ANNUAL 2019/20 REPORT

HSA
Health Sciences Authority

HEALTH SCIENCES AUTHORITY
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DRIVING TRANSFORMATION

HEALTH SCIENCES AUTHORITY

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 VISION

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

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.

DRIVING TRANSFORMATION

In today's rapidly changing landscape of scientific and technological advancements, transformation is what will help us to grow and keep up with the needs of our stakeholders. At HSA, we are driving transformation from the core, and putting new strategies and plans into action.

By leveraging science and technology to transform our operations and service delivery, we uphold our commitment to safeguard public health and safety, secure our nation's blood supply, and support the administration of justice. This journey of transformation will ensure future readiness, and solidify our position as the leading authority in protecting and advancing national health and safety.

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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
Tobacco Regulation Branch

ISO 9001:2015
Vigilance & Compliance Branch

ISO 9001:2015
Enforcement Branch

Professional Excellence

Blood Services Group

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

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

December 2005
Certified On-the-Job Training Centre

Since 1992
World Health Organization Collaborating Centre for Transfusion Medicine

Professional Excellence

Applied Sciences Group

Forensic Medicine Division

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 (ACSS) Consortium
Consortium Member

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

Blood Services Group

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

Since August 2008
American Society for Histocompatibility and Immunogenetics (ASHI)

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 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)

CHAIRMAN'S MESSAGE

PROFESSOR SATKUNANANTHAM S/O KANDIAH

Chairman

The past year has been a challenging one, especially with the COVID-19 pandemic causing many disruptions internationally, locally and at our workplaces.

KEEPING CRITICAL SERVICES AVAILABLE DURING COVID-19

As the work we do at HSA is critical, we needed to implement changes to keep our operations running during this pandemic period. This was especially challenging as many of our functions such as laboratory work, forensic services, blood bank operations and enforcement operations required our staff to be physically present in the office or out in the field. For all of these teams, ensuring their health and safety was paramount. Hence, we put in place safety measures such as working in split teams, staggered work hours and safe distancing, wherever possible.

I am glad, that despite these challenges, we have managed to make headway in our work and continue to deliver on our roles to meet stakeholders' needs.

I am happy to share some of our achievements over the past year:

ENHANCING REGULATORY EFFICIENCY

We recognise the importance of timely access to beneficial therapeutic products. To support the innovation and development of therapeutic products in Singapore, we set up an Innovation Office to provide early scientific and regulatory advice to stakeholders. Since its inception, a total of 14 research institutions and biotech pharma companies, representing 15 innovative therapeutic products, have benefitted from face-to-face regulatory and scientific consultations with HSA.

Another area that we keep a close tab on is emerging technologies. Whilst increased connectivity between medical devices and the Internet opens up new capabilities, it also introduces many new and unfamiliar cybersecurity risks. To help companies deal with such challenges, we have developed guidelines on how they could comply with the regulations on cybersecurity risk management for medical devices.

REINFORCING OUR BLOOD SUPPLY

One of the biggest challenges we face in the area of blood supply is the limited shelf life of blood products.

We are constantly studying ways to extend their shelf life to enhance the robustness of our blood supply.

We have successfully extended the shelf life of thawed frozen blood from 24 hours to 14 days. To achieve this, we implemented a closed system protocol for freezing blood to prevent contamination and introduced the use of an additive solution. With this new system, we are able to make more efficient use of thawed frozen blood for patients and at the same time, improve our blood inventory.

> *"As a scientific organisation, providing many essential and critical services, we should and have responded to extreme challenges with agility. It is through unrelenting preparedness, continuous learning and motivating one another to innovate and achieve the best we can, that we continue to stride forward with confidence.*

We are also collaborating with DSO National Laboratories and the Singapore General Hospital to study the use of cryopreservation in extending the lifespan of platelets. Clinical trials commenced in October 2019, and if the trials are successful, stockpiling cryopreserved platelets for clinical use could become a possibility. This will certainly help us to improve our emergency preparedness.

HEIGHTENING OUR SCIENTIFIC EXPERTISE

As part of our efforts to better serve our stakeholders, we are constantly looking at raising our level of scientific competence. We do this through research, learning and innovation.

Over the past year, we developed a new procedure that enables us to identify novel illicit drugs even without drug standards. Using chromatography techniques, we have been able to isolate drugs from complex matrices and identify them using various analytical instruments. This new technique has enabled us to better support the Central Narcotics Bureau with a much quicker turnaround time.

Another area that we have made progress is in disaster victim identification. By developing our whole mitochondrial genome sequencing capability and establishing a Singapore Mitochondrial DNA (mtDNA) sequence haplotype database, we are now able to recover information from challenging DNA samples encountered in scenarios where human remains are badly degraded.

TRAINING OUR PEOPLE

These achievements would not be possible without our people. As such, we are committed to provide a work culture and environment that nurtures and fulfils them. To keep the skills of our staff up-to-date, we have a series of Professional Education Programmes, which include lectures, sharing sessions and events that foster a culture of learning and collaboration.

As part of our professional education lecture series, industry professionals are regularly engaged to share their knowledge on topics ranging from crisis management and communications to aircraft accident investigations. In addition to such lectures, we have informal tea-time sharing sessions, where staff across all four professional groups give talks on innovations that they have introduced to make their work more efficient. This initiative has proven successful in getting new technologies and platforms such as the use of FormSG, Excel Macros and Python programming to be adopted across HSA.

We also hold events such as the Science and Innovation Day, to promote a culture of research and innovation in HSA. On this dedicated day, scientific information and innovative ideas are exchanged via booth exhibitions, poster presentations and laboratory visits.

RUNNING A SUSTAINABLE RACE

One common thread that underlies much of our recent progress is digitalisation. However, as digitalisation initiatives at HSA pick up pace, the threat of digital attacks also increases. In response, we have implemented new initiatives to strengthen our cybersecurity systems, such as migrating critical IT systems in HSA to the Government Data Centre.

This need for quick response and agility, however, goes beyond cybersecurity. We need to remain vigilant at all levels. As a scientific organisation, providing many essential and critical services, we should and have responded to extreme challenges with agility. It is through unrelenting preparedness, continuous learning and motivating one another to innovate and achieve the best we can, that we continue to stride forward with confidence.

CEO'S MESSAGE

DR CHOONG
MAY LING, MIMI

Chief Executive Officer

LIVING IN UNPRECEDENTED TIMES

The COVID-19 pandemic has brought about a global health crisis, socio-economic challenges, and international travel disruptions most of us could never have imagined. The speed with which it has spread around the world and its impact is unmatched in modern times.

It has affected everyone in one way or another and the world is being tested like never before.

THE COVID-19 CHALLENGE

To cope with a rapidly changing landscape arising from a global health crisis, we had to remain nimble and adaptive to ensure timely access to diagnostic tests, medicines and vaccines, whilst ensuring their safety, quality and efficacy.

Diagnostic Test Kits

To ease the global shortage of medical equipment, we expedited the approval of new diagnostic test kits based on a risk-calibrated review process to ensure essential safety and performance requirements were met. As of 31 May 2020, 65 diagnostic kits had been approved via this provisional authorisation route which included first-in-world approvals for products from local manufacturers.

3D-printed Nasopharyngeal Swabs

To support the increase in Singapore's testing capacity, we collaborated with the National Additive Manufacturing-Innovation Cluster, local researchers, innovators and 3D printers to manufacture and scale up production of 3D-printed and injection-moulded nasopharyngeal swabs.

Surgical Masks, Ventilators and Personal Protective Equipment

To cope with the surge in demand for surgical masks, particulate respirators and protective gears for healthcare workers, we waived the need for an importer's licence to facilitate the import of these medical devices. This enabled new players to bring in supplies from new sources. HSA provided scientific and regulatory advice to facilitate the development, testing and manufacturing of surgical masks for local use. We also embarked on virtual inspections of local mask manufacturing sites to ensure they met good manufacturing and distributing standards.

To mitigate potential shortages of emergency ventilators for COVID-19 patients, we introduced a provisional authorisation route to speed up the approval process of new ventilators. As at June 2020, three have been approved under this route. We also exercised regulatory flexibility and allowed anaesthesia machines to be repurposed as ventilators.

Therapeutic Products and Vaccines

We adjusted our existing workflows to help speed up the development of effective therapeutics and vaccines that are needed to combat the COVID-19 pandemic. For example, we employed a rolling submission approach, where the review of study documents are done as soon as they become available. This allows us to start on the evaluation process, even as product development is still ongoing.

"To cope with a rapidly changing landscape arising from a global health crisis, we had to remain nimble and adaptive to ensure timely access to diagnostic tests, medicines and vaccines, whilst ensuring their safety, quality and efficacy.

Since March 2020, we had facilitated the early access of remdesivir for moderate to severe COVID-19 patients in Singapore through the expeditious evaluation and approval of its use in three clinical trials. HSA also worked closely with the product owner on the filing for registration of remdesivir to ensure continued supply of the medicines for patients. Based on an expedited review of current available data, we granted conditional approval for remdesivir in June, within three weeks of receiving the application. Singapore is among the earliest countries to grant an approval for the medicine. We are continuing to review data from ongoing clinical studies to ensure the continued safety and efficacy of the product.

In addition, our early engagements with companies and research organisations had facilitated the development of COVID-19 monoclonal antibody treatments and vaccines to advance quickly to clinical trials.

Strategic Global Collaboration

During this period, we also continued to work closely with strategic global partners, such as the World Health Organization, International Coalition of Medicines Regulatory Authorities, Australia-Canada-Singapore-Switzerland (ACSS) Regulatory Consortium, and others to share information that can help to speed up the development of diagnostics, therapeutics and vaccines for COVID-19. I believe that for us to successfully overcome this crisis, we need to embrace a spirit of international collaboration.

Convalescent Plasma and Blood Supply

In the area of blood services, we worked with the National Centre for Infectious Diseases (NCID) and Tan Tock Seng Hospital (TTSH) on establishing 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.

To boost blood donor confidence so that they would continue to come forward to donate blood during this time, we implemented precautionary measures such as pre-screening of donors before they enter the blood donation centres and blood mobiles, as well as safe distancing measures. Thanks to the donors who continued to step forward, we were able to meet patients' needs even during this challenging period.

SYNERGIES WITHIN HSA

The synergies between the different professional groups within HSA enabled us to leverage each other's strengths to better protect public health.

Our Health Products Regulation Group (HPRG) and Applied Sciences Group (ASG) worked closely together to promptly develop a system to identify and remove products contaminated with unacceptable levels of nitrosamine impurities from the market.

Noting that there was no test method available internationally to analyse for nitrosamine contamination, ASG proceeded to develop its own testing methodology. This enabled HSA to become the first regulator in the world to recall ranitidine and metformin products due to nitrosamine contamination.

In the managing of this incident, we also worked closely with the Ministry of Health and the public healthcare family to coordinate the recalls. Our strong ties and close working relationships ensured that the switch to alternative medicines for affected patients was smooth and seamless.

"A key enabler for this transformation process is the use of automation to improve important but routine processes. We review current processes, and see how they can be simplified and streamlined using automation.

OUR TRANSFORMATION JOURNEY

Over this past year, we continued to push ahead in our transformation journey, guided by a comprehensive Transformation Roadmap that we developed in 2019. Organised into four broad pillars – Stakeholder-centric Product and Services, Process Transformation, Strong Partnerships and People Transformation, we have tasked each of our group directors to adopt and champion a pillar and its related transformation efforts.

To support our transformation initiatives, we have also come up with four key workgroups, namely the Digitalisation Steering Committee, the Behavioural Insights Workgroup, the Data Analytics Core Team and the Future Sensing Core Team. Additionally, we have also refreshed our 5-year strategic roadmap to better align with our ongoing transformation efforts.

I am pleased to say that we are making good progress under each of the following pillars of transformation:

Pillar 1 – Stakeholder-centric Products and Services

A guiding principle for us when we develop and revamp our products and services is to ensure that their design is centred around the stakeholder.

We launched the revamped HSA website in November 2019, which was designed from the ground up to enable visitors to access the information and services that they require in the easiest, fastest and most intuitive way.

In this new website, we have included self-help tools for users to get the help they need quickly and easily. Travellers can now check on the import restrictions of personal medicines, medical device importers can check on registration guidelines and requirements, and blood donors can check on their donation eligibility.

Blood donors are essential to securing Singapore's blood supply. As such, we are constantly trying to improve their donation experience. One thing that we have done recently is to integrate the donor portal with MyInfo, thereby allowing donors to retrieve and update their particulars with just one click. In addition, we have also streamlined the blood donation process flow for donors to proceed directly for haemoglobin test immediately after registration to minimise unnecessary waiting and improve donation experience.

Pillar 2 – Process Transformation

Process transformation is critical for us to break through existing limits and achieve higher efficiency and faster throughput.

A key enabler for this transformation process is the use of automation to improve important but routine processes. We review current processes, and see how they can be simplified and streamlined using automation. One example is the automation of a workflow between sample preparation and the gas chromatograph mass spectrometer. This has significantly cut down on the time needed for qualitative drug analysis.

Another enabler for process transformation is robotic process automation (RPA). This has already been deployed in a variety of high precision and high volume tasks, such as instrument performance checks and video frame extraction for traffic reconstruction. Through RPA, we are able to relieve our staff from repetitive labour-intensive tasks, and move them towards higher value work.

"As we continue down our transformation road, we want to ensure that the entire organisation moves together as one united HSA. While we have made good progress with our transformation efforts over the past few years, the pandemic has certainly accelerated the breadth, depth and pace of transformation, especially in the areas of digital and tech-based transformation.

Pillar 3 – Strong Partnerships

In today's hyperconnected world, it has become more important than ever for us to build and strengthen our international networks. Indeed, strong partnerships are critical to expanding our capabilities and promoting harmonisation.

In 2020, we had the honour of serving as the chairman of the International Medical Device Regulators' Forum. This was certainly exciting for us as we were able to play a part in driving the strategic directions for global medical device regulatory harmonisation and cooperation.

In this past year, we also signed a Mutual Recognition Agreement with New Zealand, as well as a Memorandum of Understanding with the Republic of Korea's Ministry of Food and Drug Safety on Good Manufacturing Practice inspections. Such partnership arrangements have helped us to reduce the duplication of efforts and facilitate quicker access to health products, thereby benefitting both industry and patients.

Through our collaborations with the ACSS Consortium, we have been able to reduce the number of regulatory checks, and facilitate quicker market entry of therapeutic products into multiple markets simultaneously. Already, we have seen three therapeutic products, including the first posaconazole generic product, enter our market through this arrangement.

Pillar 4 – People Transformation

People form the foundation to any organisation's success. Therefore, we prioritise training and development of our people. We have developed a list of Professional Future Critical Skills, and complementary Data Science Competencies to help HSA professionals equip themselves with the skills required of a future-ready workforce.

We have also refined our in-house Professional Leadership Development Programme – "Channel Leadership", to nurture the leadership potential of our staff. This past year, we were pleased to witness the graduation of our first cohort, as well as launch a second run of the programme.

To help our staff reach their full potential, we are constantly encouraging our staff to take up courses to upgrade and reskill. We have now gone one step further by embarking on an e-learning journey with LEARN. Through this LEARN platform, our officers will now be able to upskill and reskill at a pace that's comfortable for them, at any time and place.

MOVING TOGETHER AS ONE

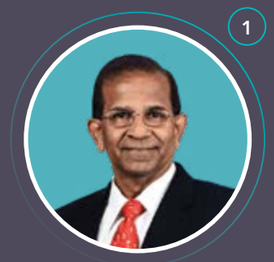
As we continue down our transformation road, we want to ensure that the entire organisation moves together as one united HSA. While we have made good progress with our transformation efforts over the past few years, the pandemic has certainly accelerated the breadth, depth and pace of transformation, especially in the areas of digital and tech-based transformation.

