

MESSAGE FROM THE CEO

I would like to applaud HSAians for their strong sense of service to the nation and passion for excellence. We have demonstrated how we are committed to integrity, professionalism, efficiency and innovativeness in carrying out our work. While the pandemic has put us to the test, I am immensely proud that in this 20th anniversary of HSA's formation, we have demonstrated our resilience, motivation and commitment in contributing to the nation's fight against COVID-19 and our ongoing organisational transformation efforts.



**DR CHOONG
MAY LING,
MIMI**

*Chief Executive
Officer*

2021 marks not just the 20th anniversary of HSA since its formation, but also one of our most challenging years. With each development of the COVID-19 pandemic, we found ourselves needing to respond quickly and adapt faster than ever before.

Through it all, we managed to remain focused and steadfast in our mission to protect public health and safety.

Facilitating speedy access to critical health products

Our health products regulatory staff have had to deal with many time-sensitive applications for vaccines, medical devices and medicines critical in supporting the nation's fight against COVID-19.

Speed without compromising safety

Since the pandemic began, we expedited the approval of many critical medical devices based on a risk-calibrated review process to ensure essential safety, quality and performance requirements were met. We approved over 195* diagnostic test kits, ranging from reverse transcription-polymerase chain reaction (RT-PCR) to serology and antigen rapid tests, to confirm COVID-19 infections; and five ventilators for seriously ill patients in ICU. More recently, in May and June 2021, we approved five antigen rapid tests (two of which were first-in-the-world approvals) for self-testing and two breathalysers. The ARTs are widely available at pharmacies and other retail outlets such as supermarkets for members of the public to buy and do the test at their convenience. The two breathalysers, which are first-in-the-world innovations developed by local start-up companies with the support of two local universities, detect COVID-19 infection by analysing breath samples from individuals and report the results in one to two minutes. HSA will continue to closely monitor the clinical performance of these tests to ensure that they continue to be safe and effective in detecting COVID-19 infections.

Expedited route for vaccines, medicines and medical devices

Recognising the urgent public health need for early access to critical novel vaccines, medicines and medical devices during the pandemic, we developed (in six months) and introduced the Pandemic Special Access Route (PSAR) on 1 December 2020. PSAR enables us to start our evaluation from the early stages of clinical studies, as and when real-time data is submitted by the companies on a "rolling" basis, instead of waiting for the full data set to be ready before starting our evaluation. PSAR allows a speedier, yet thorough, review to ensure that these novel health products meet the necessary high quality, safety and efficacy standards. To date,

*As of July 2021

we have granted the first-in-Asia interim authorisation of Pfizer-BioNTech and Moderna vaccines, in December 2020 and February 2021 respectively. These vaccines have since been used in the national vaccination programme by the Ministry of Health. In June, sotrovimab, a monoclonal antibody, was granted approval, allowing infectious disease specialists to use it for the treatment of mild-to-moderate COVID-19 in patients.

HSA continues to actively monitor the safety of the PSAR-authorised COVID-19 vaccines to detect any potential safety concerns so that relevant measures can be taken to ensure the vaccines remain safe for use. We review submitted adverse event reports together with our expert panels to ascertain that the benefits of the vaccines continue to outweigh the risks, and update the public at regular intervals on potential safety signals identified in our assessments.

Ensuring a steady blood supply

Since the start of the COVID-19 pandemic, HSA has put in place measures to safeguard the health of our donors and build donor confidence.

Blood collection dipped during the initial Circuit Breaker period. Together with our partner, the Singapore Red Cross, we asked blood donors to continue coming forward to help secure the nation's blood supply. I am heartened to share that thanks to the strong support of our blood donors and partners, blood donations continued steadily and we have managed to keep blood stocks healthy throughout the year.

Rendering forensic support

Our staff from the Forensic Medicine Division (FMD) rose to the challenge, carrying out autopsies on suspected, positive and post-COVID-19 cases. Though little was known about the virus and its risks in the beginning, processes were reviewed every day to ensure that safeguards were adequate to protect our staff and their workplaces. FMD has been steadily refining their biosafety practices, given their experience with the Severe Acute Respiratory Syndrome (SARS) outbreak in 2003, such as putting in place enhanced personal protection measures and more stringent work processes. A dedicated and competently trained forensic team had to work in a special Bio-safety level 4 autopsy suite for positive COVID-19-cases that were still infectious at the time of autopsy.

