FUTURE READY

HEALTH SCIENCES AUTHORITY

ANNUAL REPORT

2018/19

FUTURE READY

In today's challenging climate, we must transform, innovate and leverage technologies to build a future ready HSA, one that is prepared to meet any challenges that come our way.

Through stakeholder engagement and environmental scanning, we pre-empt future needs and develop necessary capabilities, so that we will remain as the leading authority in protecting and advancing national health and safety.

CONTENTS

OUR VISION

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

OUR MISSION

To wisely regulate health products

To serve the administration of justice

To secure the nation's blood supply

To safeguard public health

OUR CORE VALUES

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

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

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

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

Live Innovation
We seek constantly to improve and transform.

OUR ACCOLADES

ORGANISATIONAL EXCELLENCE

2014
The Public Service Achievement Award

2010
The Public Service Milestone Award

2006
Public Service Award for Organisational Excellence

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

2002 to March 2019
People Developer Certification

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

2014 to March 2019
Singapore Service Class

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

Since 2005
Meritorious Defence Partner Award

Since 2008
Meritorious Home Team Partner Award

Since 2003
Community Chest Awards

2004
Singapore Family Friendly Employer Award

Since June 2018
ISO 9001:2015
Corporate Services Group

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

OUR ACCOLADES

PROFESSIONAL EXCELLENCE

HEALTH PRODUCTS REGULATION GROUP

Since March 2017
ISO 9001:2015
Tobacco Regulation Branch

Since March 2017
ISO 9001:2015
Vigilance & Compliance Branch

Since March 2017
ISO 9001:2015
Enforcement Branch

Since November 2018
ISO 9001:2015
Audit & Licensing Division

Since September 2016
Member of the Management Committee for the International Medical Device Regulators Forum (IMDRF)

Since 2011
First Position in the World Health Organization (WHO) Global ICSR (Individual Case Safety Report) Database Ranking
Vigilance & Compliance Branch

Since January 2000
Accession to Pharmaceutical Inspection Co-operation Scheme (PIC/S)
Audit & Licensing Division

Since May 2013
Member of the Management Committee for the International Coalition of Medicines Regulatory Agencies (ICMRA)

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

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

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

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

August 2008
American Society for Histocompatibility and Immunogenetics (ASHI)

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

APPLIED SCIENCES GROUP

FORENSIC MEDICINE DIVISION

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

ANALYTICAL TOXICOLOGY DIVISION, BIOLOGY DIVISION, FORENSIC SCIENCE DIVISION AND ILLICIT DRUGS DIVISION

1999
Excellence for Singapore Award

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

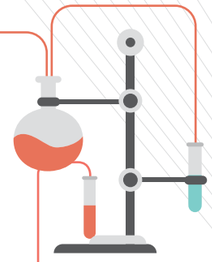
From 2017
ANSI National Accreditation Board (ANAB) Forensic Science Testing Accreditation

PHARMACEUTICAL DIVISION

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)



PHARMACEUTICAL DIVISION

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

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

Since February 2012
Observer to the European Pharmacopoeia Commission

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

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

CHEMICAL METROLOGY DIVISION

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

Since January 2014
Member of the Joint Committee for Traceability in Laboratory Medicine (JCTLM)

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

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

CHAIRMAN'S MESSAGE

I am happy to share that HSA clinched the Singapore Quality Class Star with both People and Service Niche standard certifications this year.This award, which recognises organisations with superior business practices and outstanding performance, is a nod to HSA as a best-in-class organisation and the good work that we do.

PROFESSOR SATKUNANANTHAM S/O KANDIAH

Chairman

I am happy to share that HSA clinched the Singapore Quality Class Star with both People and Service Niche standard certifications this year. This award, which recognises organisations with superior business practices and outstanding performance, is a nod to HSA as a best-in-class organisation and the good work that we do.

In our path towards future-proofing and readying ourselves for new challenges, we stepped ahead with these achievements:

Enhancing Our Regulatory Framework

We have successfully streamlined the registration process for therapeutic products to reduce regulatory burden for importers and distributors.

This was achieved through the implementation of the MIV (minor variation) Do and Tell option, which allows companies to make specified administrative changes without prior approval, as long as notifications are done within six months of implementation.

The screening process for MIV-1 (involving minor changes to quality or clinical aspects) was also removed in September 2018. This has translated into time savings of at least 25 working days for applicants.

These changes have helped to reduce the number of enquiries on submission of post-approval variations and improved efficiency, thereby allowing officers to focus on scientific evaluation work.

Ensuring Blood Safety

Another development for us is in the area of blood safety. In recent years, Human Platelet Antigen (HPA) alloantibodies have been implicated in post-transfusion adverse reactions. To build up our testing capabilities for HPA alloantibodies, HSA decided to set up HPA typing and alloantibodies tests, which were previously only available at overseas labs.

With these local testing capabilities, we are now able to provide faster turnaround to aid in rapid treatment decisions. Additionally, unlike most of the overseas labs, which are geared towards the Western population, our lab focuses on detecting anti-HPA antibody types of clinical significance among the local patient population.

Protecting Public Health, Serving the Administration of Justice

Our Health Products Regulation Group (HPRG) worked closely with our Pharmaceutical Laboratory to check and expedite the testing of angiotensin II receptor blockers (ARBs), a class of high blood pressure medicines distributed in Singapore. This step was taken following the overseas recall of several losartan medicines, under the ARB class of products, that contained a nitrosamine impurity, N-nitroso-N-methyl-4-aminobutyric acid (NMBA).

HSA tested all locally-marketed ARBs and recalled three losartan products found to contain trace amounts of NMBA, which were above internationally acceptable levels. By testing all ARBs, HSA was able to advise which brands did not contain NMBA, and help healthcare professionals decide on suitable alternatives for patients in place of the recalled brands. HSA also worked closely with the Ministry of Health and ALPS[1] to ensure the continued availability of high blood pressure medicines for the patients.

This timely response was critical in ensuring HPRG's ability to carry out vigilance and compliance activities to protect public health.

In major crime cases, rapid provision of DNA results is crucial as it potentially aids law enforcement agencies in the swift apprehension of culprits. In 2014, HSA established a first-in-Asia rapid DNA analysis method. Improving upon the previous DNA analysis method, which could process up to seven samples in 4.5 hours, we introduced an even more efficient analysis method in 2018, which is able to process two times the number of samples in a time span that is 25% shorter.

All food-related functions and testing capabilities have been consolidated under the Singapore Food Agency, which was formed on 1 April 2019. Our staff from the Food Safety Division have moved over to their National Centre for Food Science. We thank them for their hard work and contributions over the years to keep food safe in Singapore.

Developing Our People

Being future ready starts with our people and we need to build a strong foundation for HSAians.

Over the past year, the entire Professional Development Framework, which comprises Professional Development Career Tracks and Professional Actualisation Training (PAT) Roadmaps, was completed.

The first part of the framework – Professional Development Career Tracks – was developed to provide our medical, scientific, regulatory, nursing, corporate professionals and technical executives with well-defined career pathways that are linked to clear and consistent requirements and competencies at the various levels.

The Professional Development Career Tracks and PAT Roadmaps work hand-in-hand to help staff to acquire the necessary competencies to advance their professional expertise and facilitate career progress. Together, both these initiatives will empower staff to align their competencies and expectations with the work expectations and opportunities in HSA.

In line with HSA's philosophy of providing a lifelong career, we developed the Career Milestones Training Framework to guide staff on key areas for personal and professional development as they reach different career milestones with HSA. This framework highlights the importance of continuous development for all staff and shows that there are development opportunities available to all, regardless of seniority or experience in HSA.

With these strides we have made in our work, I am confident in HSA's ability to tackle the challenges ahead and carry out our vision to be the leading authority protecting and advancing national health and safety.

[1] A company set up by three public healthcare clusters to meet the procurement and supply chain needs of Singapore's healthcare system.

CEO'S MESSAGE

A Future Ready HSA – Lean, Agile, Digital

In today's volatile, uncertain, complex and ambiguous environment, transformation is the key to being future ready. With finite resources, we must do more with the same. This means transforming our processes to meet and exceed desired outcomes. It means constantly improving and enhancing our existing products and services and developing new ones so that we can serve our stakeholders better and add greater value. To advance our mission, we need to continue forging strong partnerships and leverage each other's strengths and competencies. At the heart of being future ready, we need to ensure our people have the right skills, mindset and values to realise these changes at every level.

We have started our digitalisation journey, and have begun exploring the use of smart technologies such as artificial intelligence (AI), natural language processing (NLP) and robotic process automation (RPA) to transform the way we work and deliver our services. We are also using the insights gained from data science to help us make better decisions.

In transforming to become future ready, HSA has implemented a HSA transformation framework, which focuses on four key transformation areas:

Stakeholder-centric Products and Services

We are constantly reviewing and refining existing products and services, and developing new ones, to serve our stakeholders better.

In the area of financial transactions, we have rolled out new electronic payment methods to bring about greater convenience and enhanced flexibility. We have upgraded all of our payment terminals to include card and QR code options, as well as incorporated the 'PayNow' option into all non-Giro invoices and payment letters.

With the launch of our upcoming new website, various industry stakeholders can look forward to new self-help tools. Medical device companies will be able to quickly and easily ascertain the classification of the device they are planning to bring to market, its risk classification, and what registration route to take. Additionally, visitors to Singapore will be able to check on the restrictions and import limits on different types of personal medication, while potential blood donors can check on their eligibility for donating blood.

To support the fight against drugs, we have developed a comprehensive drug analysis approach using high resolution mass spectrometry to better tackle the challenge of dealing with the ever-evolving chemical structures of new psychoactive substances (NPS). Through this new approach, the NPS positive detection rate in urine samples has reached almost 50%, as compared to less than 5% before.

Process Transformation

We aim to simplify processes to save both resources and time, and look towards science and technology to adopt smarter and better ways of doing things.

In terms of regulatory frameworks, we have made changes to our legislation to enable faster market access for lower risk medical devices. Those that meet necessary prerequisites are now exempt from prior review by HSA. This change comes about after extensive engagement with industry stakeholders to better understand the safety profile of medical devices in Singapore. We believe that through these changes, HSA will be able to focus our efforts towards newer and higher risk devices.

HSA is also transforming the way we perform rules-based and repetitive tasks. These include using new technologies such as RPA to automate the updating of patient transfusion records. This repetitive and time-consuming task, which used to take up to three hours daily, has now been shortened to under two minutes. Moreover, greater accuracy is also achieved through RPA's ability to highlight mismatched records.

Another area where we are seeing process transformation is DNA profiling. To improve operational efficiency and optimise inter-agency resources, we have started using data analytics to advise law enforcement agencies on 'good' vs 'poor' crime scene exhibits for DNA profiling. This is a marked improvement over the previous 'trial-and-error' approach.

People Transformation

Our people are the foundation for our success. We invest in training and technology to ensure that our people remain ready and relevant for whatever lies ahead.

To improve data and digital literacy among HSAians, we have adopted GovTech's recommendations from the Data Science Training Roadmap for Public Officers into the Professional Board's Professional Actualisation Training Roadmaps. This empowers staff to develop relevant data science competencies that will help them to gain deeper insights into their work and value-add to the services delivered to stakeholders.

In partnership with the Ministry of Health (MOH), we have sent our staff on courses to learn more about data analytics and its various usage applications. This training was further augmented with Power BI workshops, which equipped them with business analytics and data visualisation skills for enhanced decision making.

Another noteworthy development was the launch of Civil Service College's new digital learning platform – "LEARN". HSAians now have access to a full catalogue of online digital content and training courses covering topics such as Digital Literacy, Data Science, and Agile Project Management, and can learn anytime, anywhere.

To further hone the technical expertise of our staff, we have engaged overseas trainers to share their knowledge and experience in areas such as 'bloodstain pattern analysis' and 'forensic firearms and tool marks examination'. As a result, our staff are now better equipped to handle even more complex forensic cases than before.

Strong Partnerships

Given the rapid growth in scientific knowledge and technological developments, the knowledge, skills and competencies required for continued success can no longer reside solely in a single organisation. It is critical for HSA to identify the right partners and build strong partnerships to leverage their expertise and collaborate on mutually beneficial outcomes.

We have partnered with overseas regulators to work-share in areas such as 'evaluation of therapeutic products' and 'safety assessments for novel complementary health products ingredients'. Such partnerships increase the efficiency and robustness of the evaluation process, thereby ensuring that safe, high quality and effective health products are able to reach the market faster.

Closer to home, we have collaborated strategically with GovTech, the National University of Singapore (NUS) and Nanyang Technological University (NTU). Already, digital and smart technologies are proving to be of significant value. This was demonstrated in a recent project with the National University Hospital (NUH) and the NUS School of Computing, to identify key adverse events of interest from Electronic Medical Records using NLP and data-mining. This cooperative effort showcases the potential value of harnessing electronic healthcare records for augmenting post-market drug safety surveillance and is a step forward towards developing automated tools for detecting adverse drug reaction episodes.

HSA's transformation journey to get ahead and be future ready is well underway. It is a journey that brims with exciting prospects and possibilities, and we are looking forward to putting in motion even more technology-driven projects to stay ahead of the curve. Ultimately, our key goal is to transform HSA into a lean, agile and digital organisation that effectively delivers products and services that meet our stakeholders' needs.

DR CHOONG MAY LING, MIMI

Chief Executive Officer

HSA's transformation journey to get ahead and be future ready is well underway. It is a journey that brims with exciting prospects and possibilities, and we are looking forward to putting in motion even more technology-driven projects to stay ahead of the curve.

HSA BOARD

AS AT AUGUST 2019

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

Mrs Tan Li Lian
Executive Director
Contemporara Holdings Pte Ltd

Mr Adam Abdur Rahman
Managing Director
Head of Corporate Affairs
Citi Singapore and ASEAN

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

Professor Satkunanantham s/o Kandiah
Chairman
Health Sciences Authority

Mr Max Loh
Managing Partner
ASEAN and Singapore
Ernst & Young

Professor Alex Matter, M.D.
Chief Executive Officer
AtumRa Therapeutics Pte Ltd

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

Mr Dileep Nair
Independent Director
Keppel DC REIT Management Pte Ltd

Mr Alok Mishra
Chief Executive Officer
Value Addition

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

ANNUAL REPORT 2018/19
FUTURE READY HSA
HSA BOARD

HSA BOARD COMMITTEES

AS AT AUGUST 2019

BOARD EXECUTIVE COMMITTEE

Chairman
Professor Satkunanantham s/o Kandiah

Members
Mrs Tan Li Lian
Mr Adam Abdur Rahman
Mr Alok Mishra

AUDIT AND RISK COMMITTEE

Chairman
Mr Max Loh

Members
Professor Freddy Boey
Professor Alex Matter
Mr Jimmy Phoon

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

Mr Dileep Nair
Independent Director
Keppel DC REIT Management Pte Ltd

Mr Jeffrey Wong
Group Director
Corporate Services Group

Assoc Professor Sunil Sethi
Group Director
Applied Sciences Group

Assoc Professor Chan Cheng Leng
Group Director
Health Products Regulation Group

Dr Ang Ai Leen
Group Director
Blood Services Group

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 2019

Dr Choong May Ling, Mimi
Chief Executive Officer

Assoc Professor Chan Cheng Leng
Group Director
Health Products Regulation Group

Dr Ang Ai Leen
Group Director
Blood Services Group

Assoc Professor Sunil Sethi
Group Director
Applied Sciences Group

Mr Jeffrey Wong
Group Director
Corporate Services Group

We would like to thank **Dr Diana Teo** for her invaluable contributions in building up HSA's professional staff development and expertise in transfusion medicine and blood banking.

