
ANNUAL REPORT 2020/2021
RISING TO THE CHALLENGE
HEALTH SCIENCES AUTHORITY

RISING TO THE CHALLENGE

2020 was certainly an eventful one, as we faced unprecedented challenges and disruptions due to the COVID-19 pandemic.

As the world came face to face with the pandemic, HSAians banded together to navigate these challenges.

We accelerated our transformation and digitalisation efforts, to adapt and innovate to the situation at hand. Be it expediting the approval of new therapeutic products, safeguarding the national blood supply, or refining and enhancing our forensic and analytical services, we were ready.

Moving ahead, we will continue to stay prepared and agile. This is the best way to ensure that Singapore's health and safety remain secure and protected.

OUR VISION

To be the leading innovative authority protecting and advancing national health and safety

OUR MISSION

To wisely regulate health products
To serve the administration of justice
To secure the nation's blood supply
To safeguard public health

OUR CORE VALUES

Service to the Nation
We are part of the Singapore Public Service, committed to integrity, excellence and efficiency.

Passion for Excellence
We aim to be the best in all that we do.

Develop Our Community
We value our people and build trusted teams.

Inspire Trust
We act with credibility, professionalism and integrity, to instil public trust and confidence.

Live Innovation
We seek constantly to improve and transform.

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OUR ACCOLADES

Organisational Excellence

Since April 2019
Singapore Quality Class Star
with People and Service Niche Standards

2014 to March 2019
Singapore Service Class

2003 to March 2019
Singapore Innovation Class
First public healthcare agency to be endorsed

2002 to March 2019
People Developer Certification

Since August 2018
ISO 9001:2015
Information Management Department Corporate Headquarters

Since June 2018
ISO 9001:2015
Corporate Services Group

2014
The Public Service Achievement Award

2012
Singapore H.E.A.L.T.H. Platinum Award

2010
The Public Service Milestone Award

Since 2008
Meritorious Home Team Partner Award

2006
Public Service Award for Organisational Excellence

Since 2005
Meritorious Defence Partner Award

2004
Singapore Family Friendly Employer Award

Since 2003
Community Chest Awards

Professional Excellence

HEALTH PRODUCTS REGULATION GROUP

Since November 2018
ISO 9001:2015
Audit & Licensing Division

Since March 2017
ISO 9001:2015
Enforcement Branch

ISO 9001:2015
Tobacco Regulation Branch

ISO 9001:2015
Vigilance & Compliance Branch

BLOOD SERVICES GROUP

2021
Singapore Health Quality Service Awards
Commendation Award

Since August 2014
Compliance with PIC/S Good Manufacturing Practice Standard
Cell Therapy Facility was audited to acceptable GMP standard jointly by HPRG and Swissmedic

Since July 2013
International Society for Cellular Therapy and European Blood and Bone Marrow Transplantation (JACIE)

Since August 2008
American Society for Histocompatibility and Immunogenetics (ASHI)
First transplant testing laboratory in the Western Pacific Region to be accredited

Since May 2006
AABB Accreditation
First national blood service in Asia to be accredited

Since 1992
World Health Organization Collaborating Centre for Transfusion Medicine

APPLIED SCIENCES GROUP

Forensic Medicine Division

2021
Singapore Health Quality Service Awards
Commendation Award

Since September 2005
National Association of Medical Examiners (NAME)
First agency outside North America to be accredited

March to May 2003
Commendation for Significant Contribution in Helping Singapore Overcome SARS

Since 1999
Accreditation of Laboratory for Pathology Training by The Royal College of Pathologists of Australasia

Forensic Science Division, Biology Division, Illicit Drugs Division and Analytical Toxicology Division

From 2017
ANSI National Accreditation Board (ANAB) Forensic Science Testing Accreditation

1996 to 2017
Forensic Science Testing Accreditation under American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB)

1999
Excellence for Singapore Award

Chemical Metrology Division

Since August 2013
Accredited as a Proficiency Testing Provider under ISO/IEC 17043 by the Singapore Accreditation Council

Pharmaceutical Division

Since February 2012
Observer to the European Pharmacopoeia Commission

Since June 2009
World Health Organization Collaborating Centre for Tobacco Testing and Research

July 2003
Public Service Award for Organisational Excellence

Since August 2002
Singapore Quality Class

Since 1997
ISO/IEC 17025 Accreditation under Singapore Accreditation Council — Singapore Laboratory Accreditation Scheme (SAC-SINGLAS)

Since February 1993
World Health Organization Collaborating Centre for Drug Quality Assurance

OUR ACCOLADES

Memberships, Committees and Working Groups

HEALTH PRODUCTS REGULATION GROUP

Since June 2018
International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)
Management Committee

Since January 2018
International Pharmaceutical Regulators Programme (IPRP)
Management Committee

From January 2018 to December 2019
Pharmaceutical Inspection Co-operation Scheme (PIC/S)
Chair

Since November 2017
International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)
Regulatory Member

Since September 2016
International Medical Device Regulators Forum (IMDRF)
Management Committee

Since 2013
International Coalition of Medicines Regulatory Authorities (ICMRA)
Member

Since 2007
Australia-Canada-Singapore-Switzerland-United Kingdom (Access) Consortium
Consortium Member

Since January 2000
Pharmaceutical Inspection Co-operation Scheme (PIC/S)
Participating Authority

BLOOD SERVICES GROUP

Since 2012
International Society of Blood Transfusion (ISBT)
Rare Donor Working Party Member

Since 2006
Asia Pacific Blood Network (APBN)
Founding Member

Since 2006
International Council for Commonality in Blood Banking Automation (ICCBBA)
Asia Pacific Technical Advisory Group Member

APPLIED SCIENCES GROUP

Forensic Science Division, Biology Division, Illicit Drugs Division and Analytical Toxicology Division

Since October 2017
Provisional Member of Association of Firearms and Toolmarks Examiners

Since April 2013
Associate Member of the European DNA Profiling Group (EDNAP)

Since May 2011
Member of United Nations Office on Drugs and Crime (UNODC) International Panel of Forensic Experts

Since January 2011
Scientific Working Group for the Analysis of Seized Drugs (SWGDRUG)

Since October 2010
International Forensic Strategic Alliance (IFSA)
Representative of AFSN

Since 2008
Asian Forensic Sciences Network
Founding Member

European Network of Forensic Science Institutes

Since April 2018
Associate Member of ENFSI Expert Working Group for Marks

Since June 2017
Associate Member of ENFSI Textile & Hair Working Group

Since 2017
Associate Member of ENFSI Drugs Working Group

Since January 2016
Associate Member of ENFSI European Network of Forensic Handwriting Experts

Since November 2015
Associate Member of ENFSI Firearms and GSR Working Group

Since October 2015
Associate Member of ENFSI Document Experts Working Group

Since September 2013
Associate Member of ENFSI Paint & Glass Working Group

Since April 2013
Associate Member of ENFSI DNA Working Group

INTERPOL

Since July 2018
Member of the INTERPOL DVI Forensic Genetics Sub-Working Group (ForGenSWG)

Since May 2016
Member of the INTERPOL DNA Monitoring Expert Group

Chemical Metrology Division

Since July 2016
Member of the ASEAN Reference Material Network

Since November 2014
Member of the Consultative Committee for Amount of Substance: Metrology in Chemistry and Biology (CCQM)

Since December 2013
Member of the Joint Committee for Traceability in Laboratory Medicine (JCTLM)

Since July 2008
Full Member of the Asia Pacific Metrology Programme (APMP)

Pharmaceutical Division

Since October 2020
Co-Chair of the ASEAN Pharmaceutical Testing Laboratory Committee (APTLC)

Since May 2014
Associate Membership to the General European Official Medicines Control Laboratories Network

Since November 2012
Member of the ASEAN Cosmetics Testing Laboratory Committee (ACTLC)

Since September 2012
Member of Official Cosmetics Control Laboratories (OCCL)

World Health Organization

Since May 2016
Chair of the WHO Tobacco Laboratory Network (TobLabNet)

Since November 2013
Member of the WHO Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations

Since 2013
Western Pacific Regional Forum for the Harmonization of Herbal Medicines (FHH)

Since 2004
International Laboratories Forum on Counterfeit Medicines (ILFCM)

MESSAGE FROM THE CHAIRMAN

We participated actively in many international scientific discussions on vaccine development, and closely monitored and studied developments on emerging vaccine platforms such as messenger RNA (mRNA). We continued to share the latest updates on the development, interim authorisation and safety information of COVID-19 medical devices, medicines and vaccines. Thanks to these partnerships, HSA has kept abreast of the rapidly evolving international situation and contributed to global regulatory efforts to develop and approve high-quality, safe and effective medical devices, medicines and vaccines to address the COVID-19 pandemic.

PROFESSOR SATKUNANANTHAM S/O KANDIAH

Chairman

There was no let-up to the intensity of the previous year as the pandemic took on a new dimension.

Even with the challenges and surge in workload, we managed to maintain close ties with our partners and counterparts, and pressed on with our transformation journey to streamline our processes and enhance efficiency.

Keeping up to date on the global developments regarding COVID-19 medical devices, medicines and vaccines

We participated actively in many international scientific discussions on vaccine development, and closely monitored and studied developments on emerging vaccine platforms such as messenger RNA (mRNA). We continued to share the latest updates on the development, interim authorisation and safety information of COVID-19 medical devices, medicines and vaccines. Thanks to these partnerships, HSA has kept abreast of the rapidly evolving international situation and contributed to global regulatory efforts to develop and approve high-quality, safe and effective medical devices, medicines and vaccines to address the COVID-19 pandemic.

While vaccinations are being conducted globally, HSA has also been discussing the need for robust post-market pharmacovigilance cooperation and rapid sharing of information about adverse events with our overseas counterparts. Such cooperation will allow regulators to monitor the safety and efficacy of COVID-19 vaccines and quickly take the appropriate actions.

Maintaining our partnerships

As part of the new normal, we kept to virtual meetings to continue our networking with partner agencies and counterparts.

We shared best practices with other blood establishments within the Asia Pacific Blood Network (APBN) during the COVID-19 pandemic. This allowed us to keep up to date on developments involving donor eligibility and management, and strategies to secure the national blood supply.

We also embarked on a Blood Bank User Research Project with Singapore Polytechnic to develop strategies to improve the blood donation experience for both donors and staff, and strategies to engage and retain donors to become regular donors.

Work sharing with our overseas counterparts

In the area of health products regulation, our strong ties with our strategic global partners enabled timely exchange of information and work sharing.

We have an ongoing collaboration with the US Food and Drug Administration (FDA) Oncology Centre of Excellence to provide a framework for concurrent submission and review of oncology products among international regulatory health authorities. Through this collaboration, we have issued regulatory approvals for five applications.

In April 2020, we kicked off our first work-sharing project with Malaysia's National Pharmaceutical Regulatory Agency to evaluate generic medicines. Our progress from parallel review to work-sharing is a significant step towards achieving regulatory efficiency.

Building our knowledge

Due to a lack of data outside the Caucasian population, estimating the number of persons who contribute to a DNA mixture profile can be challenging. To better assist forensic DNA scientists in the region, we began a study on the use of simulated DNA mixture profiles based on the local Chinese, Malay and Indian populations. Through this study, we now have novel insights about the impact of allele dropout and the differences between intra-ethnic and inter-ethnic DNA mixtures.

Together with other government laboratories from Canada, Germany, UK, Australia, USA, Netherlands and Switzerland, HSA is working on an international collaborative study to determine specific cannabinoids (tetrahydrocannabinol, tetrahydrocannabinolic acid, cannabidiol and cannabidiolic acid) in cannabis products. The results will ensure greater alignment of standards across the board.

Organisation-wide digitalisation initiatives

Digitalisation continued to be a big part of our process improvements. We accelerated the adoption of digital signatures and began working with GovTech to automate and digitalise HSA's internal workflows and processes. Time and manpower savings were also achieved through the implementation of robotic process automation (RPA) to digitalise manual and repetitive tasks.

Improving workflow

We rolled out a new laboratory information management system for our Applied Sciences Group which incorporates many digitalised workflows that enable data to move seamlessly across different laboratories and instruments. Some of the features include paperless submission/collection process for key stakeholders, dispatch of e-reports, and e-inventory for tracking of chemicals, reagents and drug reference standards.

With this system, about 80% of our laboratories' workflows and processes have been digitalised. We have also received positive feedback from users and stakeholders that the system has helped to streamline their operational processes.

Improving efficiency

The laboratories also utilised RPA to replace some of the tasks which previously required human intervention. Such automation greatly reduces human transcription and interpretation errors.

RPA is also used in the blood services labs. Maintaining blood transfusion records used to be a tedious and manual task that took two to three hours a day. With RPA, the task has become much simpler, taking only two to three minutes. Likewise, the manual uploading of blood donation testing reports used to take about eight hours a month, but it now takes only 1.5 hours.

Keeping ourselves relevant

As part of our digital transformation efforts, we also developed the HSA Digitalisation Training Framework to build knowledge and equip staff with basic and specialised digital skills. A training catalogue comprising a list of courses has been curated to help staff identify suitable digital courses that are relevant for their areas of work. Such courses include data analytics, user experience design and agile project management.

Looking ahead

We recognise the importance of strengthening HSA's resilience and agility to cope with unexpected situations and challenges. We will continue to equip ourselves with the skills and knowledge necessary to thrive in this new landscape.

I am confident that we have what it takes to ride out any storm and come out enriched and stronger.

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

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.

HSA BOARD

AS AT AUGUST 2021

Professor Satkunanantham s/o Kandiah

Chairman
Health Sciences Authority

Mr Lionel Yee Woon Chin

Deputy Attorney-General
Attorney-General's Chambers

Mr Dileep Nair

Independent Director
Keppel DC REIT Management Pte Ltd

Assoc Professor Benjamin Ong

Deputy Chairman
Health Sciences Authority

Senior Vice President (Health Education and Resources)
National University of Singapore

Mr Jimmy Phoon

Chief Executive Officer
Seviora Holdings Pte Ltd

Mr Alok Mishra

Chief Executive Officer
Value Addition

Ms Aileen Tan

Group Chief People and Sustainability Officer
Singtel

Mr Tai Lee Siang

Head of Pillar, Architecture and Sustainable Design
Singapore University of Technology and Design

Professor Freddy Boey

Deputy President (Innovation & Enterprise)
National University of Singapore

Professor Leong Tze Yun

Professor of Computer Science (Practice)
National University of Singapore

Director of AI Technology
AI Singapore

Mr Lin Qinghui

Senior Director, Policy Development Division
Ministry of Home Affairs

HSA BOARD COMMITTEES

AS AT AUGUST 2021

Board Executive Committee

Chairman
Professor Satkunanantham s/o Kandiah

Members
Assoc Professor Benjamin Ong
Mr Alok Mishra
Mr Lionel Yee Woon Chin
Ms Aileen Tan

Audit and Risk Committee

Chairman
Mr Jimmy Phoon

Members
Professor Freddy Boey
Professor Leong Tze Yun
Mr Lin Qinghui

Building Development Committee

Chairman
Mr Tai Lee Siang
Head of Pillar, Architecture and Sustainable Design
Singapore University of Technology and Design

Co-Chairman
Dr Choong May Ling, Mimi
Chief Executive Officer
Health Sciences Authority

Members
Mr Dileep Nair
Independent Director
Keppel DC REIT Management Pte Ltd

Mr Jeffrey Wong
Group Director
Corporate Services Group

Assoc Professor Sunil Sethi
Group Director
Applied Sciences Group

Assoc Professor Chan Cheng Leng
Group Director
Health Products Regulation Group

Dr Ang Ai Leen
Group Director
Blood Services Group

Mr Loke Mun Sing
Director
Healthcare Infrastructure Projects Division
Ministry of Health Holdings

Mr Hoong Bee Lok
Visiting Consultant
Health Sciences Authority

BOARD UPDATES

We would like to express our deepest appreciation to Mr Max Loh who retired from the Board on 31 March 2021. As one of the longest serving board members, he had provided invaluable guidance in helping to set the strategic direction and ensuring improved management and performance.