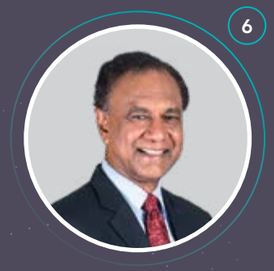
Moving forward, we must maintain the momentum of our transformation efforts. We aim to learn from other organisations and industries, and adopt the best practices to maximise our efficiency.

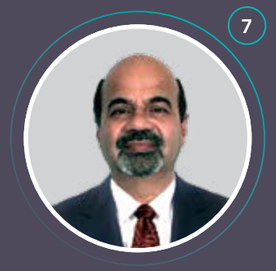
Ultimately, we are confident of the strategies we have put in place for streamlined and efficient processes and operations. By combining this with the power of digital and other new technologies, we will be in a prime position to deliver the greatest value to our stakeholders.

HSA BOARD

As at August 2020







1
Professor Satkunanantham s/o Kandiah
Chairman
Health Sciences Authority

2
Mr Max Loh
Managing Partner, Singapore and Brunei, and ASEAN IPO Leader
Ernst & Young

3
Mr Tai Lee Siang
Executive Director (BuildSG)
Building and Construction Authority

4
Professor Freddy Boey
Deputy President (Innovation & Enterprise)
National University of Singapore

5
Mr Lionel Yee Woon Chin, SC
Deputy Attorney-General
Attorney-General's Chambers

6
Mr Dileep Nair
Independent Director
Keppel DC REIT Management Pte Ltd

7
Mr Alok Mishra
Chief Executive Officer
Value Addition

8
Mr Jimmy Phoon
Chief Executive Officer & Chief Investment Officer
Seatown Holdings International Pte Ltd

9
Ms Aileen Tan
Group Chief Human Resources Officer
SingTel

10
Professor Leong Tze Yun
Professor of Computer Science (Practice)
National University of Singapore

Director of AI Technology
AI Singapore

HSA Board Committees

As at August 2020

BOARD EXECUTIVE COMMITTEE

Chairman
Professor Satkunanantham s/o Kandiah

Members
Mr Alok Mishra
Mr Lionel Yee Woon Chin, SC
Ms Aileen Tan

AUDIT AND RISK COMMITTEE

Chairman
Mr Max Loh

Members
Professor Freddy Boey
Mr Jimmy Phoon
Professor Leong Tze Yun

BOARD UPDATES

We would like to express our sincere appreciation to Mr Adam Abdur Rahman, Mrs Tan Li Lian and Professor Alex Matter, who retired from the Board on 31 March 2020. We thank them for their dedication and numerous contributions during their time on the Board. They have provided great support for HSA's programmes and activities. Their experience, insights and expertise have been invaluable in helping HSA to strengthen our capabilities and strengths.

We warmly welcome Ms Aileen Tan and Professor Leong Tze Yun who joined the Board with effect from 1 April 2020. They bring with them rich experience in their areas of expertise. We look forward to their insights and guidance as we embark on our next phase of transformation.

BUILDING DEVELOPMENT COMMITTEE

Chairman
Mr Tai Lee Siang
Executive Director (BuildSG)
Building and Construction Authority

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

Associate 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

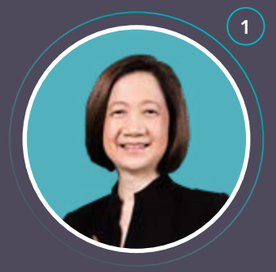
Ms Elizabeth Quah
Group Director (Planning)
Ministry of Health

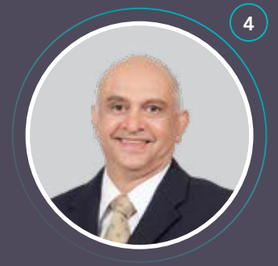
Mr Loke Mun Sing
Director
Healthcare Infrastructure Projects Division
Ministry of Health Holdings

Mr Hoong Bee Lok
Visiting Consultant
Health Sciences Authority

HSA Executive Committee

As at August 2020





1
Dr Choong May Ling, Mimi
Chief Executive Officer

2
Assoc Professor Chan Cheng Leng
Group Director
Health Products Regulation Group

3
Dr Ang Ai Leen
Group Director
Blood Services Group

4
Assoc Professor Sunil Sethi
Group Director
Applied Sciences Group

5
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 2020

HSA BOARD

INTERNAL AUDIT

CHIEF EXECUTIVE OFFICER

HEALTH PRODUCTS REGULATION GROUP

- Therapeutic Products
- Medical Device
- Complementary Health Products
- Innovation Office & Clinical Trials
- Advanced Therapy Products
- Vigilance & Compliance
- Enforcement
- Tobacco Regulation
- Audit & Licensing

BLOOD SERVICES GROUP

- Blood Resources
- Blood Supply Management
- Patient Services
- Clinical Services
- Blood Service Support
- Capability Development & International Collaboration
- Quality Management

APPLIED SCIENCES GROUP

- Forensic Medicine
- Forensic Science
- Illicit Drugs
- Analytical Toxicology
- Biology
- Pharmaceutical
- Chemical Metrology
- Quality

CORPORATE SERVICES GROUP

- Corporate Communications
- Facilities Management
- Finance
- Human Capital Management
- Information Management
- Legal
- Engagement, Innovation & Professional Development
- Risk Management, Emergency Planning & Data Governance
- Safety & Quality
- Strategy & Business Transformation
- Compliance

Advancing Health Products Regulation

- Developing the regulatory framework for new and innovative health products
- Increasing relevancy for stakeholders with user-centric digitalised systems
- Strengthening processes

HEALTH PRODUCTS REGULATION GROUP

REGULATORY REVIEWS & INNOVATION . . .

HSA regularly reviews and updates our regulatory frameworks and regulations to ensure that they are forward-looking and fit for purpose. During the year, we have developed guidances and initiatives for innovative products and new services. To support Singapore's fight against the COVID-19 pandemic, we have also responded quickly to ensure timely access to diagnostic tests, medicines and vaccines, while ensuring safety, quality and efficacy.

RESPONDING IN A QUICK AND TIMELY MANNER TO THE COVID-19 PANDEMIC

Therapeutic Product Development

To facilitate and accelerate the development of effective therapeutics and vaccines, HSA has prioritised and expedited the review of COVID-19 clinical trials. We have adopted a rolling submission approach that enables HSA to receive and initiate the review of study documents expeditiously ahead of a trial application. In early March 2020, we expedited the approval of three remdesivir clinical trials in moderate to severe COVID-19 patients.

We have also been working closely with companies and research organisations. Through our early engagements, we are able to facilitate the development of new COVID-19 monoclonal antibody treatments and vaccines to swiftly advance them to clinical trials.

The COVID-19 pandemic has affected aspects of the conduct of clinical trials of therapeutic products and medicinal products in Singapore, such as causing trial participants to be unable to visit trial sites, interruption of supply chain or presenting challenges in conducting on-site monitoring visits by trial sponsors. Hence, HSA developed a Guidance on the Conduct of Clinical Trials during COVID-19 to provide general considerations to sponsors and investigators to ensure the safety of trial participants, compliance with the clinical trials regulations and ICH GCP (R2) Guidelines, and minimise risks to trial integrity.

Access to Medical Devices

HSA has worked closely with the local industry, research institutes and organisations to ensure continued access to medical devices needed for the COVID-19 pandemic. By providing timely scientific and regulatory advice, we facilitated the development, testing and manufacturing of critical medical device products including novel test kits, personal protective equipment (PPE), respiratory and diagnostic devices.

1 Surgical masks, thermometers and PPEs

With the increased demand for items such as surgical masks, particulate respirators and protective gear for medical professionals due to the outbreak, we put in place an exemption order under the Health Products Act to facilitate the import of these medical devices from 31 January 2020. This enabled the expeditious entry of these devices from a variety of sources to cope with the urgent surging demand. We also supported and provided scientific and regulatory advice to facilitate the development, testing and manufacturing of surgical masks for local use. Keeping in line with safe distancing measures, where practicable, we adopted technology to perform virtual inspections of local mask manufacturing sites.

2 Diagnostic test kits

To ensure timely availability of COVID-19 diagnostic test kits in Singapore, we introduced a provisional authorisation route to expedite the approval process of new test kits. Provisional authorisation is based on a risk-calibrated review process, which ensures that the essential validation, safety and performance requirements are met. The first test kit was approved in early February 2020.

3 Respirators

Globally, the use of respirators, including N95, has increased sharply as a result of the COVID-19 pandemic. Respirators are typically single-use medical devices. Significant efforts have been put in place by manufacturers to develop methods for their decontamination and safe reuse, should a global shortage or disruption of respirators occur. In preparation for such situations, HSA introduced a provisional authorisation route for the expedited review of decontamination systems to ensure their safety, quality and effectiveness.

4 Respiratory devices

In view of the global shortage of ventilators, we implemented a three-pronged approach to ensure sufficient ventilators for use in Singapore.

- Firstly, we introduced a provisional authorisation route to speed up the approval process of new ventilators.
- Secondly, we allowed the use of existing anaesthesia machines or positive airway pressure devices within healthcare institutions for controlled ventilation or assisted ventilation for COVID-19 patients, provided that the device manufacturers developed specific instructions to support the safe use of such devices as ventilators.
- Lastly, we introduced an alternative pathway to facilitate faster supply of modifications to registered ventilators. Registrants only need to notify HSA via an online form on a six-monthly basis.

5 3D-printing (3DP) of medical devices

3DP technology has the ability to adapt innovative and flexible designs to products quickly and can be less sensitive to supply chain disruptions as compared to conventional approaches. With an increasing trend towards the use of 3DP technology to manufacture essential medical devices to overcome shortages during the COVID-19 pandemic, HSA published a guidance on the required regulatory requirements as well as specific technical considerations for 3DP medical devices to support and facilitate access.

As at 31 May 2020:

Expedited the approval of **6 clinical trials** of COVID-19-related treatments, including remdesivir, and other novel and repurposed therapeutic products.

65 COVID-19 **diagnostic kits** have been approved under the provisional authorisation route, including first-in-world approvals for locally-manufactured test kits.

3 ventilators have been approved under the provisional authorisation route.

Created a dedicated COVID-19 page on the HSA website providing **timely and essential guidances and advisories** for dealers and members of the public.

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

In September 2019, the revised heavy metal limits for CHPs were officially implemented. These new limits seek to enhance consumer safety and align with international standards such as those set by the World Health Organization (WHO) and ASEAN. It will also facilitate entry into other markets for companies that are dealing with such products.

Companies with existing products in the market will have until September 2020 to comply with these new standards. Additionally, HSA has provided guidance on various ways to minimise contamination by toxic heavy metals while processing the herbs used in the manufacture of CHPs.

The revised heavy metal limits for CHPs are:

33 As Arsenic	48 Cd Cadmium	82 Pb Lead	80 Hg Mercury
5ppm	*0.3ppm*	*10ppm*	*0.5ppm*[1]

PROHIBITION OF COSMETIC PRODUCTS WITH ADDED MERCURY

As of January 2020, cosmetic products that contain mercury have been prohibited. This is in compliance with the Minamata Convention on Mercury, which is an international treaty to protect human health and environment from man-made releases of mercury and mercury compounds.

Under these new guidelines:

- Manufacture, import or export of topical antiseptics with mercury or any compound of mercury will not be allowed.
- Manufacture for export and import for re-export of cosmetic products[2] that contain mercury or any compound of mercury above 1 ppm will not be allowed. The local supply of such mercury-added cosmetic products[2] is prohibited.

Prior to implementation, feedback on the proposed regulatory controls had been gathered. These new changes will help to enhance consumer safety and are in alignment with international standards.

[1] *Parts per million.*

[2] *Except for eye-area cosmetic products that use allowable mercury-containing preservatives which do not exceed the stipulated limits.*

REGULATORY GUIDANCE ON INNOVATIVE HEALTH PRODUCTS

Medical Device Software Development

Software plays an important role in some medical devices by enabling connectivity to the Internet, hospital networks and other devices. This increased connectivity, coupled with emerging technologies such as Artificial Intelligence and the Internet of Things which are rapidly being adopted for breakthrough clinical applications, have inadvertently brought about new and complex cyber-threats to medical devices.

HSA has therefore developed the Software Medical Devices (A Lifecycle Approach) guidelines for the purpose of:

- Providing clarification on regulatory requirements for software medical devices for their entire life cycle, starting from product development, product verification and validation, quality systems, to distribution and post-market duties.
- Highlighting practices for mitigating threats related to cybersecurity and emerging technologies.
- Providing clarification on how these practices could demonstrate compliance with the regulatory approaches on cybersecurity risk management for medical devices.

The guidelines were published on 30 April 2020 after a public consultation exercise in 2019.

Next Generation Sequencing (NGS) Based In-Vitro Diagnostic (IVD) Assays

NGS is an innovative technology that is widely gaining adoption in clinical genetic testing used in diagnostic test kits. Compared to traditional gene sequencing technology, it is faster and has higher throughput.

NGS-based IVD assays have important real-world applications such as screening and diagnosis of cancer, selection of patients for selective therapy and management, and in disease staging.

In December 2019, we published a regulatory guidance document to provide clarity to stakeholders on how to meet the existing regulatory requirements for NGS-based IVD tests intended to aid in the diagnosis of individuals with suspected germline or somatic mutation-related diseases, and NGS-based tumour profiling IVD tests.

DEVELOPING THE STANDARD FOR NOVEL miRNAs-BASED DIAGNOSTICS

MicroRNAs (miRNAs) are stable circulating biomarkers found in bodily fluids such as blood and saliva. The differential expression of circulating miRNAs has exhibited promising potential for disease screening, diagnosis, monitoring disease progression or recurrence, and for predicting response to therapy.

With the aim of accelerating the development of new miRNA-based diagnostics by ensuring the reliability of products through standardisation, HSA participated in the development of the Singapore Standard for the design, development and validation of novel miRNA-based diagnostics. The Standard will include specifications and procedures to make it easier for users and regulators to understand and compare competing miRNA-based diagnostic products.

The Singapore Standard was published for public comments from January to March 2020, and is expected to be the world's first national standard for the validation of miRNA-based diagnostics.

ELECTRONIC LABELLING OF PRESCRIPTION MEDICINES

We launched a pilot initiative to distribute package inserts (PI) and patient information leaflets (PIL) of prescription-only medicines electronically. This initiative represents a positive step in the direction of digitalising healthcare services at a national level, and is in line with Singapore's move to become a Smart Nation.

Through this initiative, companies will be able to:

- Disseminate the latest approved prescribing information to healthcare professionals and patients in a timely and eco-friendly manner.
- Reduce potential logistics inefficiencies that may occur during printing and physical distribution of paper PI and PIL.

Since the initiative's **launch in August 2019**, a number of companies, representing around **148 products**, have indicated interest in participating in the pilot project.

STREAMLINING OUR WORK PROCESSES . . .

We reviewed and fine-tuned our work processes to make regulatory filing as simple as possible.

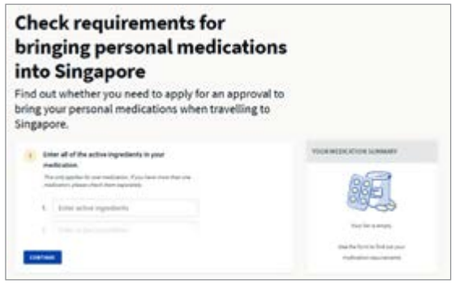
DEVELOPMENT OF NEW WEBSITE SELF-HELP TOOLS

Import of Personal Medication

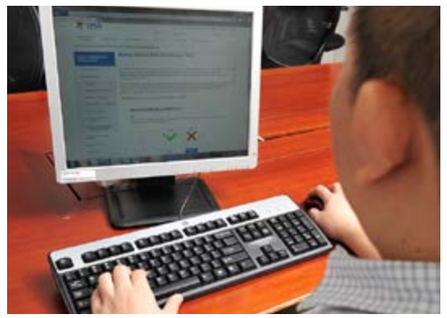
In November 2019, we launched an innovative web-based self-help tool to provide 24-hour assistance and automated responses to travellers and enquirers checking on medication import requirements.