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 return, 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 2019

INTERNAL AUDIT

HSA BOARD

CHIEF EXECUTIVE OFFICER

QUALITY SERVICE MANAGER

HEALTH PRODUCTS REGULATION GROUP

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

BLOOD SERVICES GROUP

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

CORPORATE SERVICES GROUP

- Corporate Communications
- Facilities Management
- Finance
- Human Capital Management
- Information Management
- Legal
- Professional Matters
- Risk Management & Emergency Planning
- Safety & Quality
- Strategy & Business Transformation

APPLIED SCIENCES GROUP

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

PRINCIPAL OFFICERS

AS AT AUGUST 2019

CORPORATE HEADQUARTERS

Chief Executive Officer
Dr Choong May Ling, Mimi

Quality Service Manager
Director (Concurrent Appointment)
Mr Adrian Chia

Internal Audit
Deputy Director
Ms Adeline Ho

CORPORATE SERVICES GROUP

Group Director
Mr Jeffrey Wong

Assistant Group Director
Mr Adrian Chia

Corporate Communications
Director (Concurrent Appointment)
Mr Adrian Chia

Risk Management & Emergency Planning
Deputy Director
Mr Ho Cheng Choy

Human Capital Management
Director
Ms Lily Goh

Legal
Director
Ms Ruth Teng

Finance
Director
Ms Grace Chan

Facilities Management
Director
Ms Lynette Goh

Information Management
Director
Mr Manoj Abraham

Professional Matters
Director
Mrs Sarojini Padmanathan

Strategy & Business Transformation
Director
Mr Gabriel Yeo

Safety & Quality
Director
Mr Yap Tien Siang

HEALTH PRODUCTS REGULATION GROUP

Group Director
Assoc Professor Chan Cheng Leng

Group Director's & Stakeholder Engagement Office

Director
Ms Ling Boon Lee

Medicinal Products Pre-Market Cluster

Assistant Group Director
Ms Lee Hui Keng

Innovation Office & Clinical Trials Branch
Director
Dr Lisa Tan

Therapeutic Products Branch
Director
Ms Agnes Chan

Complementary Health Products Branch
Director
Ms Hui Foong Mei

Advanced Therapy Products Branch
Director
Dr Kellathur Nadathur Srinivasan

Vigilance, Compliance & Enforcement Cluster

Assistant Group Director
Dr Dorothy Toh

Enforcement Branch
Director
Ms Annie Tan

Vigilance & Compliance Branch
Director
Ms Jalene Poh

Tobacco Regulation Branch
Director
Mr Norman Chong

Audit & Licensing Division

Division Director
Ms Jessica Teo

Audit Branch
Director
Ms Jessica Teo

Licensing & Certification Branch
Director
Dr Lai Weng Fai

Medical Devices Cluster

Assistant Group Director
Ms Wong Woei Jiuang

Medical Devices Branch
Director
Dr Sethuraman Rama

BLOOD SERVICES GROUP

Group Director
Dr Ang Ai Leen

Assistant Group Director (Operations)
Dr Tan Hwee Huang

Assistant Group Director (Administration)
Col (NS) Tay Kim Chiew

Group Director's Office

Blood Service Support
Director
Ms Koh Geok Tin

Capability Development & Knowledge Management
Senior Manager
Ms Leou Kwee Kim

Quality & Accreditation
Senior Manager
Ms J Thilakavathi

Blood Resources

Acting Division Director
Mr William Sim

Blood Donor Management
Acting Director
Dr Kam Wooi Seong

Blood Supply Management

Division Director
Ms Sally Lam

Patient Services

Immunohaematology & Cell Therapy Support
Laboratory Director
Dr Marieta Chan

Clinical Services

Acting Director
Dr Hartirathpal Kaur d/o Juspal Singh

APPLIED SCIENCES GROUP

Group Director
Assoc Professor Sunil Sethi

Acting Deputy Group Director
Dr Angeline Yap

Quality Assurance Unit

Director, Quality
Dr Lui Chi Pang

Forensic Medicine

Chief
Dr Paul Chui

Technical Capabilities & Infrastructure Branch
Branch Director
Dr George Paul

Operations Branch
Branch Director
Dr Marian Wang

Professional Practice Branch
Branch Director
Clinical Professor Gilbert Lau

Forensic Science

Acting Assistant Group Director
Assoc Professor Christopher Syn

Analytical Toxicology Division
Division Director
Dr Yao Yi Ju

Biology Division
Division Director
Assoc Professor Christopher Syn

Forensic Science Division
Division Director
Mr Lim Thiam Bon

Illicit Drugs Division
Division Director
Dr Angeline Yap

Analytical Science & Forensic Medicine Division (Administration)

Assistant Group Director
Ms Low Min Yong

Chemical Metrology Division
Acting Division Director
Dr Teo Tang Lin

Pharmaceutical Division
Division Director
Ms Low Min Yong

FORWARD–LOOKING

Health Products Regulation Group

Securing public health through a future-proof and robust regulatory system

Regulatory Reviews and Innovation

At HSA, we constantly review and update our regulatory framework and regulations to stay relevant and forward-looking.

Establishment of Pilot Innovation Office

In April 2018, a new pilot Innovation Office was established to support innovation, efficient development of, and timely access to beneficial innovative therapeutic products in Singapore. This programme is targeted at stakeholders intending to pursue clinical development and product registration in Singapore.

Through this programme, researchers, academia, biotech and pharmaceutical companies may request for early scientific and regulatory advice in the following areas:

- Non-clinical development
- Clinical development
- Quality development, i.e. chemistry, manufacturing and controls
- Manufacturing and Good Manufacturing Practice (GMP)
- Regulatory submissions

In the period from

1 April 2018

to

31 March 2019

21 research institutions and biotech pharma companies have benefitted from **25 face-to-face regulatory and scientific consultations** with HSA.

Lifting the 23-year Ban on Corydalis Yanhusuo

Since the lifting of the ban on Chinese Proprietary Medicines (CPM) containing Corydalis Yanhusuo in June 2018, 25 such CPMs have been approved for use in Singapore by HSA, as of March 2019. The first approved CPM containing Corydalis Yanhusuo entered the market in August 2018.

By having safeguards and risk mitigation strategies in place, patients and the traditional Chinese medicine (TCM) industry are now able to access the previously banned herbs and products, resulting in more treatment options, without compromising public safety.

Revising Heavy Metal Limits in Complementary Health Products (CHP)

In order to enhance safety for CHPs, the limits for heavy metals in CHPs have been revised. This was first announced to the industry in December 2018, and will be put into effect from September 2019.

These limits, which are aligned to those of the World Health Organization (WHO) and ASEAN, ensure that the presence of heavy metals are kept to a minimum, thereby safeguarding public health and safety. Additionally, this revision also facilitates companies' entry into other markets through compliance to international standards.

The revised heavy metal limits are as follows:

33 Arsenic	48 Cadmium	82 Lead	80 Mercury
As	Cd	Pb	Hg
5PPM	0.3PPM	10PPM	0.5PPM

Launch of CHP Classification Self-Help Tool

A new self-help tool was launched in December 2018 to empower members of the industry to obtain product classification and regulation information, without the need to submit enquiries to HSA.

Available on the HSA website, the tool allows industry players to identify the classification of common orally-consumed CHPs based on the product ingredients and intended purposes.

Streamlining Our Work Processes

We continually fine-tune our work processes to make regulatory filing for our stakeholders as quick and efficient as possible.

New Online Forms to Better Facilitate Industry Reporting of Product Defects and Recalls

Launched in January 2019, the new online forms for Product Defect Reporting and Product Recall Completion have received encouraging feedback. This initiative is the result of survey findings from the pharmaceutical industry.

With this change, companies can access the forms across any digital platform and submit their reports immediately. This will improve the company's form filling experience and facilitate reporting.

Facilitation of Post-approval Variations

As a way to enhance regulatory efficiency, HSA has implemented several changes regarding post-approval variations – Major Variation (MAV) and Minor Variation (MIV), including MIV-1, MIV-2 and MIV Do and Tell. In January 2019, HSA implemented the MIV Do and Tell option, which allows companies the flexibility to make specified administrative changes without prior approval, as long as notifications of these changes are done within six months of implementation. In the same month, HSA also streamlined its requirements for MAV/MIV post-approval variations which affect the product label.

Additionally, HSA published a self-guided tool for MIV applications on its website in June 2018. The tool encourages good quality submissions by helping companies to determine the appropriate application type, variation category and documentary requirements.

The screening process for MIV-1 (involving minor changes to quality or clinical aspects) was also removed in September 2018. This resulted in improved predictability of processing timelines, and translated into time savings of at least 25 working days for applicants.

These changes have helped to reduce the number of enquiries on submission of post-approval variations, and improved efficiency, thereby allowing officers to focus on scientific evaluation work.

Streamlining of Regulatory Requirements for Medical Devices and Added Clarity for Telehealth and Aesthetic Products

After extensive engagement with industry stakeholders and the public, HSA made amendments to the Health Products (Medical Devices) Regulations in June 2018. These changes allow for faster access to lower risk medical devices, as well as give added clarity on the scope of regulatory control for telehealth and aesthetic products.

Faster Access to Lower Risk Medical Devices

Class A:

Class A sterile medical devices will no longer need to be reviewed by HSA prior to supply as long as they are imported or manufactured by licensed medical device dealers.

Class B:

Class B medical devices which meet the following prerequisites will qualify for immediate market access through the immediate Class B registration route (IBR):

- No safety issues globally
- Two independent regulatory agencies' approval or one reference agency's approval and three years of marketing history

This is estimated to benefit around 75% of Class B devices.

Additionally, Class B and C standalone software and mobile applications that have obtained approval from at least one of HSA's reference regulatory agencies without safety issues globally would also qualify for the immediate registration routes.

Class A Sterile Devices

Approval Timeline

Before 1 June 2018	After 1 June 2018
30 working days	0 working days

Selected Class B Devices

Approval Timeline

Before 1 June 2018	After 1 June 2018
Expedited Route	Immediate Route
60 working days	0 working days

Regulated Telehealth Products

- For medical purposes

Not Regulated Telehealth Products

- Not for medical purposes
- Wellness devices

Regulated as Medical Device

Devices for Modification of Appearance or Anatomy

Positive list of high-risk devices:

- Implants
- Injectable dermal or mucous membrane fillers
- Invasive devices for fat removal or fat degradation purpose

*List may be expanded in future

Clearer Regulatory Controls

Telehealth products intended for medical purposes such as diagnosis and treatment are subject to medical device regulatory controls while those intended solely for well-being or lifestyle purposes would not be regulated as medical devices. Such well-being devices will, however, be required to include a clarification statement in their labels to inform users that they are not meant for medical purposes.

As for modification of appearance or anatomy devices, only high-risk ones such as those for breast implants and dermal filler injections are subject to medical device regulatory controls.

These strategic initiatives seek to support innovation and improve transparency in our regulatory controls while safeguarding patient health and safety.

Enhancement of Special Consignment Scheme

A special scheme to bring in consignments of therapeutic products during a stock-out situation in Singapore was enhanced in October 2018. To assist product registrants on this special consignment route, guidance and application forms have also been published.

The enhancement of this process improves transparency and clarity of prerequisite requirements, and allows for better predictability of turnaround times for the industry. Furthermore, the risk of supply disruptions for therapeutic products with critical medical needs is mitigated, while quality of the products in the market is ensured.

Implementation of 50-day Turnaround Time for Screening Process

For the first time, the turnaround time for screening of therapeutic drug registrations has been published. This is in conjunction with the implementation of overall screening turnaround time of 50 working days, which came into effect in April 2018.

With this implementation, companies are now able to make better submission planning through improved transparency and predictability of the overall processing time for new drug applications (NDA), generic drug applications (GDA) and major variation applications.

New and Developing Partnerships

Making new partnerships and strengthening existing ones are part of our key strategy for staying at the forefront of regulatory sciences.

Australia-Canada-Singapore-Switzerland Consortium Complementary Health Product Working Group (ACSS CHPWG)

The goal of ACSS CHPWG, for which Singapore took on chairmanship, is to enhance convergence in assessment methodology for CHPs, and refine regulatory approaches through information sharing and joint assessments.

Over the past year, CHPWG has collaborated on the joint safety assessment of three CHP ingredients of mutual interest, bringing the total number of assessed ingredients to nine since the formation of the group in 2015.

Through this collaboration, information on CHP ingredients of emerging safety concerns are shared by individual member authorities who have detected local safety signals. These alerts help other CHPWG members to assess their respective local situations and their need for regulatory actions.

Additionally, CHPWG has also initiated collaboration on the evaluation of efficacy and claims for CHPs.

International Pharmaceutical Regulators Programme (IPRP)

In October 2018, HSA assumed the co-chairmanship of the Bioequivalence Working Group for Generics with WHO, taking over from Health Canada.

PIC/S Chairman's International Involvements

As the chair of PIC/S, HSA has been advocating for GMP harmonisation and inspection reliance in order to reduce duplication of effort and time for industry and regulators. This has been done through active involvement and presentations at various international conferences including:

- PIC/S Executive Bureau and committee meetings in Geneva, Switzerland in April 2018, and in Chicago, USA in September 2018
- 2018 PIC/S Annual Seminar on Management of Risk Through the Product Life Cycle, Chicago, USA

Collaborative Project on the Pharmacogenetic Background of Reported ADRs in the EU and Singapore

HSA and the Medicines Evaluation Board (MEB) of Netherlands have strengthened their partnership through a collaborative project on the analysis of the pharmacogenetic background of reported adverse drug reactions (ADRs) for medicinal products authorised in the EU and Singapore.

The purpose of the project is to examine the extent of drug safety data in ethnic populations found in drug registration dossiers and to see how much of that information is then included in public documents like assessment reports and product labels.

As part of our ongoing partnership, Dr Marc Maliepaard, Senior Clinical Assessor, and Dr Marjon Pasmooji, Science Program Manager, MEB also visited HSA in July 2018 to discuss the study and other potential collaboration projects.