As Chairman of the Board Audit and Risk Committee, Mr Loh had played a pivotal role in strengthening HSA's corporate governance, risk management, data governance and cybersecurity.

HSA welcomes Assoc Professor Benjamin Ong, who joined the Board on 1 October 2020 as Deputy Chairman, and Mr Lin Qinghui who joined the Board on 1 April 2021. They bring with them rich experience in their areas of expertise. We look forward to their wise counsel and guidance in leading HSA towards our vision of protecting and advancing national health and safety.

HSA EXECUTIVE COMMITTEE (EXCO)

AS AT AUGUST 2021

Dr Choong May Ling, Mimi
Chief Executive Officer

Assoc Professor Chan Cheng Leng
Group Director
Health Products Regulation Group

Dr Ang Ai Leen
Group Director
Blood Services Group

Assoc Professor Sunil Sethi
Group Director
Applied Sciences Group

Mr Jeffrey Wong
Group Director
Corporate Services Group

CORPORATE GOVERNANCE STATEMENT

The HSA Board and Senior Management Team are committed to maintaining a high standard of corporate governance and complying with the recommendations set out by the Code of Corporate Governance. The Board believes that good governance is essential in enhancing corporate performance and accountability, ensuring transparency and protecting stakeholders' interests at all times. Our stakeholders include the Ministry of Health, Ministry of Finance, other government agencies, the healthcare industry, our clients, our suppliers and the public at large.

This statement outlines the main corporate governance practices of the organisation that are in place.

The Board

The Board comprises the Chairman and its members, who are appointed by the Minister for Health for a two-year or three-year term. It aims to meet every two to three months to set strategic directions, assume the role of monitoring and reviewing of policies leading to HSA's improved management and performance.

Board Members' Remuneration

HSA follows the Government's Directorship and Consultancy Appointments Council (DCAC) guidelines in determining the remuneration of the Board Members.

Notice and Declaration of Directorships and Interest in Shares and Debentures

Board Members are required to declare their directorships in various organisations and their interests in shares and debentures in various corporations. Board Members deemed to have any such interests during the meetings are required to declare them. They are to refrain from any deliberations made when such an interest has been declared.

Accountability and Audit

HSA's Senior Management Team is accountable to the Board. In turn, the Board is accountable to the Minister for Health. To allow the Board to discharge its duties adequately, Senior Management and staff are required to provide periodic updates and answer any queries that the Board may have on the operations and planning of the organisation.

For accountability purposes, the Board has established the following Board Committees:

A. Board Executive Committee

This Committee assists the Board to review and make recommendations on manpower-related issues. These include assessing the adequacy of manpower numbers to meet operational needs.

B. Audit and Risk Committee

This Committee assists the Board to review and assess the adequacy of internal controls, provide guidance on financial matters, as well as to have oversight of significant organisational risks. It meets quarterly with the Management and auditors to determine the scope of the external and internal audits, review audit findings, and to provide oversight of financial budgets.

C. Building Development Committee

This Committee assists the Board to review and provide guidance on matters related to the new HSA building project. These include having oversight of the project delivery milestones, ensuring compliance with corporate governance guidelines as well as putting forth recommendations for the various approval aspects of the project.

Communication with Stakeholders

The Professional Groups conduct regular consultations with the industry and their clients, seeking to keep them informed of new directions and regulations, and to listen to their concerns. HSA publishes an annual report to meet statutory requirements and provide information to our stakeholders. In addition, regular updates on matters of interest to our stakeholders are posted on our website. Our Quality Service Manager ensures that the organisation's professional quality standards are maintained.

Code of Business Conduct

The Board, officers and employees are required to observe and maintain high standards of integrity, and be compliant with the law, government regulations, organisation policies, and best corporate practices.

Risk Management

The Management is continually reviewing and improving business and operational activities to identify and manage areas of significant risks with appropriate measures and controls. The Management also reviews all significant control policies and procedures, and highlights significant matters to the Board, the Board Executive Committee, and the Audit and Risk Committee as necessary.

ORGANISATION CHART AS AT AUGUST 2021

HSA BOARD

CHIEF EXECUTIVE OFFICER

Internal Audit

Quality Service Manager

HEALTH PRODUCTS REGULATION GROUP

Medicinal Products Pre-Market
- Therapeutic Products
- Complementary Health Products
- Innovation Office & Clinical Trials
- Advanced Therapy Products

Vigilance, Compliance & Enforcement
- Vigilance & Compliance
- Enforcement
- Tobacco Regulation
- Audit & Licensing

Medical Devices

Group Director's Office

Stakeholders Engagement Office

APPLIED SCIENCES GROUP

Analytical Science
- Chemical Metrology
- Pharmaceutical

Forensic Science
- Analytical Toxicology
- Biology
- Illicit Drugs
- Forensic Science

Forensic Medicine

Group Director's Office

Quality Assurance Unit

BLOOD SERVICES GROUP

Professional
- Clinical Services
- Quality Management
- Capability Development and International Collaboration

Operations
- Patient Services
- Blood Supply Management
- Blood Resources

Admin
- Blood Service Support

CORPORATE SERVICES GROUP

Compliance

Corporate Communications

Engagement, Innovation & Professional Development

Facilities Management

Finance

Human Capital Management

Information Management

Legal

Risk Management & Emergency Planning & Data Governance

Safety & Quality

Strategy & Business Transformation

01 HEALTH PRODUCTS REGULATION GROUP

We are committed to maintaining the standards of health products in Singapore, while at the same time ensuring that access to essential health products is as quick and seamless as possible.

REGULATORY DEVELOPMENTS AND REVIEWS

We conduct regular reviews of our regulatory processes to facilitate the latest developments in health products.

OUR TIMELY RESPONSE TO THE PANDEMIC

Facilitation of access to medical devices for COVID-19

In light of the demand for medical devices such as medical masks, COVID-19 diagnostic test kits, respirators and ventilators brought on by the pandemic, we exercised regulatory agility to ensure timely access to these critical medical devices while not compromising on their safety and effectiveness. This included establishment of the provisional authorisation route and providing relevant regulatory guidance such as guidance on the development of 3D printed medical devices.

As part of our regulatory efforts, we also published a guidance document on our website in June 2020 that covered the key regulatory requirements for decontamination devices and good practices for healthcare institutions and other user facilities.

As of 31 March 2021, these devices were granted authorisation under the provisional authorisation route:

180 **COVID-19 diagnostic test kits**

5 **Ventilators**

3 **Decontamination devices**

Ensuring safety standards of medical masks

Due to the surge in demand for medical masks in Singapore, many local companies (including those from non-medical related industries) responded by applying to set up mask manufacturing facilities. To ensure the quality and performance of locally manufactured masks, HSA set up a virtual inspection and desktop review process to ensure compliance with international standards.

Conditional authorisation of Veklury (remdesivir)

In response to the urgent public health demands for remdesivir during the COVID-19 pandemic, HSA facilitated early access to the medicine through a conditional approval route in June 2020. This was subject to submission of data from ongoing clinical studies and manufacturing testing to ensure the continued safety and efficacy of the product.

Pandemic Special Access Route (PSAR)

We introduced PSAR in December 2020 to facilitate early access to critical novel vaccines, medicines and medical devices required during pandemic situations.

PSAR enables HSA to prioritise the review of critical COVID-19 vaccines and treatments through a rolling submission process, where companies can submit real-time data as and when they are available from ongoing studies. This allows HSA to start the evaluation early while the clinical and quality studies are concurrently underway, instead of having to wait for the full dataset to be submitted before evaluation can commence under the usual regulatory process. HSA has expedited the access to two COVID-19 vaccines through PSAR interim authorisation, while ensuring scientific rigour in the assessment of quality, safety and efficacy.

Singapore was the 1ST Asian country to approve the Pfizer-BioNTech COVID-19 vaccine and Moderna COVID-19 vaccine, on 14 December 2020 and 3 February 2021, respectively

17 **COVID-19 clinical trials, investigating novel antiviral agents, monoclonal antibody treatments, cell therapy and vaccines have been approved since the start of the pandemic**

Remote inspections during COVID-19 circuit breaker and phased transition periods

With inspections being affected by COVID-19 safety measures, we turned to the use of secure technology platforms that allowed visual and audio communications to perform virtual inspections of the premises of licensed manufacturers and dealers, as well as retail pharmacies and clinical trials.

This approach enabled us to ensure that these companies complied with regulatory requirements, including Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) standards to ensure the continued supply of safe and good quality medicines.

It also allowed us to continue our Good Clinical Practice (GCP) inspection of clinical trials, including the electronic trial master files and electronic data capture systems used in the clinical trials, and to interact with sponsor representatives from different time zones.

Building our capability in ultra-low temperature (ULT) cold chain vaccines handling

To ensure that we were able to handle ULT vaccines in our national vaccination programme, we have:

- Provided guidance and advice to distributors on ULT cold chain requirements (-70 degrees Celsius), as well as the storage and transport systems required
- Supported applications for Good Distribution Practice (GDP) Certifications and conducted audits to assess that companies' quality management systems complied with GDP requirements
- Reviewed temperature charts from temperature loggers accompanying vaccine shipments during transportation to ensure that transportation conditions were in order before the COVID-19 vaccines were released for use

As of March 2021, HSA has received and approved

4 **GDP Certifications**

2 **amendment applications for adding cold chain storage capabilities to dealers' licences**

Photo credit: Marken Time Critical Express Limited (Singapore Branch)

Inspection of a COVID-19 vaccine manufacturer in China

In December 2020, we successfully conducted a GMP inspection of a COVID-19 vaccine manufacturing facility in China.

In order to meet the tight and rigorous travel requirements, we had to start our travel nearly three weeks before the actual inspection date. During the process, we also received cross-agency support from Singapore's Economic Development Board and Ministry of Foreign Affairs, which assisted with expeditious travel approvals, special clearances and logistic arrangements.

HSA's role in ensuring that overseas manufacturing facilities supplying COVID-19 vaccines to Singapore comply with international quality standards, and the importance of close inter-governmental agency support were amply demonstrated in this mission.

NEW REGULATIONS FOR CELL, TISSUE AND GENE THERAPY PRODUCTS (CTGTP)

CTGTP are a novel and innovative class of health products. In February 2021, we gazetted 11 pieces of subsidiary legislation for CTGTP. The CTGTP regulations were implemented under the Health Products Act on 1 March 2021.

Prior to this, HSA had conducted extensive focus group discussions and public consultations with a diverse group of stakeholders. The collaborative efforts, valuable feedback and contributions of our stakeholders enabled the implementation of fit-for-purpose, risk-based regulations that support product development and commercialisation of these medically important therapies. The regulations also facilitate patients' access to novel products that meet the appropriate standards of safety, efficacy and quality.

MANAGEMENT OF NITROSAMINE CONTAMINATION IN MEDICINES

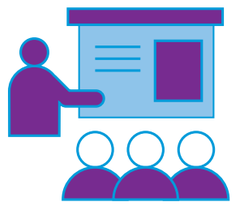
HSA continues to adopt a system-wide coordinated approach to manage the issue of nitrosamine contamination in medicines. Our efforts include:

- Collaborating closely with international regulators to discuss and formulate appropriate measures to address this issue to safeguard public health
- Engaging industry stakeholders to review the risk of nitrosamine contamination in their products and to mitigate any identified risk

In April 2020, we organised a virtual stakeholder briefing to clarify HSA's regulatory approach in managing this issue of nitrosamine contamination, to communicate the actions required by stakeholders and to address their concerns.

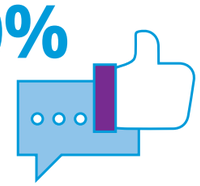
Over

200 **industry stakeholders attended the briefing**

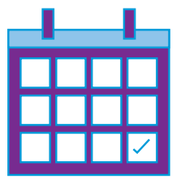


Around

90%



of the feedback received rated the briefing as useful in enhancing the understanding of HSA's requirements



As of March 2021, more than **85%** **of locally registered products were on track to meet the December 2021 deadline**

We have also been working with companies dealing with angiotensin receptor blockers (such as losartan and valsartan), which belong to a group of high blood pressure medicines, to review their manufacturing processes and implement changes to mitigate the risk of nitrosamine formation by December 2021.

NEW REGULATIONS AND GUIDELINES

To ensure our stakeholders fully understand the impact of new regulations, we came up with several guidelines over the year-in-review.

Guideline	Details
Collaboration with the Ministry of Health (MOH) for the MOH-AI Guideline for Safe Development and Implementation of Artificial Intelligence (AI) in Healthcare	• HSA addressed the risks present in the development and implementation of AI medical devices (AIMDs) in healthcare settings • The purpose of the guideline is to encourage partnership between developers and implementers to ensure patient safety • The guideline is targeted to be launched in the second half of 2021
Guideline on changes relating to the new regulatory frameworks for Medical Devices Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR)	• The European Union (EU) introduced two new regulations — MDR and IVDR, in place of the current Medical Devices Directive (MDD) • As a result of this change, revisions to device labelling and instructions for use on a significant number of medical devices are expected as many devices in Singapore share common labelling with those supplied in EU • This new guideline serves to provide clarity on the changes which would require submissions to HSA • The proposed guideline went through a focus group session in July 2020 and was finalised in October 2020
New regulatory guideline for 3D Printed Medical Devices (3DP MDs)	• 3D printing allows for the production of medical devices matched to an individual's specific anatomy • This new guideline for 3DP MDs serves to differentiate mass-produced from custom-made 3DP MDs and explain the regulatory controls involved • The guideline was published in January 2021 for consultation and is expected to be finalised in Q3 2021

PUBLISHING OF BENEFIT-RISK ASSESSMENT SUMMARY REPORTS

In June 2020, we began publishing summary reports of benefit-risk assessments for approved new chemical and biologic entities on our website. Through this initiative, we aim to enhance regulatory transparency through open communication with stakeholders and the public.

This is in line with current international best practices among global regulatory agencies and is beneficial for companies that may wish to leverage HSA's assessments as part of their filing strategy to jurisdictions that offer reliance pathways, as they can now freely access HSA's assessments and use the reports to support their regulatory filings in those countries.

IMPLEMENTATION OF REVISED HEAVY METAL LIMITS FOR COMPLEMENTARY HEALTH PRODUCTS (CHP)

From September 2020, it has become mandatory for all CHP in the local market to comply with the revised limits of heavy metals. These limits have been revised to enhance consumer safety and align with international standards such as those set by the World Health Organization and ASEAN. Additionally, it will also help facilitate entry into other markets for companies dealing with such products.

To support these new limits, HSA has provided guidance to the industry on ways to minimise heavy metal contamination in CHP.

STREAMLINED REQUIREMENTS FOR STABILITY DATA

HSA has introduced a streamlined approach for stability testing of multiple manufacturing sites for the same therapeutic product. This new approach allows the utilisation of stability data generated by one manufacturing site to support the shelf-life of the same product manufactured at another site when scientifically justified, thereby minimising the need for each manufacturing site to generate its own set of data.

ROLLING OUT OF NEW E-PHARMACY FRAMEWORK

In light of the increasing prevalence of telemedicine, HSA rolled out a new e-pharmacy framework for the dispensing of medicines in May 2020.

