in driving Thailand towards a more innovative and value-based economy. As Thailand becomes a more vibrant clinical research hub, various global biopharmaceutical companies will inevitably set up more local R&D centres and manufacturing plants and affect the economy and the patients in a positive way.

After the report was published, we worked with both academia and government to establish a roadmap to help Thailand achieve a Top Five position for clinical trials in the entire Asia region.

How would you assess the awareness and understanding of the value of innovation and innovative healthcare solutions in Thailand and how is PReMA active in this matter?

Looking towards being an innovation-driven and sustainable growth country, Thailand needs to start to look holistically into improving the awareness of the value of health innovation solutions. With the roll-out of Thailand 4.0 and focus on a value-based economy, health innovation will be one of the key drivers alongside technology and creativity.

Specifically, in the healthcare area, we need more multi-stakeholder collaboration in order to make it happen. We need to do this together and put the patient as the centre of discussion.

Our members work every day to develop better ways to improve the health of our fellow citizens, we are eager to embrace a new reality that focuses on outcomes that matter to patients and to society. Investment in innovation leads to the discovery and development of therapies that save and extend lives, and by doing that, innovation helps keep healthcare costs down and drives economic growth.

Thanks to medical innovation patients are living longer, healthier, more productive lives, a benefit that extends across the entire healthcare ecosystem to society as a whole. Simply put, the longer one lives, the more time they have to be productive and contribute to their families and society. Our patients may only be aware of the solutions that are available for them under the security system, they do not know about the more innovative solutions that could radically improve their conditions. Better choice, better chances – for this reason we hope to see the rise of patient groups which are currently not common in Thailand. There is a great opportunity for them to become more active and aware and therefore increase healthcare outcomes in the country

We still believe there is a need for more multi-stakeholder collaboration in this matter. We are involving all the key stakeholders within the ecosystem, from public and private sectors in health, academia, science and technology, and pharmaceutical, medical device industries and service providers to drive Thailand towards a more innovative path through knowledge and experience sharing and education. Through the knowledge gained, we will set up action plans to implement it. This is the Thai government's focus, which we are aligned with and will do anything in our power to help.

We also would like to communicate to the government that the newly created innovative list should aim to truly incentivize innovative health products but not be limited to local companies. The current Thai innovation list for incentivized public procurement is considered as a privilege to only a few local players.

The point is that the R&D criteria that is mentioned in order to be able to be on that list, should be true R&D, otherwise it will weaken the motivation for R&D investment coming from international companies. In order to strengthen our industry – both local and MNC – everyone should focus on R&D and truly invest in this area, not only to get the quality certificates for bioequivalents, but truly separating the originators and generic products. This does not only apply to pharmaceuticals, but to any product that gets the public procurement privilege – hence the country needs to push very hard and change the mindset to have true innovation.

Another important step will be collaboration with both public and private stakeholders to ensure Thailand has a sustainable financing system, implement innovative solutions that our members are very knowledgeable about, and showcase to everyone in the Thai healthcare sector how big of an asset the private R&D industry is.

What would be your final message on behalf of PReMA?

Finally, we will work towards increasing the value and brand of Thailand as an attractive investment destination not only for regional but also global companies, as we believe Thailand is the place to be.

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