Recognition by Swissmedic

In January 2019, Swissmedic, the Swiss Agency for therapeutic products, recognised HSA as having a comparable control system for medicinal products.

As a result, companies that are interested in entering the Switzerland market can potentially benefit from shorter processing timelines if they have already registered their medicinal products in Singapore.

ASEAN Medical Device Committee (AMDC) Meeting

The 6th AMDC, which was held in April 2018, saw HSA assume the chairmanship. One of the key highlights of the event was a stakeholder forum jointly organised by HSA and the Singapore Manufacturing Federation – Medical Technology Industry Group (SMF-MTIG) to provide regulatory updates from the various jurisdictions, as well as to facilitate dialogue between ASEAN regulators and the industry. This was attended by over 200 local and regional participants from regulatory agencies and medical technology companies.

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)

In June 2018, HSA was elected to be part of ICH's Management Committee. This is our second milestone after becoming a regulatory member in November 2017.

With this appointment, HSA will be able to take on a more active role in the development of ICH guidelines and to vote on all matters raised at ICH meetings.

Local Outreach Programmes

We organised numerous outreach programmes and initiatives to strengthen our bonds with local healthcare professionals and the public.

Building Technical Capability and Compliance to GDP Standards

With the implementation of the Health Products (Therapeutic Products) Regulations in November 2016, affected companies have been given a three-year grace period to build up technical capability and comply with HSA Guidance Notes on Good Distribution Practice (GDP) standards.

To ensure companies' preparedness in complying with GDP requirements, HSA's auditors made on-site visits to better engage these companies in 2018 to assess their compliance levels.

Additionally, HSA organised a GDP workshop in November 2018 to reinforce GDP concepts and help guide companies towards achieving GDP compliance before the deadline. 150 participants from various companies attended the workshop and it was well-received.

Towards compliance with GDP Standards

November 2016	May 2017	Throughout 2018	November 2018	1 November 2019
Implementation of Health Products (Therapeutic Products)	1st GDP Workshop organised by HSA	HSA auditors make on-site visits to ensure companies' preparedness in reaching compliance	2nd GDP Workshop organised by HSA	Deadline for companies to comply with HSA Guidance Notes on GDP standards

Facilitating Industry Compliance of CHP Regulations

HSA came out with several initiatives during the year to help industry players better comply with CHP regulations. One of these was the development of Questions & Answers and decision trees on technical guidelines to facilitate the industry in the application of these guidelines to their products.

Another initiative was a series of industry training workshops which provided insights into key issues pertaining to safety and quality of CHP, including training on GMP. These sessions were conducted to enhance the industry's knowledge on these issues.

Trade Engagement Sessions on New Tobacco Control Measure — Standardised Packaging (SP) for Tobacco Products

Last year, the Ministry of Health (MOH) proposed changes to the Tobacco (Control of Advertisements and Sale) Act, which included standardising tobacco product packaging sold in Singapore to plain packaging with enlarged graphic health warnings.

To facilitate smooth implementation of these new measures, HSA, in collaboration with MOH and the Health Promotion Board (HPB), conducted two trade briefing sessions for tobacco importers, wholesalers, retailers and key trade associations in February 2019.

During these sessions, discussions were held around the proposed specifications for the standardised layouts for tobacco product packaging as well as other operational issues, including the proposed implementation deadline. Feedback and concerns regarding this new tobacco control measure were also gathered.

Increasing the Minimum Legal Age (MLA) for Tobacco from 18 to 19 Years Old

Following the announcement of the revised MLA in early 2018, HSA's Tobacco Regulation Branch sent notifications and new signage stickers to all tobacco retailers to help them prepare for the revised age restriction that took effect in January 2019. To ensure a smooth transition, HSA officers also engaged and reminded the tobacco retailers on the new law during routine inspections.

Supporting Innovation and Priority Access for Medical Devices

Following the launch of the Pre-market Consultation (PMC) Scheme and the Priority Review Scheme to support medical device innovation in 2017, HSA conducted an outreach session in August 2018 for local medical technology research and development stakeholders.

During this session, HSA shared about the two schemes, and highlighted the importance of developing a regulatory strategy in the early phase of their device development process to ensure timely regulatory clearance for medical devices.

In addition, HSA also conducted short consultation clinics for interested participants to experience and understand the PMC scheme.

PMC Scheme

The PMC Scheme enables stakeholders to seek early regulatory advice from HSA from the device development up to the pre-registration phase. Through this consultation, they are able to perform and be familiar with the dossier preparation process, as well as receive guidance to meet regulatory requirements.

Priority Review Scheme

The Priority Review Scheme is a review pathway option that allows stakeholders to fast-track registration for new medical devices. This helps to facilitate timely access to safe and good quality medical devices in Singapore.

Continual Local Outreach Programmes

As part of our efforts to promote adverse event (AE) reporting, HSA organised a total of four roadshows over the past year to reach out to healthcare professionals.

On hand to encourage and improve AE reporting at these roadshows were medical residents from SingHealth, undergraduates from the Saw Swee Hock School of Public Health and TCM graduates from the Nanyang Technological University.

One such roadshow was held at Ng Teng Fong General Hospital for the first time. It featured a new and enhanced blended learning approach to roadshows. This comprised classroom-styled lectures, e-videos and interactive case studies via a learning mobile application.

Keeping Alert

To fulfil our mission to safeguard the health and safety of patients and consumers, we are always on the lookout for health products safety issues.

Surveillance of Local Product Defects

102
product defects were reported by companies

101
therapeutic products

1
health supplement

HSA worked with the affected companies to ensure that corrective actions were taken to mitigate the impact on the safety and quality of the defective products, as well as put in place preventive measures for future batches. Regulatory actions taken include:

10
product recalls

10
amendments to product registration

5
labelling and packaging corrections

4
Dear Healthcare Professional Letters (DHCPLs) issued

73 **cases of quality-related issues**

24 **cases of labelling and product packaging issues**

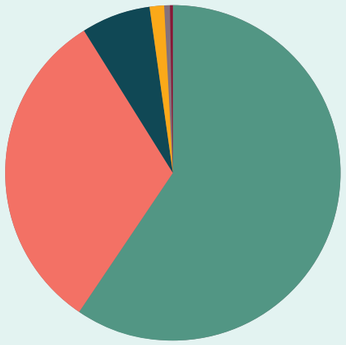
5 **cases of manufacturing deficiency issues**

Local AE Activities

Profile of AE Reports

HSA received a total of **33,461** AE reports.

- **97.3%** of these were associated with pharmaceutical drugs.
- The rest consisted of vaccines, biologics and complementary health products.
- These reports were contributed by:
- Doctors – **85.3%** contributed the most number of reports, followed by pharmacists – **10.6%**. Reports from dentists, nurses and research coordinators were also received.



59.5% Public hospitals and institutions

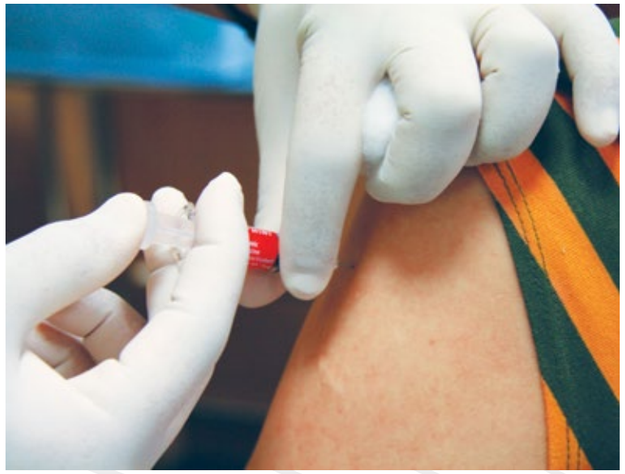
31.7% Polyclinics

6.8% GP clinics

1.2% Product registrants

0.5% Private specialist clinics

0.3% Private hospitals



Vaccine Vigilance

HSA continues to partner KK Women's and Children's Hospital to carry out active surveillance of vaccine AEs in children to ensure that the benefits/risk profile of vaccines available locally remain favourable.

CHP Vigilance

Of the **171 AE reports** involving CHPs and cosmetics:

- HSA detected **6 adulterated CHPs** with the help of astute clinicians
- The reported AEs of adulterated products were mainly associated with endocrine disorders such as Cushing's syndrome and adrenal crisis

Update on Product Risk Management

42 Singapore-Specific Risk Management Plans (RMP) reviewed at the point of product application for registration.

- Of these, **2 RMPs were implemented**. These include Imfinzi (patient medication guide) and Hemlibra (patient medication guide and patient alert card).

62 safety signals associated with therapeutic products were also assessed as part of post-market pharmacovigilance activities.

- Regulatory actions taken included the amendment of local package inserts for affected therapeutic products, as well as the communication of safety signals to healthcare professionals to raise awareness of safety concerns and to encourage reporting of local adverse reactions.
- Communication channels include the issuance of DHCPL, publication of articles in the HSA ADR News Bulletin, and product safety alerts on HSA's website.

16 risk assessments arising from health products found to contain adulterants or exceeding heavy metal limits were conducted as part of post-marketing surveillance activities.

- Regulatory actions taken included the issuance of press releases to warn public about the danger of the harmful products, and to avoid their use.

Public Safety Advisories

12
Press Releases issued

47
Company DHCPLs reviewed

3
HSA ADR News Bulletins disseminated to registered healthcare professionals

3
Safety Updates published on website

1
DHCPL written and issued

Enforcement Operations

Over the past year, we continued to partner with law enforcement agencies to combat illegal peddling of health and tobacco products.

Enforcement Against Illegal Health Products in Geylang

HSA adopts a multi-pronged approach towards limiting the supply of illegal health products in hot-spot areas. This included operations against sellers operating in Geylang, as well as mounting joint operations with the Central Narcotics Bureau (CNB) and the Singapore Police Force (SPF).

In addition, HSA also actively participated in the Inter-Agency Taskforce (IAT5) led by SPF to tackle crime and other regulatory offences in Geylang. Members of IAT5 include:

- Ministry of Manpower
- Singapore Civil Defence Force
- Singapore Customs
- Land Transport Authority
- Urban Redevelopment Authority
- National Environment Agency

From April 2018 to January 2019

HSA conducted a total of

465

operations in Geylang.

Almost

180,630

units of illegal health products, with a street value of approximately $341,026 were seized.

In December 2018

HSA successfully prosecuted a peddler who was caught in September 2017 with

300,000

units of sexual enhancement drugs, worth more than $700,000. For this largest-ever seizure of its kind, the accused was sentenced to 112 weeks' imprisonment and a fine of $19,500.

Operation Pangea XI

This internet-based enforcement operation is coordinated by INTERPOL, the World Customs Organization, the Permanent Forum of International Pharmaceutical Crime, the Head of Medicine Agencies Working Group of Enforcement Officers, the pharmaceutical industry and the electronic payment industry. The global operation targets the three main components that support the illegal online sale of health products – internet infrastructure, electronic payment and delivery service.

HSA, together with 115 other countries, participated in the 11th edition of Operation Pangea in October 2018.

Through this operation, HSA seized 4,520 units of health products worth approximately $9,000.

Enforcement for Illegal Sale and Importation of Tobacco Products

In support of the national tobacco control policy against illegal sale of tobacco products to persons below the Minimum Legal Age (MLA), HSA has suspended 18 tobacco retail licences for six months, and revoked three tobacco retail licences.

Since August 2016, HSA has been working closely with the relevant authorities to enforce against illegal smuggling of smokeless tobacco products like chewing tobacco.

In 2017, a man was caught trying to enter Singapore via Tuas Checkpoint with tobacco hidden within the rear door panel and rear speaker panels of his vehicle. He was sentenced to five weeks' imprisonment and fined $250 for illegally importing 4,560 sachets of chewing tobacco.

Photo credit: ICA

Knowledge Exchange

We believe that knowledge sharing between local and global partners is essential to raising global standards in health products regulation.

4th WHO-UMC-HSA Inter-Regional Pharmacovigilance Training *August 2018*

The 4th WHO-UMC-HSA Inter-regional Pharmacovigilance (PV) training was organised by HSA with the theme "Partnerships to Protect Public Health". This PV training was held in partnership with Duke-NUS Centre of Regulatory Excellence (CoRE) and opened for the first time to members of the industry.

Focus Group Discussion on Draft Guides for Cell, Tissue and Gene Therapy Products (CTGTP) *November 2018*

A focus group discussion was held on two draft guides – "Guidelines on Good Manufacturing Practice (GMP) for CTGTPs" and "Chemistry, Manufacturing and Control (CMC) Requirements for CTGTPs for clinical trials and product registration applications".

The objective of this session was to gather feedback from stakeholders on the fit-for-purpose CMC and GMP requirements that HSA had developed for CTGTPs to support clinical trials and product registration applications.

A total of 17 participants from healthcare institutions, research institutions and product manufacturers attended this focus group discussion.

International Coalition of Medicines Regulatory Agencies (ICMRA) Webinar Expert Sessions *December 2018*

At this session, HSA presented to the ICMRA Pharmacovigilance Increasing Adverse Event Reporting (IAER) subgroup the following topics on the Singapore experience:

- Leveraging electronic medical record system for AE Reporting
- Overview and digitisation of outreach materials to healthcare professionals on AE reporting
- A pilot project on applying behavioural insights to increase AE reporting

January 2019

HSA shared with the ICMRA Pharmacovigilance Big Data Subgroup about its work in the development and validation of algorithms to data mine hospital electronic medical records for detection of ADRs.

Topics presented include:

- Comparison of Extreme Laboratory Test (CERT) algorithm
- Algorithm for detection of statin-induced myopathy
- Text mining of unstructured discharge summaries for detection of ADRs
- Detection of ADRs associated with SGLT2i

Drug Information Association (DIA) Europe 2019

February 2019

HSA gave a presentation at DIA Europe on Text Mining Discharge Summaries of Hospital Electronic Medical Records. Through this presentation, HSA demonstrated how the development and validation of the rules-based algorithm, Readpeer for Active Pharmacovigilance (REAP), could be used to detect the presence of drug-adverse event pairs. HSA also shared about its plans to use machine learning to improve the predictive accuracy of the algorithm.

Feedback received for the session was positive, with participants saying that REAP was a novel and leading area of work among regulators in pharmacovigilance.

New Awards and Accreditations

We are proud to be able to celebrate our achievements and milestones with these accolades.

ISO 9001:2015 Certification

Converting to ISO 9001:2015

The Audit and Licensing Division (ALD) successfully converted their Quality Management System from the ISO 9001:2008 to the ISO 9001:2015 standard. The certification audit was successfully carried out in July 2018, with ALD achieving zero non-compliance.