This new framework covers the following safeguards to ensure patient safety:

- Closed loop system for the transmission of e-prescriptions to prevent prescriptions from being changed or reused by the patients, enable traceability to the prescribing doctor, and guard against cybersecurity threats
- Clear procedures and practices for the storage, packing, labelling, and secure delivery of medicines to the intended patients in accordance with the e-prescriptions received, and with the appropriate professional supervision by a qualified pharmacist
- A strict policy to prevent dispensing of medicines containing controlled substances

STREAMLINING AND ENHANCING OUR PROCESSES

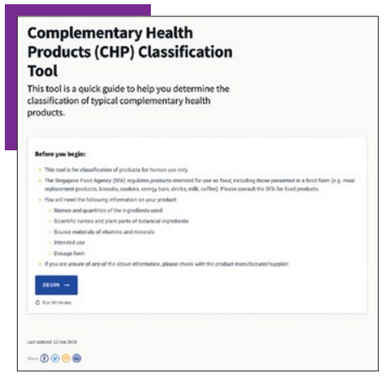
We continually streamline and enhance our processes to deliver the greatest value to all our stakeholders.

NEW STREAMLINED DOCUMENT SUBMISSION PROCESS

A new FormSG form has been introduced to streamline the submission of post-approval data and documents to fulfil therapeutic products registration conditions.

Highlights of this new form include:

- Ability to include multiple products sharing the same registration condition in one single submission
- Access to control via Corppass for added data security
- Elimination of multiple submissions for greater process efficiency

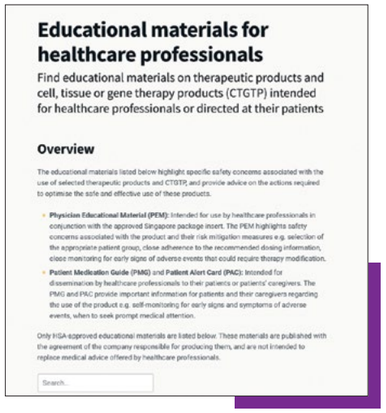


ENHANCED CHP CLASSIFICATION TOOL

In September 2020, we launched an enhanced CHP classification tool. This new tool features a more user-friendly search function, ingredient-specific advice and guidance for compliance with current controls.

We have received positive feedback that the new tool is more efficient and informative.

Since the release of our enhanced CHP tool, usage rate has increased by nearly 33%



ENHANCED ACCESS TO SAFETY INFORMATION

In line with HSA's ongoing digital transformation efforts, we have launched two new safety initiatives.

The first seeks to ensure that healthcare professionals have easy and on-demand access to trusted safety information on therapeutic products, and cell, tissue or gene therapy products either through our website or email. Healthcare professionals can access educational materials for their patients or themselves through a dedicated webpage, or subscribe to email updates regarding new postings on the HSA website.

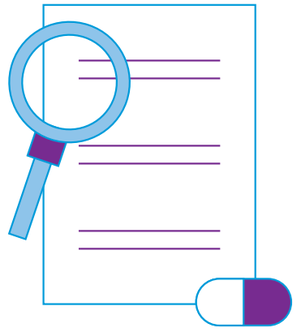
The second is an online survey which was conducted to better understand how healthcare professionals currently obtain safety information on therapeutic products from HSA, and the barriers faced in accessing our communication channels. Data obtained from this survey will help us identify potential areas for improvement.

STAYING VIGILANT

Ensuring the safety and quality of health products rank amongst our top priorities.

SURVEILLANCE OF LOCAL PRODUCT DEFECTS

Over the year-in-review, more than 180 cases of product defects relating to locally registered therapeutic products were reported. The top three issues were related to:



Manufacturing defects: 63 cases

Product packaging defects: 47 cases

Product contamination: 22 cases

In response, HSA worked with companies to ensure that the appropriate corrective and preventive actions were taken to mitigate the impact on the safety and quality of the defective therapeutic products and their future batches. Such actions included:

18 amendments to product registration

Issued 12 communications
(e.g. Dear Healthcare Professional, Dear Purchaser Letters and press releases)

Recalled 8 products from the market

MANAGING PRODUCT RISK

Singapore-specific Risk Management Plans (RMP)

39 **RMPs were reviewed** prior to therapeutic product registration

6 **new RMPs were implemented**
(including provision of educational materials to healthcare professionals and patients, and submission of periodic benefit-risk evaluation reports)

Safety signals

147 **safety signals were assessed as part of post-market pharmacovigilance activities, resulting in:**

- Voluntary withdrawal of Esmya (ulipristal acetate 5mg) in October 2020 due to the risk of serious liver injuries identified from overseas reports
- Restrictions on the use of products containing montelukast due to the known but rare risk of neuropsychiatric events
- Amendment of local package inserts to address newly emerging safety concerns
- Provision of product safety information directed at healthcare professionals

Risk assessments on adulterated health products

19 **risk assessments on adulterated products were conducted as part of post-market surveillance, resulting in the issuance of press releases to warn the public about these products**

COMMUNICATING THE IMPORTANCE OF SAFETY

In FY20/21:

12 **press releases** containing advisories on **24** **products** were issued

56 **company Dear Healthcare Professional Letters** (DHCPLs) were reviewed; and

5 **DHCPLs** were written and issued by HSA

3 **Adverse Drug Reaction News Bulletins** were published and sent to registered healthcare professionals

2 **safety updates** were published on our website

SHARING OUR KNOWLEDGE

As the authority on health products regulation, we are always ready to share our expertise and knowledge with our stakeholders and partners.

REGULATION OF IN VITRO DIAGNOSTIC DEVICES (IVDD) WORKSHOP

In September 2020, speakers from HSA were invited to speak at a "Regulation of IVDD" workshop, which was organised by Duke-NUS CoRE.

The objective of the workshop was to bring about a fundamental understanding of the principles behind effective regulation of IVDD and equip participants to make an informed decision when planning for the development, market entry and management of such devices.

Our speakers covered the following topics:

- Regulatory requirements of IVDD throughout the product life cycle
- Roles of standards and guidelines
- Post-market surveillance

REGULATION OF SOFTWARE AS A MEDICAL DEVICE (SAMD) WORKSHOP

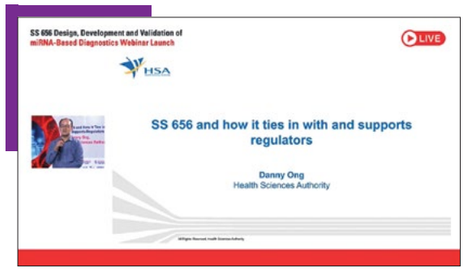
In December 2020, Duke-NUS CoRE organised a two-day workshop on the regulation of SaMD, and its related standards and guidelines.

The workshop which was targeted at industry professionals and academia, discussed the increasingly important role of software in medical devices that deliver critical healthcare services, as well as the importance of regulating them.

HSA was invited to share our approach in regulating SaMD through the software life cycle, including pre-market, post-market and change management controls. We also shared case studies to illustrate the importance of proactive monitoring in ensuring the safe and effective use of devices.

Additionally, we took the opportunity to share our regulatory approaches for AI during the workshop as we noted the increased use of AI in healthcare settings.

SINGAPORE STANDARD 656 WEBINAR LAUNCH



Over the past year, HSA has been involved in the development of Singapore Standard 656 : 2020 (SS 656), which covers the design, development and validation of microRNAs (miRNAs) based diagnostics. miRNAs are particularly significant for their potential in disease screening, diagnosis, monitoring of disease progression or recurrence, and for predicting response to therapy.

At the official launch of SS 656 in September 2020, HSA was invited to speak at the webinar alongside other prominent speakers from around the world, covering topics such as how the standard can be applied in R&D, commercialisation of in vitro diagnostic products, clinical diagnostics and medical device regulation.

IMPLEMENTATION OF MEDICAL DEVICE UNIQUE DEVICE IDENTIFICATION (UDI) SYSTEM IN SINGAPORE

In October 2020, HSA hosted a webinar to engage stakeholders, as well as gather feedback on the plans for the phased implementation of the UDI System in Singapore.

The UDI System is a globally harmonised system that facilitates unambiguous identification of medical devices through their distribution and use. It offers medical device manufacturers, distributors and healthcare providers a way to enhance traceability and identification of medical devices (e.g. during post-market actions, or recording of medical device use in patients).

Implementation of UDI in Singapore is expected to take place in phases from 2022, starting with high-risk implantable medical devices, followed by other Class D, C and B devices.

BOLSTERING OUR INTERNATIONAL LINKS

To maintain our world-class standing, we continued to foster strong ties with overseas partners.

INTERNATIONAL MEDICAL DEVICE REGULATORS FORUM (IMDRF)

Despite being the Chair of IMDRF in a year (2020) that was overshadowed by the COVID-19 pandemic, we managed to successfully organise the following events:

- First-ever virtual IMDRF Management Committee meeting
- Stakeholders' forum
- Joint cybersecurity workshop with the Global Diagnostic Imaging, Healthcare IT & Radiation Therapy Trade Association (DITTA)

We were also formally endorsed as a member of the IMDRF National Competent Authority Report exchange programme, which seeks to facilitate the exchange of post-market safety information on medical devices amongst global regulatory authorities, and trigger the rapid adoption of field safety corrective actions to better safeguard patients' health and safety.

During our 2020 IMDRF chairmanship, we:

Finalised
10 **procedural and technical guidance documents**

Approved
3 **new work item extensions on medical device adverse events terminologies, cybersecurity and personalised medical devices**

Established **1** **new working group on artificial intelligence medical devices**

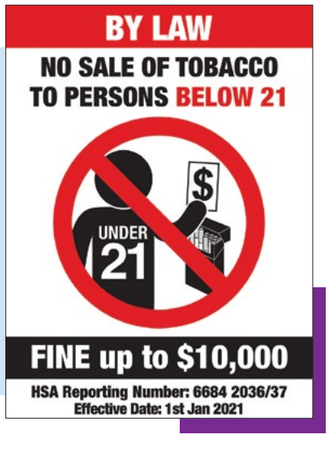
LOCAL OUTREACH PROGRAMMES

We are committed to serving our local stakeholders through various outreach programmes.

INCREASE IN THE MINIMUM LEGAL AGE (MLA) FOR TOBACCO

As part of Singapore's ongoing efforts to reduce smoking prevalence, the MLA for the purchase, use, possession, sale and supply of tobacco products was raised from 20 to 21 years old on 1 January 2021.

We sent notifications and new signage stickers to all tobacco retailers to help them prepare for the revised age restriction. Our officers also engaged with tobacco retailers to remind them about the new law during routine inspections.



STANDARDISED PACKAGING (SP) FOR TOBACCO PRODUCTS

As of 1 July 2020, all tobacco products sold in Singapore come in standardised packaging with enlarged graphic health warnings ("the SP Measure"). The SP Measure applies to all tobacco products, including cigarettes, cigarillos, cigars, beedis, *ang hoon* and other roll-your-own tobacco products.

To help tobacco manufacturers, importers, wholesalers and retailers prepare and adjust, they were given a notice period of 12 months starting from 1 July 2019. During this period, we regularly sent our officers, as well as letters and circulars, to remind tobacco licensees of this new measure.

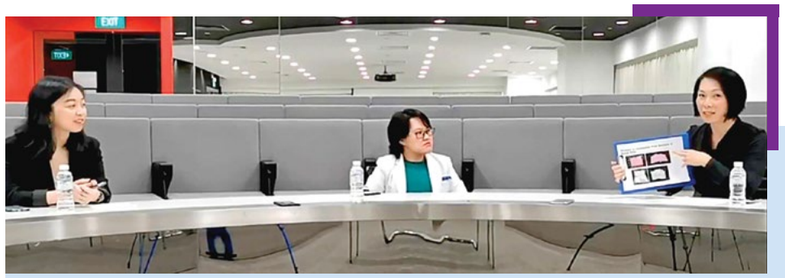
INAUGURAL VIRTUAL ROADSHOW ON ADVERSE EVENT (AE) REPORTING

In September 2020, we held our inaugural virtual roadshow on the importance of pharmacovigilance and AE reporting for healthcare professionals in Sengkang General Hospital.

The session was met with encouraging feedback from participants and demonstrated HSA's agility in adapting to new situations brought on by the COVID-19 pandemic.

1ST roadshow conducted at Sengkang General Hospital

Over 100 participants comprising doctors and pharmacists attended



PARTICIPATION IN PHARMACEUTICAL SOCIETY OF SINGAPORE PHARMACY WEEK 2020

In October 2020, we participated in Pharmacy Week's virtual carnival organised by the Pharmaceutical Society of Singapore (PSS). Pharmacy Week is a public event organised annually by PSS to educate the public on the safe and effective use of medicines.

As part of our ongoing public education initiative to raise awareness on the side effects of health products and medicines, HSA participated in a panel discussion. We also delivered a talk about the dangers of purchasing health products from dubious sources online and advised the public to consult healthcare professionals when in doubt. The video recording of the talk was posted on the PSS website together with HSA's video about the dangers of purchasing health products from dubious sources online.

NEW LOCAL PARTNERSHIPS

We collaborate and partner with local organisations to further our work in health products regulation.

UPDATE ON PUBLIC HEALTH RESEARCH IN PHARMACOGENETICS

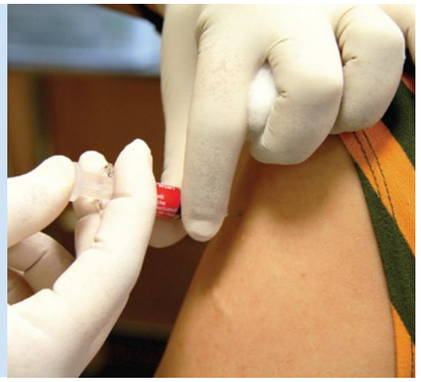
In August 2020, Sengkang General Hospital entered into a research collaboration agreement with HSA, joining four other public healthcare institutions (National University Hospital, Singapore General Hospital, Changi General Hospital and National Skin Centre) in the ongoing "Pharmacogenetics of Adverse Drug Reactions — Serious Skin Rash" study.

The findings of this study will allow HSA to evaluate the pharmacogenetics associations of serious skin reactions in the local population, and to formulate genotyping recommendations at a national level.

PROJECT AGREEMENT WITH A*STAR TO DEVELOP TESTING CAPACITY FOR COVID-19 VACCINES

In September 2020, HSA signed a project agreement with the Agency for Science, Technology and Research (A*STAR) Bioprocessing Technology Institute to develop new in-house capabilities for the testing of locally manufactured or imported COVID-19 vaccines.

Areas of collaboration include setting up and validating test methods for independent analytical testing of COVID-19 vaccines, as well as training new HSA officers to perform lot release testing functions.



KNOWLEDGE EXCHANGE

Over the year-in-review, we collaborated with international partners to share and build up our knowledge and expertise.

THAILAND'S FOOD AND DRUG ADMINISTRATION (FDA) RELIANCE-BASED PROGRAMME

In September 2020, Thailand's FDA started their reliance-based programme, which allows them to leverage HSA's evaluation reports of Singapore-registered medical devices*.

The initial pilot programme has successfully concluded with 12 reports shared, and will now become a mainstay programme between the two regulators. The next phase of the programme will additionally include capacity building sessions through virtual platforms.

*With due consent from local registrant companies

PROJECT ORBIS

Project Orbis is an ongoing collaboration with the US Food and Drug Administration (FDA) Oncology Centre of Excellence to provide a framework for concurrent submission and review of oncology products among international regulatory health authorities.

Through this collaboration, HSA issued regulatory approvals for

5 applications

ACCESS CONSORTIUM

Previously known as ACSS Consortium, it was renamed in October 2020 to Access Consortium. With this new name comes the inclusion of the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) as a new member.

Evaluation of

4 therapeutic products applications have been completed by HSA through this work-sharing collaboration

HSA-NATIONAL PHARMACEUTICAL REGULATORY AGENCY (NPRA) COLLABORATION

As part of our ongoing collaboration with Malaysia to evaluate generic medicines, we kicked off our first work-sharing project in April 2020. Our progress from parallel review to work-sharing is a significant step towards achieving regulatory efficiency.