This tool streamlined the handling of enquiries and allowed officers to focus on evaluating complex applications and issuing approvals for visitors bringing controlled medicines into Singapore.

HSA will continue to monitor the use of this new tool and refine its ease of use, as well as update on new controlled substances, when required.



Since its launch, the new **personal medications self-help tool** has been one of the most popular sites on the HSA website, with more than **2,000** visits weekly.



Medical Device Classification

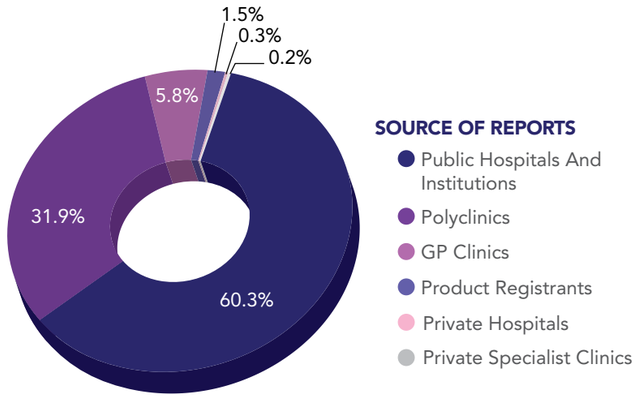
Two new self-help tools were implemented in October 2019 to respond to common queries regarding product classification, registration routes and dealer licence types:

- The tool "Is it a Medical Device?" helps users to determine if products are classified as Medical Devices and if registration is required.
- "Medical Device Registration and Licensing Tool" assists users in determining the appropriate registration route and type of dealer's licence required.

These user-friendly tools assist companies to meet the technical requirements for their products. They also save time and increase productivity by eliminating the need to email HSA for such queries.

STAYING VIGILANT . . .

To ensure the well-being of patients and consumers, we are always on the lookout for safety issues pertaining to health products.



LOCAL ADVERSE EVENT ACTIVITIES

A total of 30,182 adverse events (AE) were reported to HSA by the various healthcare institutions in Singapore. HSA also continued to partner with the KK Women's and Children's Hospital to conduct active surveillance of vaccine AEs.

- 97.3% of the reports received were linked to chemical drugs, while the remainder were related to vaccines (1.2%), biologics (1.0%) and complementary health products (CHPs) (0.5%).
- The two largest contributors of these reports were doctors (88.4%) and pharmacists (6.9%). The rest were from dentists, nurses and research coordinators.
- 137 AE reports involved CHPs and cosmetics.
- Of these, 7 adulterated CHPs and cosmetics were discovered with the help of astute clinicians.
- Reported AEs of adulterated products were mainly associated with endocrine disorders such as Cushing's syndrome and adrenal crisis.

SURVEILLANCE OF LOCAL PRODUCT DEFECTS

Over the year-in-review, more than 150 cases of local product defects were reported. The top 3 issues encountered were:

- **43 cases** Manufacturing defects
- **30 cases** Product packaging defects
- **30 cases** Product contamination

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 health products and their future batches. Such actions included:

- Recalling **11** products from the market
- Making **21** amendments to product registration
- Issuing **14** communications (e.g. Dear Healthcare Professional and Dear Purchaser Letters, and Press Releases)

UPDATE ON PRODUCT RISK MANAGEMENT

Singapore-Specific Risk Management Plans (RMP)

- 35 RMPs were reviewed at the point of product application for registration.
- 3 new RMPs involving the distribution of educational materials for patients or the submission of periodic benefit-risk evaluation reports were implemented.

Safety Signals

- 96 safety signals associated with therapeutic products were assessed as part of post-market pharmacovigilance activities.
- Regulatory actions taken included the amendment of the local package inserts for affected therapeutic products, as well as communication of the safety signals to healthcare professionals through Dear Healthcare Professional Letters (DHCPL), articles in the HSA Adverse Drug Reaction (ADR) News Bulletin and product safety alerts on HSA's website.

Risk Assessments on Adulterated Products

- 13 risk assessments were conducted on adulterated products detected from post-marketing surveillance activities.
- Regulatory actions taken included the issuance of press releases to warn the public about the adulterated products, and to avoid buying or using them.

ADVISORIES ISSUED

- **Safety advisories** on **24 products** were issued through **8** press releases.
- **39 company DHCPLs** were reviewed
- **5 DHCPLs** were written and issued
- **3** HSA **ADR News Bulletins** were published and disseminated to registered healthcare professionals
- **5 safety updates** were published on the HSA website

NEW ELECTRONIC PLATFORMS FOR EFFICIENT ONLINE SUBMISSIONS

New Resources for Product Defect Reporting and Recall

HSA first launched the use of new online forms for product defect and recall reporting in January 2019. To further help the industry understand the reporting process, HSA produced a video on Product Defect and Recall Reporting, as well as a self-guided tool on Product Defect Risk Classification in May 2019.

These resources helped industry stakeholders to better understand the technical requirements and the process involved, enabling them to determine which product defects needed to be reported.

Feedback received from the industry has so far been very positive. Some of the compliments include:

The **Product Defect Risk Classification tool** is the first of its kind to be made available to the industry by a drug regulatory agency.

HSA is a progressive agency that continually identifies **new approaches for enhancing processes**.

The **new resources** are **comprehensive** and **easy to use**.

New Electronic Special Access Route (SAR) Application Form

In February 2020, a new SAR e-form was launched to facilitate the online submission of applications for consignment approval of unregistered therapeutic products. This enhancement replaces the existing PDF application form for fax submission.

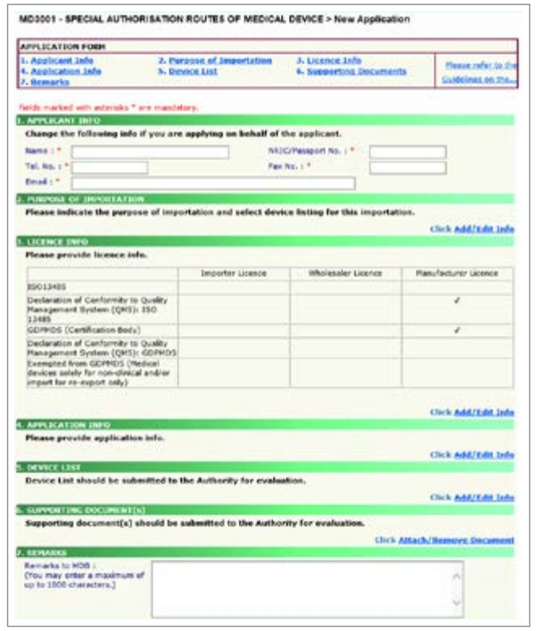
Highlights of the new submission process include access control via CorpPass for added data security, enhanced traceability, and significant reduction in manual work processing and data entry.

Revamped SAR Application Process

Since October 2019, the process for SAR applications has been streamlined to increase efficiency, save costs and improve clarity. These changes have significantly reduced the time needed for industry to complete the submissions.

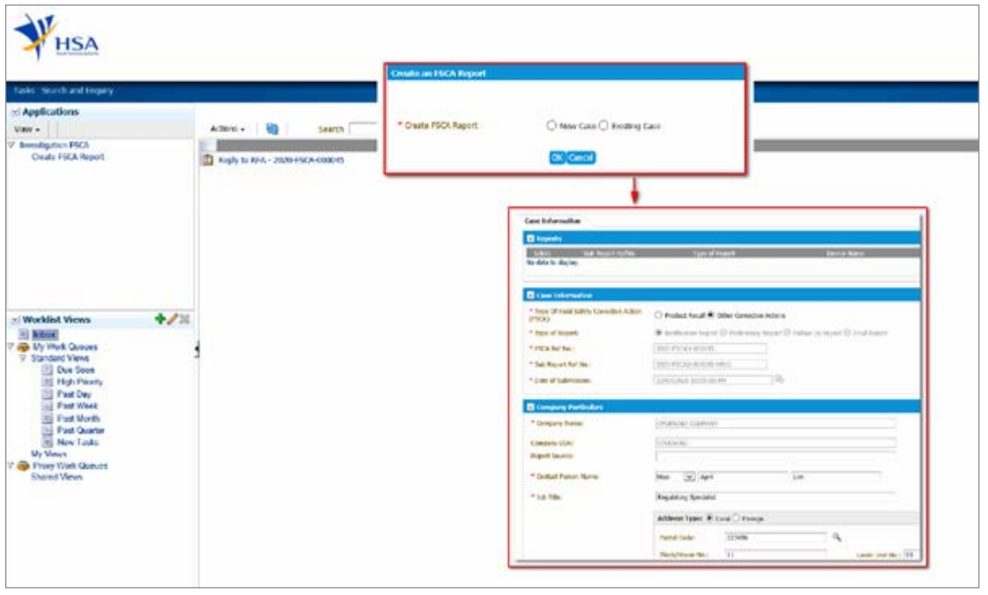
Highlights of these changes include:

- Replacing manual submission for SAR applications with online MEDICS submission.
- Re-designing SAR guidance, application and declaration forms to be more concise.
- Enabling the tracking of electronic submissions via the online database.
- Allowing companies with medical device importer and wholesaler licences to import unregistered medical devices for re-export purposes without the need to apply for GN-28 Import for Re-export.



OSCAR Reporting Platform

A new Medical Device Field Safety Corrective Actions (FSCA) reporting platform was launched in January 2020 to facilitate the online submission of medical device post-market reports. With this change, stakeholders can now enjoy greater efficiency and convenience in tracking and following up on their FSCA reports.



ADVANCING LOCAL COLLABORATIONS . . .

We foster close collaborations with local partners for greater synergy and to enable us to serve the public better.

RESEARCH COLLABORATION WITH NUS PHARMACY DEPARTMENT

From August to October 2019, HSA collaborated with the National University of Singapore (NUS) Pharmacy Department to conduct a qualitative research study on consumer perceptions of health products and its regulations (medicines and complementary health products) in Singapore.

The research findings have helped us to refine our public advisories, consumer messaging and selection of communication channels.

They have also helped in the planning of future strategies that include:

- Targeted educational initiatives.
- Refining the framework for future consumer adverse event (AE) reporting.
- Empowering consumers with the knowledge needed to make discerning purchasing decisions concerning health products.

SETTING THE STANDARD FOR THE SUPPLY AND DELIVERY OF MEDICATION

In October 2019, a new national standard, Singapore Standard 644 (SS 644) for the supply and delivery of medication to patients was launched. This project was done in collaboration with the Singapore Standards Council, the Pharmaceutical Society of Singapore and Enterprise Singapore, as well as partners in the healthcare, regulatory and logistics sector. It sought to formulate the expectations and best practices needed to support last mile delivery of medicines in Singapore.

STRENGTHENING GLOBAL PARTNERSHIPS . . .

Strong global partnerships are critical for us to stay up-to-date with the latest developments in health sciences.

INTERNATIONAL MEDICAL DEVICE REGULATORS FORUM (IMDRF)

HSA assumed chairmanship for the IMDRF in 2020 to drive the strategic directions for global medical device regulatory harmonisation and cooperation. On 18 March 2020, we chaired the 17th IMDRF Management Committee closed virtual meeting, which was attended by regulators from Australia, Brazil, Canada, China, the European Union, Japan, Russia, Singapore, South Korea and the United States. Representatives of the World Health Organization (WHO) participated as Official Observers.

One of the key outcomes was Singapore's commitment to the National Competent Authority Report (NCAR) Exchange Programme, which facilitates the global dissemination of medical device adverse events information. Leveraging this programme enables HSA to further strengthen our post-market surveillance system to ensure the continued safe use of medical devices in Singapore.

INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE (ICH)

Highlights of the recent ICH meeting held in November 2019 include:

First-ever meeting held in **Singapore**.

Attended by over **450** participants from **ICH's 16 members** and **32 observers**.

Convening of 14 ICH Working Groups (which included 6 new Working Groups) to commence work on recently approved topic proposals.

Updates by the Medical Dictionary for Regulatory Activities (MedDRA) Management Committee on recent activities.

INTERNATIONAL PHARMACEUTICAL REGULATORS PROGRAMME (IPRP) MANAGEMENT COMMITTEE (MC)

The 4th International Pharmaceutical Regulators Programme (IPRP) Management Committee (MC) was held on 20 and 21 November 2019 in Singapore, with representatives from 25 IPRP Members and Observers. The IPRP establishes a forum for exchange of information on issues of mutual interest and enables regulatory cooperation among its members and observers.

AUSTRALIA-CANADA-SINGAPORE-SWITZERLAND (ACSS) CONSORTIUM

HSA worked with Australia, Canada and Switzerland on the joint assessment of three drugs approved before 1 April 2020. This collaboration promotes greater harmonisation in regulatory requirements and alignment in scientific considerations.

Furthermore, it improves regulatory efficiency by dividing the review of the application dossier among ACSS regulators and consolidating evaluation queries.

PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME (PIC/S)

As the PIC/S Chair from 2018 to 2019, HSA:

- Advocated inspection reliance, and the expansion of PIC/S membership and PIC/S Inspectorates Academy (PIA).
- Chaired PIC/S Executive Bureau, PIC/S Committee and PIC/S associated meetings in Geneva, Chicago and Toyama.

On 31 December 2019, HSA handed over the chairmanship to Ireland's Health Products Regulatory Authority.

PARTICIPATION IN PROJECT ORBIS

In October 2019, HSA hosted a delegation led by Dr Richard Pazdur, the Director of US Food and Drug Administration (FDA)'s Oncology Center of Excellence as part of Project Orbis.

The Project Orbis initiative provides a framework for concurrent submission and review of oncology products among participating agencies, thereby facilitating earlier access to oncology drugs and therapies for patients with unmet medical needs.

Singapore is the first Asian country participating in this initiative alongside international jurisdictions including Australia, Canada and Switzerland.

PARTICIPATION IN THE CORE-MILKEN INSTITUTE INAUGURAL ROUNDTABLE

In October 2019, HSA participated in the inaugural roundtable on Integrating Patient Engagement into Healthcare & Access to Medicines in the Asia-Pacific Region. This event was hosted by Duke-NUS Medical School's Centre of Regulatory Excellence (CoRE) and FasterCures, a Center of the Milken Institute. It was part of an important global conversation among health system stakeholders on the value of engaging patients and involving them in medical research and product development.

This event brought together **56** participants and **observers from 13 countries** representing patient groups, ministries of health, national regulatory agencies, clinicians, healthcare administrators, academics and industry.

CEMENTING OUR GLOBAL PARTNERSHIPS IN FY19/20

Malaysia — Apr 2019

HSA started collaborating with the National Pharmaceutical Regulatory Agency (NPRA) on the joint assessment of generic medicine registration applications filed with both HSA and NPRA.

South Korea — Nov 2019

Photo credit: Ministry of Communications and Information

Signing of a Memorandum of Understanding (MoU) with South Korea's Ministry of Food and Drug Safety to facilitate MRA on GMP inspections of pharmaceutical products manufacturers.

New Zealand — May 2019

Signing of Mutual Recognition Agreement (MRA) on Conformity Assessment to recognise the conclusions of Good Manufacturing Practice (GMP) inspections of medicinal products manufacturers and manufacturing certificates issued by Singapore and New Zealand.

Australia — Nov 2019

Recognised as a Comparable Overseas Bodies for Complementary Medicines by Australia's Therapeutic Goods Administration.

Thailand — Jan 2020

Thailand's Food and Drug Administration (FDA) started utilisation of a reliance-based programme that allows them to leverage HSA's evaluation reports of Singapore registered medical devices, with due consent from the local registrant companies.

ASEAN ACTIVITIES

FDA Philippines Included as 5th ASEAN LIS

Together with the ASEAN Panel of Experts (PoE), HSA conducted an on-site assessment of Food and Drug Administration Philippines (FDA Philippines) in Manila in April 2019. FDA Philippines is now the 5th ASEAN Listed Inspection Service (LIS) after Singapore's HSA, Malaysia National Pharmaceutical Regulatory Agency (NPRA), Indonesia's National Agency of Drug and Food Control and Thailand FDA.

