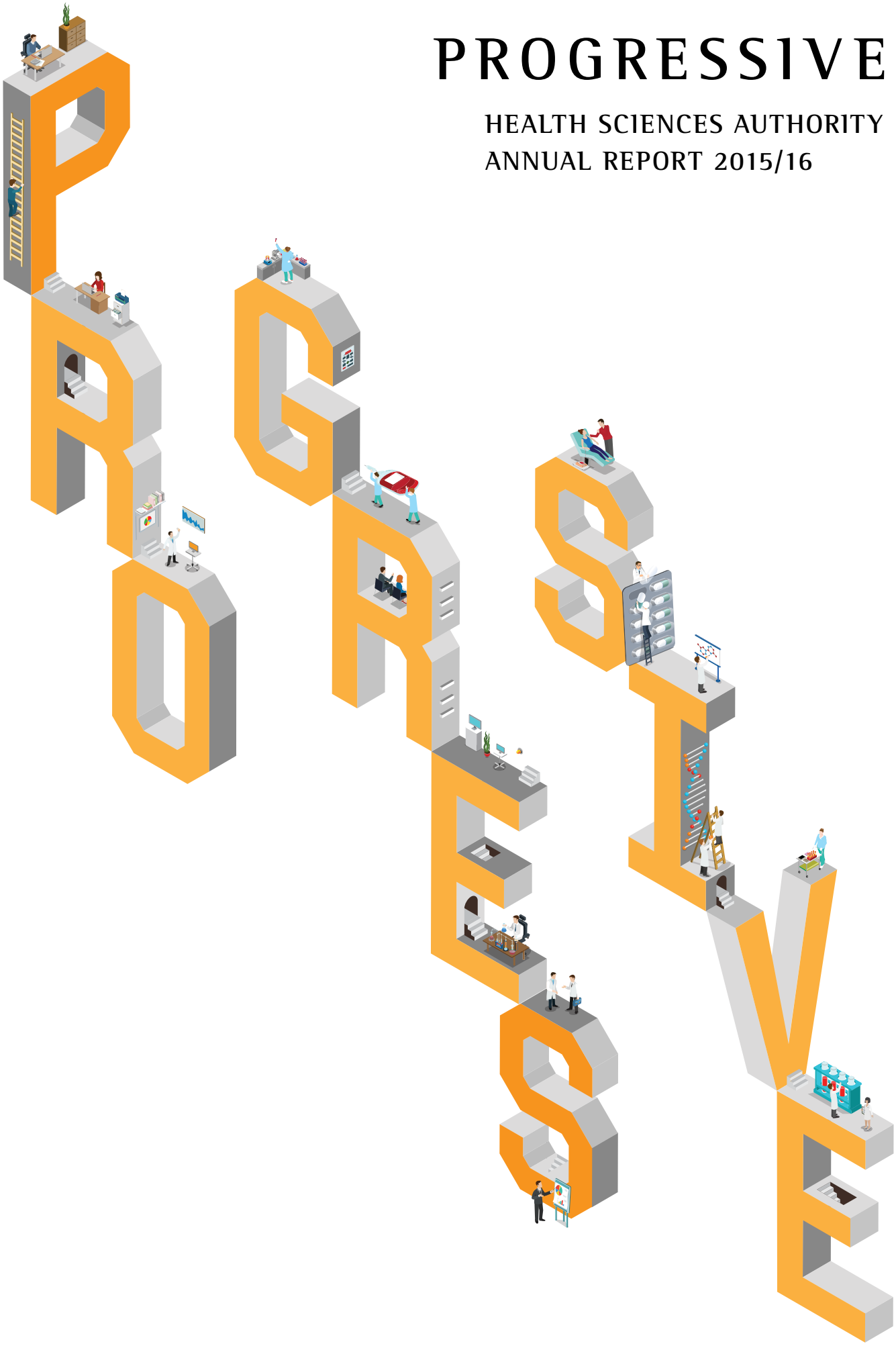
PROGRESSIVE

HEALTH SCIENCES AUTHORITY
ANNUAL REPORT 2015/16



PROGRESSIVE

We look to the future, to progress from strength to strength.

The Health Sciences Authority plays a critical national role in securing and advancing public health, through providing access to health products that are safe and of the highest quality; ensuring the safety of the nation's blood supply; and supporting the administration of justice.

Our roles are founded on scientific rigour, excellence and innovation. To excel, we strive towards going beyond our present capabilities, and build ourselves up to face the challenges in serving our nation and the international community.

We continue to make advancements in every area, from improving our knowledge and capabilities, to leveraging technology to improve the efficiency and quality of our services. We also put in place robust governance frameworks to instil public confidence and are constantly innovating to do our job better.