PARTICIPATION IN WORLD HEALTH ORGANIZATION (WHO) UPPSALA MONITORING CENTRE (UMC)'S MEDSAFETYWEEK 2020

In November 2020, HSA participated in WHO UMC's 5th MedSafetyWeek, a global social media campaign which carried the theme of "Every Report Counts" and garnered participation from 76 countries. HSA was part of the six-member organising committee and contributed to the development of three short animated videos that were aimed at encouraging the public and healthcare professionals to report AE.

Other highlights included:

- Collaborating with the Pharmaceutical Society of Singapore and Health Promotion Board to post video animations on their social media platforms
- Being featured in the October 2020 Uppsala Report (an e-publication by WHO-UMC)

PILOT PROJECT ON PHARMACEUTICAL GMP INSPECTION BETWEEN KOREA AND SINGAPORE

In August 2020, we embarked on a one-year pilot project with Korea's Ministry of Food and Drug Safety (MFDS) to mutually recognise GMP inspections of pharmaceutical products conducted by both authorities.

The scope of this project applies to all pharmaceutical products for human use, including investigational medicinal products, drug substances, biopharmaceuticals and herbal medicinal products.

The eventual aim is for both authorities to sign a Mutual Recognition Agreement on GMP inspection of pharmaceutical products under the framework of the Korea-Singapore Free Trade Agreement.

As of March 2021, both authorities have exchanged 7 GMP inspection reports each

INVOLVEMENT IN PIC/S ACTIVITIES

In December 2020, we participated in the 2020 Pharmaceutical Inspection Co-operation Scheme (PIC/S) Seminar on "Distant Assessment of GMP Compliance", which was hosted online by the Finnish Medicines Agency (FIMEA). The event saw regulators from different jurisdictions sharing their experience on "the conduct of distant GMP assessment" and "the security of information technology and communication tools".

HSA also participated as a member of the PIC/S Working Group on Revision of Annex 2 (Manufacture of biological medicinal substances and products for human use), which has been completed and effective since 1 May 2021.

INVOLVEMENT IN INTERNATIONAL CONFERENCES

We were invited to share about the topics of "Remote Inspections within HSA and ASEAN", as well as "the Pharmaceutical Inspection Co-operation Scheme (PIC/S) and International Reliance Programmes" at several local and international events.

This included an invitation by Korea's Ministry of Food and Drug Safety (MFDS) to speak at the 2020 Korea-ASEAN Pharmaceuticals Inspectors Training and 2020 Korea-ASEAN GMP Conference in November 2020, and another by the ISPE Singapore Affiliate for the 2020 ISPE Singapore Virtual Conference in December 2020.

INVOLVEMENT IN WHO WORKING GROUP

From October to December 2020, HSA participated as a member of the WHO Listed Authority (WLA) Working Group for Regulatory Inspections and Establishment.

The objective of this working group was to add a performance evaluation framework to the existing WHO Global Benchmarking Tool (GBT), to enable better assessment of national regulatory authorities that were applying for WLA status.

Our participation in this working group validated our experience and expertise in the area, and demonstrated our strong support to the WLA initiative.

CLAMPING DOWN ON ILLEGAL ACTIVITIES

We stayed vigilant in our efforts to disrupt illegal activities involving health and tobacco products.

TARGETED RAIDS

Over the year-in-review, we collaborated with law enforcement agencies to disrupt the illegal supply of sexual enhancement medicines, cough syrups and pills through targeted raids in areas such as Geylang.

120 joint operations conducted

Illegal health products seized amounted to a street value of more than **$335,000**

34 suspects investigated

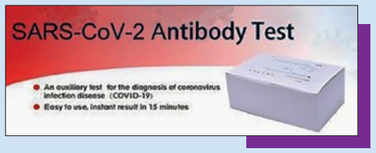
SMUGGLING THROUGH OVERSEAS PARCELS

Together with the Singapore Police Force (SPF), we discovered six overseas parcels containing illegal sexual enhancement medicines (SEMs) in a Sims Drive residential unit.

62,000 units of SEMs worth over **$90,000** seized

HEALTH PRODUCTS SOLD ONLINE WITH FRAUDULENT AND MISLEADING COVID-19 CLAIMS

At the start of the COVID-19 pandemic in Singapore, there was an increase in the online sale of health products with fradulent and misleading claims such as being able to prevent, treat or diagnose COVID-19. Such products included home-based test kits, health supplements, herbs, traditional medicines and hand sanitisers.



652 listings removed from local e-commerce platforms including Carousell, Lazada, Shopee, eBay and Facebook

Over **451** warning letters issued to the sellers

REVOCATION AND SUSPENSION OF TOBACCO RETAIL LICENCES

In our fight against the illegal sale of tobacco products to persons below the Minimum Legal Age (MLA), we revoked

3 tobacco retail licences and suspended a further **8** licences (for a period of 6 months)

Photo credit: ICA

SMUGGLING CHEWING TOBACCO

In September 2020, Immigration & Checkpoints Authority officers at Tuas Checkpoint detected sachets of chewing tobacco in the engine compartments and drivers' cabin bed bunks of five Malaysia-registered bowser lorries.

The case was referred to HSA and our investigations revealed that the smugglers used a similar mode of operation in all their smuggling activities — by delivering illegal chewing tobacco to designated contact persons at carparks in Singapore.

53,249 sachets of chewing tobacco worth around **$213,000** in street value seized

5 smugglers aged between **37** and **51**, were convicted in court and sentenced to imprisonment terms ranging from **5** to **16** weeks

SALE OF ILLEGAL ELECTRONIC VAPORISERS (E-VAPORISERS)

Between April 2020 and March 2021, we successfully cracked down on the illegal sale of e-vaporisers through cyber-surveillance and enforcement activities. These peddlers had purchased e-vaporisers and related components from overseas suppliers and sold them illegally on various local social media and e-commerce platforms.

26 peddlers were prosecuted for selling e-vaporisers and related components, and fined between **$5,000** and **$47,500**

In total, fines of more than **$484,500** were meted out to convicted persons

A 33-year-old repeat offender was sentenced to **1** week's imprisonment and fined **$61,000**

The youngest offender, aged 20, was sentenced to **15** months supervised probation

NEW AWARD

We achieved the following award in recognition of our efforts to keep our community smoke-free.

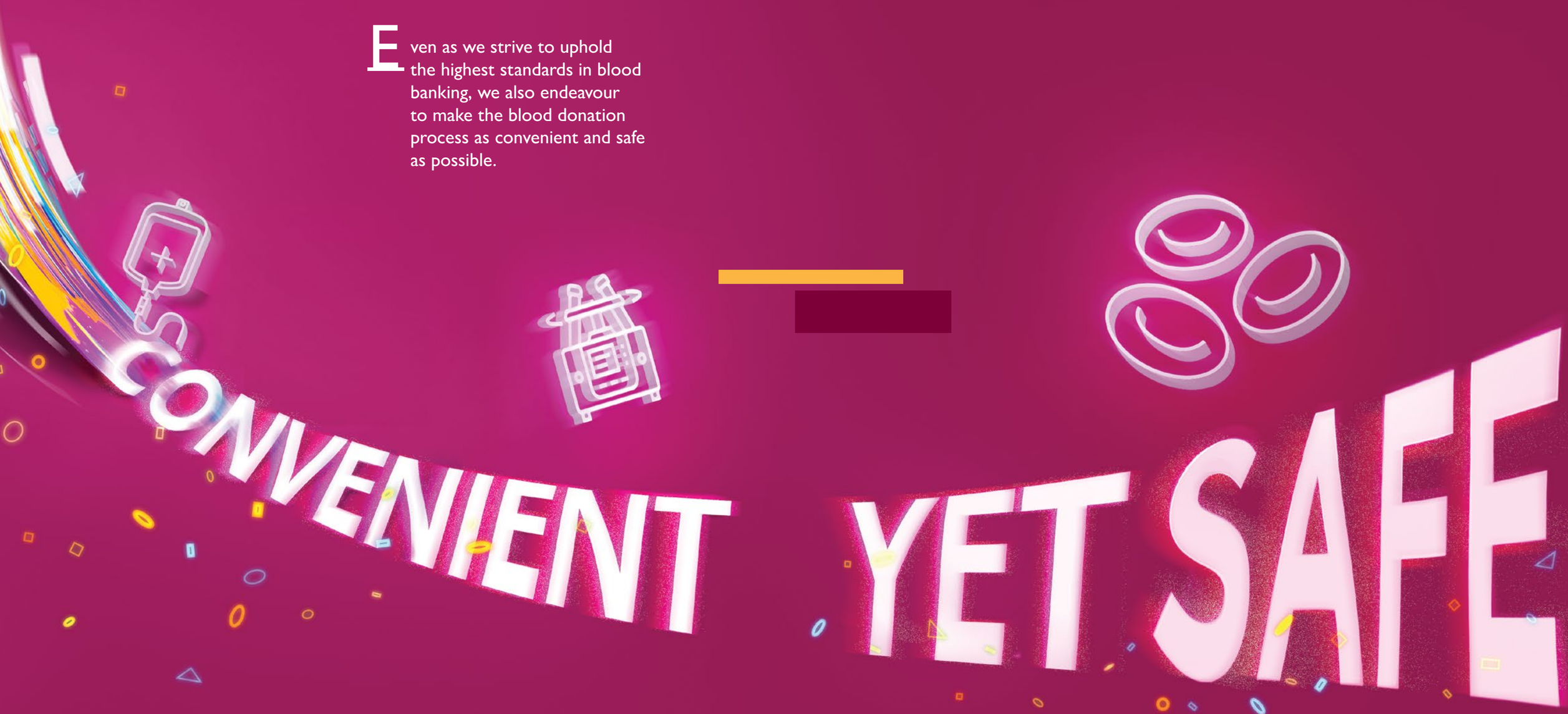
WHO "WORLD NO TOBACCO DAY AWARD"

2020's theme for World No Tobacco Day was "Protecting youth from industry manipulation and preventing them from tobacco and nicotine use".

For our work in providing analytical and advisory services as well as enforcement support on tobacco products, we were jointly awarded, together with the Ministry of Health and Health Promotion Board, WHO's "World No Tobacco Day Award" on 31 May 2020.

02 BLOOD SERVICES GROUP

Even as we strive to uphold the highest standards in blood banking, we also endeavour to make the blood donation process as convenient and safe as possible.



IMPROVING THE BLOOD DONATION PROCESS

We believe in continuously raising the bar and improving the blood donation experience for our donors.

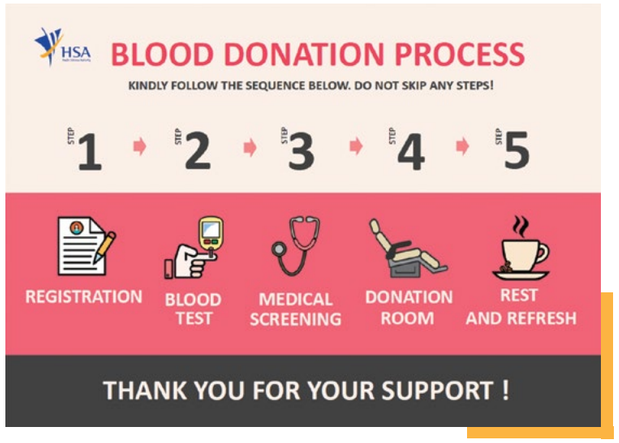
BLOOD BANK USER RESEARCH PROJECT

In September 2020, we embarked on a Blood Bank User Research Project with Singapore Polytechnic to develop strategies to improve the blood donation experience for both donors and staff, and strategies to engage and retain donors to become regular donors.

As part of our development process, we created a user journey map using different donor personas to gain deeper insights into our current processes. We also worked closely with donors, blood bank staff and Singapore Red Cross staff to co-create solutions.

In line with HSA's efforts to embrace digitalisation, one of our ideas included digitalising functions such as a donor guide, personalised check-in, donation milestone accomplishments, donation care tips and appointment sharing.

With the project completed in March 2021, it is envisioned that we will soon be able to roll out these new initiatives that can improve donor and staff satisfaction, as well as grow our pool of regular donors.



BETTER COMMUNICATION REGARDING THE BLOOD DONATION PROCESS

As part of our continuous improvement efforts, we introduced a donation flow checklist in July 2020 to ensure that donors follow the streamlined blood donation process and do not miss any blood donation station.

For further clarity, we also came up with signage to highlight the various blood donation stations and provided additional verbal reminders to donors to proceed to the next station.

So far, donors have commended the usefulness of the posters in reminding them about the order of stations, while staff have found the checklist to be helpful in identifying donors who may have missed out any of the stations prior to blood donation.

COVID-19 AND BLOOD BANKING

We stepped up and navigated the challenges brought on by the pandemic to secure our blood supply.

ENSURING ADEQUATE BLOOD SUPPLY FOR PATIENTS

The COVID-19 pandemic had an impact on the blood supply, especially during the early phase of the pandemic and during the Circuit Breaker period when the blood collection dipped. To protect the safety of our blood donors and to reassure blood donors and the general public so that they would continue to come forward to donate blood, we rolled out a number of additional precautionary measures such as:

- Pre-screening of donors before they enter the blood donation centres and blood mobiles
- Safe management measures such as placing the donation beds as far apart as possible
- Increased frequency of cleaning of blood banks

With the support of our donors, partners and stakeholders, we managed to bring the blood supply back to healthy levels.

ESTABLISHING SINGAPORE'S CONVALESCENT PLASMA PROTOCOL

HSA worked with the National Centre for Infectious Diseases (NCID) and Tan Tock Seng Hospital (TTSH) to establish the COVID-19 Convalescent Plasma protocol for Singapore. We shared our donor selection and blood collection protocols, and trained staff from TTSH to enable them to collect convalescent plasma from recovered COVID-19 patients. We also extended our service to test and process COVID-19 convalescent plasma for patients' use.

RAISING BLOOD SAFETY STANDARDS

We are committed to our mission of providing safe blood for patients in Singapore.

ADDITIONAL SAFETY PROTOCOL FOR PATIENTS WITH NO BLOOD GROUP RECORD

To prevent the occurrence of incompatible blood transfusions, matching of patient's blood group needs to be performed and historical records are typically used as a means of additional verification.

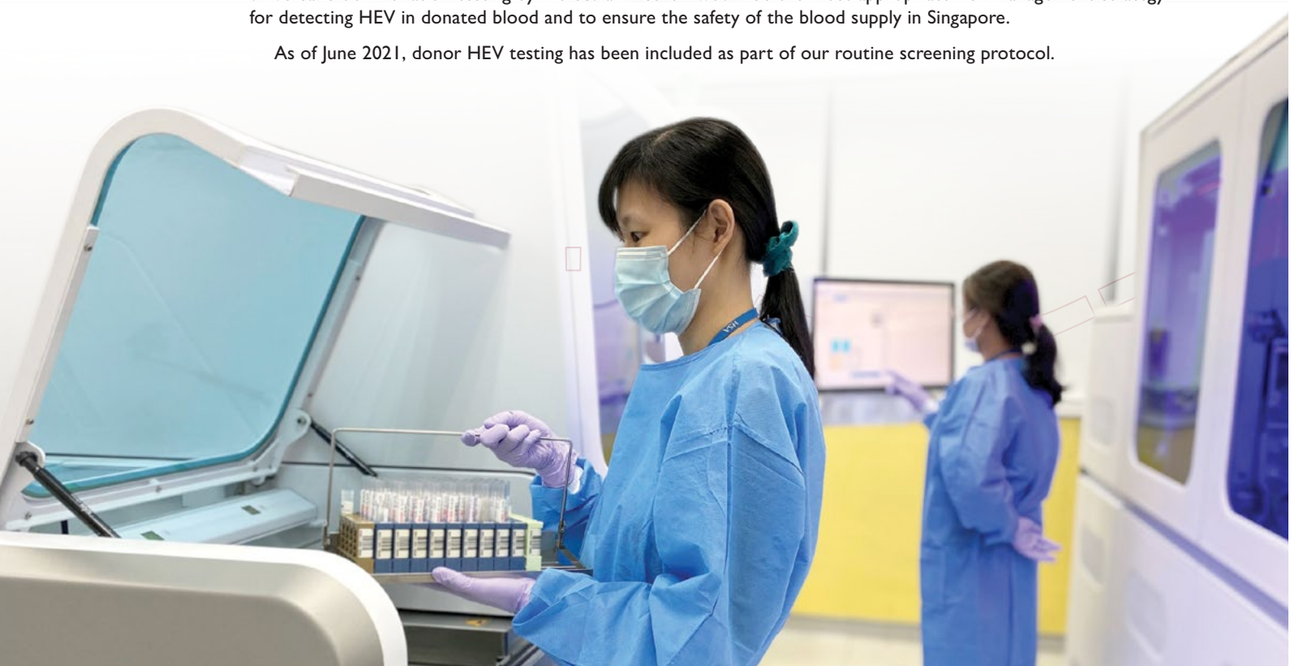
However, this can prove problematic in cases where patients have no historical blood group records. To enhance transfusion safety, an additional blood sample from patients with no historical blood group records is now required for the confirmation of the patient's blood group.

