PEP-SBF Awards 2021

Pro-Enterprise Initiative (PEI) Award - Gold

Name of Initiative

Regulatory Agility – Supporting Businesses and Timely Access to Health Products During the Pandemic

Agency

Health Sciences Authority

Could you share briefly on what was the impetus that eventually led to the initiative, and how did you motivate yourself/your team to pursue it?

We recognised very early on at the out start of the pandemic, that as a small city sate, we will be faced with immense challenges when competing against global demands and major markets for critical therapies and medical devices. We had to act swiftly, boldly, and exercise regulatory agility and flexibility in working with our industry stakeholders to stay ahead of the curve and differentiate ourselves competitively to secure our nation's access to those critical health products.

As the national health products regulator, my team and I are driven by the mission to safeguard our population and advance public health. The key drivers that underpinned our COVID-19 efforts are the deep sense of commitment to deliver for our people, working on good science to assure the public and industry's trust on us, ensuring good teamwork so that we build upon the strength of one another and demonstrating resilience at work to handle the numerous challenges and curve balls thrown our way.

A/Prof Chan Cheng Leng

What were the challenges that you/your team encountered, and how did you/your team overcome them?

Singapore relies heavily on imported health products and has limited manufacturing capacity. Global supply chain disruptions thus threatened our continued access to critical therapies.

A key challenge in authorisations of vaccines and therapeutics was not having sufficiently robust, long term clinical and scientific data to ensure safety and efficacy. Similarly, diagnostic tests lack of clinical specimens in the early stages of the pandemic. We set up rolling submissions and the Pandemic Special Access Route, enabling companies to continue collecting relevant data without waiting for all the data to be completed before submitting to HSA for review. We also adopted alternative approaches e.g. leveraging bioinformatics to ensure that the diagnostic tests are of reasonably good quality and performance. The team then continued to assess the follow up studies from the manufacturers to ensure the continued safety and efficacy of these health products.

Due to safe-distancing measures, physical audits and inspections of our industry stakeholders were a challenge. The team embarked on a hybrid model of onsite and virtual inspections, through online video platforms and other technologies. This has enabled us to inspect the importers and distributors of COVID-19 vaccines as well as manufacturers of surgical masks during the pandemic.

We also capitalised our good international standing as a competent regulatory authority and the strategic partnerships forged through years of international collaborations with other authorities. This has facilitated expeditious information sharing and judicious adoption of good scientific and regulatory best practices which were critical in support regulatory decisions during this period.

A/Prof Chan Cheng Leng

What was the most memorable moment while working on this project?

The whole experience in its entirety has been most memorable and humbling to me: Seeing my colleagues work so expeditiously without cutting corners. Ensuring that we offer innovative solutions to companies to develop/market critical health products locally. The long hours spent evaluating the scientific data thoroughly, balancing risks versus benefits based on interim data to arrive at a sound regulatory decision on whether or not to approve a particular vaccine or a diagnostic test, or to recommend certain safety measures post-vaccination.

I recall with pride how we worked with EDB, A*STAR, MOH, NCID on a WOG approach to convince a company to initiate clinical trials in Singapore. This has enabled our patients to be among the earliest worldwide to access the first evidenced-based COVID-19 antiviral medicine.

As at 30 June 2021, we have approved 17 clinical trials, 192 therapeutic products and medical devices, 26 new local manufacturers and conducted 15 manufacturing/distribution sites audits, and 289 consultations for the industry.

A/Prof Chan Cheng Leng

Knowing that the agile regulatory and facilitative efforts that we have put in had translated into expeditious access to critical health products to fight the pandemic while actively safeguarding public health is the most memorable moment!

Dr Dorothy Toh

Our officers had to work within a tight timeline to review the submissions and provide advice to the test kit developers. We managed to get critical diagnostic kits approved within 48 hours in the early stages. Through the hard work, we are pleased to see that our effort had supported the nation in responding to the local demand swiftly.

Ms Wong Woei Jiuang

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pro enterprise panel

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https://www.hsa.gov.sg/covid-19-information-and-advisories