Countries under ASEAN LIS recognise one another's Good Manufacturing Practice (GMP) inspection outcomes, thereby facilitating trade and quicker access of medicinal products for ASEAN patients without compromising quality standards.

ASEAN Medical Device Committee (AMDC)

AMDC serves to achieve regulatory convergence amongst the member states by harmonising medical device regulations. FY19/20 highlights include:

- Singapore completed its chairmanship tenure of AMDC, and handed over chairmanship to Thailand during the 8th AMDC meeting.
- Improved transparency regarding the implementation timeline of ASEAN Medical Device Directive (AMDD) through the development and publishing of a Gantt Chart that includes pre-market, post-market and ratification status of member states on the AMDC website.
- The AMDC Technical Committee reached consensus on risk classification for 66 medical devices and 82 product classifications. The endorsed list of harmonised products have since been published on the ASEAN website.

WHO ACTIVITIES

Pre-Qualification Inspection of Two Active Pharmaceutical Ingredient (API) Manufacturers in China

In October 2019, HSA was involved in a World Health Organization (WHO) pre-qualification inspection of two API manufacturers in China. The experience gained from the WHO inspections has contributed to a better understanding of GMP compliance and quality assurance of APIs.

Participation in WHO Uppsala Monitoring Centre's (UMC) MedSafetyWeek

HSA participated in WHO UMC's MedSafetyWeek Campaign in November 2019. The campaign, which is a joint effort between 57 medicine regulatory agencies, aims to raise awareness among patients, carers and healthcare professionals on the potential risks of taking multiple medicines at the same time, as well as the importance of reporting suspected side effects.

Social media and online platforms were utilised to maximise outreach to the public. These included the posting of animated videos on HSA's website, YouTube and Twitter.

LOCAL OUTREACH PROGRAMMES . . .

Over the past year, we engaged local healthcare professionals and the public through various outreach programmes.

STANDARDISED PACKAGING FOR TOBACCO PRODUCTS

In May 2019, the Ministry of Health, Health Promotion Board and HSA conducted a final briefing on the new measure to introduce standardised packaging with enlarged graphic health warnings for tobacco products in Singapore.

Topics covered in the briefing include:

- Proposed specifications for the tobacco product packaging.
- Proposed implementation deadline.

All tobacco importers, wholesalers and retailers were informed by HSA that the new law would take effect on 1 July 2020.

INCREASE IN THE MINIMUM LEGAL AGE FOR TOBACCO

The minimum legal age (MLA) for tobacco was raised from 19 to 20 years as part of national efforts to curb tobacco consumption in Singapore. To facilitate the compliance to the law, HSA engaged over 4,000 tobacco retailers via formal reminders, outlet visits and the distribution of revised signages for the retailers to display to their customers.

GOOD MANUFACTURING PRACTICE (GMP) SEMINAR

HSA organised a GMP Seminar in September 2019 for the pharmaceutical industry.

Close to **350** participants from **108 companies attended.**

95% of the respondents indicated that they were **very satisfied** or **satisfied** with the seminar and found the presentations to be useful.

ENGAGEMENT WITH HEALTHCARE PROFESSIONALS TO IMPROVE MANAGEMENT OF SAFETY ISSUES

Publication of Adverse Event (AE) Guides for Healthcare Professionals

AE guides are developed to assist healthcare professionals to recognise the early signs of drug-induced AEs and how to manage them. These guides include:

- AE guide on Iatrogenic Cushing's Syndrome and steroid-related AEs, published in September 2019: HSA collaborated with endocrinologists from SGH to develop and publish this guide to help healthcare professionals recognise the signs of excessive chronic exposure to steroids, manage such AEs, and facilitate detection of adulterated products through the reporting of AEs.
- AE guide on Severe Cutaneous Adverse Reaction (SCAR), published in December 2019: HSA collaborated with clinical dermatologists to develop and publish this guide to raise awareness among healthcare professionals on medicines that are commonly associated with locally-reported SCARs, as well as to facilitate early recognition and prompt treatment in affected patients.

Clinical Lecture Series on Management of Drug-induced AEs

A series of six clinical lectures was conducted by local clinicians to deepen HSA staff's knowledge on the clinical management of common drug-induced AEs. Attended by a total of 301 participants, this collaboration with local clinicians serves to strengthen working relationships and encourage AE reporting.

LOCAL EDUCATION OUTREACH TO SCHOOL STUDENTS

In July 2019, HSA conducted an educational outreach programme to secondary school students on the dangers surrounding the illegal supply of medicines and how to be discerning when purchasing health products online. The programme included two lectures as well as a screening of HSA's video on the dangers of health products sold by dubious websites and sellers.

STAYING ALERT . . . .

We continue to stay vigilant towards safety issues and breaches that jeopardise the health and safety of patients and consumers.

MANAGEMENT OF NITROSAMINE CONTAMINATION IN MEDICINES

HSA took a multi-pronged risk-based approach to manage the issue of nitrosamine contamination in medicines. We conducted comprehensive testing of all locally marketed losartan, ranitidine and metformin products for nitrosamine impurities and recalled those that were found to contain nitrosamine impurities above acceptable levels. Recalled products include:

- **3** brands (6 products) of losartan (high blood pressure medicine) in March 2019
- **8** brands (11 products) of ranitidine (gastric medicine) in September 2019
- **2** brands (3 products) of metformin (diabetes medicine) in December 2019

A system-wide coordinated approach was taken, in which HSA partnered closely with:

- The public healthcare family to facilitate recalls as well as switches to alternative medicines for affected patients.
- Industry stakeholders to review the risk of contamination in their products and to mitigate any identified risks.
- International regulators to formulate measures to address this issue and to safeguard public health.

ENFORCEMENT OPERATIONS . . .

We used our scientific expertise to assist law enforcement agencies in clamping down on illegal activities related to health and tobacco products.

ENFORCEMENT ACTIONS AGAINST ILLEGAL HEALTH PRODUCTS IN GEYLANG

HSA collaborated with law enforcement agencies on raid operations in targeted areas such as Geylang to disrupt the illegal supply of health products, especially sexual enhancement medicines, cough syrup and illicit pills.

Additionally, HSA also participated in the Inter-Agency Taskforce (IAT5), working together with the Singapore Police Force, Central Narcotics Bureau and Singapore Customs to clamp down on illegal activities in the Geylang area.

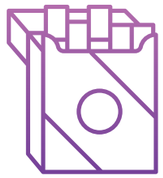
A total of **235** joint operations were conducted, resulting in the seizure of health products worth an estimated street value of **$490,000.**

SUSPENSION AND REVOCATION OF TOBACCO RETAIL LICENCES

HSA supports the national tobacco control policy against the illegal sale of tobacco products to persons under the Minimum Legal Age (MLA) and conducts enforcement activities against retailers who flout the law.

In the past year, we:

Suspended **14** tobacco retail licences



Revoked **1** tobacco retail licence

SMUGGLING AND PEDDLING CASES

HSA investigated a number of smuggling and peddling cases involving electronic vaporisers (e-vaporisers) and other prohibited tobacco products.

E-VAPORISERS

Over the past year, HSA put a stop to various e-vaporiser smuggling cases:

JUL 2019
Woodlands Checkpoint

- 6 sets of e-vaporisers and 223 electronic liquid cartridges were found in a Singapore-registered car's gear shift compartment.
- Further investigations uncovered another 26 sets of e-vaporisers and 412 electronic liquid cartridges in a SingPost POPStation.

SEP 2019
Changi Airfreight Centre

- 31 parcels containing 27 sets of e-vaporisers and 400 pieces of related accessories were detected by the Immigration & Checkpoints Authority (ICA).
- Subsequent house searches by HSA uncovered additional prohibited items.
- Total seizure: 63 sets of e-vaporisers and 2,368 e-vaporiser accessories, worth a street value of $29,460.

NOV 2019
Changi Airfreight Centre

- 8 parcels addressed to one individual were found to contain 24 sets of e-vaporisers and 1,209 related accessories.
- Through further tracing, an additional 165 sets of e-vaporisers and 3,394 accessories were discovered in storage units and other consignments.
- Total seizure: $66,000 worth of e-vaporisers and accessories.

JAN 2020
Woodlands Checkpoint

- Over 2,000 e-vaporisers, e-vaporiser cartridges and bottled e-liquids were discovered in various compartments of an arriving car.
- Further investigations led to the apprehension of 5 peddlers aged between 20 and 27 years old.
- Total seizure: 4,000 e-vaporiser related items worth more than $60,000.

This past year also saw one e-vaporiser peddler who was prosecuted and sentenced to a landmark fine of $99,000.

- This is the stiffest penalty imposed since 2014, when an offender was fined $64,500.
- The peddler's unlawful activities included the illegal purchase of the prohibited products from various overseas suppliers and then selling them via an e-commerce website.
- Despite the peddler's extra measures to hide his illegal activities, they were uncovered through HSA's online surveillance and investigation.

CHEWING TOBACCO

MAY 2019

A man was sentenced to 7 months' jail for smuggling almost 26,000 sachets of chewing tobacco.

- Street value of the chewing tobaco was worth more than $50,000.
- This is the stiffest punishment to-date for such offences.

Aug 2019

A joint operation was conducted at Little India with the Singapore Police Force.

- Largest-ever raid at a storage facility on chewing tobacco.
- The 2-day joint operation resulted in 17 persons being caught for the peddling and possession of chewing tobacco and the seizure of over 21,000 sachets with a street value of about $42,000.

HSA and the Singapore Customs jointly prosecuted a man for storage and sale of duty-unpaid cigarettes and possession of chewing tobacco.

- The street value of the chewing tobacco was estimated to be more than $24,000 and the total Goods and Services Tax evaded on the cigarettes amounted to more than $120,000.
- The man was sentenced to 19 months and 11 weeks' jail.

KNOWLEDGE EXCHANGE . . .

Knowledge shared between partners, both locally and globally, is essential for maintaining the highest standards in health products regulation.

DUKE-NUS CENTRE OF REGULATORY EXCELLENCE (CoRE) GRADUATE CERTIFICATE IN PHARMACEUTICAL REGULATION

HSA was part of the teaching faculty in the inaugural run of the Duke-NUS CoRE Graduate Certificate in Pharmaceutical Regulation for "Pharmacovigilance" and "Surveillance & Enforcement".

These two modules were conducted in May 2019 and February 2020 respectively and attracted participants from national regulatory agencies, academia and industry members from across the Asia Pacific region.

NEW AWARDS AND ACCREDITATIONS . . . .

The following milestones were achieved over the year-in-review.

SINGAPORE PHARMACY COUNCIL (SPC) EXCELLENT PRECEPTOR AWARD 2018

At the SPC Pharmacists' Pledge Affirmation Ceremony in June 2019, a HSA preceptor was named as one of the two winners of the SPC Excellent Preceptor Award. This is the first time that a winner was chosen from the non-patient care sector.

DATA ARCADE TOURNAMENT 2019

The Data Arcade Tournament was a competition organised by the Government Technology Agency (GovTech) to level up the data science capabilities of our public service officers, and to encourage them to be more data-driven. For the competition, participants were required to obtain their own dataset and prepare a visualisation using either Tableau or Qlik software. They were then judged based on their ability to derive useful insights via data visualisation tools (data storytelling).

HSA teamed up with the Ministry of Home Affairs (MHA) in July 2019. There were a total of 144 teams and our HSA-MHA team made it all the way to the finals, where they were tasked with crunching up a large dataset to produce a dashboard within just five hours.

The HSA-MHA team won second runner-up at the Data Science Connect event in November 2019 where they presented their insights to a panel of judges as well as the audience.

PUBLIC SECTOR PRO-ENTERPRISE INITIATIVE AWARD

The Public Sector Pro-Enterprise Initiative Award aims to recognise the work of officers and agencies which have contributed useful pro-enterprise initiatives to serve businesses better.

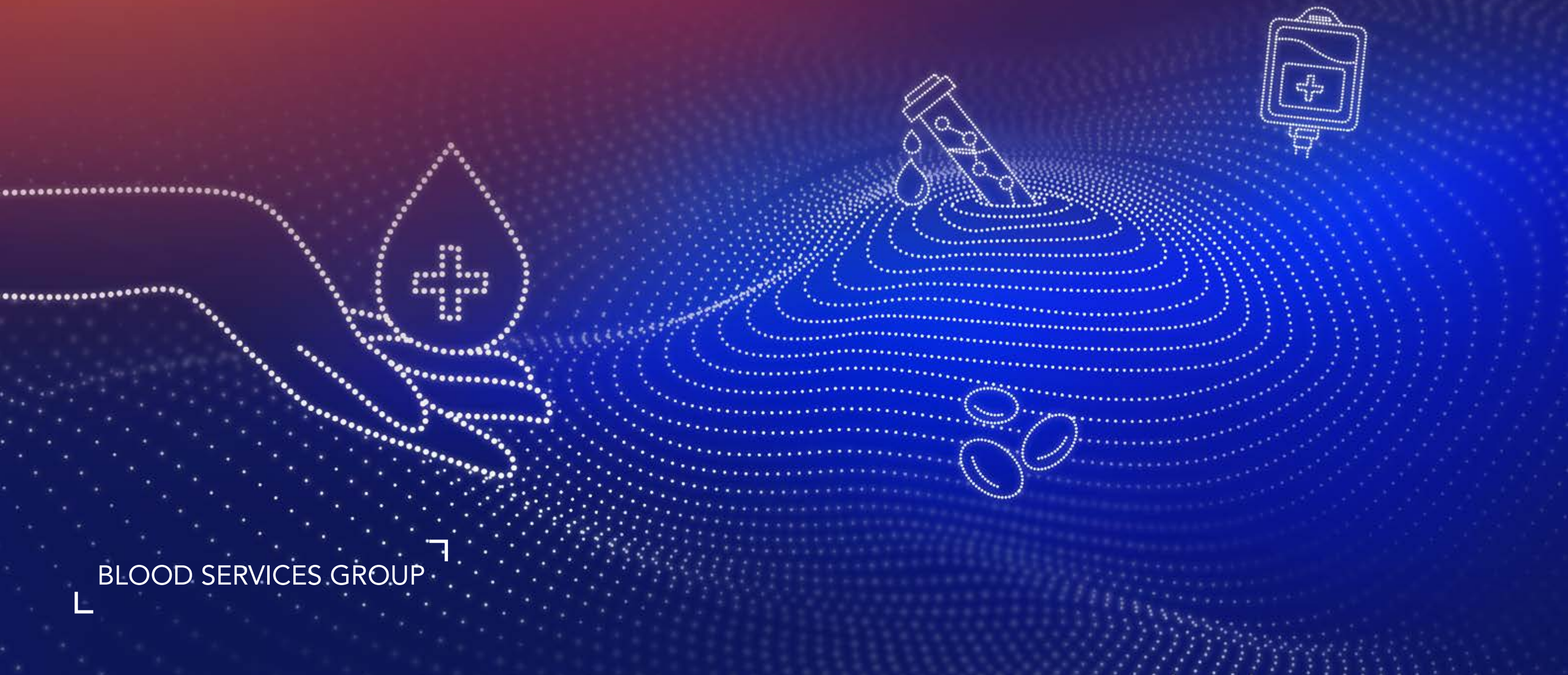
HSA received awards for:

- Lifting the 23-year ban on traditional Chinese medicines (TCM) containing Corydalis yanhusuo and facilitating market access through risk mitigation strategies[1].
- Introducing a self-help complementary health product (CHP) classification tool to provide guidance and quick access to information for dealers[2].
- Developing digital tools (a classification tool, a video, and two online forms) to guide industry stakeholders on product defect and recall reporting for therapeutic products[2].

[1] *Awarded for the period from July to December 2018*
[2] *Awarded for the period from January to June 2019*

Digitalising and Improving Blood Banking Services

- Simplifying the blood donation process
- Automating for greater efficiency
- Upholding the highest standards in blood banking



BLOOD SERVICES GROUP

FOR OUR DONORS

The selfless contributions of our blood donors save lives during times of need. We seek to recognise their contributions and ensure that the blood donation experience is made as pleasant as possible.