IMPLEMENTATION OF HEPATITIS E VIRUS (HEV) SCREENING

In 2017, we identified HEV as a potential transfusion transmissible infection through our Risk-Based Decision Making Framework.

After subsequent studies, including a viraemia and seroprevalence study in 2017 and 2018, we proposed that universal blood donation testing by molecular method would be the most appropriate risk management strategy for detecting HEV in donated blood and to ensure the safety of the blood supply in Singapore.

As of June 2021, donor HEV testing has been included as part of our routine screening protocol.



INCREASING OUR EFFICIENCY

Through smarter working processes, we are empowered to deliver greater value to all our stakeholders.

USING ROBOTIC PROCESS AUTOMATION (RPA) TO ENHANCE OUR PRODUCTIVITY

Maintaining records manually is a time-consuming process. Using RPA, we managed to reduce the time spent on these tasks significantly.

RPA for maintaining blood transfusion records

On a typical day, we receive hundreds of blood transfusion records from all hospitals. Our staff then spend hours downloading patients' transfusion records and integrating them into our blood bank's IT system. Further contributing to the tediousness of the process was the need to manually retrieve and return erroneous records to the hospitals for correction.

With RPA, the same task now takes only 2–3 minutes to complete instead of 2–3 hours previously, giving our staff more time to focus on other higher-value tasks

RPA for maintaining blood donation testing records

We receive an average of 80 blood donation testing reports performed by external laboratories a month which had to be manually uploaded into our IT system, requiring eight man-hours of work.

With RPA, we managed to reduce the time taken to upload these records by 80%

From taking an average of 8 hours a month to upload records, we now take around 1.5 hours a month

DIGITALISATION INITIATIVES

Digital transformation goes beyond the adoption of technology into our work processes. It also requires a change in the way we imagine and do things.

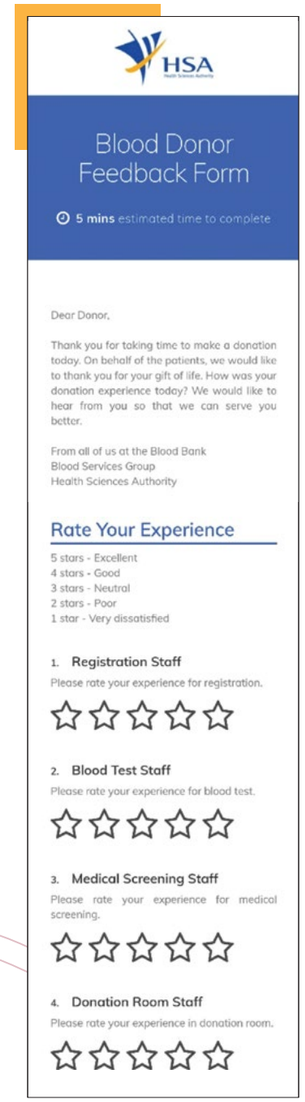
SWITCHING TO AN ONLINE DONOR FEEDBACK FORM

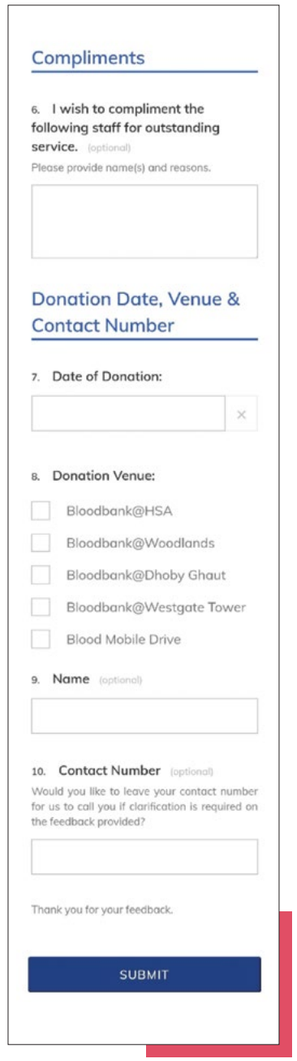
By replacing our manual Blood Donor Feedback Form with FormSG, donors can now submit feedback online at their own convenience. This also improves our efficiency in collating and analysing their feedback, which was previously performed manually.

We have managed to channel more than

170 man-hours

each year towards higher value tasks





DIGITALISATION OF ALL PATIENTS' DATA AND RECORDS

Over the past year, we have been involved in an exercise to move all of our patients' data and records from 1987 into searchable PDF files. As of December 2020, we have successfully completed the user acceptance testing phase of our Digital Documentation and Online Forms project.

By going digital, we have:

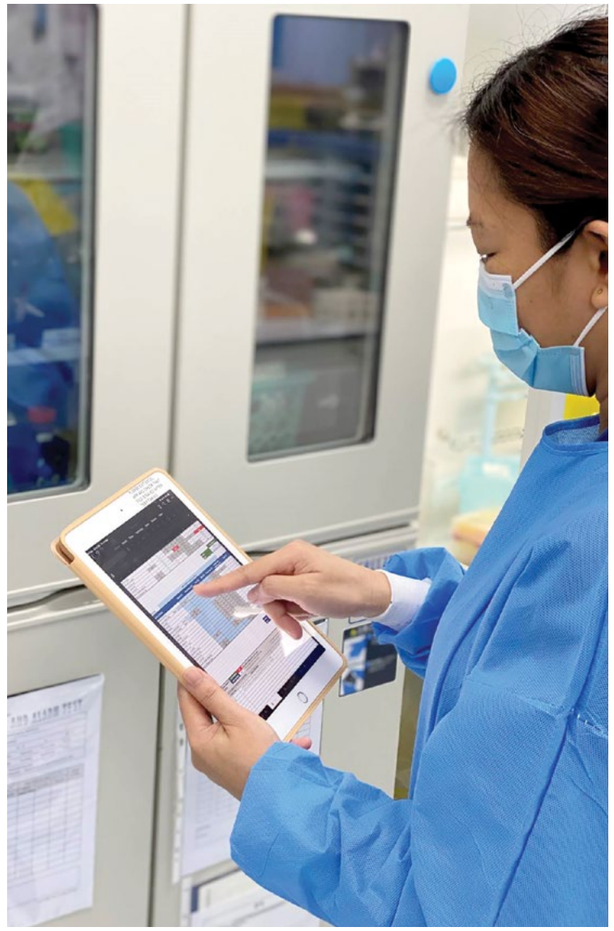
- Made retrieval of patients' records faster and easier
- Reduced physical storage formerly required to store hardcopy records
- Lowered our paper consumption
- Cut down the waiting time for clients requesting duplicate reports

USING QR CODES TO FACILITATE RECORD-KEEPING

For the Cell Therapy Facility, manually recording material and equipment information on hardcopy forms and electronic records would often result in transcription errors and discrepancies.

To improve accuracy, we introduced the use of QR codes and a 2D barcode scanner, and converted most of the hardcopy forms into electronic records. With this new process, staff just need to scan the QR code to facilitate recording and auto-populate data. This eliminates transcription errors as well as reduces the time required by staff to log information by up to 80%.

Additionally, electronic forms also allow for expired materials to be automatically flagged.



GOING PAPERLESS FOR BETTER EFFICIENCY

Monitoring of temperature in the laboratories and equipment

Maintaining the ideal temperature in the laboratories is important to ensure the accuracy and stability of tests. Recording of temperatures used to be done manually on paper logs.

To improve the process of monitoring the temperature of laboratories and critical equipment, paper logs have now been combined into a single excel workbook, which is updated using a tablet. With this new system, logging is faster, records are cleaner, and abnormalities that require attention can be automatically flagged.

This new system also automatically generates charts which allow for quick and efficient reviews of temperature deviations which occur in the laboratories.

Monitoring the temperature of temperature-sensitive storage devices

The daily temperature readings of storage devices were handwritten on hard copies, which could be messy. For greater convenience and to be more efficient, we introduced digital forms. The readings are now entered into an excel file stored in a tablet.

Formulas are used to check if the temperatures are out of range and any deviations will be flagged out so that staff can take immediate action. Charts can be easily plotted to monitor the temperature trend and performance of the storage devices.

03 APPLIED SCIENCES GROUP

Whilst continuing to push forward to deliver cutting-edge scientific services, we remain clear that our mission is first and foremost to serve the administration of justice and safeguard public health.

NEW AND IMPROVED TECHNIQUES

We are always refining and enhancing our techniques in the pursuit of higher efficiency.

NEW METHOD TO PROCESS SAMPLES FOR HUMAN IDENTIFICATION

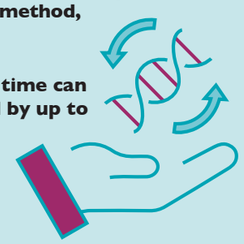
Processing hard tissue samples such as bone and teeth in mass fatality incidents (MFI) is a difficult task that often yields less than satisfactory results.

To improve our chances of successfully obtaining DNA profiles, we have implemented a new two-pronged method, which involves machine pulverisation of samples, as well as a semi-automated DNA extraction protocol.

With our new MFI sample processing method,

processing time can be reduced by up to

8x



while improving the likelihood of obtaining a DNA profile

DETECTING CONTAMINATION IN RIFAMPICIN PRODUCTS

In February 2020, our overseas counterparts alerted us to the potential contamination of 1-nitroso-4-methylpiperazine (MNP) in rifampicin drug substances. As there were no standard tests for such analysis available internationally, we proceeded to develop our own testing methodologies.

Our dedicated team was able to quickly develop a Liquid Chromatography Hybrid Tandem Mass Spectrometry (LC-MS/MS) test to quantitate the presence of MNP in rifampicin products.

As of March 2021, a total of 17 rifampicin products in Singapore have been analysed using our test method, producing responsive analytical results that have enabled us to take appropriate regulatory actions

INSIGHTS TO METABOLISM OF NEW PSYCHOACTIVE SUBSTANCES (NPS)

Some of the challenges that we face in supporting enforcement agencies to detect the abuse of new psychoactive substances (NPS) include the constant emergence of new substances, as well as limited published metabolism data about such drugs.

To tackle this issue, we collaborated with the National University of Singapore Pharmacy Department and the Faculty of Pharmaceutical Sciences from Ghent University, Belgium on an in vitro drug metabolism study that uses human liver microsomes (HLM) to identify NPS biomarkers.

The result of this research project was published in the Archives of Toxicology in November 2020.

ENHANCED DNA METHODOLOGIES

Faster and more accurate DNA age prediction models

In 2017, we successfully developed a model which could predict the age of a person based on a blood stain.

Building upon that achievement, we have now come up with two new prediction models using an artificial neural network (machine learning) algorithm. The results of this project have since been published in a Nature Portfolios Journal — Scientific Reports.

We are now able to better support the police with valuable DNA intel through our new prediction models, which:

Feature an enhanced accuracy of

±3.7 years; and

Require

8x less input DNA

First Y-STR profiling evaluation system in the world

At HSA, a small team of four forensic DNA scientists process close to 5,000 Y-STR DNA profiles each month.

To maximise efficiency, we implemented an expert system to automatically evaluate Y-STR profiles. This system requires minimal human input and automatically highlights samples with quality issues to the scientist for review.

We are the 1ST in the world to implement such a system for Y-STR analysis

Analysis time has now been cut by up to 65%

CHIROPTICAL METHOD IN CHIRAL DRUG ANALYSIS

The problem:

Identification of the active isomer is a crucial part of the pharmaceutical analysis of chiral drugs. However, previous analysis methods, using specialised chiral columns, were expensive and time-consuming.

Our solution:

We developed a chiroptical test method that allows us to use the common liquid chromatographic separation technique to analyse a wide range of chiral drugs.

Our improved testing methodology has resulted in a

60% reduction in analysis time

STREAMLINING THE DETECTION OF TOXICOLOGICALLY RELEVANT DRUGS

01

In September 2020, we developed, validated and implemented a comprehensive screening and quantitation method for 73 toxicologically relevant drugs in blood

02

This new method, which uses liquid chromatography with quadrupole time-of-flight mass spectrometer (LC-QTOF/MS):

Streamlines the use of 6 different methods into 1

Requires just 0.2 ml of blood, as compared with 4.5 ml previously

Has ↑ sensitivity and ↑ confirmative power

Can also simultaneously screen for >300 drugs using automated library searching software

Provides faster results and value for $ testing for our clients

OUR COVID-19 RESPONSE

Over the year-in-review, we remained adaptable and responded promptly to the constantly evolving COVID-19 situation.

HANDLING OF DECEASED COVID-19 PATIENTS

This past year, we worked closely with the Coroner's Court and the Singapore Police Force (SPF) to modify our existing work processes for safe transfer and handling of deceased persons who had or were suspected to have COVID-19.

These modifications relate to:

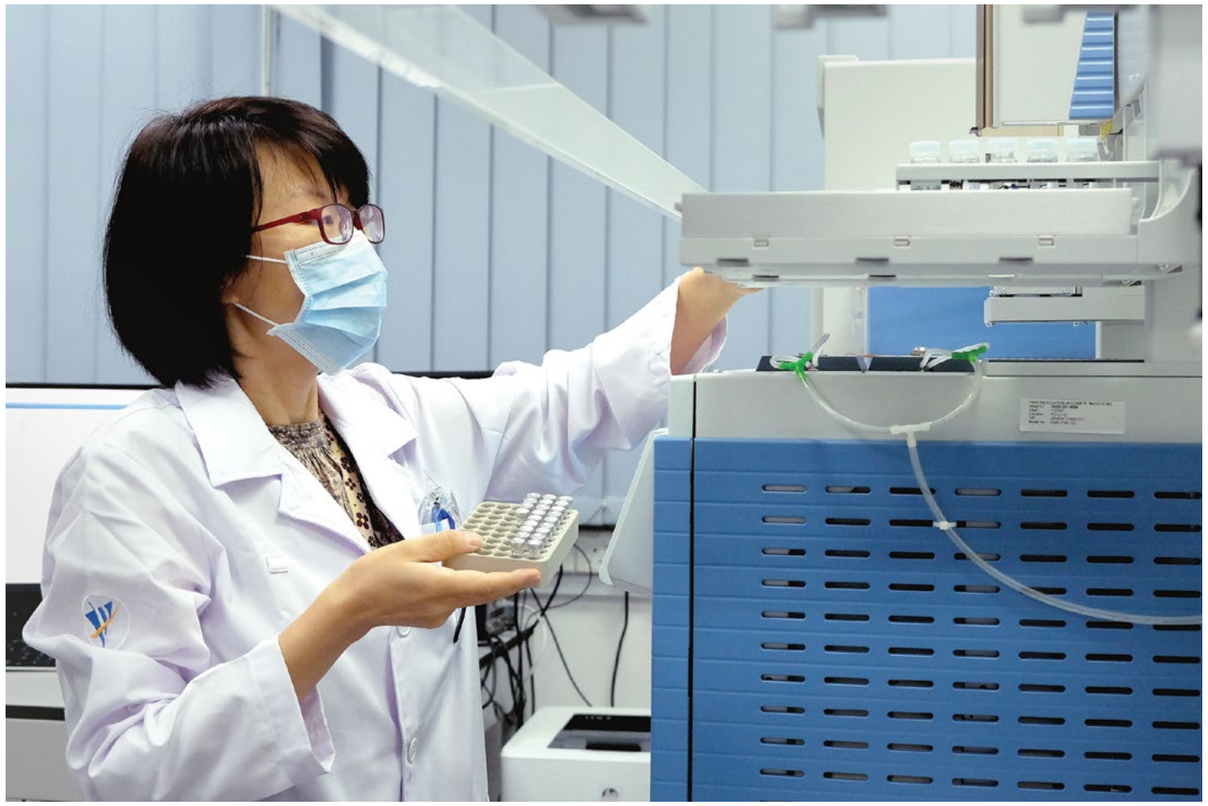
The safe transfer of the deceased from hospitals

Body identification in a high level, bio-containment environment

The safe release of the deceased to the undertaker and next-of-kin

We also held conversations with SPF regarding the handling of COVID-19 homicide cases, and provided our recommendations on the collection of evidence for forensic testing.