Dedication towards up-keeping and maintaining our Quality Management System is one way that the various divisions support HSA's mission to wisely regulate health products and safeguard public health.

Maintaining ISO 9001:2015 Certification

In February 2019, the Enforcement Branch, Tobacco Regulation Branch and Vigilance & Compliance Branch, which are all ISO 9001:2015 certified, were put through surveillance audits to ensure compliance with the standards of the certification. All of them passed with no non-conformities.

Pro-Enterprise Panel – Singapore Business Federation Awards 2018

In November 2018, HSA received two Pro-Enterprise Panel – Singapore Business Federation (PEP-SBF) Awards.

The first award was for ranking 8th among 28 participating government agencies in the 2018 Pro-Enterprise Survey. The other was the Public Sector Pro-Enterprise Initiatives (Silver) Award for 2018, which was given in recognition of HSA's initiative of "Streamlining requirements to facilitate access to lower risk medical devices".

The PEP-SBF Awards is an annual award that recognises the efforts by the public sector, and collaboration between the private and public sectors in contributing towards a pro-enterprise regulatory environment.

Blood Services Group

Using technologies and innovation to ensure adequacy and safety of the national blood supply

For Our Donors

We are always looking out for ways to show our appreciation for blood donors and to provide a better donation experience for them.

New Donor Portal

To improve donor experience and to encourage more donors to step forward, a new appointment booking system was implemented in November 2018 to replace the old DonorCare platform.

To develop this new portal, we adopted concepts from behavioural insights and user experience to make it more user-friendly. Apart from appointment booking and filling of the Donor Health Assessment Questionnaire and Declaration Form, donors can also check their past donation records and milestones.

15th World Blood Donor Day

The 15th World Blood Donor Day, which was themed "Be There for Someone Else. Give Blood. Share Life" was held at the Flower Field Hall at Gardens by the Bay in June 2018. The event was graced by Guest of Honour, Minister for Education, Mr Ong Ye Kung and Member of Parliament for Marine Parade, Mr Edwin Tong.

This event

attracted more than

12,000

donors and guests

honoured a record

21

donors who achieved the "Medal for Life" award

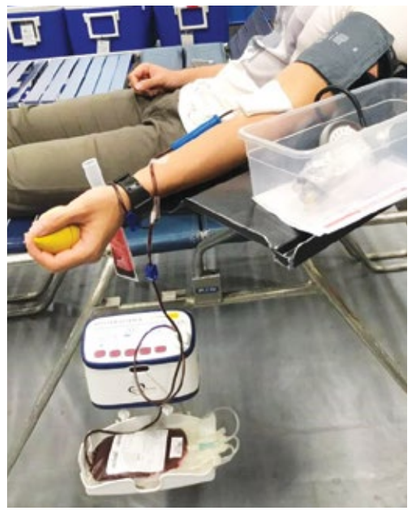
Improving Productivity and Efficiency

We continually improve our processes and facility to ensure the quality of our blood products.

Automated Blood Mixers for Mobile Blood Drives

Previously, our staff at mobiles had to manually shake the blood bags during the collection process at regular intervals. This was to ensure that the blood collected mixed well with the anti-coagulant in the bags to prevent blood clots from forming. Since June 2017, we have adopted automated blood mixers to replace this manual and laborious shaking process. Full conversion was successfully completed in July 2018.

This new system also includes safety functions such as alarms to signal that the donation process is completed or warn of problems encountered, as well as data processing capability to facilitate our digitalisation journey.



New Walk-In Freezer Rooms

To increase the storage capacity of our frozen plasma, which has doubled over the past 10 years, we built two new freezer rooms in 2018.

The increased capacity allows for more plasma to be stored with space for air circulation and staff movement to ensure cold-chain integrity of the frozen plasma, and a safer work environment for our staff.

Lean Six Sigma Projects Completed

Several of our Lean Six Sigma projects were selected for poster presentations at various international conferences in 2018.

Project Topic:

Improving Identification of HLA-matched Platelets in Apheresis

To be presented at ISBT Conference in Bangkok, Thailand.

Objective:

To improve identification and labelling proficiency of Human Leucocyte Antigen (HLA) matched platelet units.

Suggested Improvements:

- Change the HLA-matched platelets paper label to a more secure sticker label on the apheresis blood bag.
- Introduce the Personal Digital Assistance (PDA) system to blood bank doctors so that they can search for HLA-matched donor information effectively.
- Engage Blood Professional Executives to key in donor information when necessary.
- Put in place a common system where nurses can inform the doctors directly while safeguarding confidential data.

Outcome:

By improving upon the current labelling system, we are able to reduce time required to search for HLA-compatible platelets.

Project Topic:

Review Staff Rostering for Blood Donation Testing Lab

Presented at the International Society of Blood Transfusion (ISBT) Conference in Basel, Switzerland.

Objective:

To reduce the number of staff working the afternoon shift at the Blood Donation Testing (BDT) Lab without affecting the downstream processes and the timely release of blood products.

Suggested Improvements:

- Train more staff for Bacterial Testing so that the afternoon shift duties are evenly spread out.
- Shift one headcount from blood group testing to the morning shift, since blood group testing has the shortest turnaround time and therefore the least impact on the release of testing results for the downstream processes.

Outcome:

Cost savings as a result of reducing the number of staff needed to work the afternoon shift.

Keeping Our Blood Supply Safe and Secure

Our mission is to ensure the safety of the blood supply for patients in Singapore. We do this by systematically assessing the risks involved and evaluating the mitigating strategies.

Enhancing HPA Alloantibodies Testing Capabilities

In recent years, Human Platelet Antigen (HPA) alloantibodies have been implicated in post-transfusion adverse reactions such as foetal and neonatal alloimmune thrombocytopenia (FNAIT), post-transfusion purpura (PTP) and platelet refractoriness. Hence, to build up our testing capabilities for HPA alloantibodies, HSA decided to set up HPA typing and alloantibodies tests, which were previously only available at overseas labs.

With these local testing facilities, we are now able to give quicker testing support for rapid treatment decisions. Additionally, unlike most of the overseas labs, our lab provides value-added services by detecting anti-HPA antibody types of clinical significance among our patient population.

Key Highlights:

- We rolled out a workflow which enables clinicians to identify HPA antibodies in suspected cases of FNAIT, PTP and platelet refractoriness more accurately. This workflow uses sensitive and specific methodologies for detection of HPA antibodies together with HPA genotyping.
- The Tissue Typing & Platelet Reference Laboratory (TTPR) began performing HPA genotyping on donor platelets to create an inventory of HPA-identified donors. This will help in situations where patients with HPA antibodies may require HPA specific platelets.
- Some of our staff attended a Platelet Immunology Course organised by the ISBT Platelet Immunology Working Party and Japan Platelet and Granulocyte Workshop in March 2019. The course gave them a chance to learn more about current methodologies and interact with international counterparts and experts in the field.

Emergency Preparedness

In September 2018, HSA conducted a manpower activation exercise to test our preparedness in recalling staff to support our blood bank's operations during a civil emergency.

In addition, we also conducted a table-top exercise (TTX) on blood collection in October 2018. The TTX ensured a high state of readiness among the key stakeholders during a civil emergency.

Sharing Our Knowledge With Local and Overseas Partners

We continued to work closely with local and overseas collaborators across various knowledge exchange platforms. Such partnerships not only strengthen and position HSA as a regional leader in blood services, but also allow us to learn from the experiences of our overseas counterparts.

Clinical Trials

Singapore National Eye Centre

The Cell Therapy Facility (CTF) assisted the Singapore National Eye Centre (SNEC) and Singapore Eye Research Institute (SERI) to assess the safety and efficacy of using the Tissue Engineered Endothelial Keratoplasty (TE-EK) procedure for corneal transplantation. This method uses expanded primary human corneal endothelial cells as a tissue-engineered graft substitute.

For this trial, we provided a clean room facility for SERI to manufacture tissue-engineered grafts under current Good Manufacturing Practice (cGMP) conditions. The grafts were then used in the Phase I trial held at SNEC.

If successful, the study will provide an alternative source of corneas for corneal endothelial transplantation from standard cadaveric donor corneas.

National Heart Centre

Through the SingXpand pilot study (SINGaporean Program Performed with an eXPANsion Medical Device), HSA partnered with the National Heart Centre (NHC), and Cell Prothera to determine the potential ability of CD34+ stem cells to regenerate structurally and functionally damaged heart tissue after Acute Myocardial Infarction (AMI).

Our role in this trial involved manufacturing CD34+ stem cells under cGMP conditions for use in the Phase I/II trial that was held at NHC.

Through this trial, which has already shown promising results in several European countries, we hope to be able to demonstrate the safety and efficacy of such a treatment for local patients.

Research Collaboration with EHI/NEA

We provided 4,000 residual blood samples for the Environmental Health Institute (EHI) / National Environment Agency's (NEA) project on "Seroprevalence study of Dengue, Chikungunya and Zika virus infections among healthy youths and adults in Singapore".

STUDY VISITS BY OUR FOREIGN COUNTERPARTS

Malaysia *May 2018*

Three transfusion medicine specialists from Malaysia's Blood Services came to learn about blood banking and transfusion medicine practices in Singapore.

People's Republic of China *November 2018*

We hosted a study visit for four overseas delegates from Zhejiang Blood Centre, the People's Republic of China. Areas of interest included blood donation, donor recruitment, quality management, the red cell reference laboratory, blood donation testing and blood service management.

India *January 2019*

HSA played host to a five-person delegation from India's Kerala Blood Centre, which consisted of transfusion doctors and laboratory officers. They visited HSA's facilities to better understand our blood processing operations, laboratory processes and clinical transfusion services.

The four-day programme also included lectures and in-depth discussions with our subject matter experts, as well as a dialogue on patient blood management and haemovigilance practices.

Job Attachments and Internships

To support the advancement of the health sciences profession, we organised various attachment programmes.

Ministry of Education (MOE) Job Shadowing Programme

For the past two years, HSA has been participating in MOE's Job Shadowing Programme. Held every November, this week-long attachment for Secondary 3 students explores a specific career of interest either through hands-on experience or by observing employees at work in various different companies.

At HSA, the programme gave students the experience of working in a blood bank and a mobile drive. Activities included taking of donors' temperature, weight and blood pressure, checking of blood bags before dispatch to the laboratory, and bandaging donors' arms after donation.

During the debrief, positive feedback was received and we are confident that these students will become strong advocates for our National Blood Programme.

ITE Student Attachment

From November 2018 to March 2019, we ran the third round of our internship programme for the Higher Nitec Biotechnology students from the Institute of Technical Education (ITE), College East. The programme provided students with exposure to good laboratory practices, as well as gave them on-the-job experiences to develop work-ready skills.

Job Attachment for Staff from Raffles Hospital

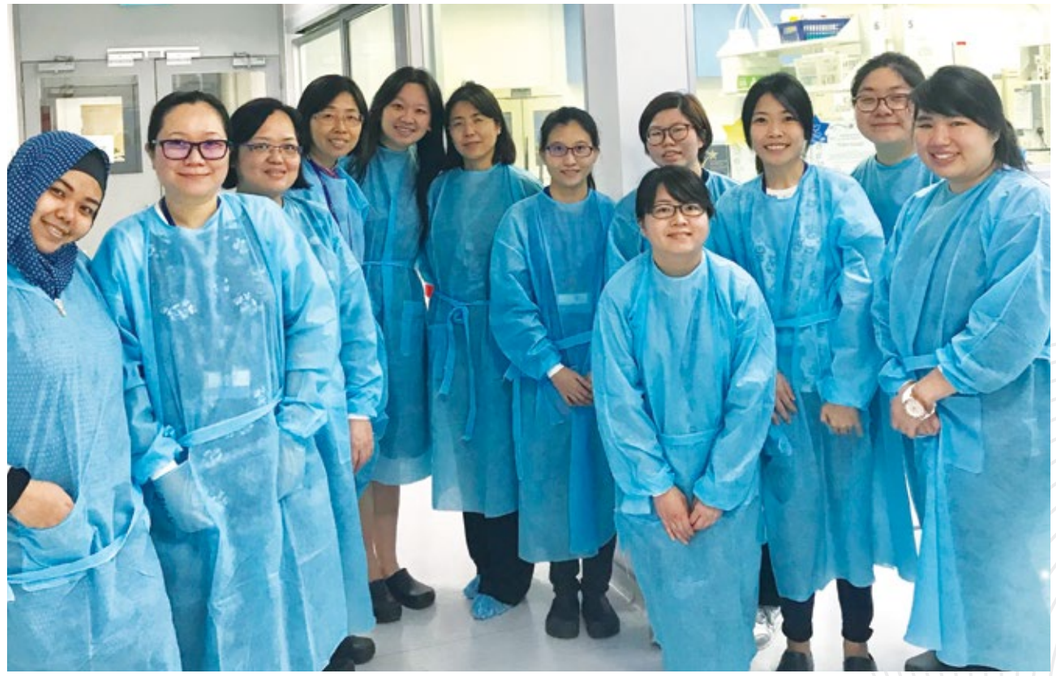
In June 2018, senior laboratory staff from Raffles Hospital were attached to HSA to better understand the operation of a cross-match laboratory, and the setup of such a lab in their hospital.

Accreditations

Through successful accreditations, we benchmark ourselves to the highest international standards in blood banking.

American Society for Histocompatibility and Immunogenetics

2018 marks the 10th year that we have completed and passed the American Society for Histocompatibility and Immunogenetics (ASHI) inspection.



AABB Assessment

In March 2018, we successfully completed the re-assessment of the Quality System by AABB.

Applied Sciences Group

Leveraging innovative scientific methods and technologies to meet the needs of our stakeholders, and to support the administration of justice

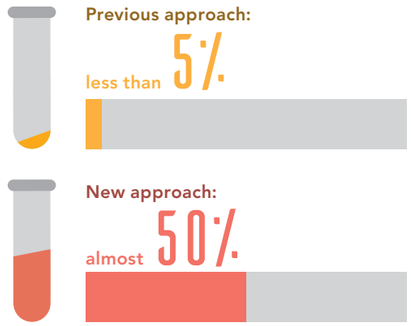
Enhancing Our Expertise

Our world-class capabilities ensure that we are able to stay on top of today's fast-moving environment.

New Approach to Detect NPS Abuse in Urine Samples

The continual influx of new psychoactive substances (NPS) into the illicit market has made it challenging to keep on top of the changing chemical structures of such substances.

To tackle this challenge, we developed a new comprehensive drug analysis approach using high resolution mass spectrometry that we constantly update with the latest profiles of NPS and its metabolites. This new approach allows for early detection of emerging synthetic cannabinoids such as 5-Fluoro-MDMB-PINACA and 5-Fluoro-MDMB-PICA, which are known to be extensively metabolised in humans upon consumption.