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

The Public Service Achievement Award
2014

The Public Service Milestone Award
2010

Singapore Quality Class Star
March 2014

Singapore Quality Class
since 2009

People Developer Certification
since 2002

Singapore Innovation Class
first public healthcare agency to be endorsed
2003

Singapore Service Class
March 2014

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

Public Service Award for Organisational Excellence
2006

Meritorious Defence Partner Award
since 2005

Meritorious Home Team Partner Award
since 2008

Community Chest Awards
since 2003

Singapore Family Friendly Employer Award
2004

ISO 9001:2008
Corporate Headquarters
since June 2015

ISO 9001:2008
Information Management Department
Corporate Headquarters
since 2011

Our Accolades

Professional Excellence

HEALTH PRODUCTS REGULATION GROUP

ISO 9001:2008
Audit & Licensing Division
since October 2015

ISO 9001:2008
Tobacco Regulation Branch
since February 2011

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

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

BLOOD SERVICES GROUP

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

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

American Society for Histocompatibility and Immunogenetics (ASHI)
August 2008

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

Certified On-the-Job Training Centre
December 2005

World Health Organization Collaborating Centre for Transfusion Medicine
since 1992

APPLIED SCIENCES GROUP

Forensic Medicine Division

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

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

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

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

Excellence for Singapore Award
1999

American Society of Crime Laboratory Directors/ Laboratory Accreditation Board (ASCLD/LAB)
since June 1996

Pharmaceutical Division & Food Safety Division

Public Service Award for Organisational Excellence
July 2003

Singapore Quality Class
since August 2002

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

Pharmaceutical Division

Associate Membership to the Official Medicines Control Laboratories (OMCL)
since May 2014

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

ASEAN Leading Country for Colorants and Tretinoin Analysis in Cosmetic Products
since 2004

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

Food Safety Division

ASEAN Reference Laboratory for Mycotoxins Analysis
since June 2004

World Health Organization Collaborating Centre for Food Contamination Monitoring
since July 1992

Chemical Metrology Division

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

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

A Chat with Our Chairman

HSA is celebrating its 15th year – how would you describe our journey thus far?

HSA has grown significantly over the past 15 years. We have come a long way, from a merger of what were five separate agencies then, to the cohesive, highly specialised, scientific organisation today. We have also gained recognition nationally and internationally for our expertise.

We have been successful in fulfilling our mission and vision. While we have had our share of challenges, it is these challenges that have helped strengthen our foundation and made us more resilient.

I am grateful to the many HSAians who have dedicated their long careers to the work of HSA. These pioneers have been an integral part of our growth, striving together to build and advance our services, and ensure our success. The firm foundation they laid will serve us well into the future. While we can be proud of our achievements, we cannot afford to be complacent. As new needs surface, they have to be met. Globally, new technologies are emerging, and we have to learn to take advantage of them quickly and strengthen our scientific capabilities.

What is the outlook for HSA?

This year's theme — Progressive — encapsulates HSA's mindset. We are looking towards making further advancements, growing our knowledge, improving our infrastructure, and innovating to build efficiency and provide better services. Our commitment to our key priorities drives us — to advance public health and safety, secure the nation's blood supply, and support the administration of justice.

Science is the means through which we realise our purpose. We will continue to look at how science can be employed to further improve public health and safety. For example, our Chemical Metrology Laboratory runs an External Quality Programme for clinical laboratories in Singapore to assess the accuracy of their test results for chronic diseases like diabetes and heart disease. By improving the accuracy of these measurements, we can assist with the screening, diagnosis and management of these diseases and help to improve public health in Singapore.

Our Health Products Regulation Group's Vigilance and Compliance Branch has also been recognised for their achievements, winning the inaugural "Mrs Tan Shook Fong – PSS Innovation and Scientific Research Award 2015" for their pharmacogenetic project to identify increased risk of serious skin reactions with the anti-epileptic drug carbamazepine (CBZ) in patients with the HLA-B*1502 gene. As a result of this finding, it is now the standard of care for doctors in Singapore to test patients for this gene before commencing treatment with CBZ. Since the implementation of the HLA-B*1502 genotype screening in 2013, HSA has not received any reports of adverse events associated with the use of CBZ in patients screened for the gene. In comparison, there was an average of 15 CBZ-induced adverse events per year in the past.

We have also leveraged on advances in new technology to help us enhance our capabilities. A good example is how our Blood Services Group looks at new testing and process technologies to make our blood supply even safer. We have been closely monitoring developments in Pathogen Reduction Technology, a technology for reducing infectious agents in blood components. This heralds a new approach to blood safety. We are also looking at using RFID technology for real-time tracking of the national blood inventory to enhance productivity and accuracy.

Science and technology have helped our Applied Sciences Group to achieve more precise and accurate analysis to support the courts and law enforcement agencies in the investigation and prosecution of criminals. For instance, the Forensic Chemistry and Physics Laboratory has acquired a Reflectorless Total Station to aid in traffic accident reconstruction. The Reflectorless Total Station enables us to do longer-range measurements in traffic crash reconstruction, and when used in conjunction with the 3D laser scanner, can provide more visuals in our reports to aid in investigations.

Besides continuing to embrace new and innovative solutions, we will look at enhancing productivity

through automation. We can expect more innovative drugs and novel therapies to be developed. This means we will have to develop innovative regulatory approaches to enable fast and safe access to these health products for the population.

What challenges do you think HSA faces ahead?