These newly modified processes and guidelines are not restricted to COVID-19 and will be useful in future pandemics.



COVID-19 AND HAND SANITISERS

Due to a global shortage of pharmaceutical-grade ethanol during the COVID-19 pandemic, some manufacturers began to use lower-grade ethanol in their hand sanitiser products. To ensure public safety, we developed an analytical method utilising Gas Chromatography-High Resolution Accurate Mass (GC-HRAM) technology to detect a range of impurities in hand sanitisers.

We analysed 96 alcohol-based hand sanitisers in a market survey between April and June 2020

Products that were found to contain ↑ levels of impurities or adulterated with methanol were recalled

KNOWLEDGE AND INNOVATION

We push the boundaries of knowledge to stay at the forefront of scientific advancements.

GAINING INSIGHTS ON DNA DEPOSITION

We are often approached by the courts to explain what affects DNA deposition. A key factor is the concept of "shedder status", which categorises individuals based on their propensity to deposit DNA via contact with a surface. Till now, studies on shedder status have largely been based on short-term data.

To better support the courts and to gain further insights into this aspect of DNA deposition, we began a longitudinal study which followed the changes in shedder status of participants after a one-year interval. The study was presented at the 2020 Asian Forensic Sciences Network (AFSN) DNA workgroup.

LOCALISED DATA ON DNA MIXTURE PROFILES

Estimating the number of persons who contribute to a DNA mixture profile can be challenging due to a lack of data outside the Caucasian population. Hence, to better assist forensic DNA scientists in the region, we began a study on the use of simulated DNA mixture profiles based on the local Chinese, Malay and Indian populations.

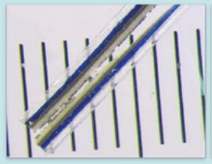
Through this study, we now have novel insights about the impact of allele dropout and the differences between intra-ethnic and inter-ethnic DNA mixtures. These key findings have since been published in Scientific Reports (a Nature Portfolio journal).

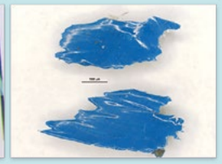
ASSESSING AUTOMOTIVE PAINT EVIDENCE

Recognising the data gaps that exist in our local population studies, especially in automotive distribution, we embarked on several automotive-related projects.

These studies have helped us to better understand automotive paint characteristics and its significance in casework, as well as evaluate the discriminating power of our laboratory's standard paint examination protocol, which consist of visual and microscopical examinations, Fourier Transform Infrared (FT-IR) Spectroscopy and Scanning Electron Microscopy with Energy Dispersive X-ray (SEM/EDX) Spectroscopy.

The discrimination study consisted of a comparative analysis of 256 paint samples from six colour groups.





INTER-LABORATORY STUDY ON CANNABIS PRODUCTS

The interpretation of the legality of cannabis products varies globally as a result of different quality control standards being developed and published in various pharmacopoeia.

Seeking greater alignment, the Laboratory Coordination and Scientific Support Unit of Health Canada organised an international collaborative study to determine specific cannabinoids (tetrahydrocannabinol, tetrahydrocannabinolic acid, cannabidiol and cannabidiolic acid) in cannabis products.

HSA was one of the participants in this study, which together with other government laboratories from Canada, Germany, UK, Australia, USA, The Netherlands and Switzerland are working to establish an internationally recognised testing approach.

The outcome of this study will be presented at international meetings involving regulatory groups, such as the International Laboratory Forum on Counterfeit Medicines, the Permanent Forum on International Pharmaceutical Crime and OMCL Network.

SHARING OUR EXPERTISE

In the spirit of cooperation, we continued to share our knowledge and expertise with the local and international community.

DNA DATABASING AND Y-STR ANALYSIS

In September 2020, we were invited to share our experiences in DNA databasing and Y-STR analysis at the 44th European Network of Forensic Science Institutes (ENFSI) DNA Working Group meeting.

Topics that we presented included our implementation of Y-STR analysis and statistical evidence to support law enforcement agencies, the insights on various statistical calculation methods, as well as the possibility of using Y-STRs to accurately predict ethnicity using a machine learning model.

At the virtual 26th Annual National CODIS Conference in December 2020, we had the opportunity to present to the international community updates such as our recent establishment of the Y-STR database, as well as our implementation of the automatic profile evaluation system, which cuts the time taken to analyse Y-STR profiles by up to 65%.

DVI WORKSHOP

In December 2020, the Singapore Police Force organised the inaugural Disaster Victim Identification (DVI) Preparatory Workshop, which aims to equip designated personnel with the knowledge and skillsets for DVI operations during mass fatality incidents.

As part of the workshop, HSA was invited to facilitate a session on the use of DNA in identification. The session covered both theory and practical components.

DNA ANALYSIS OF SEXUAL ASSAULT EXHIBITS

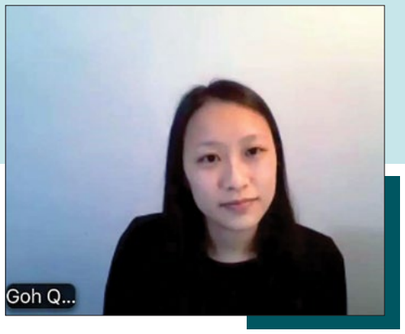
For the first National Sexual Assault Training virtual workshop organised by National University Hospital (NUH) and CID's Specialised Sexual Crimes Branch (SSCB) in February 2021, HSA was invited to deliver a presentation on the handling of sexual assault evidence.

Topics that were covered during this session included an overview of forensic DNA techniques with a special focus on semen and DNA testing, current research initiatives undertaken to improve the analysis of sexual assault evidence, and overseas guidelines relating to the medical examination of sexual assault patients.

The workshop was attended by over 70 NUH staff, as well as counterparts from the Attorney-General's Chambers (AGC) and SSCB

CRIMINAL LEGAL AID SCHEME (CLAS) TRAINING

In August and September 2020, we conducted two virtual training sessions on drug abuse and DNA testing, where a total of over 400 criminal lawyers attended. The sessions helped these practising lawyers gain a better understanding of how HSA conducts testing in these areas.



SUPPORTING SPECIAL OPERATIONS COMMAND

In September 2020, we provided technical support and consultation to the Special Operations Command and HTX's Weapons & Armament, Platforms Systems Sustainment Centre for their ammunition research at the Gurkha Cantonment range. A high-speed camera was used to obtain impact footage and calculate the projectile's speed.

COLLABORATION WITH IMMIGRATION & CHECKPOINTS AUTHORITY (ICA)

In December 2020, we started a two-year collaboration with the Identity Authentication & Document Analysis Branch (IADA) of ICA on the examination of travel and identity documents. We plan to establish a framework for knowledge sharing and to build a database on common security features and forgeries found in such documents.

DELIBERATING ON WHO-ECDD RECOMMENDATIONS FOR CANNABIS AND CANNABIS-RELATED SUBSTANCES

From 2019 to 2020, we were part of an inter-agency committee comprising Attorney-General's Chambers (AGC), Ministry of Foreign Affairs (MFA), Ministry of Health (MOH), Central Narcotics Bureau (CNB) and Ministry of Home Affairs (MHA), which was set up to deliberate on the World Health Organization Expert Committee on Drug Dependence's (WHO-ECDD) recommendations on cannabis and cannabis-related substances.

Our contributions included providing technical advice, as well as participating in the Commission on Narcotic Drugs (CND) meetings as part of the Singapore delegation.

TRAINING SERVICES

In the past year, HSA has expanded its training services to include the following:

- A course covering statistical methods used in proficiency testing programmes following ISO 13528:2015[1] for Singapore Accreditation Council; Singapore Food Agency (SFA) and Biotransformation Innovation Platform — Agency for Science, Technology and Research (A*STAR)
- A dedicated workshop covering the requirements of organising proficiency testing programmes following ISO/IEC 17043[2] for SFA

[1] ISO 13528:2015 Statistical methods for use in proficiency testing by interlaboratory comparison

[2] ISO/IEC 17043:2010 Conformity assessment — General requirements for proficiency testing

LEVERAGING TECHNOLOGY

Through the thoughtful use of technology, we are able to continually raise our efficiency standards.

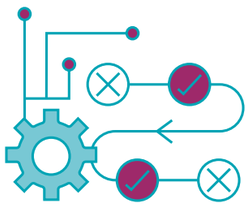
DIGITALISATION IN THE LABORATORIES

After three years of hard work, we successfully digitalised most of our routine workflows and achieved a near paperless environment, with the launch of our new Labware Laboratory Information Management System (LIMS) in September 2020. The LIMS incorporates many digitalised workflows that enable data to move seamlessly across different sites and instruments, and the laboratories also utilise Robotic Process Automation (RPA) to replace some of the tasks which previously required human intervention.

Some of the features include:

- Paperless submission/collection process for key stakeholders with system interface
- Automatic interface of analysis requests and results, and despatch of e-reports
- Implementation of e-inventory for tracking of chemicals, reagents and drug reference standards
- Digitalisation of laboratory processes, such as electronically capturing the movement of exhibits (chain of custody), case assignment, review and reporting
- Configuration to trigger and automate actions at various decision points, which greatly reduces human transcription and interpretation errors

About 80% of our laboratories' workflows and processes have been digitalised



We have also received positive feedback from users and stakeholders that the system has helped to streamline their operational processes

AUTOMATING VIDEO ANALYSIS FOR VEHICLE SPEED CALCULATIONS

We developed a Visual Basic for Applications (VBA) Excel macro to automate traffic accident reconstruction video speed calculations.

Manually calculating vehicle speed used to be a tedious process that took 1 hour per video

Our new customised macro allows us to automatically extract data, perform calculations and plot graphs in just 5 minutes

BENCHMARKING OURSELVES

We maintain the highest standards of work by benchmarking to global standards.

PROFICIENCY TESTING AND INTERNATIONAL COMPARISONS

Over the year-in-review, we participated in various benchmarking programmes, achieving excellent results in the process.

Type of Benchmarking	Proficiency Testing (PT)	International Comparisons
Details	• Potentiometric determination of pH in ascorbic acid and sodium ascorbate Assay of Nitrofurazone, organised by European Directorate for the Quality of Medicines & HealthCare (EDQM) • Assay of Progesterone by UV spectrophotometry, organised by EDQM • Disintegration of tablet, organised by Laboratory of the Government Chemist (LGC), UK	• Consultative Committee on Amount of Substance: Metrology in Chemistry and Biology (CCQM) key comparison on zearalenone in maize, organised by National Institute of Metrology, China (NIM) • CCQM key comparison on amino acid in human plasma, organised by LGC • External Quality Assessment Scheme for Reference Laboratories in Laboratory Medicine (RELA)- International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) comparison on glycated haemoglobin (HbA1c)

ESTABLISHMENT OF INTERNATIONAL CHEMICAL REFERENCE SUBSTANCES

We participated in inter-laboratory collaborative studies, organised by EDQM, to establish the reference substances for Ivermectin and Amodiaquine Hydrochloride for WHO International Pharmacopoeia.

EXPANDING OUR CHEMICAL METROLOGY SERVICES

We are always on the lookout to expand our metrology services, and routinely add new substances to our testing capabilities.

OUR CERTIFIED REFERENCE MATERIALS (CRM) LIST HAS BEEN EXPANDED TO INCLUDE:

August 2020
Inorganic Elements (As, Cd, Pb) in Herbal Material

October 2020
Non-volatile inorganics in n-butyl paraben

September 2020
Pure substance 4-cumylphenol

November 2020
Pure substance sibutramine hydrochloride monohydrate

OUR ACCURACY-BASED PROFICIENCY TESTING/EXTERNAL QUALITY ASSESSMENT PROGRAMMES HAVE BEEN EXPANDED TO COVER:

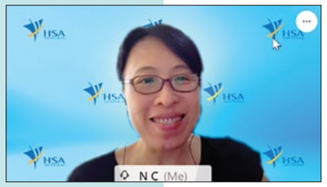
- Aflatoxins in plant-based food material for food testing laboratories (seven participating laboratories in Singapore)
- Trace elements (arsenic, antimony, barium, cadmium, lead, manganese and selenium) in drinking water for water testing laboratories (20 participating laboratories across Singapore, Myanmar and Chinese Taipei)
- Total protein in human serum for clinical laboratories in Singapore

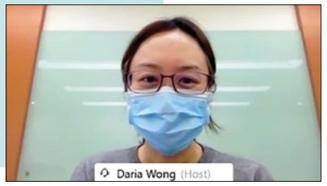
INTERNATIONAL COLLABORATIONS

We continued to collaborate with the international community by offering our expertise and through knowledge sharing.

GOVERNMENT LABORATORY OF HONG KONG (HKGL) ACCREDITATION ASSESSMENT

In January 2021, we were invited by the Hong Kong Accreditation Service (HKAS) to conduct a remote assessment for HKGL in the examination of questioned documents. This is the second time in two years that we have been invited to be the technical expert in conducting assessments using the ISO/IEC 17025:2017 standard.





GLASS INTERPRETATION INTER-LABORATORY STUDIES

Over the past few years we have been involved in inter-laboratory glass tests organised by Dr Jose Almirall from Florida International University to evaluate the interpretation of glass refractive index measurements.

In our latest project with Dr Almirall's team, together with seven other international laboratories, we served as reference laboratories in a study to determine the concentrations of trace elements in new float glass standards. The results of this study will contribute towards creating new commercially-available glass calibration standards for the Laser Ablation Inductively-Coupled-Plasma Mass Spectrometry (LA-ICP-MS) application.

AGREEMENTS AND MEMORANDUM

Over the past year, we inked and renewed the following agreements:

Agreements	Partner(s)
Purity assessment of therapeutic proteins	National University Health System (NUHS)
Commutability study on small molecules and/or protein diagnostic markers in human biological fluids	
To support the national standards and conformance infrastructure, and strengthen the dissemination of metrological traceability to local laboratories	Enterprise Singapore through Singapore Accreditation Council
Cooperative research on the development of novel techniques and methods for the detection of SARS-CoV-2	National Institute of Metrology, China

OUR COLLABORATIONS WITH WHO

We continued to actively support WHO as a collaborating centre through the following activities:

Drug Quality Assurance

Monograph development work for the international pharmacopoeia

We partnered WHO in the monograph development of Ulipristal Acetate and Ulipristal Acetate tablets for the International Pharmacopoeia.