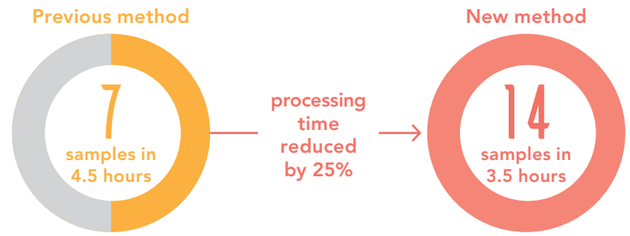
Through this new approach, the NPS positive detection rate reached almost 50%, as compared to less than 5% before.

Rapid DNA Analysis

In major crime cases, rapid provision of DNA results is crucial as it potentially aids law enforcement agencies in the swift apprehension of culprits. In 2014, HSA established a first-in-Asia rapid DNA analysis method, which could process samples within a few hours.

In 2018, we introduced a new analysis method, which is not only more efficient, but also does away with the need for special instrumentation.

Improving upon the previous DNA analysis method, which could process up to seven samples in 4.5 hours, we introduced an even more efficient analysis method which is able to process twice the number of samples, while reducing processing time by 25%.



Launch of the Y-chromosome DNA Analysis Service

Y-chromosome testing is a valuable tool in sexual assault cases as it specifically detects male DNA, which is often present at lower amounts as compared to the female victim's DNA. The potential benefits of using this tool to solve sexual assault crimes prompted HSA and the Singapore Police Force (SPF) to launch the Y-chromosome DNA analysis services for law enforcement agencies in June 2018. With this new service, we are now able to double the detection of potential male perpetrators in sexual crimes.

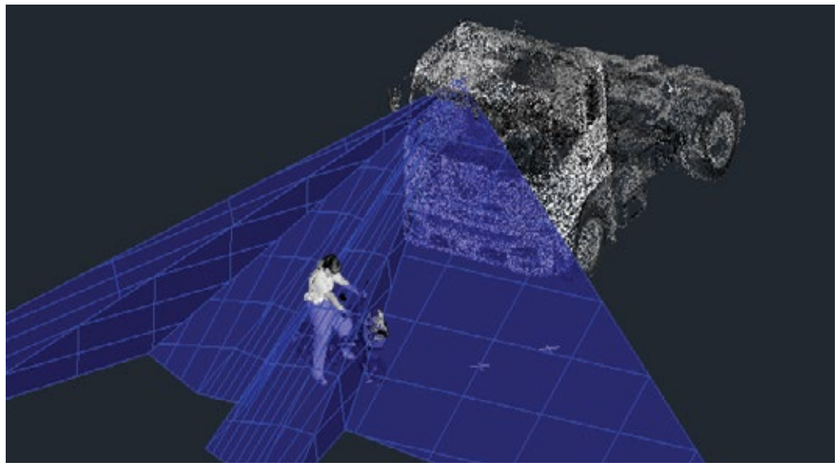
Additionally, due to the predominance of male perpetrators in violent crimes, we are further collaborating with SPF to extend Y-chromosome DNA analysis service to other crime types. This milestone is the result of close cooperation between HSA and its stakeholders to serve the administration of justice.

Use of 3D Modelling for Blind Zone Analysis

In the area of traffic accident reconstruction, a new method which uses 3D technology for blind zone analyses was developed to reduce time spent off-site, as well as improve the ability of the courts to make more informed judgements.

This method uses a 3D laser scanner to simultaneously record the spatial relationship of the blind zones, the vehicle, and the driver's ocular point to provide an accurate 3D model of the vehicle and its blind zones.

By introducing the 3D laser scanner into the workflow, scientists are able to move individual elements separately, thereby facilitating the reconstruction of the crash in the laboratory. Furthermore, 3D modelled diagrams can also be generated to provide the courts with a better visual presentation of the driver's view and the proportion of the object outside the blind zone.



Validation of X-ray Fluorescence Spectrometer Method

We successfully used the X-ray Fluorescence spectrometer (XRF) to quantitate sulphur content in a liquid sample. Previously, XRF, which is essentially an analytical instrument used for performing elemental analysis, was used mainly for analysing solid and powdered samples in the laboratory.

For this experiment, we measured the variances in sulphur content across several distillates of oil samples, which occur as a result of the varying processes used by different manufacturers.

Protecting Health and Safety

A key part of our work in protecting the public involves rigorous product testing.

New Methods for Food Safety

Five new analytical methods were developed to help improve food safety testing in Singapore. These new methods enable testing for the latest harmful substances and process contaminants, including glycidyl esters in edible oils and perfluorinated compounds in food. This, in turn, translates to better quality and safer food for the nation.

Detection of Prohibited Substance in Toothpaste

Following reports from Hong Kong of Tranexamic Acid being detected in some of their toothpastes, HSA's Cosmetics Control Unit promptly tasked the Cosmetics Laboratory (CL) to develop a fit-for-purpose testing method. Within the span of one week, CL came up with a new method that utilises a separation technique coupled with mass spectrometry detection to scan for Tranexamic Acid, which is prohibited in oral hygiene products under the ASEAN Cosmetic Directive.

Timely Response to Deal with Cancer-causing Impurities Detected in ARB Medicines

The Pharmaceutical Laboratory (PL) provided its technical expertise to support the Health Products Regulation Group (HPRG) in detecting new nitrosamine impurities in medicines.

This issue first came to light after the first nitrosamine impurity, N-nitrosodimethylamine (NDMA), was detected overseas in June 2018.

With subsequent detection of the additional impurities – N-nitrosodiethylamine (NDEA) and N-nitroso-N-methyl-4-aminobutyric acid (NMBA) in September 2018 and February 2019, respectively, the laboratory has tested a total of 89 products in Singapore.

A total of 89 products were submitted for urgent testing of nitrosamine impurities.

We reorganised work resources and manpower to expedite the turnaround time.

This timely response was critical in ensuring HPRG's ability to carry out vigilance and compliance activities to protect public health.

Fine-Tuning Our Processes

We are constantly refining and improving our processes to ensure maximum efficiency.

Digitally Enhancing Our Illicit Drugs Weighing Procedure

Weighing is an essential and critical step in drug testing at the Illicit Drugs Laboratory. Traditionally, the process of weighing seized drugs was recorded manually, but has since been enhanced digitally with a balance data management system. With this new system, data is now contained within a secured database, which ensures full traceability and data integrity.

Lab Digitalisation Efforts in Our Pharmaceutical Laboratory

We developed an in-house automated Laboratory Instrument Management System, which can track the calibration/maintenance schedules of all instruments, as well as send relevant email reminders to staff.

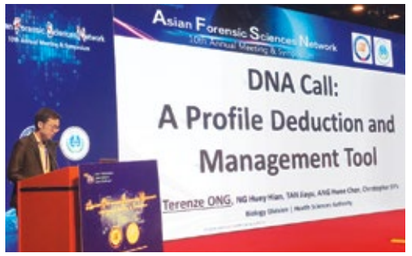
This system also provides detailed instrument information, thereby allowing for effective planning and tracking of assets, which are due to be condemned or replaced. This development has greatly enhanced the effectiveness of asset management, reduced non-conformities related to calibration/maintenance of instruments and improved work productivity.

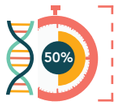
Digitalising Data Analysis with DNA Call

DNA profiling is a valuable tool that assists law enforcement officers in identifying the perpetrator of a crime. However, the analysis of DNA profiles is a challenging and laborious process, involving many steps in interpretation and statistical calculations. Moreover, with an increase in both the number of markers and the sensitivity of detection kits, the amount of data that is generated for analysis is also growing.

To cope with the burgeoning demand for data analysis, we developed "DNA Call" in 2018 to semi-automate the process. DNA Call works by identifying profiles which pass quality parameters, while flagging out potential issues in other profiles to the scientist.

This work was presented at the 10th Asian Forensic Sciences Network (AFSN) Annual Meeting and Symposium held in Beijing, China in September 2018.





DNA Call has significantly reduced DNA processing time by more than 50%.

New CT Scanner to Enhance Our Forensic Capabilities

A core part of the workflow in Coroner's cases involves the use of a CT scanner. We have therefore installed a more powerful machine to enhance the professional capabilities of our forensic pathologists.

Partnerships and Collaborations

Strong partnerships and collaborations are essential for us to remain at the forefront and reach greater heights.

Collaborating with the Hospitals and Polyclinics

A commutability study on human haemolysate Certified Reference Materials (CRMs) was conducted in collaboration with several hospitals and polyclinics.

The study sought to ascertain the similarity of HbA1c in human haemolysate CRMs certified by the Chemical Metrology Lab (CML) to actual patients' samples when measured by clinical analysers. The results of the study subsequently demonstrated that the CRMs were generally similar to real patients' samples, which is crucial for their use as quality control materials and in method validation of routine clinical test methods.

These results were published in the journal "Clinical Chemistry and Laboratory Medicine" in December 2018.

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 reference substances for Clindamycin and Methylthioninium Chloride for the WHO International Pharmacopoeia.

Collaborating with United States Pharmacopoeia on Reference Ranges

For over 10 years, HSA has actively collaborated with the United States Pharmacopoeia (USP) on reference ranges. In 2018, we completed a collaborative study on the acceptance range on USP Prednisone Tablets (Lot R080J0). This established range will be used as a reference for the Dissolution Apparatus Suitability Test.

5th AFSN Inter-Laboratory DNA Exercise

We organised the 5th AFSN Inter-Laboratory DNA Exercise to compare the efficiencies of differential DNA extraction systems for sexual assault cases and to identify potential areas for improvement.

The exercise garnered the participation of **15 forensic laboratories from 7 countries**, namely China, Indonesia, Malaysia, Mongolia, Philippines, South Korea and Thailand.

The findings of this exercise were subsequently presented in September 2018 to **over 200 participants** at the 10th AFSN Annual Meeting and Symposium held in Beijing, China.

Examining the Effects of Fingerprint Enhancement Techniques on Forensic DNA Recovery

We partnered with the SPF's forensic division on a project to evaluate the effects of various fingerprint enhancement techniques on subsequent DNA recovery. From these studies, a total of three methods were identified to be effective in enhancing latent fingerprints on surfaces tested, and were compatible with subsequent DNA profiling.

With this new knowledge, officers attending to crime scenes are now better equipped to select the appropriate fingerprint enhancement technique to maximise their chances of identifying suspects.

Disaster Victim Identification – Ground Deployment Exercise (DVI-GDX)

Members of the DNA Profiling Lab and the Forensic Medicine Division were invited to participate in the DVI-GDX exercise organised by the SPF Criminal Investigation Department (CID) in January 2019. Held at the Home Team Tactical Centre and HSA Mortuary, HSA and CID gained valuable insights in developing standard operating procedures and streamlining work processes to assist in victim identification through post-mortem medical examinations and DNA testing.

Asia Pacific Metrology Programme (APMP)

Focus Group Initiative Grant

In March 2018, China's National Institute of Metrology, the Korea Research Institute of Standards and Science and HSA was jointly awarded an APMP Focus Group Initiative Grant to support measurements and capability development activities on veterinary drug residues in meat and seafood for members and associate members of the APMP.

Residues of Veterinary Drugs in Meat and Seafood Workshop

A two-day workshop on "Measurement and Capability Building in Residues of Veterinary Drugs in Meat and Seafood" was organised by HSA in Singapore as part of the 34th APMP General Assembly & Related Meetings. During the workshop, we gave a laboratory demonstration on sample preparation of seafood tissues for the analysis of veterinary drugs to metrologists from Thailand, Malaysia, Philippines, South Africa, Kenya and India.

International Federation of Clinical Chemistry and Laboratory Medicine (IFCC)

The Chemical Metrology Division (CMD) became a member of the IFCC Working Group for Standardisation of Procalcitonin Assays (WG-PCT).

Current projects that CMD is involved in include the production and characterisation of candidate primary calibrators, as well as the development of a candidate reference method for absolute quantification of PCT by isotope dilution mass spectrometry.

World No Tobacco Day 2018

In conjunction with World No Tobacco Day on 30 May 2018, the Health Promotion Board organised a student engagement session for around 80 students from various schools to raise awareness on the benefits of leading a tobacco-free lifestyle. The guest of honour for the event was Senior Parliamentary Secretary for the Ministry of Home Affairs & Ministry of Health, Mr Amrin Amin.

Various activities were designed to discourage youths from experimenting with tobacco products, including a site visit to the Cigarette Testing Laboratory, as well as a sharing session on the anatomy of a cigarette and its harmful effects.

Broadening Our Knowledge

We widen our horizons through joint training sessions and knowledge exchange programmes with overseas experts.

Applying Crime Scene Reconstruction to Bloodstain Pattern Scenarios *June 2018*

The crime scene reconstruction team was put through a rigorous eight-day training by Mr Ross Gardner, a renowned bloodstain pattern analysis expert from the United States. This advanced level training has not only enhanced the expertise of our Forensic Chemistry and Physics Laboratory staff, but also equipped them to handle more complex cases.

The programme covered new applications in experiment design and bloodstain pattern scenarios, as well as reinforced existing principles of bloodstain pattern analysis and crime scene reconstruction.

Use of Event Data Recorders (EDR) in Traffic Crash Reconstruction *September 2018*

The Traffic Accident Reconstruction Team, together with several officers from SPF, attended a five-day training programme on the mechanics and logic of how data is written into an EDR during a crash. The training was conducted by Mr Richard Ruth and included practical sessions on extracting kinematics-related data from different accident vehicles. These sessions gave participants an overarching and wider perspective towards understanding a typical vehicle system.

Such training allows us to better serve clients, as well as to future-proof ourselves in the area of accident reconstruction works.

AGC-HSA Queen's Counsel, "Eliciting Expert Evidence" Training *September 2018*

The Attorney General's Chambers (AGC) and HSA came together for the first-ever AGC-HSA inter-agency Queen's Counsel (QC) Moot Court training. The event was opened by Mr Kow Keng Siong, Chief Prosecutor of the Criminal Justice Division, AGC, and graced by The Hon. Mrs Justice Geraldine Andrews, The Hon. Mrs Justice McGowan and QC Jacqueline Perry.

The training comprised case conferences, moot courts and lectures, and was attended by forensic scientists from the Drugs Abuse Testing Unit, Crime Scene Reconstruction, Questioned Documents and Traffic Accident Reconstruction teams. The examination-in-chief and cross examination were intertwined by replays and demonstrations by the trainers, which exposed the scientists to the different approaches adopted by the Deputy Public Prosecutors (DPPs), as well as provided DPPs with tips on how best to examine expert witnesses.

Benchmark Study to the National Institute of Food and Drug Safety Evaluation (NIFDS) *October 2018*

Last October, a consultant analytical scientist and a senior analytical scientist visited NIFDS, under Korea's Ministry of Food and Drug Safety (MFDS), to learn more about emerging trends in analytical development, regulatory compliance testing, and quality control of pharmaceutical and cosmetic products.