BUILDING A BIGGER POOL OF DONORS IN THE NORTHEAST DISTRICT

In May 2019, we started bi-monthly fixed mobile blood donation drives at Sengkang General Hospital. This is a prelude to the launch of the 4th satellite blood collection site at Punggol Town Hub, which is slated for 2023.

This initiative will bring about greater convenience for donors living and working at the northeast region of Singapore, enabling them to donate more regularly. We also aim to cultivate a larger donor pool in this region.

ENHANCING THE DONOR EXPERIENCE

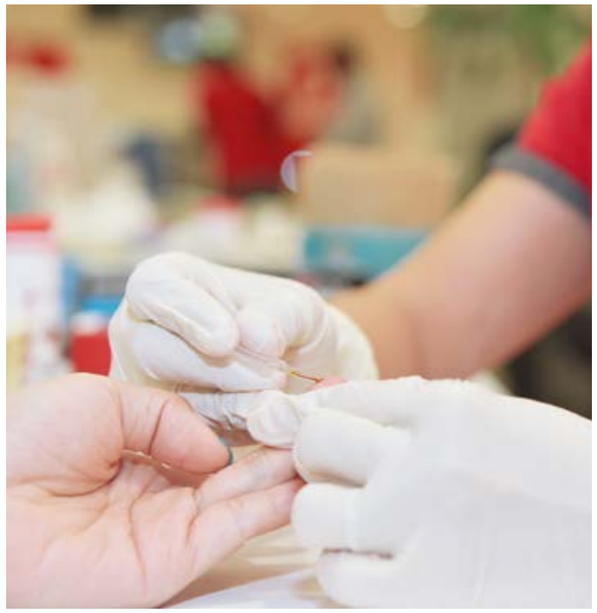
Seamless and Secure Donor Portal System

In November 2019, we integrated our donor portal system with MyInfo, a one-stop data platform that saves time by automatically filling out government e-forms. With this new change:

- New donors can retrieve and update their particulars with just one click.
- Security of the system has been enhanced with a password policy and new infrastructural architecture set-up for a more secure connection.

Refining the Donation Process

We have streamlined the donation process to improve donation experience and turnaround time. Blood donors can now proceed directly for the haemoglobin test immediately after registration. This means that only donors who have passed the haemoglobin test need to undergo medical screening. This has brought greater convenience to blood donors and the shorter donation time has led to increased overall donor satisfaction.



Recognising Our Blood Donation Champions

A total of **496** Award Recipients attended

27 donors received the Champion of Champions Award

14 received the Medal for Life Award

16TH WORLD BLOOD DONOR DAY

In June 2019, we celebrated the 16th World Blood Donor Day at Downtown East with our Guest of Honour, Dr Amy Khor, Senior Minister of State, Ministry of Health and Ministry of the Environment and Water Resources. Also present as a special guest was Member of Parliament for Tampines GRC, Ms Cheng Li Hui.

Highlights of the event, which was themed "Be There for Someone Else. Give Blood. Share Life." included:

- Table-top games, skit performances and inflatable obstacle courses.
- Booths showcasing services from the Blood Donor Recruitment Programme, Thalassemia Society and the National Organ Transplant Units.

SECURING OUR BLOOD SUPPLY IN A SUSTAINABLE MANNER . . .

To ensure the safety of Singapore's blood supply, we rigorously conduct tests, as well as come up with appropriate mitigation strategies while ensuring precious resources are well-utilised.

REVISED MALARIA TESTING STRATEGY FOR AT-RISK DONORS

Previously, all donations from donors with malaria risk exposure and a history of travel to malaria-endemic areas have to be tested using both antibody test and molecular test by polymerase chain reaction (PCR) technique. However, we have observed that the malaria antibody is as sensitive as malaria PCR for donors who have no history of residence in malaria-endemic areas. Hence, we have revised the malaria testing strategy in December 2019.

Now, all at-risk donations will undergo the antibody test and the additional PCR test is only required for the following groups of donors:

- Donors who have resided for at least 6 consecutive months in a malaria-endemic country.
- Donors who travel more frequently than once in every 4 months to malaria-endemic areas.
- Regular donors with previous history of malaria.

IMPROVING PRODUCTIVITY AND EFFICIENCY . . . .

We are committed to pursuing excellence through the improvement of our work processes.

ADOPTING FLOW CYTOMETRY AS THE NEW STANDARD FOR DETECTING SENSITISATION IN RENAL PATIENTS

With the advancement of technology, the Complement Dependent Cytotoxicity (CDC) Method to screen renal patients on the kidney transplant waitlist for human leucocyte antigen (HLA) antibody has been replaced by Flow Cytometry.

Benefits of this new method include:

- More accurate level of sensitisation in patients, thereby enabling physicians to make better decisions with regard to pre- and post-transplant management.
- Better accuracy in determining whether a patient is suitable for transplant.
- Results within 7 working days as compared to 21 days using the old CDC method.

EXTENDING THE SHELF-LIFE OF THAWED FROZEN BLOOD TO 14 DAYS

By implementing a closed system protocol for freezing blood to prevent contamination, and introducing the use of red cell additive solution (AS-3), we have extended the shelf life of thawed frozen blood from 24 hours to 14 days.

This new protocol has helped us to improve our blood inventory, as well as enabled us to make more efficient use of thawed frozen blood for patients.

PARTNERSHIPS AND COLLABORATIONS . . . . .

Over the past year, we partnered with hospitals and laboratories to improve patient health outcomes.

PROJECT CRYOSPHERE II

Project Cryosphere II is a clinical study, done in collaboration with DSO National Laboratories and the Singapore General Hospital (SGH), to test the safety and efficacy of using the cryopreservation method to lengthen the lifespan of platelets from five days to two years.

For the study which started in October 2019, HSA provided operational support by helping in the preparation of cryopreserved pooled platelets for clinical study. If successful, we will be able to stockpile cryopreserved platelets for specific clinical use, as well as improve our emergency preparedness.

AN ALTERNATIVE SOURCE OF SKIN

HSA commenced a clinical study involving the SGH Skin Bank to assess the safety and efficacy of laminin-based Culture Epithelial Autograft (CEA) as a skin equivalent for treating burns and plastic surgery patients.

We provided a clean room facility for the SGH Skin Bank to manufacture the epithelial autografts. With the validation currently underway, there are plans to apply for the clinical study certificate by the end of this year.

WORKING TOWARDS PRODUCING CHEAPER LOCALLY-PRODUCED CAR-T CELL PRODUCTS

We partnered with KK Women's and Children's Hospital and SGH's Haematology department to assess the safety and efficacy of using CD19+ CAR-T cells for patients with relapsed or refractory B-cell leukaemia and lymphoma.

Our Cell Therapy Facility helped manufacture genetically-engineered T cells under Current Good Manufacturing Practices (cGMP) conditions for clinical studies. If successful, this initiative will pave the way for patients to have access to CAR-T cell products locally, as well as expand on more customised directed treatments for patients.

SHARING OUR KNOWLEDGE . . . . .

Over the year-in-review, HSA engaged with partners through various knowledge sharing platforms to raise the standards of blood services.

SUCCESSFULLY CONCLUDED FIRST CERTIFICATE COURSE WITH SINGAPORE POLYTECHNIC

Over a duration of 10 weeks, a total of 16 participants from private and public hospitals attended a training course "Principles and Practices in Immunohaematology" at Singapore Polytechnic.

Through this course, participants were:

- Updated on the latest developments in the field of immunohaematology.
- Able to improve their technical competencies in pre-transfusion testing through hands-on practical sessions.

SRS (STAFF REGISTRAR SCHEME) DIPLOMA IN TRANSFUSION MEDICINE

The SRS Diploma in Transfusion Medicine offered by Academy of Medicine Singapore is a structured two-year course that seeks to equip resident physicians at HSA with the necessary expertise in transfusion medicine.

In April 2020, we saw our second batch of students graduate from the programme.

Harnessing Research and Innovation

- Leveraging technologies to provide cutting-edge scientific services
- Establishing strategic partnerships to meet evolving needs
- Inspiring thought leadership in regional and international scientific committees and workgroups

APPLIED SCIENCES GROUP

BUILDING CAPABILITIES . . . .

To stay ahead of today's rapidly changing environment, we are constantly enhancing our capabilities to provide innovative and cutting-edge scientific solutions.

ENHANCING DNA RECOVERY FROM COLD CASE EXHIBITS

HSA acquired an innovative tool to improve the recovery of DNA deposited on porous exhibits, including those with rough surfaces. Unlike conventional methods of DNA collection, this tool makes use of a unique wet-vacuum technology to enhance DNA recovery from exhibits, thereby potentially maximising the evidential value of exhibits from cases that have previously failed to yield DNA profiles during initial examination. Working in tandem with the Singapore Police Force (SPF), HSA has already successfully developed profiles from a cold case exhibit, which was collected more than 20 years ago.

NEW PROCEDURES TO ISOLATE NOVEL ILLICIT DRUGS FOR IDENTIFICATION

HSA has developed new procedures to identify novel illicit drugs without existing drug standards. The drugs can be isolated from drug matrices using either Preparative Thin Layer Chromatography or Preparative Liquid Chromatography techniques and then identified using a comprehensive analytical workflow consisting of various analytical instrumentations. This facilitates timely detection of new drugs, hence enabling the Central Narcotics Bureau (CNB) to prosecute drug abusers and traffickers promptly.

MITOCHONDRIAL DNA – A VALUABLE NEW TOOL FOR ANALYSING HIGHLY DEGRADED SAMPLES

Mitochondrial DNA (mtDNA) is a specialised type of maternally inherited genetic material in the body that is present in copious amounts. Due to its robust nature, there is a higher success rate of recovering mtDNA from degraded samples.

Recognising the value of mtDNA analysis for Disaster Victim Identification (DVI) and other scenarios where highly degraded samples are common, HSA undertook a massively parallel sequencing approach to develop our whole mitochondrial genome sequencing capability, and establish a Singapore mtDNA sequence haplotype database.

In 2019, we participated in a collaborative mtDNA study organised by the European DNA Profiling group (EDNAP) to validate our competency in this new capability.

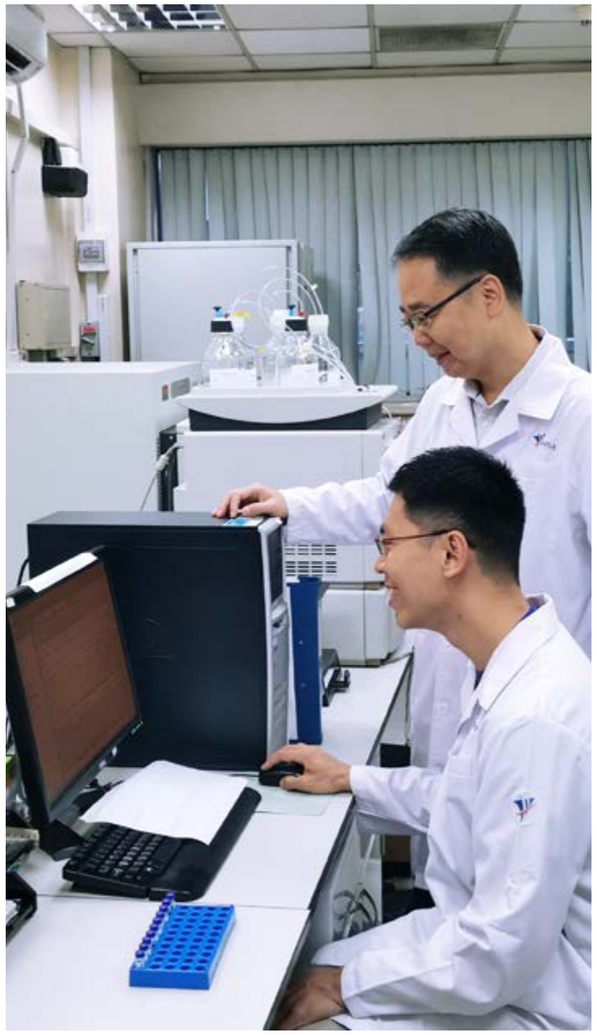
PROTECTING PUBLIC HEALTH . . . .

We ensure public health and safety is maintained through rigorous product testing.

DETECTING NEW CANCER-CAUSING IMPURITY IN RANITIDINE AND METFORMIN PRODUCTS

In July 2019, HSA was alerted to the potential contamination of N-nitrosodimethylamine (NDMA) in ranitidine-containing products by its overseas counterparts. As there was no test method for such analysis available internationally, we had to develop our own testing methodologies. We successfully developed Liquid Chromatography-High Resolution Mass Spectrometry (LC-HRMS) and Liquid Chromatography Hybrid Tandem Mass Spectrometry (LC-MS/MS) methods to identify and quantitate the presence of NDMA in ranitidine products. We have since shared our test methods with overseas counterparts and the industry.

In October 2019, we went on to develop a highly sensitive High Resolution Accurate Mass-Gas Chromatography Mass Spectrometry (HRAM-GCMS) method for the detection of NDMA specifically in metformin products. This procedure requires a detection limit that is 10 times lower, due to the high therapeutic daily dose of metformin.



We tested a total of **66** **ranitidine** and **134** **metformin products**. Staff went the extra mile to achieve a fast turnaround-time, enabling HSA to recall the affected products in a timely manner. Great synergy and teamwork between the Applied Sciences Group and the Health Products Regulation Group was essential in protecting public health and safety.

IMPROVING OUR PROCESSES . . . .

We continually improve our work processes by leveraging new technologies to enhance efficiency.

BOOSTING LABORATORY EFFICIENCY THROUGH AUTOMATION

An automated system for qualitative drug analysis was developed using a multi-purpose automated sampler mounted onto a gas chromatograph mass spectrometer (GC-MS). This system has the ability to perform a series of laborious manual sample preparation steps, such as addition of solvents to sample vials, mixing of contents within the vials and transferring the contents to vials for instrumental analysis.

With the creation of a seamless workflow between sample preparation and the GC-MS, we were able to achieve better efficiency and a reduction in analysis time.

TAPPING ON SINGAPORE-WIDE 3D POINT CLOUDS FOR TRAFFIC ACCIDENT RECONSTRUCTION

3D point clouds provide our forensic scientists with comprehensive, highly accurate data to visualise, measure and model crash sites remotely. HSA has been leveraging very successfully on the point cloud data of Singapore's roads collected by the Singapore Land Authority (SLA), as part of the Smart Nation initiative.

This platform has been greatly beneficial, eliminating inconveniences caused by road closures, and enabling a more efficient allocation of resources from HSA and its partners.

AUTOMATION OF LABORATORY PROCESSES USING ROBOTIC PROCESS AUTOMATION (RPA)

Through an RPA training in 2019, our staff realised the potential for the automation of mundane tasks that required high accuracy to free up time to do higher-value work. Two projects have since been undertaken:

Automation of Daily FTIR Performance Checks

Sensitive Fourier-Transform Infrared (FTIR) spectroscopic techniques are used for trace material analyses. To ensure accurate and reliable results, the performance of the instrument is checked thoroughly prior to each day of analysis. Traditionally, the process for a single daily check including manual verification could add up to quite a few hours each month. This RPA project enabled automation of text scraping, pass-criteria evaluation, e-filing of records and output to the monitoring software.

Time-savings of up to **15 minutes** per check

Consistent and **error-free data**

Automation of Video Frame Extraction for Traffic Reconstruction Cases

To determine the speeds of vehicles accurately for traffic reconstruction cases, videos are converted into a series of individual images ("frames") via an extraction process. Timestamp information may be present and is an indicator of time accuracy. For cases that involve proprietary video player programmes, timestamp information for each frame has to be obtained manually and cannot be retrieved using generic video extraction software. As videos typically contain several hundreds to thousands of frames, the process can be time-consuming. This RPA project allowed for automatic frame extraction and consolidation of each frame's timestamp information to a log file.