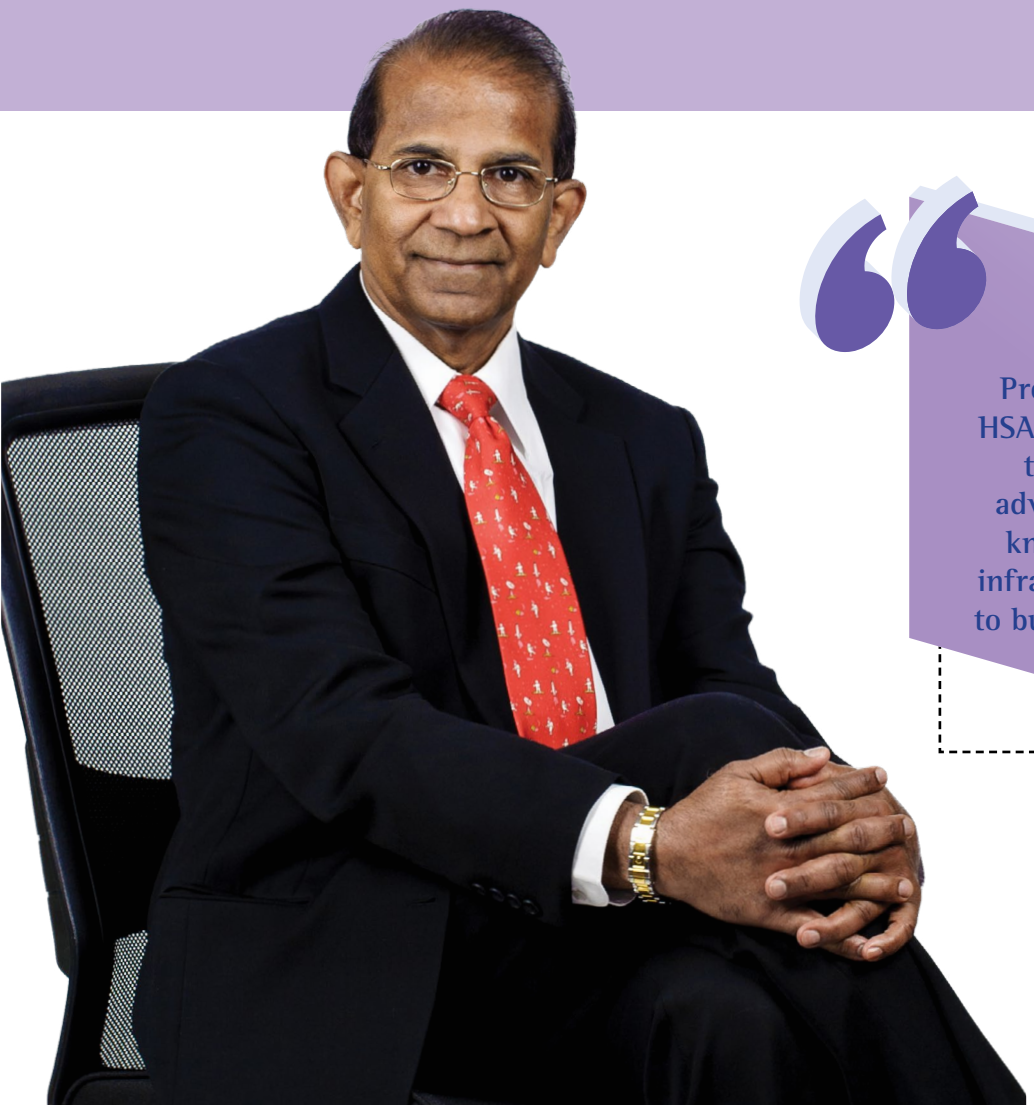
In the health arena, we are always kept on our toes with new challenges. Globally we are seeing continuing outbreaks of infectious diseases like Ebola and MERS, and now outbreaks of the Zika virus. We have to ensure our blood products remain safe.

We are also navigating challenging economic and business conditions, and it is our responsibility as a public service organisation to manage our resources prudently. It is of vital importance that we remain mindful of how our policies and processes impact our stakeholders. We will continue to streamline and simplify our regulatory and business processes to minimise duplication and unnecessary costs.

One major event that HSAians are certainly looking forward to is moving to the new high-rise, energy efficient HSA building located along Jalan Bukit Merah — our new home for the entire HSA family. In our building design and planning, we need to not only facilitate process efficiency but also create the most conducive working environments, setting aside space for staff collaboration and interaction for greater exchange of knowledge and ideas and to nurture innovations.

Then, as now, we will continue to use the best science to fulfil our goals of protecting public health and safety, securing the nation's blood supply and supporting the administration of justice.

Professor Satkunanantham s/o Kandiah
Chairman



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Reviewing the Year with Our CEO

How would you define HSA and what we do?

HSA is an organisation with many critical functions. We play a vital role in serving the nation — safeguard public health through regulating health products, save lives through providing a safe and secure blood supply, and serve the administration of justice through our forensic medicine, and forensic and analytical science services.

What underpins all our functions is our scientific expertise. Our scientific rigour and commitment to excellence and innovation have enabled us to consistently deliver reliable and quality services to our stakeholders, and to the public. HSA's work is continually benchmarked against the best-in-class organisations, and has garnered strong international repute and professional standing.

As a progressive organisation, we are always looking forward and seeking ways to enhance our competencies and capabilities and utilise our resources to achieve even more.

What is the foundation of HSA's success?

Without a doubt, our people are the foundation of HSA's success.

The heart of our success lies in the team of competent and committed staff who are aligned to our goals. The know-how, skillsets and expertise of our people are vital to our ability to carry out our roles well. So we are committed to recruiting talented individuals who resonate with HSA's mission, vision and core values. We are also focused on retaining our talents, and giving them opportunities to attain their fullest potential.

We have a Professional Board, which helps us attract, retain and develop talent by developing and strengthening specialist career tracks. This helps us ensure that our career tracks remain relevant and comparable with our peers.

An example would be HSA's review of our nursing career track, which is now aligned with career paths in public sector hospitals. Our nurses now enjoy more opportunities to develop their professional careers, and to advance nursing expertise and practice in transfusion medicine.