This visit provided a useful platform for technical exchange and sharing of good laboratory practices.

Joint Clandestine Lab Exercise *November 2018*

HSA's Clandestine Lab Team, together with the Central Narcotics Bureau (CNB) and Singapore Civil Defence Force (SCDF) successfully completed the second round of the Joint Clandestine Laboratory Training and Exercise.

This four-day training course conducted by the Australian Federal Police and New South Wales State Police brought together a total of 30 participants from the three agencies. Through a series of classroom lectures and a one-day joint exercise among the three agencies, participants were equipped with the necessary knowledge and skills to handle clandestine laboratory investigations.

Applying Surface Metrology to Forensic Firearms and Toolmarks Examination *January 2019*

Our Firearms and Toolmarks Team was introduced to the various concepts of surface metrology during a two-day training session by Dr Theodore Vorburger, a Guest Researcher at the National Institute of Standards and Technology (NIST). Dr Vorburger and his team at NIST are involved with several research projects relating to the analysis and statistics of firearms and toolmarks examination using 3D Technology, including the development of standards for the implementation of 3D instrumentation in forensic laboratories.

Through this training, the team gained a better understanding of surface topography and the uncertainty associated with computer-assisted 3D measurements. This knowledge is especially useful for the laboratory's development of computer-assisted methods for patterns comparison using the 3D microscope system which was recently acquired.

Benchmarking Our Standards

As part of our commitment towards maintaining the highest level of technical competencies in our area of expertise, staff took part in various regional and international comparisons/ proficiency tests during the year-in-review.

Chemical Metrology Division

Key Highlights:

- Completed **2 international comparisons** – benzo[a]pyrene in oil, and purity assessment of 4,4′-bisphenol A.
- Continued to organise accuracy-based External Quality Assessment (EQA) programmes for local clinical laboratories. **47 public and private clinical laboratories** participated in this latest programme, which covered a total of **17 clinical analytes**.
- Organised **2 accuracy-based Proficiency Testing (PT) Schemes** – one on trihalomethanes in water for the water testing laboratories, and the other on trace elements in lipstick for the cosmetic testing laboratories.
- Ran **1 pilot EQA programme** for HbA1c testing on mainframe analysers and portable devices using fresh human whole blood. Both clinical laboratories and medical clinics participated in the programme.
- Added **4 Certified Reference Materials** to its list:
  - n-propyl paraben;
  - steroid hormones (cortisol) in human serum;
  - veterinary drugs in salmon fish tissue; and
  - trace elements in lipstick.

Forensic Chemistry & Physics Laboratory

The Questioned Documents team participated in three collaborative tests with forensic document examiners around the world, passing all of them. These tests included the:

- PT by the Hong Kong Government Laboratory on Chinese handwriting and signature examination;
- ENFSI/European Network of Forensic Handwriting Experts Collaborative Exercise on English signature examination; and
- ENFSI/European Document Experts Working Group Quality Assurance Trial on document alteration and association of document with printer.

Pharmaceutical Division

The Pharmaceutical and Cigarette Testing Laboratories in the Pharmaceutical Division achieved excellent results in the following benchmark PT Programmes over the past year:

Pharmaceutical Laboratory

- Volumetric Titration of Sorbic Acid and Sodium Chloride by European Directorate for the Quality of Medicines & HealthCare (EDQM)
- Assay of Cimetidine by ASEAN Bureau of Drug and Narcotic
- Melting point measurements of Vanillin, Salicylic Acid and Saccharin by EDQM

Cigarette Testing Laboratory

- Nicotine in e-cigarette liquid by Dienstleistung Lebensmittel Analytik GbR, Germany
- Bilateral comparison study on nicotine in e-cigarettes by the Government Laboratory, The Government of the Hong Kong Special Administrative Region

Local and International Events

Over the year-in-review, we actively participated in industry events both here and abroad.

2018 Meeting of the UNODC International Panel of Forensic Experts

April 2018 / Vienna, Austria

Highlights of this meeting included discussions on the setting up of a toxicology portal for the United Nations Office on Drugs and Crime (UNODC) Early Warning Advisory on NPS, as well as the use of data collected for regular Threat Assessment Reports to inform the forensic and healthcare communities about the abuse and risks of detected NPS.

World Metrology Day Conference – Constant Evolution of the International System of Units

May 2018 / Singapore

At last year's World Metrology Day Conference, which was organised by the National Metrology Centre (NMC) A*STAR and HSA, CMD gave a presentation on "Quality Assurance through Accuracy-based Proficiency Testing Programmes".

23rd Official Medicines Control Laboratories (OMCL) Annual Meeting

May 2018 / Sarajevo, Bosnia & Herzegovina

In addition to sharing updates on the latest regulatory and technical developments in the quality control of medicinal products in Europe, participants also explored ways to improve communication and work-sharing amongst the OMCL network, as well as strategies to maintain depth of competence while remaining responsive to the increasing demands of a fast-evolving pharmaceutical world.

Attended by
230
participants

From
38
countries

Representing
65
official laboratories

2nd Plenary Session of the Committee for Cosmetics and Consumer Health / 2nd Joint Session of the Network of Official Control of Cosmetic Laboratories (OCCL)

October 2018 / EDQM Headquarters, Strasbourg, France

Cosmetics Laboratory was the only ASEAN member invited to attend the 2nd Plenary Session of the Committee for Cosmetics and Consumer Health. During the session, various discussions including the use of cannabis/hemp extracts in cosmetic products and cannabinoids analysis were held.

European Pharmacopoeia Network of Observers Special Meeting

November 2018 / Strasbourg, France

As an observer to the European Pharmacopoeia Commission, we had the privilege of attending this special meeting in which regulatory laboratories from across Europe came together to discuss issues such as pharmaceutical testing, anti-counterfeiting and healthcare.

34th Asia Pacific Metrology Programme (APMP) General Assembly and Related Meetings

November 2018 / Singapore

About
500
delegates from 59 metrology institutes in 31 economies attended

2
laboratory visits were conducted for the delegates

62nd Session of the Commission on Narcotic Drugs

March 2019 / Vienna, Austria

HSA was invited to speak at a side event organised by the Brazilian Health Regulatory Authority (ANVISA) on "Drug scheduling: forensic challenges in implementing a generic classification system".

WHO Activities

As one of WHO's Collaborating Centres, we actively supported them in the following activities.

Monograph Development Work

Our successful development of a high-performance liquid chromatography (HPLC) assay test for the draft monograph on Tetracycline Hydrochloride has been accepted by the WHO Expert Committee for inclusion to the Eighth Edition of The International Pharmacopoeia. In addition, we are also supporting the WHO in the review of its proposed monographs on Pyrimethamine and Pyrimethamine tablets.

EVENTS

WHO Consultation Meet on Quality Control Laboratory Tools and Specifications for Medicines

May 2018 / Geneva, Switzerland

We attended as a WHO Temporary Advisor and presented draft monographs which we developed for the International Pharmacopoeia.

Meeting on Tobacco Addictiveness Reduction Measures

May 2018 / Berlin, Germany

We were invited to attend this meeting as Chair of the WHO Tobacco Laboratory Network. The outputs from this meeting contributed to the body of knowledge on tobacco addictiveness reduction measures.

International Laboratories Forum on Counterfeit Medicines

June 2018 / Würzburg, Germany

Hosted by Germany Bundeskriminalamt, the forum was attended by representatives from 11 national regulatory control laboratories and research institutes from USA, Europe, South Korea and Singapore.

Various presentations were made on topics relating to the testing of toxic natural alkaloids in complementary health products, investigation on illegal health products and introduction of new technology for vacuum ultraviolet detection.

8th Session of the Conference of Parties to WHO Framework Convention on Tobacco Control

October 2018 / Geneva, Switzerland

Highlights of this international treaty conference included a technical discussion on tobacco product regulation, as well as deliberations on emerging tobacco products.

Third Regional Forum of WHO Collaborating Centres in the Western Pacific

November 2018 / Ho Chi Minh City, Vietnam

We were invited as representatives of the WHO Collaborating Centre to discuss plans to maximise contributions in developing and strengthening institutional capacity for countries in the Western Pacific Region.

Regional Action Plan on the Tobacco Free Initiative in the Western Pacific

February 2019 / Manila, Philippines

The consultation meeting reviewed the progress and challenges in the implementation of the current Regional Action Plan (RAP) in alignment with relevant global initiatives. Potential priorities, objectives and actions for the formation of new RAP were discussed for the period from 2020 to 2030.

WHO Workshop on Regulation of Tobacco Product Contents, Emissions and Design to Reduce Product Attractiveness

March 2019 / Singapore

Together with Health Canada, WHO and the Southeast Asia Tobacco Control Alliance (SEATCA), we provided training at this workshop. A total of 18 participants from 11 countries attended this 3-day workshop which included a visit to HSA's Cigarette Testing Laboratory.

Involvement in ASEAN Activities

As a member of ASEAN, we are committed to raising the standards of analytical sciences across the region.

ASEAN Reference Substances Project

We continued to be actively involved in the ASEAN Reference Substance Project, which establishes reliable ASEAN secondary drug references for use in ASEAN member countries.

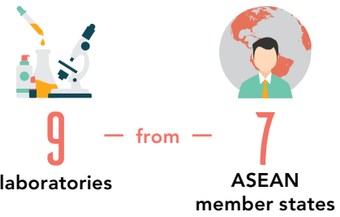
Highlights:

- Led the establishment of an ASEAN Reference Substance, Amitriptyline, together with Indonesia, Philippines, and Vietnam
- Participated in the inter-laboratory study of Flavoxate Hydrochloride, led by Indonesia

ASEAN Cosmetics Testing Laboratory Committee (ACTLC)

The Cosmetics Laboratory contributed proactively to the ACTLC to help strengthen the competency of national laboratories in ASEAN.

Participated in an inter-laboratory comparison study on "Determination of Salicylic Acid (Beta Hydroxy Acid) in cosmetic products", which involved:



16th Western Pacific Regional FHH / 7th FHH International Symposium

Last October, we attended the 16th Standing Committee Meeting and the 7th International Symposium on Western Pacific Regional Forum for the Harmonization of Herbal Medicines (FHH) in Tsubaka, Japan.

Sharing Our Knowledge

Knowledge exchange helps to build mutual trust among communities, and to promote greater regional and international trade.

CHEMICAL METROLOGY DIVISION

Metrology Training
April to September 2018

Over the year-in-review, CMD organised a training course on measurement uncertainty for clinical laboratories, as well as on-site training on basic statistical tools, method validation and measurement uncertainty for local testing laboratories.

FOOD SAFETY LABORATORY

Training on Aflatoxin Analysis *May 2018*

A three-day training workshop on aflatoxin analysis was conducted at the Food Chemical Laboratory of FDA in Myanmar. The on-site training, which involved 12 participants from FDA, Myanmar and two technical trainers from Food Safety Division of HSA, helped to raise the reliability of the lab's results, as well as improve the technical competencies of its staff.

Multi-mycotoxins Training
July 2018

In collaboration with the Department of Technical Cooperation, International Atomic Energy Agency, the Food Safety Laboratory conducted a one-week multi-mycotoxins training for two staff from Quality Assurance and Testing Center 3 (Quatest 3), Ministry of Science and Technology, Vietnam. Through this training, participants were exposed to more efficient analytical techniques of multi-mycotoxins analysis in daily operation.

PHARMACEUTICAL LABORATORY

Training Attachment for National Medicines Regulatory Authority, Sri Lanka *April 2018*

Pharmaceutical Laboratory hosted a one-week training attachment for five officers from Sri Lanka's National Medicines Regulatory Authority in April last year. The training covered topics such as laboratory quality management systems, general analytical testing workflow for western medicines, complementary health products (CHPs) and cosmetics testing.

Technical Visit from Taiwan Food and Drug Authority

August 2018

We hosted a technical visit for a delegation of three officers from the Taiwan Food and Drug Authority. Through this visit, they got to learn more about Singapore's approach in screening for adulterants in CHPs, as well as our experience in the testing of drug analogues and adverse drug reactions associated with the consumption of CHPs.

FORENSIC CHEMISTRY AND PHYSICS LABORATORY

Sharing Session with the Forensic Chemistry Division, National Forensic Service

July 2018 / Korea

We were invited to share Singapore's perspective on forensic chemistry with Korea's National Forensic Service. This was part of AFSN Trace Evidence Working Group's (TEWG) initiatives to facilitate laboratory staff exchange between member institutes. One of our staff members, who is incidentally the Chairperson of TEWG and a trace evidence expert, presented on the methodology, workflow, reporting and quality issues involving trace evidence and materials analysis.

Participation in the ANSI National Accreditation Board (ANAB) Assessment *August 2018*

We were approached to assist in the ANAB assessment of the Department of Chemistry, Malaysia, in Petaling Jaya.

Two of our forensic scientists working in the area of fire debris and trace evidence (chemical unknowns, paint and glass) participated in the assessment as technical experts, assisting the lead assessor in the review of case records and other documents related to the assigned scope of assessment.

This assessment involved:

32
assessors assessing a total of

13
laboratories located across various states in Malaysia

10th European Document Experts Working Group (EDEWG) Conference

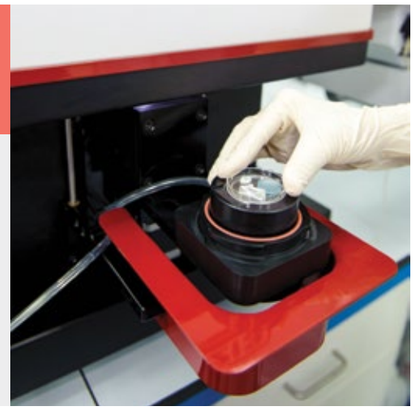
November 2018 / Lisbon, Portugal

HSA invited two officers from the Intelligence Division, Immigration & Checkpoints Authority (ICA) to attend the 10th EDEWG conference. The conference, which was themed "The Chain of Identity", saw forensic institutes from Europe share their experiences and insights on deterring illegal entry into their countries, as well as how latest technologies were being used to examine forged identity documents.

International Inter-Laboratory Tests of Glass Samples

Paper published in December 2018

Together with nine other international laboratories, we participated in two inter-laboratory tests to evaluate the analysis of glass samples using the Laser Ablation Inductively Coupled Plasma Mass Spectrometry (LA-ICP-MS) technique. These tests were organised by Dr Jose Almirall of Florida International University (FIU), who is a leading forensic expert in the use of this technique.