Event	Date
WHO consultation meet on quality control laboratory tools and specifications for medicines	May 2020
WHO Regional Meeting (WPRO)	August 2020
55th Expert Committee on Specifications for Pharmaceutical Preparations	October 2020
WHO Forum on "From Containment to Suppression — COVID-19 Lessons"	December 2020

Tobacco Testing and Research

Lead author for first horizon paper

We are the lead author of the first horizon paper titled, "Nicotine forms in tobacco plant, chemical modifications and implications for electronic nicotine delivery system". The paper is jointly authored with the American University of Beirut, Lebanon.

Establishment of standard operating procedures (SOPs)

We collaborated with WHO and EU Joint Action on Tobacco Control to establish SOPs in the determination of nicotine, glycerol and propylene glycol in e-liquid.

Webinar series on tobacco product regulation

HSA's Dr Cheah Nuan Ping was invited in her capacity as Chair of the Tobacco Laboratory Network to present six chapters from the WHO handbook for a webinar series.

The objective of the webinar titled "Building laboratory testing capacity" is to advance tobacco regulation in WHO member states and improve their understanding of testing-related activities.

In just the first week alone, more than

7,000 people

viewed the web series on tobacco product regulation

We led a total of

16 laboratories to establish a WHO method

for measuring nicotine content in smokeless tobacco products

Tobacco-related events

Event	Details	Date
Virtual workshop organised by Ministry of Health, Family and Welfare of the Government of India	We conducted a "Research Methodology Workshop" to encourage and stimulate interest in tobacco research in India	May 2020
Tobacco testing training for scientists and technical personnel from Noida, Mumbai, Guwaharti and Bangalore, India	We conducted a series of tobacco analysis training workshops	June 2020
WHO's 148th Executive Board Meeting	Singapore's contributions in the area of tobacco product regulation was shared	January 2021

BUILDING AND SHARING OUR KNOWLEDGE

ASEAN Pharmaceutical Testing Laboratory Committee (APTLC) meeting

APTLC is a newly formed committee, which aims to strengthen ASEAN's capability in pharmaceutical testing.

In October 2020, we attended the APTLC virtual meeting, which saw the terms of reference and the development of the work programme for the next few years being discussed and finalised. At this meeting, Singapore was appointed as Vice-Chair to support the current Chair — Indonesia.

ASEAN Reference Substances Project

HSA continued its active involvement in the ASEAN Reference Substance Project, which aims to establish ASEAN secondary drug reference standards for use in ASEAN member countries.

Highlights of this past year include leading and working with five other countries to establish and study Hydroxyzine Hydrochloride as an ASEAN Reference Substance (PARS), and participating in the Thailand-led inter-laboratory study of Amoxicillin Trihydrate PARS.

ACTLC comparison study

We continued to contribute proactively to the ASEAN Cosmetics Testing Laboratory Committee (ACTLC), through a comparison study on "Determination of 1,4 dioxane in cosmetic products". This study was done in collaboration with ASEAN member states and Korea's Ministry of Food and Drug Safety.

18th Western Pacific Regional Forum for the Harmonization of Herbal Medicines (FHH)

In February 2021, we were invited to attend the 18th Standing Committee Meeting of the Western Pacific Regional Forum for the Harmonization of Herbal Medicines.

The meeting and symposium, which was organised virtually by the National Institute of Food and Drug Safety Evaluation of Korea, provided a very good platform for networking and exchanging of information on the regulation of Chinese proprietary medicines, pre- and post-market activities, and risk management strategies for traditional Chinese medicine safety, as well as the development of test methods for herbal drugs.

South East Asia Tobacco Control Alliance (SEATCA) webinar

We were invited to speak at the following webinars organised by SEATCA:

Topic	Date
Protecting Youth from New Tobacco Products Webinar — "Are electronic nicotine delivery systems and heated tobacco products really less harmful?"	June 2020
Tobacco Industry Monitoring Network Webinar — "Electronic smoking devices: Countering front groups and responding to misleading information."	November 2020

AWARDS AND ACCREDITATIONS

Our awards and accreditations serve to recognise and affirm our efforts that we are moving forward in the right direction.

ISO/IEC 17025 ASSESSMENT

As of March 2021, we have expanded our scope of accreditation to include the Determination of Nicotine in tobacco products by GC-FID, and are now fully compliant with ISO17025:2017.

MINISTRY OF HOME AFFAIRS (MHA) OPERATIONAL EXCELLENCE AWARD

We were honoured to receive the MHA Operational Excellence (OE) Award for our contribution towards uncovering a chemical lacing laboratory during Operation HOVOD in July 2019. This is the third consecutive year that we have been recognised for our partnership efforts to support MHA in shutting down clandestine laboratories.

DIGITAL & VIDEO/IMAGING TECHNOLOGY AND ANALYSIS (DVITA) ACCREDITATION

As evidence submissions for traffic accident and crime scene reconstruction cases become increasingly digital in nature, we recognise the need for knowledge gaps to be filled. To improve our competency, we have accepted unconventional cases, published a paper on estimating distances in speed analysis videos, participated in international digital evidence training, and joined an overseas digital forensics network.

In preparation for accreditation, our team also reviewed international best practices, validated methods and developed SOPs, while at the same time streamlining processes with automation and programmatic scripting.

All of these collective efforts have paid off with HSA being accredited in the area of DVITA at the ANSI National Accreditation Board audit.

04 CORPORATE SERVICES GROUP

Our ongoing goal of driving transformation is aimed at improving productivity, building up skills and capabilities, and enhancing user-experience.

PUBLIC SECTOR TRANSFORMATION @ HSA

We continuously improve ourselves to ensure relevance to our stakeholders' needs and the future landscape.

HSA'S TRANSFORMATION FRAMEWORK AND FOCUS AREAS

HSA has embarked on a transformation journey to ensure our future readiness.

TRANSFORMATION FOCUS AREAS

Transformation Outcome

Lean, agile and digital organisation that delivers products and services that meet our customers' and stakeholders' needs.

Stakeholder Centric Products & Services

- Improving customer experience
- Improving products and services for better outcomes and stakeholders' convenience
- Creating new products and services to meet emerging needs

Process Transformation

- Reviewing, recalibrating and removing processes to improve efficiency while maintaining desired outcomes
- Leveraging digital technologies to change business model and enhance productivity where possible

People Transformation

- Positioning our people better for the future by empowering and engaging them
- Cultivating a growth mindset and equipping them with the relevant skillsets through continuous learning

Strong Partnerships

- Advancing professional expertise and interests
- Leveraging scientific and technological knowledge and experience of external experts
- Co-creating solutions with stakeholders for mutual benefits

KEY ENABLER: DIGITALISATION

Adopt digital and smart technologies such as artificial intelligence, natural language processing, robotic process automation and machine learning. Other enablers include UX design, design thinking, behavioural insights and data analytics.

DIGITAL TRANSFORMATION @ HSA

We accelerated the adoption of digital signatures and began working with GovTech to automate and digitalise HSA's internal workflows and processes. By adopting a whole-of-government (WoG) Signing Certificate, we are now able to convert and digitally sign forms that previously required hard copy wet-ink signatures. Time and manpower savings were also achieved through the implementation of robotic process automation (RPA) to digitalise manual and repetitive tasks.

As part of our digital transformation efforts, we also developed the HSA Digitalisation Training Framework to build knowledge and equip staff with basic and specialised digital skills. A training catalogue comprising a list of courses has been curated to help staff identify suitable digital courses that are relevant for their areas of work. Such courses include data analytics, user experience design and agile project management.

PEOPLE AND VALUES

We care about nurturing individuals who are driven by the right values, who take pride in what they do, and who feel a strong sense of camaraderie.

WE CARE SERIES

In May 2020, we started a series of Coffee Chat sessions to support the mental and social well-being of staff.

As of December 2020, a total of 15 virtual Coffee Chat sessions have been organised for staff to communicate and connect with each other amidst the COVID-19 pandemic. Experts were also invited to these sessions to provide self-care tips such as mindfulness, resilience, stress management and positive psychology.

We regularly sent staff specially curated self-care related Electronic Direct Mailers (EDMs) that contained helpful messages and tips, reminding staff to care for themselves and look out for others.

Singapore Health Quality Service Awards 2021 (Special Edition)

The awards specially honoured healthcare professionals and partners who stood up and contributed to the nation's fight against the COVID-19 pandemic.

There were three winners from HSA:

01 Dr Paul Chui, Applied Sciences Group
SuperHero Award (Clinician – Merit)

02 Forensic Medicine Division
Team Commendation Award

03 Blood Services Group
Team Commendation Award

HSA CUSTOMER SERVICE DAY 2021

HSA held its 12th Customer Service Day on 26 February 2021 with the theme, "Redefining Service in the New Norm".

EVENT HIGHLIGHTS

1st-ever virtual HSA Customer Service Day

A total of 40 HSA Outstanding Service to Customers Award (OSCA) 2020 were presented in the virtual ceremony.

These included:

- **1 Star Award**
- **3 Gold Awards**
- **9 Silver Awards**
- **17 Bronze Awards**
- **10 Team Awards**

PUBLIC SECTOR TRANSFORMATION AWARDS 2020

Terenze Ong, Biology Division, Applied Sciences Group
Exemplary Innovator Award

In response to the time-consuming task of processing raw data from instruments and performing manual calculations for over 30,000 DNA profiles each year, Terenze decided to come up with a tool that could automate the process.

As part of the development process, he actively solicited feedback from fellow scientists to identify pain points before using Microsoft Excel-Visual Basic to come up with the 'DNA Call' tool. He also coordinated testing efforts to ensure adherence to international accreditation standards.

Tobacco Regulation Branch (TRB), Health Products Regulation Group
One Public Service Award

Staff from TRB streamlined the application process for tobacco licensing through our contribution and partnership to the G2B GoBusiness Licensing Portal, which helps guide prospective applicants through the entire process of applying for their business licences.

The GoBusiness Licensing Portal has enabled TRB officers to reduce the amount of verification and checks on tobacco licensing by 1 man-day per application.

SUPPORTING OUR STAFF

We seek to foster a dynamic and resilient spirit, whilst staying sensitive to the needs and concerns of our people.

CARE PACK FOR HSAIANS

As part of the battle against COVID-19, we gave out care packs with items such as healthy snacks and disinfectant sprays to all HSAians as a gesture of care and concern.

LAUNCH OF COVID-19 EMPLOYEE SUPPORT PORTAL & TELECOMMUTING CLAIM

A one-stop COVID-19 Employee Support Portal was launched in December 2020 to enable staff to look for relevant information easily. The portal houses information related to COVID-19, overseas travel notifications, Quarantine Order (QO)/Stay Home Notice (SHN) reporting and flu vaccinations. A one-time telecommuting claim of up to $150 was also implemented to support employees who had been working from home during the pandemic.

FACILITATING WORK FROM HOME (WFH) ARRANGEMENTS

To better facilitate WFH and split team arrangements, we implemented the following initiatives:

01 **Equipped meeting rooms in HSA with video conferencing capabilities to enable hybrid-meetings between physical and remote participants**

02 **Established IT Spot (Walk-in IT support helpdesk stations)**

03 **Provided support for Professional Groups in their various virtual events**

04 **Set up Remote Desktop Support (RDSS)**

In FY20/21, we expedited the tech refresh of 450 laptops and ramped up the acquisition of 245 Virtual Private Networks (VPNs) & 22 laptops

ENGAGEMENT AND BRANDING

We engaged the media to shine the spotlight on pertinent issues and showcase HSA's scientific excellence and regulatory rigour.

MEDIA ENGAGEMENT

Besides working with various media to profile HSA's work, we had the added challenges of ensuring that timely, accurate information was provided to the media for factual reporting, and preventing the spread of misinformation in the time of the COVID-19 pandemic. To this end, we conducted proactive media engagements to inform and educate the public on various topics of interest.

HIGHLIGHTS

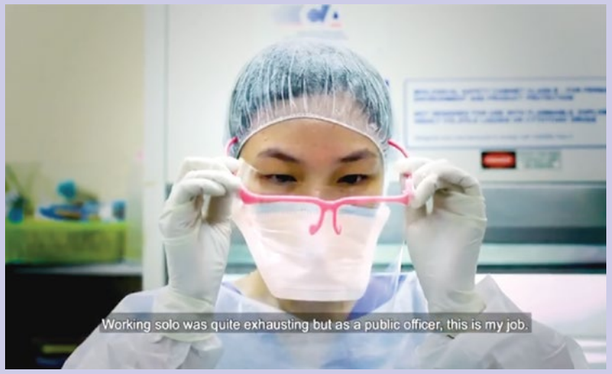
1. Extensive media engagement and profiling by broadcast, print and online media on:
   a. the introduction of the Pandemic Special Access Route to facilitate early access to critical novel vaccines, medicines and medical devices during the COVID-19 pandemic
   b. COVID-19 vaccines evaluation and approval process
   c. the facilitated import and expedited authorisation of medical devices such as diagnostic test kits, masks, thermometers, ventilators and protective gear
   d. the conditional approval of remdesivir to treat adult patients with COVID-19 infection
   e. the removal of products making false COVID-19 claims in the market

2. Working with the media to feature colleagues from the Forensic Medicine Division in exclusive stories to share their experiences during the pandemic.

3. The raising of the alert to DORSCON Orange saw blood stocks dipping. With our prompt media engagement, the various media outlets amplified the call for blood donors and shared on the enhanced safe management measures at our blood banks. This expeditiously aided in building the blood supply back to healthy levels.

4. HSA collaborated with the Science Centre Singapore to host the quarterfinals of the National Science Challenge (NSC) 2020, to nurture the passion for scientific inquiry and develop creative problem-solving skills among the participants as well as the audience.

   We supported the Illicit Drugs Laboratory, which came up with the challenge for students from Hwa Chong Institution, School of Science and Technology, Nan Hua Secondary School and Swiss Cottage Secondary School.



In total, we published

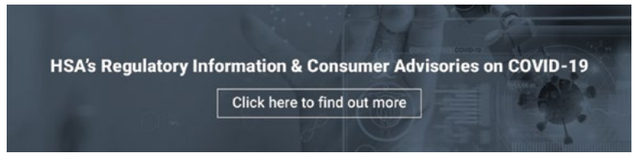
22 press releases | **5** HSA updates

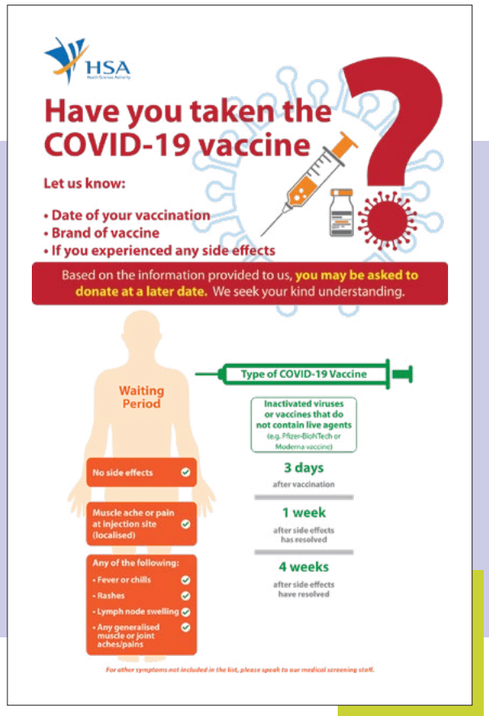
which resulted in

2,069 media articles

MARKETING COLLATERALS AND WEBSITE UPDATES

We created a wide range of collaterals, ensuring that stakeholders would get timely updates to crucial information through posters, or via newsletters. A prominent page with information related to COVID-19 updates was also published on the HSA website.





We created a total of:

59 marketing collaterals

8 event collaterals

TECHNOLOGY AND INFRASTRUCTURE

We achieve greater efficiency by embracing a forward-looking attitude and an openness to change and new technologies.