Previous method:

120 minutes to process a case

Automated method:

15 minutes to process a case

EMBRACING AUTOMATION: DISSOLUTION TESTING PROCESS

We successfully completed the verification study involving the automation of the Pharmaceutical Laboratory's dissolution work processes in September 2019.

By automating the media preparation and washing processes, we managed to greatly enhance operators' reproducibility, alleviate laborious work processes and increase staff productivity.

DIGITISATION OF CONTROL FORMS AND EQUIPMENT MAINTENANCE RECORDS

We implemented an initiative to digitise the bulk of hard-copy records maintained in the Pharmaceutical Division labs. Handwritten control forms were converted to writable PDF documents with the incorporation of electronic signatures. This initiative is an important part of the division's journey towards a paperless work environment.

FORGING STRONGER TIES WITH OUR PARTNERS . . . .

Collaborations and close relationships with our partners enable us to keep reaching greater heights.

COLLABORATION WITH CHINA TO STRENGTHEN MYCOTOXIN TESTING CAPABILITY IN FOOD

In 2017, HSA and the National Institute of Metrology (NIM), China signed a Partnership Agreement for a cooperation project, which was funded by the Ministry of Science and Technology of the People's Republic of China.

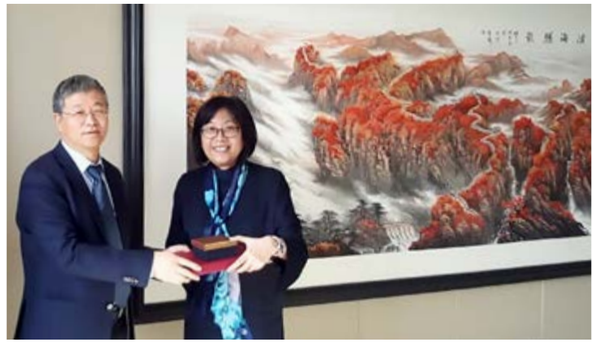
As part of this partnership agreement, a Scientist from the Chemical Metrology Division (CMD) was attached to NIM from August to October 2019 to work on mycotoxins in different matrices. Additionally, an inter-regional proficiency testing programme on zearalenone in maize was also co-organised with NIM from November 2019 to March 2020.

LEADERSHIP IN ASIAN FORENSIC SCIENCES NETWORK

Asian Forensic Sciences Network (AFSN) has been an important platform for forensic scientists in Asia to share research and advances, exchange data, discuss best practices and enhance quality of forensic services through training and education. HSA was elected as the President for a two-year term in September 2019.

VISIT TO THE NATIONAL INSTITUTES OF FOOD AND DRUG CONTROL (NIFDC)

We visited the new campus of NIFDC in Daxing District, Beijing, China, in November 2019. The visit provided a better understanding on the functions and scope of the different Institutes under NIFDC and the opportunity to explore possible areas of collaboration.



INTERNATIONAL WORKSHOP ON THE REGULATION AND DISCLOSURE OF THE CONTENTS OF TOBACCO PRODUCTS IN BEIJING, CHINA

In December 2019, the Cigarette Testing Laboratory (CTL) was invited to speak at a workshop which was organised and hosted by China's State Administration for Market Regulation (SAMR) and the Chinese Academy of Inspection and Quarantine (CAIQ). The workshop covered technical advances in tobacco contents control and disclosure, which are valuable for CTL in advancing its tobacco research work.

2ND INTERNATIONAL SYMPOSIUM OF FORENSIC DRUG TESTING LAB DIRECTORS

In July 2019, laboratory directors and toxicologists from 23 countries came together in Singapore to establish the concept of a global toxic adulterant database. This meeting enabled the various laboratories to exchange information, establish drug trends, and share knowledge on emerging new drugs and toxic adulterants in illicit drugs. HSA delivered two presentations and facilitated a practical demonstration on handheld screening devices. We also hosted a visit to the HSA Forensic Labs.

COLLABORATIONS WITH THE SINGAPORE POLICE FORCE (SPF)

Improving Disaster Victim Identification Operations

Together with the SPF and a forensic odontologist, we organised a Disaster Victim Identification – Ground Deployment Exercise (DVI-GDX) in November 2019. Key focuses of the exercise included downstream integration with the DNA Profiling Lab's processes for DNA samples and testing of the DVI module of Forensic Medicine Division case management system. Coupled with the GDX organised by SPF in January 2019, which focused on upstream processes, a greater understanding of DVI operations as a whole was achieved.

Alternate Light Source for Stain Selection

In sexual assault cases, the successful detection of semen on exhibits is crucial as it may provide leads on the identity of the perpetrator. Technologies such as the alternate light source facilitate the identification of semen-stained areas on exhibits – potentially saving time and resources, particularly when processing exhibits with large surface areas. To maximise the potential of this technology, we initiated a joint study with SPF to fine-tune the process of stain selection on exhibits for a more efficient workflow.

VISITORS FROM THE STATE COURTS

In October 2019, HSA welcomed 11 officers from the State Courts, including Ms Kamala Ponnampalam, State Coroner, Mr Seah Chi-Ling, Deputy Principal District Judge, and Mr Toh Han Li, District Judge.

The visit provided the officers from the State Courts with a better understanding of forensic evidence, and gave brief insights into the value of various evidence types and how exhibits are handled at the different forensic laboratories. We also took the opportunity to interact and exchange experiences from two different perspectives – Science and Law.

PARTNERING HEALTH PROMOTION BOARD (HPB) IN SINGAPORE'S NATIONAL SMOKING CONTROL PROGRAMME

We were invited to share on the science and myths of vaping to a group of professional nurses and allied health professionals, who provide lifestyle counselling to at-risk youths. This sharing session, held in November 2019, is part of HPB's continuous upskilling programme to promote a healthy lifestyle among Singaporeans.

CHAO TZEE CHENG PROFESSORSHIP IN PATHOLOGY AND FORENSIC SCIENCE PROGRAMME 2019

In December 2019, HSA collaborated with NUS to organise a one-day workshop on forensic science as part of the programme's scientific track. The workshop covered topics on traffic crash reconstruction and the detection of New Psychoactive Substances in drugs and urine, as well as its clinical effects. Many participants from various agencies such as the Immigration & Checkpoints Authority, SPF, Attorney-General's Chambers, hospitals and educational institutions attended the event.

TRAINING PROGRAMME FOR CENTRAL NARCOTICS BUREAU (CNB) IN EXHIBIT PROCESSING

In partnership with CNB, we developed an exhibit processing training programme for 12 Forensic Response Team (FORT) officers, which was tailored to their existing work processes. Officers were introduced to basic concepts in DNA profiling, with a focus on techniques in exhibit processing, and good practices to observe in preserving exhibit integrity. To simulate a real case scenario, mock exhibits were used, which helped to reinforce key learning points taught.

INCREASING OUR KNOWLEDGE BASE . . . .

We conduct regular training sessions and knowledge exchange programmes with overseas counterparts to support successful collaborations in scientific developments.

HUMAN IDENTIFICATION IN DISASTER VICTIM IDENTIFICATION (DVI)

May 2019

We attended a one-day seminar conducted by experts from Austria, Belgium, Netherlands, Poland and Sweden, on human identification in DVI scenarios. This panel of experts, consisting of fellow members from the INTERPOL DVI Forensic Genetics Sub-Working Group (ForGenSWG), also shared updates on current efforts in victim identification from the MH17 plane crash, and the methods and work processes their laboratories had in place to facilitate victim identification. Such sharing among laboratories provides valuable insights into workflow considerations in DVI scenarios, and helps to refine our preparations for future DVI scenarios and exercises.

WORKSHOP ON TOXICOLOGY

June 2019

Staff from the forensic labs, together with officers from SPF, attended a two-day workshop conducted by Dr Marc LeBeau, a senior science advisor at the Scientific Analysis Section of the US FBI Laboratory. The workshop covered topics including cause mapping approach to root cause analysis, drug facilitated sexual assault challenges and method validation.

Y-CHROMOSOME WORKSHOP FOR FORENSIC DNA PRACTITIONERS

November 2019

To strengthen the capabilities of laboratories in Y-chromosome testing, a tool that is used increasingly in sexual assault cases, HSA co-hosted the workshop, "The Y-Chromosome in the Forensic Laboratory: Sexing, Profiling and Matching Male DNA", with Promega. Led by Professor Lutz Roewer, the pioneer of Y-chromosome testing, the workshop encompassed a series of lectures and hands-on sessions, including pertinent topics in Y-chromosome testing such as interpretation guidelines, as well as methods for statistical calculations.

The **3-day workshop** was attended by **75 participants** from 11 countries all over Asia.

EMERGING TRENDS AND TECHNOLOGIES IN FORENSIC GENETICS

November and December 2019

Dialogue sessions held with forensic genetics experts – Associate Professor Ricky Ansell from the Swedish National Laboratory of Forensic Science, Dr. Bo Thisted Simonsen, head of the forensic genetics division and Professor Niels Morling from the Department of Forensic Medicine, University of Copenhagen provided HSA with insights on the latest trends and technologies in forensic genetics. Beyond that, the sessions also deep-dived into research activities within each team. The experts concurred that our research projects were aligned with the international forensic community and of the depth essential to advancing our capabilities in forensic genetics testing.

EXPANDING OUR CHEMICAL METROLOGY CAPABILITIES . . . .

We continually expand our chemical metrology capabilities and translate these into relevant services for the local testing community.

PARTICIPATION IN INTERNATIONAL COMPARISONS

We completed five international comparisons to benchmark our capabilities against other metrology institutes and reference laboratories in laboratory medicine. These included:

- HbA1c in Lyophilised Human Haemolysate
- Total Glycerol (Total Glycerides) in Lyophilised Human Serum
- Calcium in Lyophilised Human Serum
- Fipronil-sulfone in Chicken Egg Powder
- Elements (Arsenic, Cadmium, Copper and Lead) in Seawater

INTERNATIONAL/REGIONAL COMPARISONS

We organised/co-organised the following international/regional comparisons:

- Consultative Committee for Amount of Substance: Metrology in Chemistry and Biology (CCQM) key comparisons and parallel pilot studies on Purity Assessment of Glycated and Non-Glycated Hexapeptides (as calibrators for HbA1c Measurement)
- Asia Pacific Metrology Programme (APMP) supplementary comparison and parallel pilot study on Elements (Arsenic, Cadmium, Mercury and Lead) in Lipstick Material
- Inter-laboratory comparison for members of the ASEAN Reference Material Network (ARMN) on Determination of Water, Residual Organic Solvent and Total Non-Volatiles in an Organic Compound

PROFICIENCY TESTING (PT) AND EXTERNAL QUALITY ASSESSMENT (EQA) PROGRAMMES

We organised/co-organised four accuracy-based PT schemes on chemical testing. These included:

- Polycyclic Aromatic Hydrocarbons in Olive Oil for food testing laboratories
- Inorganic Elements (Arsenic, Cadmium & Lead) in Herbal Material for food and pharmaceuticals testing laboratories
- Zearalenone in Maize, co-organised with the National Institute of Metrology, China for food testing laboratories
- Additives in Tomato Sauce, co-organised with the members of the ASEAN Reference Material Network for food testing laboratories in Indonesia, Malaysia, Philippines, Singapore and Thailand

We organised two accuracy-based EQA programmes:

A regular programme which covered a total of 16 clinical analytes.

41 local public and **private clinical laboratories** in Singapore participated

A mandatory programme on HbA1c testing for laboratories and clinics providing HbA1c results for the initial screening of diabetes mellitus.

59 public and **private clinical laboratories** and **medical clinics** in Singapore participated

CERTIFIED REFERENCE MATERIALS (CRMs) PROGRAMME

We expanded our list of CRMs to include two food matrix materials and one clinical matrix material. They were:

Food Matrix Materials

- Polycyclic aromatic hydrocarbons (benz[a]anthracene and benzo[a] pyrene) in olive oil.
- Additives (benzoic acid, sorbic acid, methyl paraben, n-propyl paraben and n-butyl paraben) in soy sauce.

Clinical Matrix Material

- Testosterone in human serum

TRAINING COURSES CONDUCTED

We conducted the following training sessions on mass spectrometry and statistics for:

Participants	Subject
Two scientists from the National Metrology Laboratory-Industrial Technology and Development Institute of Philippines	"Isotope Dilution Mass Spectrometry" and "Standard Addition for Inorganic Analysis"
Two scientists from Biotransformation Innovation Platform, Agency for Science, Technology and Research (A*STAR)	"Linear Regression Isotope Dilution Mass Spectrometry for Organic Analysis"
Local testing laboratories and assessors	"Statistical Methods for Use in Inter-Laboratory Comparisons" based on ISO 13528, in partnership with the Singapore Accreditation Council

ALIGNING TO GLOBAL STANDARDS . . . .

A key priority of HSA is ensuring that we are continually raising the bar and keeping pace with international standards.

PROFICIENCY TESTING (PT) SCHEME STUDIES

We achieved excellent results in the following benchmark PT Programmes:

- Assay of Nitrofurazone by ASEAN Bureau of Drug and Narcotic (BDN)
- Assay of Nalidixic Acid Tablet by European Directorate for the Quality of Medicines & HealthCare (EDQM)

GLASS INTERPRETATION WORKING GROUP INTER-LABORATORY TRIAL

In January 2020, we participated in an inter-laboratory collaborative exercise for an ongoing project by the Glass Interpretation Working Group. This is the first in a series of inter-laboratory tests organised by Dr Jose Almirall of Florida International University in a project to create new commercially-available glass calibration standards for use with the Laser Ablation Inductively-Coupled-Plasma Mass Spectrometry (LA-ICP-MS) application. Our Forensic Chemistry & Physics Lab, together with various international laboratories, are serving as reference laboratories for the validation of these standards.

ESTABLISHMENT OF INTERNATIONAL CHEMICAL REFERENCE SUBSTANCES (ICRS)

We participated in inter-laboratory collaborative studies, organised by the European Directorate for the Quality of Medicines & HealthCare (EDQM) to establish the reference substances for Ciprofloxacin hydrochloride and Moxifloxacin hydrochloride for WHO International Pharmacopoeia.

SUPPORTING ISO ACCREDITATION SCHEMES LOCALLY AND ABROAD

The Laboratory Director and Deputy Laboratory Director of the Pharmaceutical Division (PD), were engaged by Singapore Accreditation Council (SAC) to be their Team Leader and Technical Assessor, respectively, in local audit activities. PD's Laboratory Director was also appointed by Gulf Accreditation Council (GAC) to be their technical assessor in the field of cosmetics and tobacco testing. They participated in seven assessments during the year-in-review with three overseas assignments.

APPOINTMENT AS HOKLAS TECHNICAL EXPERTS

Two staff from the Forensic Chemistry & Physics Laboratory and Quality Assurance Unit, were appointed as Hong Kong Laboratory Accreditation Scheme (HOKLAS) technical experts. As part of their appointment, they were invited in April 2019 to the Government Laboratory of Hong Kong to assess the laboratory under HOKLAS test categories of "Proficiency Testing Providers" and "Forensic Testing" for forensic science.

LOCAL AND INTERNATIONAL EVENTS . . .

We were actively involved in the following local and overseas scientific events.

ACCREDITATION ASSESSMENT OF THE GOVERNMENT LABORATORY OF HONG KONG

Hong Kong
Apr 2019

ASEAN REGIONAL WORKSHOP ON ELECTRONIC NICOTINE DELIVERY SYSTEMS (ENDS) AND HEATED TOBACCO PRODUCTS (HTPS)

Bangkok, Thailand
Oct 2019

36TH SYMPOSIUM OF KOREAN SOCIETY OF FORENSIC SCIENCES

South Korea
Jun 2019

INTERFORENSICS 2019 INTERNATIONAL CONFERENCE OF FORENSIC SCIENCE

São Paulo, Brazil
May 2019

11TH REGIONAL SYNTHETICS MONITORING: ANALYSES, REPORTING AND TRENDS (SMART) WORKSHOP FOR EAST AND SOUTHEAST ASIA (ORGANISED BY UNITED NATIONS OFFICE ON DRUGS AND CRIME)

Singapore
Aug 2019

Singapore
Nov 2019

INTERNATIONAL ORGANISATION FOR STANDARDISATION ISO/TC272 FORENSIC SCIENCES MEETING

Taipei, Taiwan
Jun 2019

2019 APEC INTERNATIONAL WORKSHOP ON FOOD SAFETY AND THREAT FROM NPS

COLLABORATING WITH THE WORLD HEALTH ORGANIZATION (WHO) . . . .