ILLICIT DRUGS LABORATORY

Training on the Analysis of NPS *February 2019*

By invitation from the Office of the Narcotics Control Board, we provided training for about 100 narcotics analysts from Thailand on NPS. Topics shared included the analysis workflow for NPS samples, the use of various analytical instruments and technologies for the identification of NPS, and the legislative control of NPS in Singapore.

Awards and Accreditations

As a scientific organisation, it is essential that we adhere to the highest benchmarking standards.

On-site Peer Reviews by Singapore Accreditation Council (SAC) and the International Chemical Metrology Community *March 2018*

CML successfully completed two on-site peer reviews. The first was by SAC based on the management requirements of ISO/IEC 17025:2005, and the second was by a team of experts from the international chemical metrology community based on the requirements of ISO/IEC 17025:2005 and ISO 17034:2016.

CML also completed the surveillance assessment by SAC and maintained its accreditation as a PT/EQA Provider in accordance with the requirements of ISO/IEC 17043:2010. It remains the only such accredited facility in Singapore.

Ministry of Home Affairs (MHA) Operational Excellence Award

September 2018

At the Minister's Awards Presentation Ceremony, the Illicit Drugs Laboratory received a Certificate of Appreciation for its involvement in Operation Nicrosil, which resulted in 2.6 kg of synthetic cannabis being seized by CNB. Supported by the SCDF and HSA, the operation allowed all three agencies to test for the first time the joint Clandestine Laboratory standard operating procedure, which was rolled out in March 2017.

ISO/IEC 17025 Assessment

The Pharmaceutical Division achieved full compliance to ISO/IEC 17025 in its SAC-SINGLAS annual assessment. The details of each laboratory's accreditation results are as follows:

- The Pharmaceutical Laboratory successfully added four new test methods into its accreditation scope during the annual SAC-SINGLAS renewal assessment:
  - Determination of Aristolochic Acid I & II in Health Products by LCMSMS
  - 4-in-1 Toxic Metals Analysis in Complementary Health Products by ICPMS
  - Determination of Pesticides by GCMSMS/LCMSMS
  - Determination of Tetrahydropalmatine in Health Products by HPLC

- The Cosmetics Laboratory successfully added two new methods in its accreditation scope:
  - Determination of p-phenylenediamine in hair care products by HPLC
  - Identification of Benzene in nail products by GCMS-Headspace
- The Cigarette Testing Laboratory successfully underwent the SAC-SINGLAS annual renewal assessment, maintaining its current accreditation scope.

Corporate Services Group

Working collaboratively with our Professional Groups to develop solutions to address both their present and future needs

People and Values

People are the foundation and key to HSA's continued success and sustainability. Hence, HSA constantly reviews our human resource (HR) policies and strategies to ensure market competitiveness and alignment with best practices.

Enhancing the Effectiveness of Talent Identification and Retention

HSA implemented a competency-based recruitment process with a new assessment matrix that focuses on attributes that measure candidates' suitability for the job. In addition to academic qualifications, HSA also assesses the candidate's other relevant skills and competencies.

Shifting away from an emphasis on academic qualifications, HSA also came up with a new compensation framework where qualifications will no longer be the only factor that determines a candidate's starting salary.

Staff Engagement Initiatives

We ran several engagement activities for staff to discuss and dialogue on topics that were important and of interest to them. The engagement sessions on Career Development and Performance Management were held in May and October 2018 respectively. Through these sessions, staff were able to interact directly with staff from our Human Capital Management department to discuss, clarify doubts and give feedback on specific topics and general HR matters.

As part of HSA's multi-generation workforce engagement strategy to retain experienced staff for knowledge transfer, and to motivate millennials to stay and grow their careers in HSA, we organised the "La Kopi with Veterans" programme and "Young Officers' Retreat" in October and November 2018 respectively. These sessions allowed us to hear directly from both experienced and millennial staff on how HSA could further improve engagement efforts to ensure that all staff feel appreciated and valued.

Lifelong Learning

In line with HSA's philosophy of providing a lifelong career, we developed the Career Milestones Training Framework to guide staff on key areas for personal and professional development as they reach different career milestones with HSA. This framework highlights the importance of continuous development for all staff and shows that there are development opportunities available to all, regardless of seniority or experience in HSA. This was shared with staff from September to November 2018.

HSA Customer Service Day

HSA held its 10th Customer Service Day in March 2019 with the theme, "Going Digital – Make it Easy, Simple & Clear". The guest speaker for the event was Mr Jeremy Soo, Managing Director and Head of the Consumer Banking Group of DBS Singapore. He shared his personal experience and involvement in the digital transformation journey of DBS Singapore's consumer banking business.

A total of 45 HSA Outstanding Service to Customers Awards (OSCA) 2018 were presented. These comprised:

- **1** Star Award
- **6** Gold Awards
- **9** Silver Awards
- **23** Bronze Awards
- **6** Team Awards

Professional Matters

We look at policy and management issues relating to professional matters in HSA, and oversee the professional development of staff and initiatives to promote a culture that encourages research and innovation.

Professional Development Framework

Over the past year, the entire Professional Development Framework, which comprises Professional Development Career Tracks and Professional Actualisation Training (PAT) Roadmaps, was completed.

The first part of the framework – Professional Development Career Tracks – has been developed to provide our medical, scientific, regulatory, nursing professionals and technical executives with well-defined career pathways that are linked to clear and consistent qualifications and competency requirements at the various levels. The PATs provide guidance on the training programmes that are relevant to each level.

The Professional Development Career Tracks and PAT Roadmaps work hand-in-hand to help staff to acquire the necessary competencies to advance their professional expertise and facilitate career progression. Together, both these initiatives will empower staff to align their competencies and development needs with the work expectations and opportunities in HSA.

Continuing Professional Education Programmes

Science and Innovation Day 2018 *July 2018*

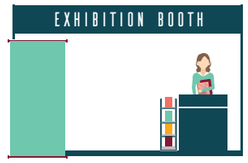
"Today's Imagination. Tomorrow's Reality". This annual half-day event seeks to promote the culture of research and innovation in HSA, facilitate exchange of scientific information and innovative ideas, and showcase and recognise staff who have contributed to research and innovation projects in HSA.

In addition to presentations and exhibition booths, we also had the privilege of having Assoc Professor Lim Tit Meng, Chief Executive of the Science Centre Singapore as our keynote speaker for the event.

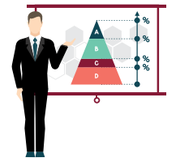
370 Staff participated

49 Abstracts accepted

43 Posters presented



6 Exhibition booths



6 Projects awarded under the oral presentations category

5 Best posters chosen from each of the Research & Innovation categories

Professional Education Lecture Series

June to October 2018

Started in 2017, this educational lecture series delves into important aspects of professional practice that staff will find relevant to their work.

We had renowned speakers such as Professor Lam Kwok Yan, Professor of Computer Science, School of Computer Science and Engineering, Nanyang Technological University and Ms Rebecca Chew, Deputy Managing Partner, Rajah & Tann Singapore LLP & Rajah and Tann ASIA, speaking in relation to the 2018 theme "Data and Ethics".

The topics shared were "Artificial Intelligence: Promise or Bubble?" and the "Ethical Use of Healthcare Data".

Tea-time Tidbits *August 2018*

The internal sharing by HSA Professional Staff at the "Tea-time Tidbits" session was centred around the theme "Spotting the Unusual".

Speakers from our three Professional Groups spoke on the following interesting topics such as:

- Not the Usual 'High': An Insider's Scoop on Synthetic Drugs
- Fishing for Rare Blood Types
- Adulterated Complementary Health Products: The Tell-tale Signs

Encouraging a Research and Innovation Culture at HSA

HSA Research Seed Grant

The HSA Research and Innovation Seed Grant Scheme is part of HSA's continued efforts to facilitate research and to foster an innovative culture. This grant is open to all HSA staff who wish to undertake research/innovation projects in areas related to their work.

Each project team can apply for an amount of up to S$10,000

Teams have 18 months to complete their project

Over the past year, 8 projects received a combined amount of $79,500

HSA Research Clinic

A new bi-monthly initiative, involving an experienced biostatistician and data analyst, has been started to support HSA researchers in areas such as research design and methodology.

Through this clinic, HSA aims to provide personalised research and statistical guidance for researchers, allowing them to strengthen their research proposals and apply the most appropriate methodology towards answering their research questions.

Planning for the Future

To cement our place at the forefront of health sciences, we continually look to the future and build capabilities to support our plans.

Scenarios Planning Workshop

AUGUST 2018

Organised by
HSA Corporate Services Group and the Centre for Future Strategies

Key Highlights

40
staff attended

- Driving forces and possible future states for the next 3 to 5 years were discussed
- A future sensing think-piece highlighting 14 key technology trends that would shape and catalyse HSA's transformation was developed
- Participants of the workplan seminar generated 241 transformation ideas, which will be taken into consideration as we develop HSA's next five-year strategic plan

Capability Building in Data Analytics and Behavioural Insights (BI)

In January 2019, HSA partnered the Ministry of Health (MOH) to provide data analytics training for staff. A total of 20 HSA officers attended the training. Through the programme, attendees were able to gain a deeper appreciation for data analytics, as well as better understand its application across various areas such as decision-making.

Key Highlights:

- More than 200 staff were equipped with business analytics and data visualisation skills for better decision-making through two Power BI workshops
- Nine data analytics projects were piloted. Completed projects include:
  - Common pain points and profile analysis of first-time applicants vs. return applicants in Chinese Proprietary Medicines registration
  - Analysis of blood donors' profile for mobile retention
- Partnered MOH and the UK Behavioural Insights Team to develop in-house capabilities in using "nudges" to encourage more donors to donate again
- Seven BI projects to "nudge" desired outcomes were piloted. These projects included:
  - Redesigning letters and notices to encourage on-time payment by offenders and tobacco retailers
  - Redesigning text messages to encourage donors to keep to their blood donation appointments and for more young donors to donate blood regularly

Digitalisation of Our Work

The HSA Digitalisation Steering Committee was formed in March 2018 to identify and support key digitalisation initiatives and technologies in HSA.

Some of the key elements of HSA's Digitalisation Strategy include:

- Leveraging smart tech and data to make transactions easy, seamless and secure for our stakeholders
- Automating and streamlining some of the manual and repetitive work processes
- Developing better policies, processes and decisions through the integrated use of data and digital technologies

HSA's Digitalisation Strategy is aligned with the Digital Government Blueprint that was announced in June 2018.

The key pilot projects that have been rolled out include:

- Robotic Process Automation (RPA) pilot to automate some of the repetitive and manual work processes in the Blood Services Group
- Adoption of FormSG to digitise forms
- Adoption of User Experience Design and development of self-help tools for the first phase of the new HSA website

IT Security

In today's digitalised environment, efficient IT systems are crucial to keep us running at full speed.

Maximising IT Resources

In place of traditional IT systems where one system is hosted on multiple physical computer servers, HSA's IT team has now rolled out an innovative hyper-converged framework software solution to virtually stretch the capacity of our physical server by many folds.

This hyper-converged technology dynamically extends the computing and storage resources of the physical computer server through intelligent allocation and convergence of the computer server's processing and storage in tandem with network demands.

Additionally, management of processing, storage and networks have also been consolidated into one virtual environment to simplify the provisioning of IT systems and bring about flexibility in the management of HSA's computer resources.

This new virtualised framework enables HSA to deploy new IT systems without the need for new physical computer servers, thereby delivering cost savings and greater efficiency.

Corporate Social Responsibility (CSR) Activities

At HSA, we believe in not just fulfilling our mission and vision, but contributing to society as well. With our people, strengths and resources, we actively strive to create a caring and sharing community through our yearly CSR activities.

HSA CAREs

HSA is committed to giving back to society through our Corporate Social Responsibility (CSR) Framework, known as CARE – "Community Action, Responsible for our Environment".

Integrated Learning Journey with APSN Katong School at Snow City *April 2018*

- **24 HSA volunteers** and **87 primary students and their teachers** from the Association for Persons with Special Needs (APSN) Katong School participated.
- **3 interesting activities** from the 'Winter Olympics' programme were pre-selected by the school to challenge the students' minds and physical agility.

Hair for Hope *June 2018*

HSA and the Children's Cancer Foundation (CCF) jointly organised the 6th Hair for Hope satellite event, which was held at HSA's Outram office. This event helped to raise awareness of childhood cancer, garner support from families and friends of staff members, and raise funds for children who have been diagnosed with cancer.

- **20 volunteers**, including **3 female employees**, came forward to go bald for this good cause, **raising a total of $21,800**.

Shopping for a Cause with the Seniors *September 2018*

On 28 September 2018, 40 HSA volunteers accompanied 35 seniors from the Lions Befrienders for a trip to Kallang Wave Mall for grocery shopping and tea.

The day ended with volunteers helping seniors to carry the heavy groceries back to their homes. Despite being tired out by the day's events, there were happy smiles on everyone's faces.

Learning Visit to an Urban Farming Set-up *December 2018*

HSA staff had the chance to learn more about urban farming in Singapore with a visit to Citiponics in December 2018.

Through this onsite experience, staff got to know more about some of the innovative technologies that aid in recycling water, saving space, and saving energy.

Fostering a Healthy Work Environment

A healthy and balanced lifestyle makes for effective and productive employees.

HSA Bring-Your-Kids-To-Work & Active Day *August 2018*

HSA held its 4th Bring-Your-Kids-To-Work Day. The event received overwhelming response with some 60 kids joining in for a day of fun-filled activities that revolved around the theme of science. These included a Science Show & Workshop, lava lamp building, bouncing bubble solution making, as well as various other fringe activities.

They also toured the office to see their parents' workstations, and visited the laboratories and the blood bank. The event ended with HSA Active Day at Coney Island, which saw staff and their family members going on a nice walk to enjoy the tranquillity of the island.

This event coincided with Families for Life's "My Family Weekend", which was held from 31 August 2018 to 2 September 2018. During the weekend, families were encouraged to continue with family bonding activities that were organised throughout the island.

HSA Family Day 2019
January 2019

This year's HSA Family Day was organised by the HSA Recreation Club, which planned an outing to Universal Studios at Sentosa. Taking advantage of the subsidised ticket prices, staff got to spend a fun-filled Saturday with their family members and other HSAians enjoying the various theme park attractions. A special highlight was the Family Day Photo Contest, where staff could submit photographs of themselves having fun with their families to win prizes!

Our Commitment to Excellence

Our awards and certifications are proof of our commitment towards upholding a high standard of excellence at HSA.

Upholding Excellence

HSA underwent an assessment in March 2019 by Enterprise Singapore under its enhanced Business Excellence (BE) Framework to benchmark ourselves against other organisations that have displayed best practices in organisational excellence.

We were awarded the Singapore Quality Class (SQC) – STAR with People and Service niche standard certifications which is an encouraging testament of our high levels of performance. In addition to reaffirming our niche capabilities, this BE assessment also serves as an institutional health check for our progress towards organisational excellence.