LAUNCH OF UNIFIED CLOUD PLATFORM

In September 2020, we transitioned to a single unified cloud platform — Workday, which allows users to access corporate service functions anytime, anywhere.

Workday provides us with the opportunity to transform HR, Finance and Procurement functions across the whole-of-government (WOG) to bring about greater synergy, scalability and reduced maintenance. Through its user-friendly and intuitive interface, we can move towards newer and more agile ways of working.

Features of this new cloud platform include:

01 **A single sign-in platform for employees and managers to access and process leave applications, claims, course sign-ups, etc**

02 **Cloud computing which enables faster processing and decision-making, with real-time feedback for all users**

03 **Ability for staff to perform key transactions on the go through the Workday app on their mobile devices**

04 **Streamlining of finance controls. For example, purchase orders, goods receipts and invoices are matched and payment made without additional approvals required**

05 **Managers have greater visibility through the "team view" which displays useful information such as staff on absence, performance and budget**

AWARDS AND ACCREDITATIONS

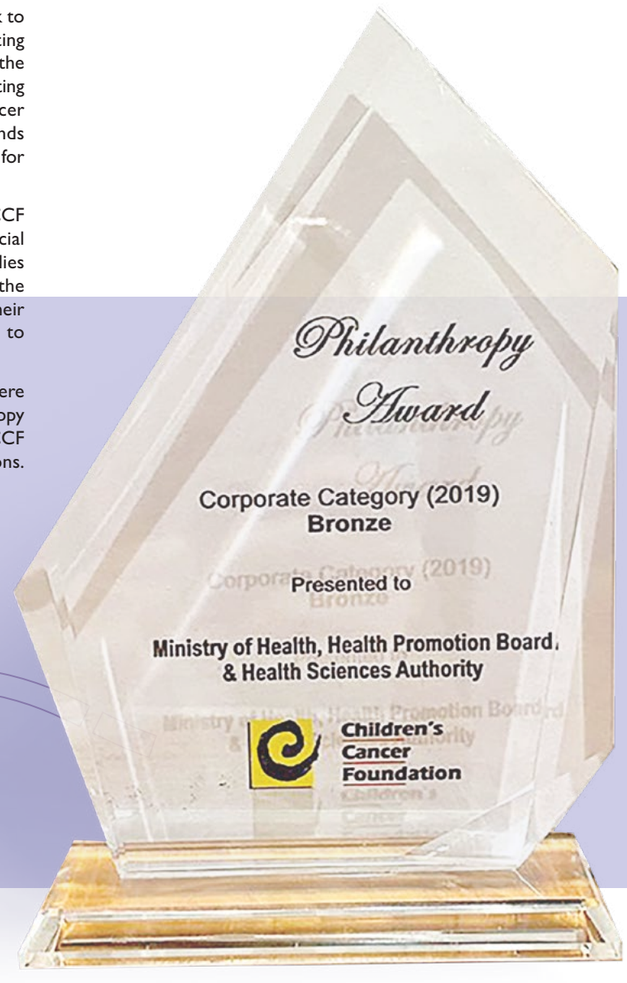
We strive to make a difference, where it counts the most.

CCF'S PHILANTHROPY (CORPORATE) BRONZE AWARD

HSA believes in contributing back to the community through supporting our adopted beneficiaries. Over the years, HSA staff have given unstinting support to the Children's Cancer Foundation (CCF) by raising funds and making donations to its Hair for Hope initiative.

This support has enabled CCF to deliver free psycho-social services to children and families affected by cancer, giving them the strength and resources in their difficult journey from diagnosis to treatment to aftercare.

On 27 November 2020, we were presented with the Philanthropy (Corporate) Bronze Award by CCF in recognition of our contributions.

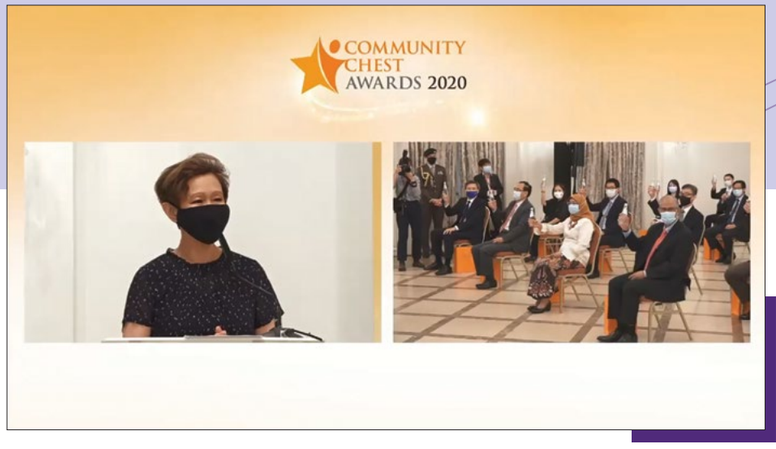


SHARE PLATINUM AWARD 2020

HSA was recognised at Community Chest Awards 2020, which brought together distinguished corporates and individuals to recognise and celebrate their outstanding contributions to the social service sector.

We received the SHARE Platinum Award which is given in recognition to organisations with employees who actively participate through the SHARE programme.

Donations through SHARE provide continuous funding for a wide range of social service agencies, especially those that are less visible.



OUR WORK IN FIGURES

BLOOD SERVICES GROUP

KEY STATISTICS AS AT END-DECEMBER 2020

72,130
Blood Donors

117,272
Whole Blood Donations

9,618
Apheresis Donations

385,877
Blood Components Processed

1,362,317
Laboratory Tests Conducted

APPLIED SCIENCES GROUP

KEY STATISTICS AS AT END-MARCH 2021

PHARMACEUTICAL DIVISION

2,039
Analytical Cases

6,828
Analytical Tests

ANALYTICAL TOXICOLOGY DIVISION

16,552
Forensic Cases

28,215
Forensic Exhibits

BIOLOGY DIVISION

13,853
Forensic Cases

20,954
Forensic Exhibits

FORENSIC SCIENCE DIVISION

326
Forensic Cases

1,493
Forensic Exhibits

ILLICIT DRUGS DIVISION

2,327
Forensic Cases

7,752
Forensic Exhibits

FORENSIC MEDICINE DIVISION

4,251
Coroner's Cases

1,081
Coroner's Autopsies

HEALTH PRODUCTS REGULATION GROUP

KEY STATISTICS AS AT END-MARCH 2021

30
Therapeutic Products Containing New Chemical/ Biological Entities Approved

223
Therapeutic Products Registrations Approved (New Drug Applications and Generic Drug Applications)

5,353
Approved Products on the Register of Therapeutic Products

1
Reclassified Therapeutic Product

5,332
Therapeutic Products Variation Applications

1,311
Medical Device Product Listings Approved (Class B, C & D)

18,747
Approved Products on the Singapore Medical Device Register

576
Field Safety Corrective Action Reporting for Medical Devices Received

668
Adverse Events (Local) Reporting for Medical Devices Received

3,343
Medical Device Change Notification Applications

4,460
Licensed Tobacco Retail Outlets

531
Tobacco Retail Licences Approved

9,187
Electronic Vaporiser Cases Handled by HSA

2,304
Medical Advertisement Permits Approved

23,584
Spontaneous Adverse Drug Reaction Reports Captured

2,016
Post-market Feedback Received (Relating to Potential Contravention of Health Product Legislation)

11,911
Chinese Proprietary Medicines Listed

707
New Chinese Proprietary Medicines Listed

173,291
Cosmetic Products Notified

39,831
New Cosmetic Products Notified

371
Site Audits Conducted for Good Manufacturing & Good Distribution Practices and Pharmacies

APPLICATIONS APPROVED

567
Licences/Certificates for Manufacturers of Health Products

3,050
Licences/Certificates for Importers of Health Products

2,209
Licences/Certificates for Wholesalers of Health Products

394
Certificates of Medical Devices

336
Registration of Retail Pharmacies

285
Licences/Certificates for Exporters of Health Products

2,223
Applications for Import of Medicinal Products for Personal Use Processed

148
New Clinical Trials Applications Approved

159
New Clinical Trials Applications Processed

FINANCIAL HIGHLIGHTS

STATEMENT OF FINANCIAL POSITION

	FY20/21	FY19/20	Increase / (Decrease)	
	$'000	$'000	$'000	%
Property, Plant & Equipment	77,060	81,777	(4,717)	(6)
Intangibles	13,009	11,718	1,291	11
Right-of-Use Assets	13,626	16,019	(2,393)	(15)
Current Assets	218,574	194,530	24,044	12
Total Assets	**322,269**	**304,044**	**18,225**	**6**
Equity	232,077	210,910	21,167	10
Non-Current Liabilities	14,662	16,744	(2,082)	(12)
Current Liabilities	75,530	76,390	(860)	(1)
Total Equity and Liabilities	**322,269**	**304,044**	**18,225**	**6**

STATEMENT OF COMPREHENSIVE INCOME

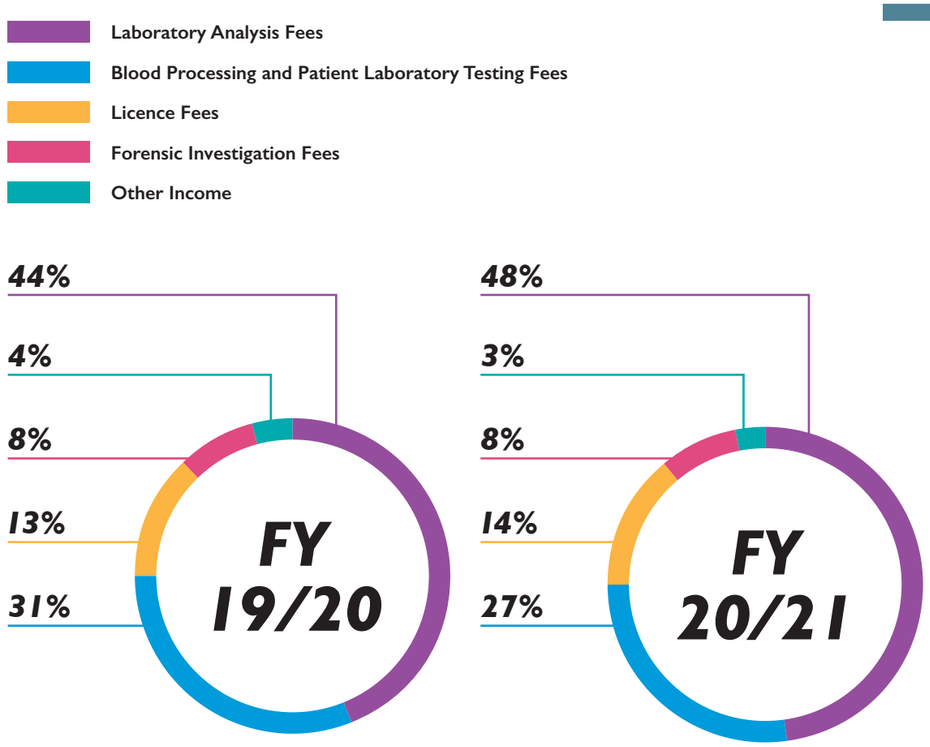
The Authority achieved an overall net surplus of $23.7m for FY20/21.

	FY20/21	FY19/20	Increase / (Decrease)	
	$'000	$'000	$'000	%
Operating Income	149,866	151,973	(2,107)	(1)
Operating Expenditure	(208,943)	(212,298)	(3,355)	(2)
Deficit before Government Grants	**(59,077)**	**(60,325)**	**(1,248)**	**(2)**
Government Grants	87,620	102,535	(14,915)	(15)
Surplus before Contribution to Consolidated Fund	**28,543**	**42,210**	**(13,667)**	**(32)**
Contribution to Consolidated Fund	(4,854)	(7,176)	(2,322)	(32)
Net Surplus	**23,689**	**35,034**	**(11,345)**	**(32)**
Other Comprehensive Income	41	(241)	282	117
Net Surplus and Comprehensive Income for the Year	**23,730**	**34,793**	**(11,063)**	**(32)**

OPERATING INCOME

The Authority earned a total operating income of $149.9m in FY20/21, a decrease of $2.1m (1%) from FY19/20's revenue of $152.0m.

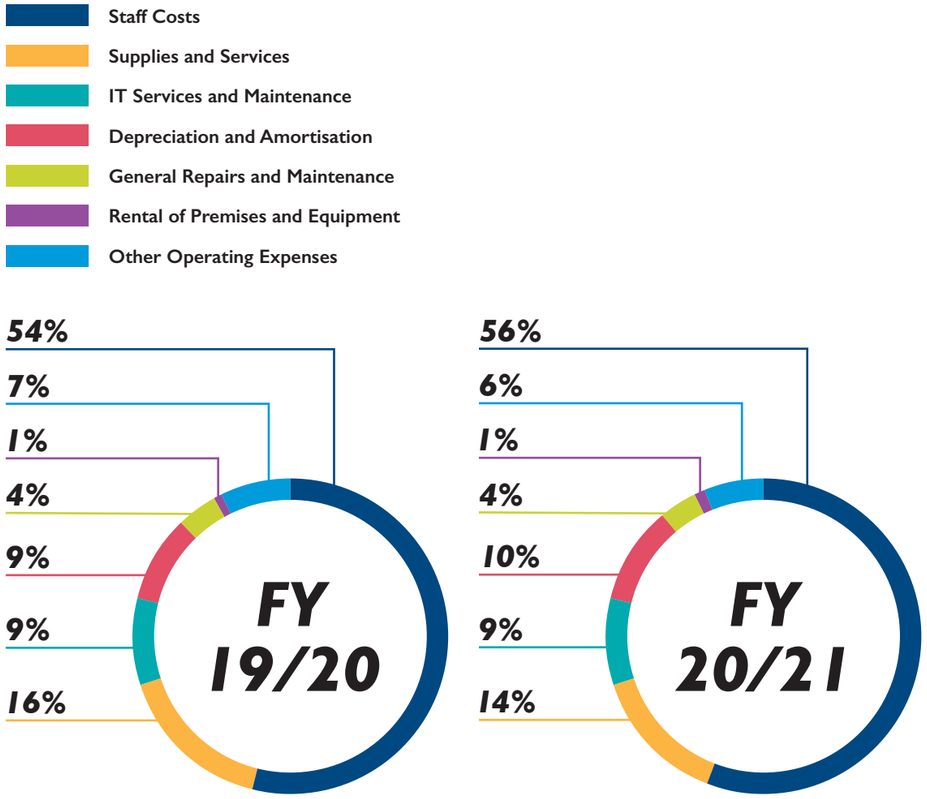
	FY20/21	FY19/20	Increase / (Decrease)	
	$'000	$'000	$'000	%
Laboratory Analysis Fees	72,583	67,587	4,996	7
Blood Processing and Patient Laboratory Testing Fees	40,492	47,218	(6,726)	(14)
Licensing Fees	20,267	18,978	1,289	7
Forensic Investigation Fees	12,702	12,526	176	1
Other Income	3,822	5,664	(1,842)	(33)
Total Operating Income	**149,866**	**151,973**	**(2,107)**	**(1)**



OPERATING EXPENDITURE

The Authority incurred a total operating expenditure of $208.9m in FY20/21, a decrease of $3.4m (2%) from FY19/20's expenditure of $212.3m.

	FY20/21	FY19/20	Increase / (Decrease)	
	$'000	$'000	$'000	%
Staff Costs	117,481	115,210	2,271	2
Supplies and Services	29,035	33,458	(4,423)	(13)
IT Services and Maintenance	18,853	19,309	(456)	(2)
Depreciation and Amortisation	20,876	19,963	913	5
General Repairs and Maintenance	8,341	7,623	718	9
Rental of Premises and Equipment	2,195	2,592	(397)	(15)
Other Operating Expenses	12,162	14,143	(1,981)	(14)
Total Operating Expenditure	**208,943**	**212,298**	**(3,355)**	**(2)**



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