During the year-in-review, we continued to actively participate in WHO activities.

MONOGRAPH DEVELOPMENT WORK FOR THE INTERNATIONAL PHARMACOPOEIA

We successfully completed the development of a high-performance liquid chromatography (HPLC) assay test for the draft monograph on Tetracycline Hydrochloride. This monograph was accepted by the WHO Expert Committee in October 2019 for inclusion to the Ninth Edition of *The International Pharmacopoeia*. The laboratory also supported the WHO in the review of its proposed monographs on Pyrimethamine and Pyrimethamine tablets, which is scheduled for publication in the Tenth Edition of *The International Pharmacopoeia* in 2020.

REVIEW OF THE LATEST SCIENTIFIC EVIDENCE ON CIGARETTE VENTILATION

In June 2019, we co-authored a background paper with Professor Dorothy Hatsukami, a renowned researcher in tobacco addiction. This paper, together with seven other papers on the same subject, were subsequently discussed at a WHO Meeting to review the latest scientific evidence on the impact of cigarette ventilation on cigarette use in November 2019.

The outcome of this meeting has been shared with regulators worldwide, including the Ministry of Health (MOH) and HPB, to facilitate better understanding of the subject and examine how regulations could further strengthen the implementation of Articles 9 and 10 of the WHO Framework Convention on Tobacco Control (FCTC). The reviewed paper will be published in the WHO Technical Report Series and peer-reviewed journals.

WHO CONSULTATION MEET ON QUALITY CONTROL LABORATORY TOOLS AND SPECIFICATIONS FOR MEDICINES

The event was held at the WHO Headquarters in Geneva, Switzerland in May 2019.

PARTICIPATING IN ASEAN ACTIVITIES . . . .

We continue to work closely with our ASEAN counterparts to share knowledge and best practices.

ASEAN REFERENCE SUBSTANCES PROJECT

Through the ASEAN Reference Substances Project, ASEAN secondary drug reference standards have been established to provide an important source of reliable drug reference substances for use in ASEAN member countries. We took the lead in the establishment of an ASEAN Reference Substance (PARS) – Hydroxyzine Hydrochloride, together with Indonesia, Philippines and Vietnam in an inter-laboratory collaborative study. In addition, we were also involved in the inter-laboratory study of Amoxicillin Trihydrate, led by Thailand.

ASEAN COSMETICS TESTING LABORATORY COMMITTEE (ACTLC) COMPARISON STUDY

We participated in an inter-laboratory comparison study on "Determination of 1,4 dioxane in cosmetic products" together with other laboratories from ASEAN member states and the Korean Ministry of Food and Drug Safety. The comparison study served as a form of capability building for the national laboratories in ASEAN, as well as provided a good platform for scientific collaboration between Korea and ASEAN.

FIRST ASEAN ACCURACY-BASED PT PROGRAMME ON ADDITIVES IN FOOD SAUCE

HSA, the National Metrology Laboratory-Industrial Technology and Development Institute of Philippines, and Thailand Institute of Scientific and Technological Research jointly organised the first-ever ASEAN Reference Material Network accuracy-based PT programme on additives in food sauce. Two other metrology institutes, the Department of Chemistry, Malaysia, and National Measurement Standards – National Standardization Agency, Indonesia, also launched the PT programme for their local testing laboratories.

The PT programme has been offered to over 40 laboratories in five ASEAN economies (Indonesia, Malaysia, Philippines, Singapore and Thailand) to enable them to assess their capabilities in the measurement of the additives against reference values assigned by metrology institutes.

WORKSHOP ON PHARMA LAB NETWORK

In June 2019, we attended a workshop under the ASEAN Pharmaceutical Product Working Group (PPWG) Penang, Malaysia. Our representatives shared about their General Official Medicines Control Laboratories associated membership experience with ASEAN Counterparts.

At this workshop, which was supported by the ARISE (ASEAN Regional Integration Support/EU) Plus programme, it was agreed that there was a significant need to establish a formal network of national pharmaceutical laboratories within ASEAN. We were appointed to take the lead in supporting ARISE to draft the Terms of Reference for the formation of this network.

GAINING RECOGNITION . . ..

At HSA, we are continually striving to uphold the highest standards in all that we do. Our awards and accolades are testament to this.

MINISTRY OF HOME AFFAIRS (MHA) OPERATIONAL EXCELLENCE AWARD

At the Minister's Awards Presentation Ceremony at ITE College West in September 2019, the Illicit Drugs Laboratory received a Certificate of Appreciation for their help in providing scientific support at the scene, and for analysis of drug exhibits in Operation Nova Prime I, II and III. These efforts contributed to the busting of a clandestine laboratory in April and May 2018.


Certificate of Appreciation

Presented to

Health Sciences Authority

for

involvement in Operation Nova Prime I, II and III

K SHANMUGAM
Minister for Home Affairs And
Minister for Law
30 September 2019

PUBLIC SECTOR TRANSFORMATION (PST) AWARDS

During the PST Awards Celebration in January 2020, Ms Hilda Loh of the Analytical Toxicology Laboratory received the Exemplary SkillsFuture @ Public Service Award (one of five categories under the Public Sector Transformation Awards).

Her efforts towards learning new digital skills, deepening existing capabilities, and upskilling of herself and others has made her a role-model for lifelong learning and people development.

Igniting Change for Enhanced Productivity

- Formulating solutions for future readiness
- Supporting organisation-wide transformation
- Ensuring seamless corporate service experiences

CORPORATE SERVICES GROUP

LOOKING TO THE FUTURE . . . . .

To tackle future challenges and achieve our goals, we regularly review our strategies to ensure they remain relevant and work towards ensuring the requisite capabilities are in place.

HSA 5-YEAR STRATEGIC ROADMAP (2020-2024)

We have refreshed our 5-year strategic roadmap to align our strategic direction with the on-going transformation efforts.

Our goals over the next five years include:

1. Having a fit-for-purpose and least burdensome regulatory approach that safeguards and advances public health; supported by a user-centric, digitalised system.
2. Building a digitalised, automated and secured blood service.
3. Providing cutting edge scientific services, supported by seamless, digitalised, automated work processes.
4. Delivering a seamless corporate service experience.

These strategies are built upon the following strategic pillars as the foundation:

ENHANCED CYBERSECURITY ENVIRONMENT

As we embrace digitalisation, we recognise the need to enhance cybersecurity to safeguard IT systems and data in HSA. In line with cybersecurity best practices, critical IT systems in HSA have been migrated to the Government Data Centre which features state-of-the-art cybersecurity tools and a scalable hosting environment.

PROFESSIONAL MATTERS . . .. . .

We continually review our staff development policy and develop programmes to ensure our staff acquire the skillsets needed for their professional development and personal growth.

PROFESSIONAL DEVELOPMENT FRAMEWORK

Professional Critical Skills Identification Exercise

As a follow-up to the exercise completed in FY17/18 to identify the critical skills for business continuity and sustainability, HSA developed a list of Professional Future Critical Skills, complemented by a set of Data Science Competencies. This will help HSA professionals equip themselves with the skills required for the future.

Professional Leadership Development Programme 2020

Our in-house Professional Leadership Development Programme (PLDP) – "Channelling Leadership", provides selected participants from across HSA an opportunity to nurture their leadership potential through the Modular Management Training (MMT), project work and informal coaching.

Comprising three modules, the MMT provides participants the opportunity to engage with external and internal subject matter experts, as well as HSA senior professionals to learn more about the knowledge and practices relating to management.

In February 2020, participants from our 2018 pilot cohort received their certificates for completing the programme. At the same time, a second-run of PLDP also commenced.

Attended by more than **300** staff.

CONTINUING PROFESSIONAL EDUCATION PROGRAMMES

Science and Innovation Day 2019

In July 2019, HSA held its 3rd Science and Innovation Day. This event promotes a research and innovation culture in HSA by facilitating the exchange of scientific information and innovative ideas, and recognising staff who have contributed to research and innovation.

The theme for this event was "i-Transform the Future". The keynote speaker, Ms Gladys Wong, Senior Principal Dietician at Khoo Teck Puat Hospital shared about her own personal journey of embracing new technology (3D food printing) to fulfil a bigger dream of creating safer and personalised puree meals.

Highlights included **oral/ poster presentations, booth exhibitions** and **laboratory tours**, as well as a **hand-painted Garden of Transformation wall mural** consisting of various innovation and transformation ideas.

Professional Education Lecture Series – Turning Error and Risk Management into Opportunities

As part of our professional education lecture series, more than 100 participants attended each of the following talks held in 2019:

May 2019

"Aircraft Accident Investigation"

by ***Mr Chan Wing Keong and Mr Michael Alan Toft from the Transport Safety Investigation Bureau and Ministry of Transport.***

Aug 2019

"Crisis Management and Communications"

by ***Mr Priveen Raj Naidu, Chief Executive Officer, Reapra Aviation Partners.***

Tea-Time Tidbits – Life Hacks across HSA

Through our Tea-Time Tidbits initiative, 13 speakers across all four professional groups in HSA shared about innovative ideas and hacks that had been implemented in their course of work.

The ideas shared in the three sessions held at the HSA auditorium included the use of FormSG, Microsoft Access, Excel Macros to Python Programming, Data Analytics and 3D technology – all of which could potentially be adopted by fellow HSAians.

ENCOURAGING A RESEARCH AND INNOVATION CULTURE IN HSA

Research and Innovation Seed Grant

Our Research and Innovation Seed Grant seeks to facilitate research projects, as well as foster an innovative culture in HSA.

A total of **$40,000** was **awarded to 4 research projects in 2019.**

Research Clinics

Research clinics are conducted from time to time to support researchers in areas such as research design and methodology. In November 2019, A/Prof Alex Cook, Vice Dean (Research) from the Saw Swee Hock School of Public Health, gave a lecture-cum-research clinic on Bayesian Statistics.

Research Collaboration Workshop with A*STAR

In September 2019, a research collaboration workshop was held to discuss areas of mutual interest and to explore potential research collaborations between HSA and A*STAR. They include video and image analytics, cognitive and psychometrical computing, and materials and fluid-structure interaction simulation.

A total of **14 representatives from A*STAR** and **14 staff from HSA** attended the Research Collaboration Workshop.

ENGAGEMENT AND BRANDING . . . .

To raise awareness for issues that impact public health and safety, we engaged the media and public through a variety of platforms.

LAUNCH OF NEW USER-CENTRIC HSA WEBSITE

In November 2019, we unveiled a brand new user-centric HSA website. The new site was developed using User Experience (UX) design, and enables visitors to self-help and find the information they require in the easiest, fastest and most intuitive way.

For this project, we analysed data on website usage, and identified user behaviour and needs through in-depth interviews with key stakeholders. Feedback was also gathered and used to make improvements through the launch of beta sites.

1 **New UX-driven information architecture**

Key changes:

2 **Content rewritten to be succinct and clear**

3 **Self-help web tools**

Some of the newly launched tools include:

Blood donor eligibility tool: By answering a series of questions, potential donors are able to check on their eligibility to donate blood.

Traveller's medicine tool: Visitors to Singapore can check on the restrictions and import limits on different types of personal medication.

Medical device tools: Medical device companies are able to quickly and easily ascertain whether their product is considered a medical device in Singapore, the risk classification of their device, and what registration route to take.

MEDIA ENGAGEMENT

In FY 19/20, we engaged the media through issuance of press releases and news stories to raise awareness on issues that impact public health and safety, which include alerts on health products and appeal for blood.

Altogether, we published:

27 press releases

13 HSA updates

which resulted in **744** media articles

Highlights

1. A comprehensive feature on blood donation featuring interviews with HSA and Singapore Red Cross spokespersons, blood donors and blood beneficiaries on Frontline.
2. Clear and timely communications regarding drug recall issues such as ranitidine and metformin.
3. Participation in Channel NewsAsia's 3-part series "Crime Science", which explores how science and technology can aid in solving crimes. Our scientists shared about how New Psychoactive Substances were detected, how DNA phenotyping could predict the appearance of a person, and how traffic accident reconstruction was conducted.

MARKETING COLLATERALS

In FY19/20, we created marketing collaterals for various services and events such as the International Medical Device Regulators Forum.

We created a total of **271** marketing collaterals:

222 business collaterals

49 events

PUBLIC EDUCATION EFFORTS

Online Campaign – The Dangers of Buying Health Products Online

We continued our efforts to educate consumers on the dangers of buying health products from dubious or unknown online sources. In this campaign, the target audience comprised Internet-savvy Singaporeans, who:

- Bought health products (e.g. weight loss products, contact lenses and pain relief medicines) online.
- Were aged 18-65 years.

The six-week campaign featured HSA's animated video and artwork, which were deployed through advertisements run on Google platforms (YouTube and Google Display Network), and a video marketplace called Unruly, from late-January 2020 to March 2020.

Collaborating with MOM to Warn about Adulterated Health Products

We reached out to migrant workers, including domestic helpers, to advise them on the prohibition on supply of medicines, and the serious consequences of consuming adulterated health products.

We worked with the Ministry of Manpower (MOM) to broadcast our messages in:

- Newsletters
- Facebook posts on "MOM Friends" page
- Mobile app push notifications in English, Mandarin, Bengali and Tamil

Partnering with NCADA to Reach Out to Students

We collaborated with the National Council Against Drug Abuse (NCADA) to use social media to help correct the misconception among students that all legally available medicines were safe for consumption. We communicated to students the dangers of abusing prescription medicines such as modafinil to boost alertness and memory.

PEOPLE AND VALUES . . .

At HSA, we are committed to nurturing value-driven individuals who feel a strong sense of belonging, and who take pride in the work that they do.

PAYING TRIBUTE TO SERVICE DELIVERY OFFICERS

The #ServingSG series is an initiative launched by President Mdm Halimah Yacob, to pay tribute to the people who work tirelessly behind the scenes to serve Singapore and Singaporeans. As part of the series, the President's Office invited about 400 service delivery officers from across the various public service sectors to a tea reception at the Istana in January 2020. Five HSA officers, who were nominated for consistently delivering and upholding exemplary service standards, attended the reception.

SINGAPORE HEALTH QUALITY SERVICE AWARDS (SHQSA) 2020

In January 2020, HSA was invited to participate for the first time in SHQSA 2020. SHQSA is a nationwide award that recognises and celebrates the exemplary service excellence efforts of staff in the healthcare family. Altogether, there were three Gold winners from HSA.

HSA CUSTOMER SERVICE DAY 2020

In March 2020, HSA held its 11th Customer Service Day with the theme, "The Magic of the Human Touch". Speaking at the event was international speaker and business coach, Mr Christian Chua, who shared about how the human touch has the magical ability to lift and enhance the customer service experience.

A total of 52 HSA Outstanding Service to Customers Award (OSCA) 2019 were presented during the event. These included:

LEARN (E-LEARNING APPLICATION)

As part of the Smart Nation initiative to embrace digital transformation in the Public Sector, HSA started its e-learning journey with LEARN. LEARN is a one-stop digital learning platform developed by the Civil Service College that allows officers to upskill and reskill anytime, anywhere and at their own pace through learning resources that are available online.

CORPORATE SOCIAL RESPONSIBILITY (CSR) ACTIVITIES . . . .

At HSA, our commitment towards the community and the environment is expressed through our CSR Framework called CARE – "Community Action, Responsible for our Environment". Here are some highlights of our CSR initiatives in FY 19/20.

MOH-HPB-HSA HAIR FOR HOPE

In June 2019, HSA joined efforts with our colleagues from the Ministry of Health (MOH) and Health Promotion Board (HPB) to raise awareness and funds for the Children's Cancer Foundation.