Besides our COVID-19 related work, we achieved several milestones in our health product regulatory, blood services and analytical testing work.

Implementation of regulations for cell, tissue and gene therapy products

In February 2021, we gazetted subsidiary legislation to effect the implementation of cell, tissue and gene therapy products (CTGTP) regulations. CTGTP is an exciting therapeutic area that is developing rapidly. It is a new class of health products, comprising stem cells, tissues and genetically modified organisms, that can potentially offer cures for chronic and debilitating diseases. The implementation of the regulations was a significant milestone that had been years in the making, from policy conceptualising to public consultation and drafting of the regulations.

Enhancing the safety of donated blood

HSA has included Hepatitis E (HEV) testing as part of our routine screening protocol as of June 2021, further enhancing the safety of donated blood. HSA identified Hepatitis E (HEV) as a potential transfusion transmissible infection based on worldwide clinical and transfusion data. After conducting local viraemia and seroprevalence studies, we decided to use the molecular method for detecting HEV in donated blood. We continue to assess the risks of emerging and re-emerging transfusion-transmissible infections and evaluate the appropriate risk management strategies in a systematic and comprehensive manner to benefit patients at risk.

Maintaining dexterity in our testing and detection methods

To combat the issue of hand sanitiser manufacturers using lower-grade ethanol in their products, we came up with an analytical method utilising Gas Chromatography-High Resolution Accurate Mass (GC-HRAM) technology to test for impurities. Subsequently, hand sanitisers that were found to contain a high level of impurities or adulterated with methanol were recalled.

When regulatory agencies worldwide learned about the potential contamination of 1-nitroso-4-methylpiperazine (MNP) in rifampicin drug substances, there were no standard tests for such analysis available internationally. Our dedicated team from the Pharmaceutical Laboratory expeditiously developed a Liquid Chromatography Hybrid Tandem Mass Spectrometry (LC-MS/MS) test to quantitate the presence of MNP in rifampicin products. Our ability to analyse these products enabled us to take the appropriate regulatory actions.

Being recognised for our good work

HSA won a total of three Public Sector Transformation Awards in 2021. These are awards that recognise public officers and agencies for work and organisational excellence. We won two One Public Service Awards — one for building capacity and capability for COVID-19 testing, and another for securing access to COVID-19 vaccines. We also won an Agility award, which was awarded to our colleagues from the Health Products Regulation Group for our concerted fight against COVID-19.

The Singapore Health Quality Service Awards 2021 accords special honour on healthcare professionals and partners who have stood up and contributed to the nation's fight against the COVID-19 pandemic. The Forensic Medicine Division and the Blood Services Group won the Team Commendation Award, and Dr Paul Chui garnered the SuperHero Award (Clinician – Merit).

Supporting our staff

The pandemic has radically changed the way we work. We entered a full work from home arrangement for staff who could, and put in place additional safety measures for staff who had to continue to work in the frontline (blood banks) or in the labs or conduct enforcement work. Online meetings with colleagues, stakeholders, partners and overseas counterparts are now the norm instead of face-to-face interactions. This new work arrangement has required us to adapt and adopt a shift in mindset.

To better facilitate the remote working arrangement, we equipped meeting rooms in HSA with video conferencing capabilities to enable hybrid-meetings between physical and remote participants, and strengthened IT touchpoints and support, including a tech refresh of laptops.

To ease our staff into the new routine of working remotely, we started a series of regular virtual get-together sessions. These Coffee Chat sessions were organised to enable staff to communicate and connect with each other. We invited experts to share on topics such as mindfulness, resilience, stress management and positive psychology. Specially curated self-care tips were also sent via Electronic Direct Mailers (EDMs) to motivate and remind staff to care for themselves and look out for others.

A one-stop COVID-19 Employee Support Portal was also launched in December 2020 to enable staff to look for relevant information, such as overseas travel notifications and Quarantine Order (QO)/Stay Home Notice (SHN) reporting.

Forging ahead

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