Aside from reviewing career tracks, the Professional Board also looks at developing training roadmaps to serve as a guide for all staff at every stage of their career. This helps our staff to be better-informed on how they can do well and grow further in their jobs.

Going forward, how can HSA continue to remain relevant and work towards its mission?

The future is bright, but it also holds many challenges. To help us be future ready, responsive and relevant, we have a five-year strategic roadmap to guide us on our journey.

Knowledge and Innovation

As a science-based and tech-centric organisation, knowledge and innovation are critical. We have to always be on the lookout for new developments and findings that have the potential to enhance our capabilities.

For example, our DNA Profiling Lab is developing the capability to estimate the age, appearance and ethnicity of an individual from blood samples recovered from crime scenes. There is also ongoing work to extend this capability to other biological materials like semen and saliva. Such capabilities can help provide the authorities with more investigative leads to narrow down their search for perpetrators of crimes.

Our Pharmaceutical Lab supports the Health Products Regulation Group in ensuring the safety of health products in Singapore. Unscrupulous manufacturers are always coming up with new ways to adulterate health products with dangerous drug substances, and detecting these unpermitted substances can be difficult as they cannot be identified by routine testing methods. Through our vigilance and using our scientific expertise, we managed to detect a new compound, lorcaserin, in samples of health supplements. We have since added this compound to our adulterants screening library, further strengthening and expanding our analytical testing capabilities.

To remain a leader in what we do, we must continue to access and assimilate new knowledge and information, share best practices, and undertake research collaborations with our counterpart institutions. We must also maintain good local and global knowledge networks to remain at the forefront of science, technology and medicine.

We are currently working to set up a comprehensive research governance framework and structure to manage and promote the conduct of research in HSA. This organisation-wide framework will ensure our compliance with new national biomedical research regulations, and provide guidance to our researchers in critical areas such as ethics approval, and grant applications, where applicable.

Technology and Infrastructure

With the smart use of technology, we are able to scale up our capabilities, ensure quality and consistency in processes, and improve efficiency and productivity.

An example would be the purchase of an X-ray irradiator by the Blood Services Group. This has increased workflow efficiency and lessened radiation risks. The Blood Services Group also studied and successfully implemented an alternative method of freezing red blood cells to extend their shelf life from 24 hours to 14 days. This facilitates better management of the thawed frozen blood inventory and enables us to better mitigate shortages in months of low blood collection.

We have also started various Information Technology

initiatives, including a revamp of existing laboratory information systems to improve operational efficiency and strengthen IT infrastructure.

Infrastructure-wise, we opened our third satellite blood collection centre, the Bloodbank@Westgate Tower, in June 2015 to serve donors from western Singapore. Bloodbank@Dhoby Ghaut was also expanded to accommodate more donors in a more comfortable environment. We hope these moves will make blood donation more convenient for donors, and attract more donors to help us meet an increasing need for blood.

Governance and Stewardship

It is essential for us to have a robust governance framework and good stewardship in place to help us to optimise the use of our resources, improve efficiency, and ensure proper checks and balances in all we do.

We also conduct regular reviews and audits of our processes to ensure that our quality management systems are robust. One of the ways we have shown our dedication to this is the achievement of the ISO 9001:2008 Certification by our Corporate Services Group, as well as the Audit & Licensing Division. I am proud to share that we attained both certifications with zero non-conformities, which is a testament of our commitment to continual improvement in delivering consistent quality services to our stakeholders.

HSA is a pro-enterprise organisation, and we are mindful that the decisions we make can impact the industry. We continually engage our partners and stakeholders to hear about their issues and concerns, and work together on solutions. On the regulatory front, HSA is transferring the current regulatory controls of therapeutic products to the Health Products Act. The Health Products Regulation Group has held many consultations with industry stakeholders and healthcare professionals to ensure a smooth transition. These consultations are critical in making sure that we adopt relevant risk and confidence-based regulatory controls that safeguard patient health and safety, without creating unnecessary regulatory burden and compliance costs for the industry.

To tackle any future challenges that come our way, we must continue to fine-tune and strengthen our risk management competencies to help us anticipate and address potential challenges and scenarios — this will safeguard our value to stakeholders and help to maintain our good reputation.

With strong leadership, and staff who are both united and committed to achieving the goals in our five-year plan, I believe that HSA will be more than able to fulfil our responsibility of safeguarding public health and justice in Singapore.

Dr Mimi Choong
Chief Executive Officer

> What underpins all our functions is our scientific expertise. Our scientific rigour and commitment to excellence and innovation have enabled us to consistently deliver reliable and quality services to our stakeholders, and to the public. HSA's work is continually benchmarked against the best-in-class organisations, and has garnered strong international repute and professional standing.