Process and Service Improvement with ISO

To boost our service commitments to the three Professional Groups, we did a major review of our corporate standard operating processes and embarked on a preparation journey for transition from ISO 9001:2008 to ISO 9001:2015 certification standards in 2018.

To ensure effective implementation of the procedures, multiple discussions and sharing sessions were conducted to identify the systems and outcomes that would advance HSA towards a new wave of growth. HSA was awarded the new ISO certification in June 2018 following the successful completion of the external audits.

Playing Our Part to Educate the Public

Our work at HSA includes raising awareness on issues that impact public health and safety. We do this by engaging the media with stories and news relating to public health.

Media Engagement

Some notable announcements included the recall of Losartan medicines and other product alerts, as well as putting up an appeal to get more 'O' blood donations.

Additionally, we worked with the media to profile our staff and share the work that they do, such as a video featuring our forensic scientist which was done in collaboration with the Public Service Division.

Website Redesign

The HSA Website Committee has completed the first phase of the website redesign, leveraging User Experience Design to develop its information architecture, for a website that is customer-centric, simple and easy to use.

By analysing data on website usage and conducting in-depth interviews to identify user behaviour and needs, several tools to enable users to self-help were also developed and tested.

Marketing Collaterals

We also created marketing collaterals for our various services and events, such as the 10th anniversary video for the Asian Forensic Sciences Network annual meeting, and an infographic on the risk of breast implant associated-anaplastic large cell lymphoma.

Our Work

In FY18/19, we saw:

- **1,057** Media Articles
- **23** Press Releases
- **9** HSA Updates

And created:

- **108** Business Collaterals
- **189** Event Collaterals
- **297** Marketing Collaterals

OUR WORK IN FIGURES

BLOOD SERVICES GROUP

Key statistics as at end-December 2018

73,619
Blood Donors

115,826
Whole Blood Donations

8,382
Apheresis Donations

373,951
Blood Components Processed

1,353,774
Laboratory Tests Conducted

APPLIED SCIENCES GROUP

Key statistics as at end-March 2019

Food Safety Division

3,545 Analytical Cases

26,549 Analytical Tests for Laboratory Samples

Pharmaceutical Division

2,600 Analytical Cases

11,694 Analytical Tests for Laboratory Samples

Analytical Toxicology Division

19,443 Forensic Cases

34,501 Forensic Exhibits

Biology Division

19,870 Forensic Cases

25,847 Forensic Exhibits

Forensic Medicine Division

4,054 Coroner's Cases

1,340 Coroner's Autopsies

Forensic Science Division

364 Forensic Cases

1,347 Forensic Exhibits

Illicit Drugs Division

3,001 Forensic Cases

7,432 Forensic Exhibits

HEALTH PRODUCTS REGULATION GROUP

Key statistics as at end-March 2019

4,532
Licensed Tobacco Retail Outlets

489
Tobacco Retail Licences Approved

1,930
Electronic Vaporiser Cases Referred to HSA

1,388
Medical Device Product Listings Approved (Class A, B, C & D)

17,295
Approved Products on the Singapore Medical Device Register

523
Field Safety Corrective Action Reporting for Medical Devices Received

422
Adverse Events (Local) Reporting for Medical Devices Received

2,788
Medical Device Change Notification Applications

34
Therapeutic Products Containing New Chemical/Biological Entities Approved

388
Therapeutic Products Registrations Approved (New Drug Applications and Generic Drug Applications)

5,400
Approved Products on the Register of Therapeutic Products

8
Reclassified Therapeutic Products

4,668
Therapeutic Products Variation Applications

2,182
Medical Advertisement Permits Approved

33,461
Spontaneous Adverse Drug Reaction Reports Captured

2,673
Post-market Feedback Received (Relating to Potential Contravention of Health Product Legislation)

Applications Approved

474
Licences/Certificates for Manufacturers of Health Products

3,062
Licences/Certificates for Importers of Health Products

2,102
Licences/Certificates for Wholesalers of Health Products

496
Certificates of Medical Devices

358
Registration of Retail Pharmacies

469
Licences/Certificates for Exporters of Health Products

6,318
Applications for Import of Medicinal Products for Personal Use Processed

11,623
Chinese Proprietary Medicines Listed

483
New Chinese Proprietary Medicines Listed

182,718
Cosmetic Products Notified

51,596
New Cosmetic Products Notified

356
Site Audits Conducted for Good Manufacturing & Good Distribution Practices and Pharmacies

Clinical Trial Applications

135
New Trials Approved

145
New Trials Processed

FINANCIAL HIGHLIGHTS

BALANCE SHEET

	FY18/19	FY17/18	Increase / (Decrease)	
	$'000	$'000	$'000	%
Property, Plant & Equipment	91,957	88,224	3,733	4
Intangibles	9,598	8,547	1,051	12
Current Assets	176,019	161,009	15,010	9
Total Assets	**277,574**	**257,780**	**19,794**	**8**
Equity	175,620	159,892	15,728	10
Long-Term Loans	14,788	15,470	(682)	(4)
Other Non-Current Liabilities	7,193	7,406	(213)	(3)
Current Liabilities	79,973	75,012	4,961	7
Total Equity and Liabilities	**277,574**	**257,780**	**19,794**	**8**

INCOME & EXPENDITURE STATEMENT

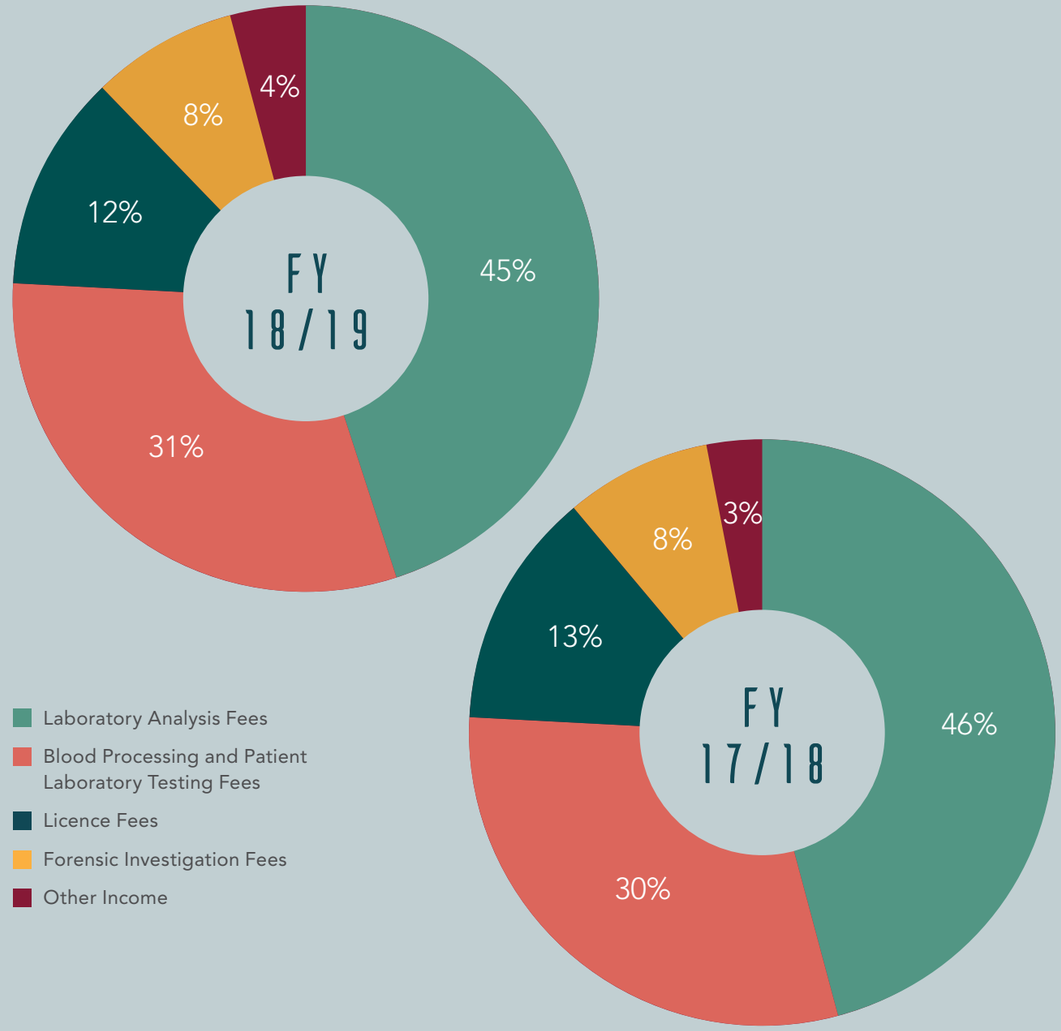
The Authority has achieved an overall net surplus of $15.2m for FY18/19.

	FY18/19	FY17/18	Increase / (Decrease)	
	$'000	$'000	$'000	%
Operating Income	149,392	142,995	6,397	4
Operating Expenditure	(217,951)	(212,634)	5,317	3
Deficit before Government Grants	**(68,559)**	**(69,639)**	**(1,080)**	**(2)**
Government Grants	87,281	84,370	2,911	3
Surplus before Contribution to Consolidated Fund	**18,722**	**14,731**	**3,991**	**27**
Contribution to Consolidated Fund	(3,183)	(2,504)	679	27
Net Surplus	**15,539**	**12,227**	**3,312**	**27**
Other Comprehensive Income	(345)	8	(353)	(4,413)
Net Surplus and Comprehensive Income for the Year	**15,194**	**12,235**	**2,959**	**24**

OPERATING INCOME

The Authority earned a total operating income of $149.4m in FY18/19, an increase of $6.4m (4%) over FY17/18's revenue of $143.0m.

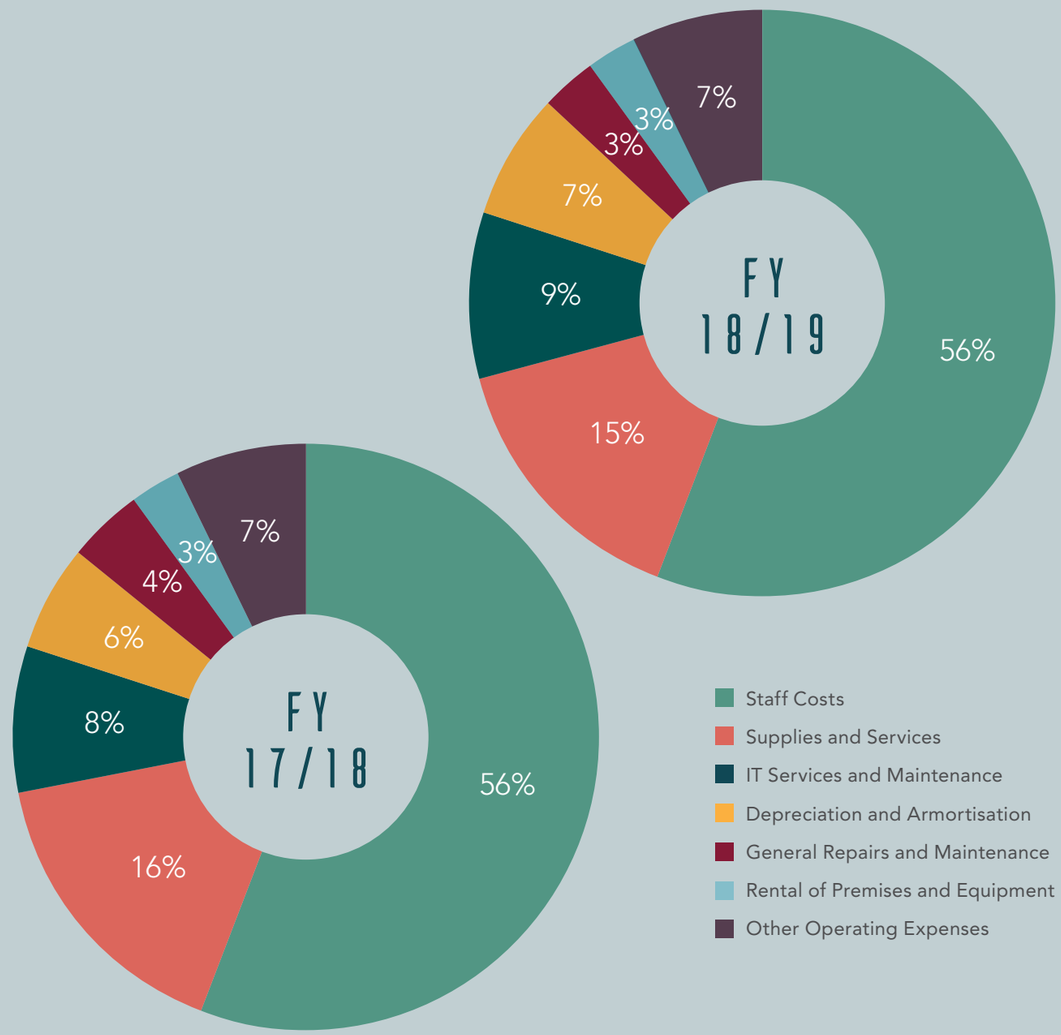
	FY18/19	FY17/18	Increase / (Decrease)	
	$'000	$'000	$'000	%
Laboratory Analysis Fees	67,358	66,240	1,118	2
Blood Processing and Patient Laboratory Testing Fees	45,610	42,982	2,628	6
Licence Fees	18,220	18,069	151	1
Forensic Investigation Fees	12,015	11,518	497	4
Other Income	6,189	4,186	2,003	48
Total Operating Income	**149,392**	**142,995**	**6,397**	**4**



OPERATING EXPENDITURE

The Authority incurred a total operating expenditure of $218.0m in FY18/19, an increase of $5.3m (3%) over FY17/18's expenditure of $212.6m.

	FY18/19	FY17/18	Increase / (Decrease)	
	$'000	$'000	$'000	
Staff Costs	122,483	119,842	2,641	2
Supplies and Services	31,579	33,318	(1,739)	(5)
IT Services and Maintenance	18,556	16,816	1,740	10
Depreciation and Amortisation	14,922	12,215	2,707	22
General Repairs and Maintenance	7,498	7,858	(360)	(5)
Rental of Premises and Equipment	7,369	7,497	(128)	(2)
Other Operating Expenses	15,544	15,088	456	3
Total Operating Expenditure	**217,951**	**212,634**	**5,317**	**3**



EDITORIAL TEAM

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Editors
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Ms Lee Min Jie
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Ms Wong Pui Yoke
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Ms Zoe Teo

HEALTH SCIENCES AUTHORITY

11 Outram Road Singapore 169078
Tel: (65) 1800 213 0800
Fax: (65) 6213 0749
www.hsa.gov.sg
hsa_info@hsa.gov.sg