20 volunteers from **MOH, HPB and HSA** shaved their heads to show children with cancer that they are not alone in their fight against cancer.

Together as a **One-MOH family**, we raised a total of

$31,794

for the Children's Cancer Foundation.

SHOP FOR A CAUSE WITH THE SENIORS

In October 2019, 36 HSA staff brought 35 seniors from the Lions Befrienders on a supermarket shopping trip to Giant Supermarket, Suntec City. This event is HSA's annual CSR initiative with the Lions Befrienders.

The smiles from the seniors were evident as they shopped for groceries and other necessities with our volunteers. The event ended with an afternoon tea break where our volunteers got to interact with the seniors.

SUSTAINABILITY WORKSHOPS@HSA

In December 2019, two Sustainability Workshops were organised to encourage HSAians to adopt a low or zero waste lifestyle. Our staff have given positive feedback and expressed their interest to join similar workshops in the future.

During the two workshops:

35 staff participated in the making of **Nature Bio Beeswax Wrap**, while another **26** staff **created diffusers using food ingredients**.

NURTURING A HEALTHY WORK ENVIRONMENT . . . . .

A healthy work environment is one where staff can co-create solutions for the workplace, have fun and learn together.

"BRING YOUR KIDS TO WORK" & HSA ACTIVE DAY

In September 2019, HSA held its annual "Bring Your Kids to Work" day. In total, we played host to around 50 children who participated in a Junior Investigator programme and collected evidence for a simulated "crime scene" activity.

On the same day, we also had our HSA Active Day, where staff and their children visited the Sustainable Singapore Gallery at Marina Barrage, and enjoyed a day of kite-flying.

HSA MAKEATHON

In September 2019, HSA engaged its officers through a Makeathon to come up with ideas to transform the experience of work into a fun and joyful one.

During the Makeathon, HSAians were introduced to various brainstorming tools such as "workplace journeys" – a process mapping tool to facilitate the brainstorm of ideas to streamline and improve work processes for greater efficiency and productivity.

Through this Makeathon, a couple of good ideas were generated, and are now further considered for implementation by the relevant divisions and departments.

OUR COMMITMENT TO EXCELLENCE . . . .

Over the year-in-review, we continued our pursuit for excellence by achieving the following certification standards.

SINGAPORE QUALITY CLASS (SQC) STAR WITH PEOPLE AND SERVICE NICHE STANDARDS CERTIFICATION

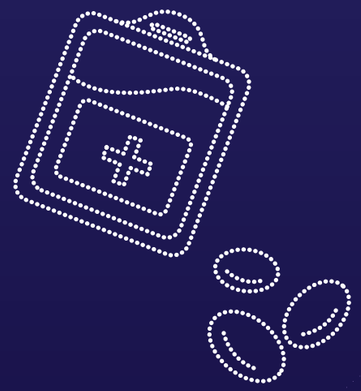
HSA's commitment towards organisational excellence was recognised with the achievement of the SQC STAR with People and Service Niche Certification. This accolade reaffirms our commitment to continually improve our organisation's systems, processes, practices and performance.

At the 25th Business Excellence Presentation Ceremony in October 2019, Chairman of the Singapore Quality Award (SQA) Governing Council, Professor Cham Tao Soon, and Director-General of Enterprise Singapore and SQA Administrator, Ms Choy Sauw Kook, presented the plaque of recognition to CEO of HSA, Dr Mimi Choong.

OUR WORK IN FIGURES

Blood Services Group

Key statistics as at end-December 2019



75,655
Blood Donors

116,789
Whole Blood Donations

7,809
Apheresis Donations

380,082
Blood Components Processed

1,307,966
Laboratory Tests Conducted

Applied Sciences Group

Key statistics as at end-March 2020

Pharmaceutical Division

2,396
Analytical Cases

10,413
Analytical Tests

Analytical Toxicology Division

20,175
Forensic Cases

35,231
Forensic Exhibits

Biology Division

19,262
Forensic Cases

26,351
Forensic Exhibits

Forensic Science Division

356
Forensic Cases

1,551
Forensic Exhibits

Illicit Drugs Division

2,900
Forensic Cases

7,175
Forensic Exhibits

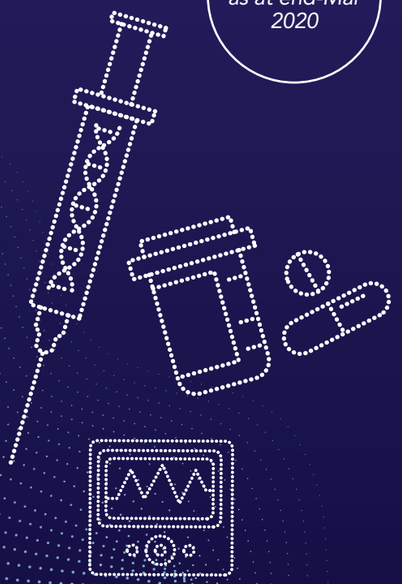
Forensic Medicine Division

4,156
Coroner's Cases

1,315
Coroner's Autopsies

Health Products Regulation Group

Key Statistics as at end-Mar 2020



37
Therapeutic Products Containing New Chemical/Biological Entities Approved

265
Therapeutic Products Registrations Approved (New Drug Applications and Generic Drug Applications)

4,676
Electronic Vaporiser Cases Referred to HSA

2,142
Medical Advertisement Permits Approved

30,182
Spontaneous Adverse Drug Reaction Reports Captured

5,442
Approved Products on the Register of Therapeutic Products

5
Reclassified Therapeutic Products

2,707
Post-market Feedback Received (Relating to Potential Contravention of Health Product Legislation)

11,803
Chinese Proprietary Medicines Listed

480
New Chinese Proprietary Medicines Listed

4,629
Therapeutic Products Variation Applications

1,320
Medical Device Product Listings Approved (Class A, B, C & D)

181,018
Cosmetic Products Notified

43,171
New Cosmetic Products Notified

314
Site Audits Conducted for Good Manufacturing & Good Distribution Practices and Pharmacies

17,987
Approved Products on the Singapore Medical Device Register

561
Field Safety Corrective Action Reporting for Medical Devices Received

518
Adverse Events (Local) Reporting for Medical Devices Received

2,998
Medical Device Change Notification Applications

4,415
Licensed Tobacco Retail Outlets

474
Tobacco Retail Licences Approved

7,322
Applications for Import of Medicinal Products for Personal Use Processed

Applications Approved

471
Licences/Certificates for Manufacturers of Health Products

2,959
Licences/Certificates for Importers of Health Products

2,079
Licences/Certificates for Wholesalers of Health Products

353
Certificates of Medical Devices

350
Registration of Retail Pharmacies

389
Licences/Certificates for Exporters of Health Products

Clinical Trial Applications

122
New Trials Approved

6
New Trials Withdrawn

128
New Trials Processed

BALANCE SHEET

	FY19/20	FY18/19	Increase / (Decrease)	
	$'000	$'000	$'000	%
Property, Plant & Equipment	81,777	91,957	(10,180)	(11)
Intangibles	11,718	9,598	2,120	22
Right-of-Use Assets	16,019	-	16,019	-
Current Assets	194,530	176,019	18,511	11
Total Assets	**304,044**	**277,574**	**26,470**	**10**
Equity	210,910	175,620	35,290	20
Long-Term Loans	-	14,788	(14,788)	(100)
Other Non-Current Liabilities	16,744	7,193	9,551	133
Current Liabilities	76,390	79,973	(3,583)	(4)
Total Equity and Liabilities	**304,044**	**277,574**	**26,470**	**10**

INCOME & EXPENDITURE STATEMENT

The Authority has achieved an overall net surplus of $34.8m for FY19/20.

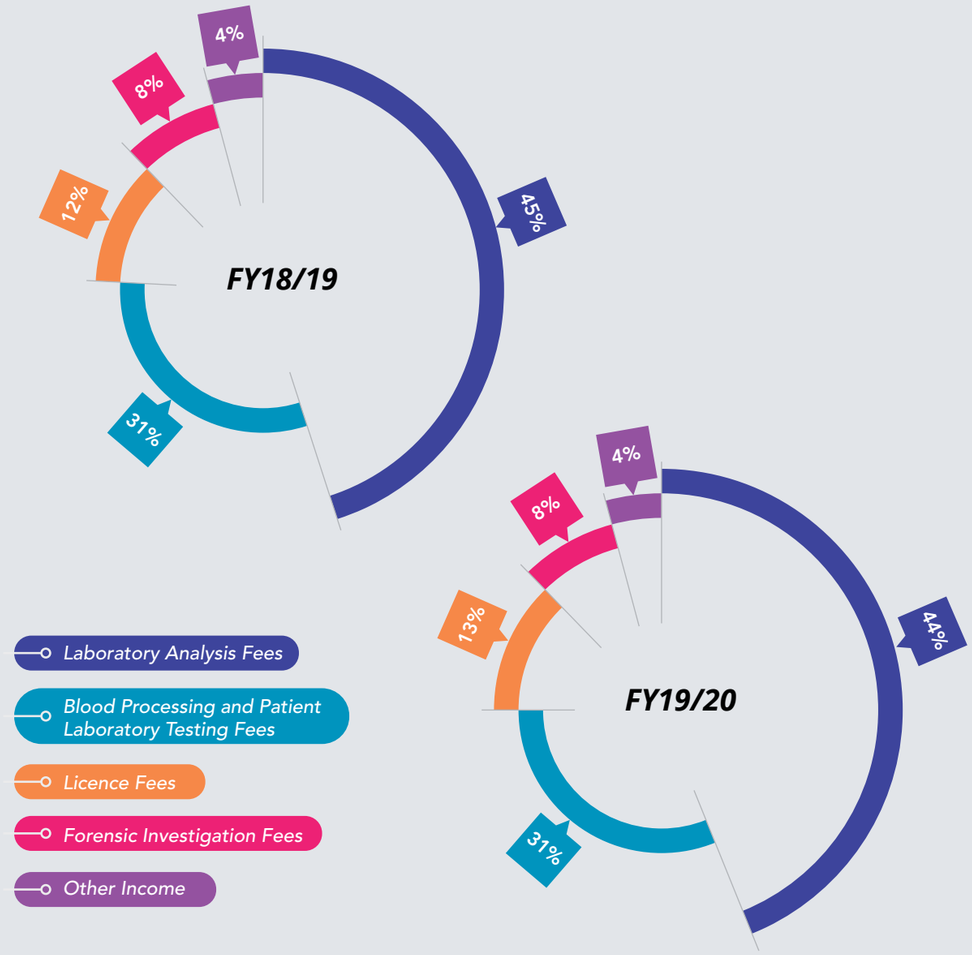
	FY19/20	FY18/19	Increase / (Decrease)	
	$'000	$'000	$'000	%
Operating Income	151,973	149,392	2,581	2
Operating Expenditure	(212,298)	(217,951)	(5,653)	(3)
Deficit before Government Grants	**(60,325)**	**(68,559)**	**(8,234)**	**(12)**
Government Grants	102,535	87,281	15,254	17
Surplus before Contribution to Consolidated Fund	**42,210**	**18,722**	**23,488**	**125**
Contribution to Consolidated Fund	(7,176)	(3,183)	3,993	125
Net Surplus	**35,034**	**15,539**	**19,495**	**125**
Other Comprehensive Income	(241)	(345)	104	30
Net Surplus and Comprehensive Income for the Year	**34,793**	**15,194**	**19,599**	**129**

FINANCIAL HIGHLIGHTS

OPERATING INCOME

The Authority earned a total operating income of $152.0m in FY19/20, an increase of $2.6m (2%) over FY18/19's revenue of $149.4m.

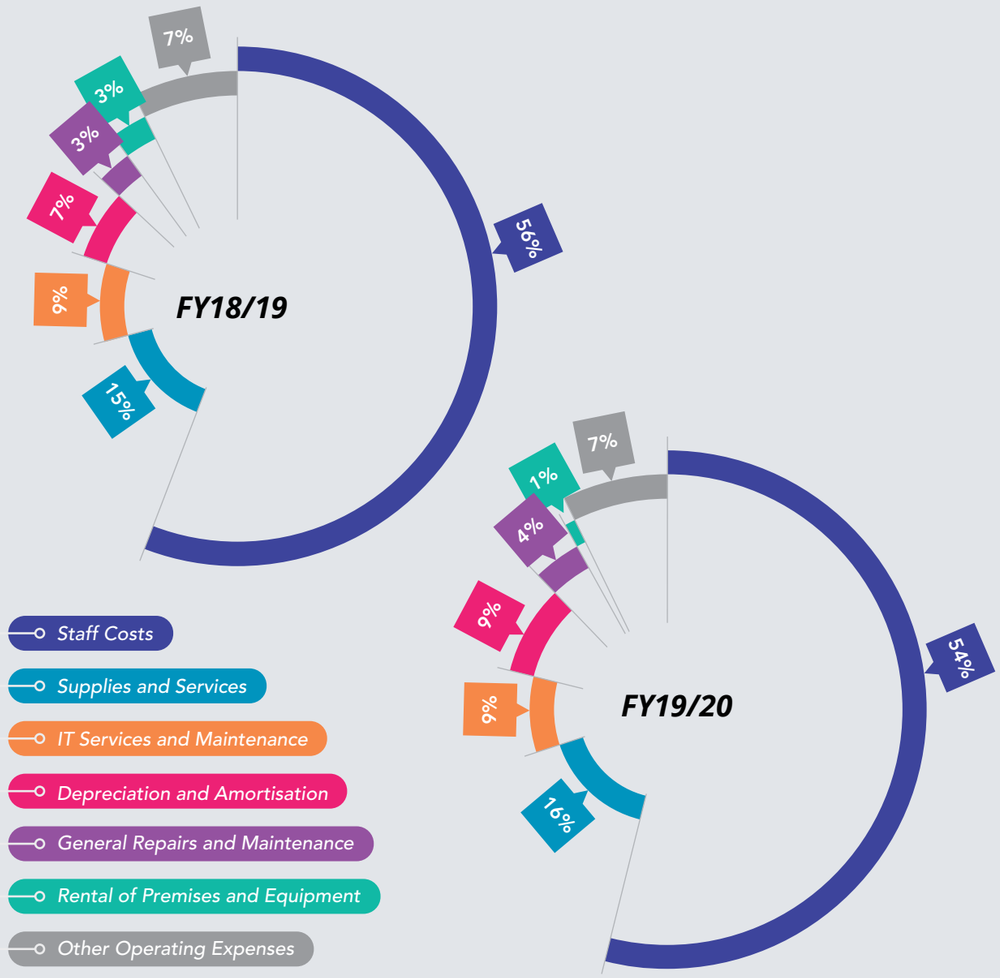
	FY19/20	FY18/19	Increase / (Decrease)	
	$'000	$'000	$'000	%
Laboratory Analysis Fees	67,587	67,358	229	0
Blood Processing and Patient Laboratory Testing Fees	47,218	45,610	1,608	4
Licence Fees	18,978	18,220	758	4
Forensic Investigation Fees	12,526	12,015	511	4
Other Income	5,664	6,189	(525)	(8)
Total Operating Income	**151,973**	**149,392**	**2,581**	**2**



OPERATING EXPENDITURE

The Authority incurred a total operating expenditure of $212.3m in FY19/20, a decrease of $5.7m (3%) over FY18/19's expenditure of $218.0m.

	FY19/20	FY18/19	Increase / (Decrease)	
	$'000	$'000	$'000	%
Staff Costs	115,210	122,483	(7,273)	(6)
Supplies and Services	33,458	31,579	1,879	6
IT Services and Maintenance	19,309	18,556	753	4
Depreciation and Amortisation	19,963	14,922	5,041	34
General Repairs and Maintenance	7,623	7,498	125	2
Rental of Premises and Equipment	2,592	7,369	(4,777)	(65)
Other Operating Expenses	14,143	15,544	(1,401)	(9)
Total Operating Expenditure	**212,298**	**217,951**	**(5,653)**	**(3)**



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