HSA Board

As at August 2016

Professor Satkunanantham s/o Kandiah
Chairman
Health Sciences Authority

Mr Max Loh
Managing Partner
ASEAN and Singapore
Ernst & Young

Mr Tai Lee Siang
Chair
World Green Building Council

Ms Serene Wee
Chief Executive
Singapore Academy of Law

Professor Freddy Boey
Deputy President and Provost
Nanyang Technological University

Mr Clifton Tan
Director
Pembrooke Investments Pte Ltd

Mrs Tan Li Lian
Executive Director
Contemporara Holdings Pte Ltd

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

Professor Alex Matter
Chief Executive Officer
Experimental Therapeutics Centre/
Drug Discovery & Development
A*STAR

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

HSA Board Committees

As at August 2016

BOARD EXECUTIVE COMMITTEE

Professor Satkunanantham s/o Kandiah	Chairman
Ms Serene Wee	Member
Mrs Tan Li Lian	Member
Mr Adam Abdur Rahman	Member

AUDIT AND RISK COMMITTEE

Mr Max Loh	Chairman
Mr Clifton Tan	Member
Professor Freddy Boey	Member
Professor Alex Matter	Member

BUILDING DEVELOPMENT COMMITTEE

Mr Tai Lee Siang Chair World Green Building Council	Chairman
Dr Mimi Choong Chief Executive Officer Health Sciences Authority	Co-Chairman
Mr Lionel Yee Woon Chin, SC Solicitor-General Attorney-General's Chambers	Member
Mr Jeffrey Wong Group Director Corporate Services Group	Member
Assoc Professor Sunil Sethi Group Director Applied Sciences Group	Member
Asst Professor Raymond Chua Group Director Health Products Regulation Group	Member
Dr Ang Ai Leen Acting Group Director Blood Services Group	Member
Ms Elizabeth Quah Group Director (Planning) Ministry of Health	Member
Mr Loke Mun Sing Director Healthcare Infrastructure Projects Division Ministry of Health Holdings	Member
Mr Hoong Bee Lok Visiting Consultant Health Sciences Authority	Member

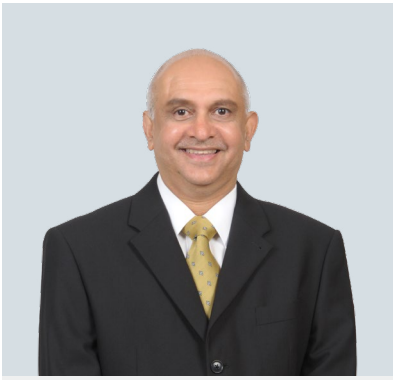
HSA Executive Committee (EXCO)

As at August 2016

Dr Mimi Choong
Chief Executive Officer

Asst Professor Raymond Chua
Group Director
Health Products Regulation Group

Mr Jeffrey Wong
Group Director
Corporate Services Group



Assoc Professor Sunil Sethi
Group Director
Applied Sciences Group

Dr Ang Ai Leen
Acting Group Director
Blood Services Group

Dr Diana Teo
Chairman
Professional Board
Senior Director
Blood Services Group

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

Corporate Governance Statement

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

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

The Board

The Board comprises the Chairman and its members, who are appointed by the Minister for Health for a 2-year or 3-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 and budgets 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

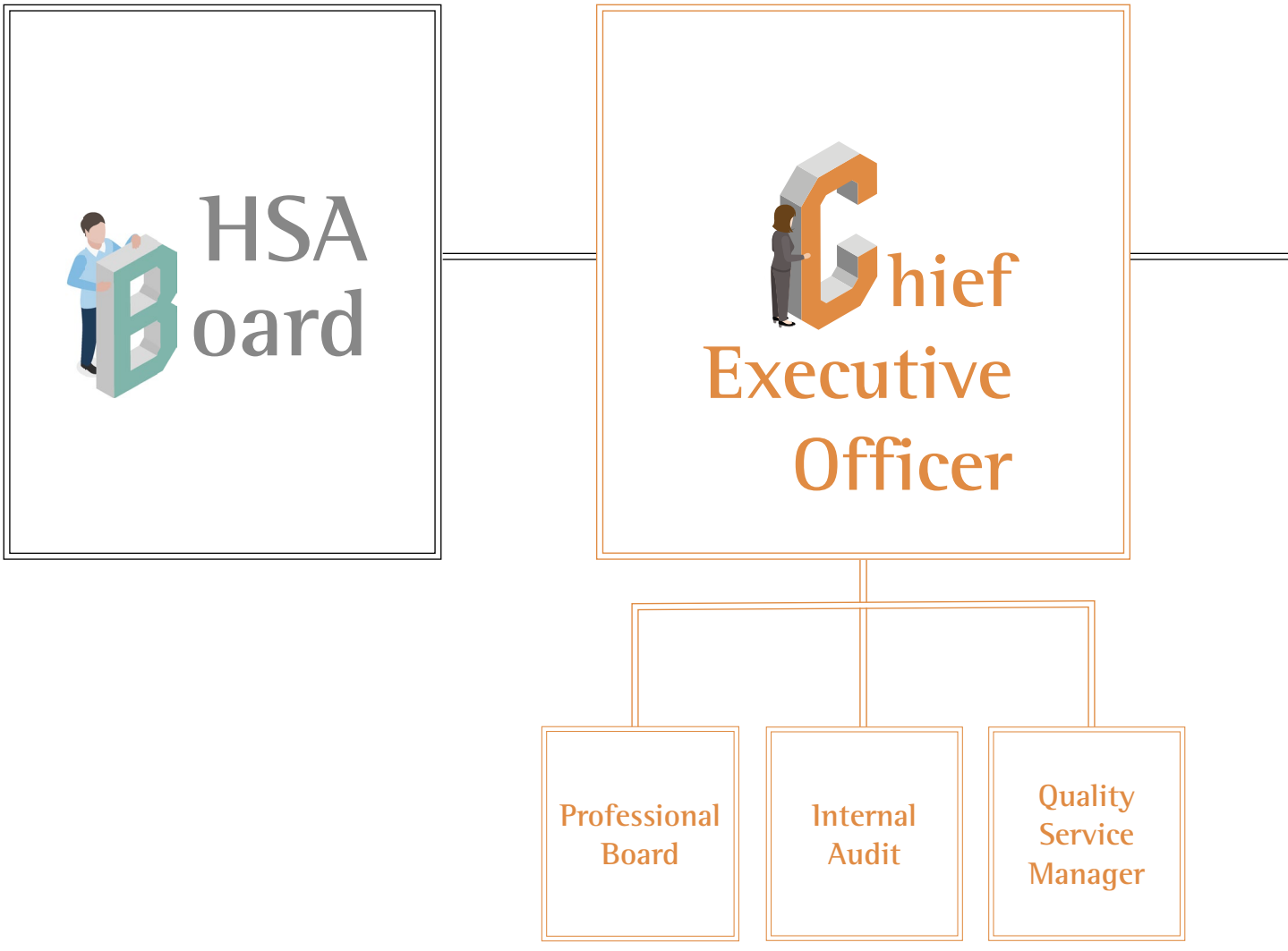
The Board, officers and employees are required to observe and maintain high standards of integrity, and be compliant with the law, government regulations, organisation policies, and best corporate practices.

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 2016



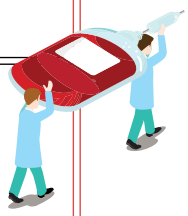
Corporate Services Group

Departments

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

Health Products Regulation Group

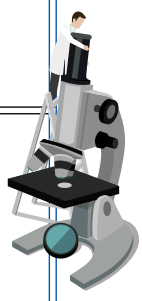
- Therapeutic Products
- Medical Devices
- Complementary Health Products
- Clinical Trials
- Advanced Therapy Products
- Vigilance & Compliance
- Enforcement
- Tobacco Regulation
- Audit & Licensing



Blood Services Group

Branches

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



Applied Sciences Group

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

Principal Officers

As at August 2016

CORPORATE HEADQUARTERS

Chief Executive Officer
Dr Mimi Choong

Professional Board
Chairman
Dr Diana Teo

Quality Service Manager
Director
Professor Bosco Chen Bloodworth

Internal Audit
Assistant Director
Ms Adeline Ho

CORPORATE SERVICES GROUP

Group Director
Mr Jeffrey Wong

Acting Assistant Group Director
Mr Adrian Chia

Corporate Communications
Director (Concurrent Appointment)
Mr Adrian Chia

Risk Management & Emergency Planning
Director
Mr Axel Chan

Human Capital Management
Director
Ms Lily Goh

Legal
General Counsel
Ms Linda Chen

Legal Policy & Prosecution
Director
Assoc Professor Stella Tan
(till 1 Sept 2016)

Director
Ms Grace Lim
(with effect from 1 Sept 2016)

Finance
Director
Ms Grace Chan

Facilities Management
Director
Ms Lynette Goh

Information Management
Director
Mr Manoj Abraham

Professional Board Administration
Director
Mrs Sarojini Padmanathan

Strategy & Business Transformation
Deputy Director
Mr Gabriel Yeo

Safety & Quality
Director
Professor Bosco Chen Bloodworth

HEALTH PRODUCTS REGULATION GROUP

Group Director
Asst Professor Raymond Chua

Deputy Group Director
Assoc Professor Chan Cheng Leng

GROUP DIRECTOR'S & STAKEHOLDER ENGAGEMENT OFFICE

Director
Ms Ling Boon Lee

PRE-MARKET CLUSTER

Assistant Group Director
Ms Lee Hui Keng

Clinical Trials Branch
Director
Mr Foo Yang Tong

Therapeutic Products Branch
Director (Clinical)
Ms Agnes Chan

Director (Quality)
Dr Dinesh Khokal

Medical Devices Branch
Director
Ms Wong Woei Jiuang

Complementary Health Products Branch
Director
Ms Hui Foong Mei

Advanced Therapy Products Unit
Head
Dr Kellathur Nadathur Srinivasan

POST-MARKET CLUSTER

Assistant Group Director
Dr Dorothy Toh

Enforcement Branch
Acting Director
Ms Annie Tan

Vigilance and Compliance Branch
Director
Ms Jalene Poh

Tobacco Regulation Branch
Director
Mr Norman Chong

Audit & Licensing Division
Acting Division Director
Ms Jessica Teo

Audit Branch
Director
Ms Jessica Teo

Licensing & Certification Branch
Director
Dr Lai Weng Fai

BLOOD SERVICES GROUP

Acting Group Director
Dr Ang Ai Leen

Senior Consultant
Dr Diana Teo

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
Ms Wong Wai Cheng

Quality & Accreditation
Senior Manager
Ms J Thilakavathi

BLOOD RESOURCES

Branch Director
Mr William Sim

BLOOD SUPPLY MANAGEMENT

Laboratory Director
Ms Sally Lam

PATIENT SERVICES

Immunohaematology & Cell Therapy Support
Laboratory Director
Dr Marieta Chan

CLINICAL SERVICES

Director
Dr Jason Chay

APPLIED SCIENCES GROUP

Group Director
Assoc Professor Sunil Sethi

QUALITY

Director
Dr Chow Shui Tse

FORENSIC MEDICINE

Chief
Dr Paul Chui

Infrastructure Branch
Branch Director
Dr George Paul

Technical Capabilities Branch
Branch Director
Assoc Professor Cuthbert Teo

Professional Practice Branch
Branch Director
Assoc Professor Gilbert Lau

Operations Branch
Branch Director
Dr Marian Wang

FORENSIC SCIENCE

Assistant Group Director
Dr Angeline Yap

Analytical Toxicology Division
Division Director
Dr Yao Yi Ju

Biology Division
Division Director
Assoc Professor Christopher Syn

Forensic Science Division
Acting Division Director
Mr Lim Thiam Bon

Illicit Drugs Division
Division Director (covering)
Dr Angeline Yap

ANALYTICAL SCIENCE

Assistant Group Director
Ms Low Min Yong

Senior Scientific Advisor
Professor Bosco Chen Bloodworth

Chemical Metrology Division
Division Director
Dr Lee Tong Kooi

Food Safety Division
Division Director
Ms Joanne Chan

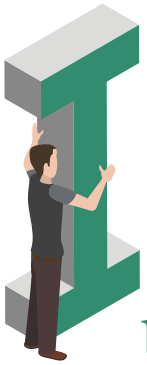
Pharmaceutical Division
Division Director
Ms Low Min Yong

HEALTH

We are Enhancing Our Regulatory System for Public Health and Safety

HEALTH PRODUCTS REGULATION GROUP

Our primary role is to protect public health by wisely regulating drugs, innovative therapeutics, medical devices and health-related products. We do this through safety, quality and effectiveness checks, auditing, licensing, post-market surveillance, and close partnerships with local and international counterparts. Ultimately, we envision having safer health products for the public, more streamlined requirements for the industry, and a stronger regulatory system for stakeholders.



Improving Work through Innovation

We work hard to ensure that Singaporeans have access to innovative and improved health products that meet stringent standards of safety, quality and effectiveness. To this end, we constantly review current regulatory processes and facilitate regulatory innovation.

Pre-market Initiatives

Transferring Regulatory Controls of Pharmaceutical Products to Health Products Act

As an ongoing initiative by HSA to update and consolidate the regulatory controls of health products into a single legislation, we are working on transferring controls of pharmaceutical products from the Medicines Act and Poisons Act to the Health Products Act, where pharmaceutical products will be regulated as 'therapeutic products'. To facilitate this, extensive consultations with stakeholders such as industry and healthcare professionals were conducted. There were multiple focus group discussions with pharmacy personnel, clinical trial stakeholders (industry and healthcare institutions), industry professionals, stakeholders in medical device clinical research materials, and industry associations.

The intended Therapeutic Products (TP) port-over will refine the existing controls to ensure that the new regulations will remain relevant to the evolving pharmaceutical development landscape, and are adequate to safeguard public health and facilitate timely access to TP. Six pieces of subsidiary legislation for the controls of therapeutic products were finalised and gazetted on 15 July 2016. The port-over will be completed and new regulations under the Health Products Act implemented on 1 November 2016.

Annual Reclassification Exercise for Medicinal Products

We have been working to make more drugs available as over-the-counter (OTC) drugs to bring greater convenience to consumers as they purchase these drugs from retailers or from a pharmacist without a doctor's prescription. These medicines have a proven history of use both locally and internationally and are deemed safe enough to be consumed without medical supervision, if taken in accordance with the product information.

In January 2016, we launched a yearly reclassification exercise to further enhance access to effective and safe medicines by the general public. This initiative was the result of focus group discussions with the Pharmaceutical Society of Singapore Community Chapter and other industry stakeholders. We will identify and review the candidates for reclassification, taking into consideration proposals by healthcare professionals and industry stakeholders, as well as international regulatory best practices.

Priority Reviews for Life-saving Medicinal Products

Advances in technology often lead to the discovery of new medicines to help patients. Priority reviews may be considered for medicinal products that are intended to treat life-threatening conditions and address unmet medical needs. In 2015, nine medicinal products were approved under the priority review programme, facilitating timely access of these life-saving medicines for the treatment of cancers and infectious diseases such as Hepatitis C.

Approving First Generic Drugs

First generics are drug products that have never been approved before as generic drug products and are new to the marketplace. First generic drugs provide an alternative to brand name drugs when patent and data exclusivity barriers to approval have been lifted, often leading to lower drug prices for patients and the healthcare system. In 2015, 14 first generic drugs were approved. It is projected that this will result in potential savings of several million dollars for the healthcare system in the following year.

Singapore Quality Overall Summary Workgroup

Working closely with representatives from the pharmaceutical industry helps us identify possible areas of improvement in our processes. A workgroup comprising representatives from HSA, the Singapore Association of Pharmaceutical Industries and Singapore Pharmaceutical Trade Organisation/Singapore Pharmaceutical Manufacturer's Council was formed in January 2015. The aim was to discuss and address the challenges encountered when using the Singapore Quality Overall Summary (SQOS) in the submission of New Drug and Generic Drug applications. Based on the workgroup's recommendations, HSA will work towards the removal of SQOS as a submission requirement to reduce this regulatory burden.

Further Enhancement of Drug Screening Processes

We initiated a programme review project that aims to enhance evaluation efficiency, improve transparency and the processing timeline of New Drug and Generic Drug Applications, such as the introduction of new screening guidelines. We will continue to conduct industry consultations to get feedback on the proposed changes.

Work-sharing Projects and Collaboration with International Regulatory Agencies

HSA participated in the 8th and 9th Australia-Canada-Singapore-Switzerland (ACSS) Consortium Generic Working Group Meetings in May 2015 in Pretoria, South Africa and in October 2015 in Seoul, South Korea. The key outcome from these meetings was the establishment of the framework of the Generic Medicines Work-Sharing Trial, modelled after the European Union's Decentralised Procedure. The experience gained from undertaking this trial is expected to support regulatory decision-making within each jurisdiction and lead to future work-sharing initiatives. The four agencies acknowledged the importance of pro-active engagement with their respective generic industry associations and other stakeholders to facilitate the timely availability of safe, effective and quality generic drugs.

In September 2015, we participated in the first face-to-face ACSS Consortium New Chemical Entity (NCE)/Benefit Risk Working Group meeting in Montreux, Switzerland. One of the objectives of the Working Group is to explore work-sharing arrangements on new drugs for the consortium agencies. The Working Group has initiated cluster discussions in 2016 for selected topics of common interest as part of confidence building, information sharing and promoting regulatory convergence for the consortium agencies.

Advancing Cell Therapy in the ASEAN Region

In January 2016, HSA was invited as a speaker at the Advanced Therapeutics Workshop organised by the Centre of Regulatory Excellence (CoRE) at Duke-NUS Medical School. The objectives were to share and learn evaluation experiences of cell therapy products; to develop a better understanding on the dossier requirements and regulatory expectations; to understand the basis of the various regulatory frameworks, and the upcoming challenges in regulation. Attendees included regulators from ASEAN member states, regulatory professionals from the industry, academia and government agencies.

Review of Change Notification Processes

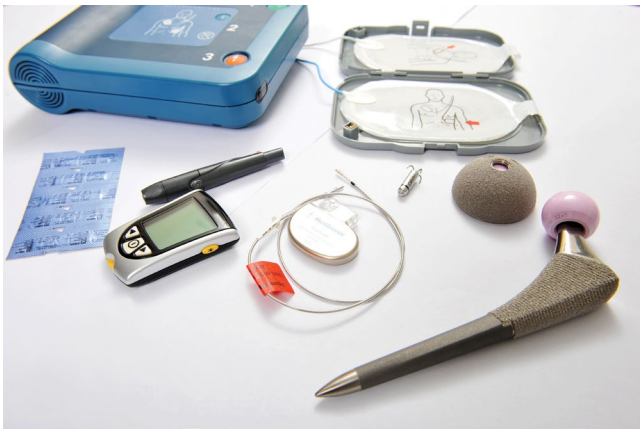
As part of our regular regulatory process review, we examined the key feedback regarding medical device Change Notification (CN) and Field Safety Corrective Action-Change Notification (FSCA-CN) processes. Key industry dialogue sessions were initiated together with the local industry associations where representatives shared and provided feedback on the related processes. Training and focus group discussions were organised with the Association of Medical Device Industry, Singapore (AMDI) in April 2015. A HSA-industry dialogue session was initiated together with the Singapore Manufacturing Federation-Medical Technology Industry Group (SMF-MTIG) in July 2015. The valuable interaction with the stakeholders helped us collate the diverse industry-wide concerns and suggestions for the ongoing CN and FSCA process review. We also invited local industry representatives, including members of the SMF and AMDI to provide feedback and participate in a CN workgroup to maintain relevance and streamline the CN process for the immediate future. The workgroup's industry inputs and accepted recommendations were implemented in December 2015 for a clearer and simplified CN process.

Launching Field Safety Notices Webpage

We keep medical professionals up-to-date about the safety of medical devices through Field Safety Notices (FSN). These used to be uploaded to a Ministry of Health Alert website, but this was only available to doctors, dentists and pharmacists using their professional accounts. We initiated the uploading of FSN on HSA's new medical device FSN webpage in September 2015 to make it more readily available. Now, other stakeholders such as biomedical engineers of healthcare institutions (HCI) can access the information, facilitating timely identification of the affected medical devices and the resolution of corrective actions in their facilities. This complements HSA's post-market surveillance activities, which include the monitoring of the effective conduct of medical devices FSCA by the companies.

Refining the Field Safety Corrective Action Process

Medical devices suspected of being potentially harmful to users are subject to a FSCA by their product owners, dealers or manufacturers. The overall FSCA reporting and review processes were simplified to improve the FSCA reporting process and for faster FSCA regulatory decisions which would minimise disruption to the local supply of medical devices. As a result of thorough reviews using Lean Six Sigma methodologies, this refinement has led to quicker processing for both dealers and HSA, and provided greater clarity and predictability to companies when dealing with FSCA.



Allowing the Use of Chinese Herbs Containing Berberine

Berberine was prohibited in Singapore since 1978 following concerns that it was among the several causes of severe jaundice and brain damage in glucose-6-phosphate dehydrogenase (G6PD) deficient infants.

Based on reviews conducted, there were no major safety concerns with berberine when used appropriately. The ban was thus lifted in phases. In January 2013, Chinese proprietary medicines (CPM) containing berberine were allowed for sale and import. In April 2016, the ban on Chinese herbs containing berberine was also lifted, providing Traditional Chinese Medicine (TCM) practitioners with greater options in the use of TCM in their practice. Local CPM manufacturers who want to import such herbs for the manufacturing of CPM are also no longer required to apply for the Form A Poisons Licence from April 2016.

Post-market Initiatives

Product Risk Management

When significant safety concerns associated with medicinal products are identified at the point of market approval or emerge after market authorisation, HSA may require the implementation of risk management plans (RMPs) for these products to minimise the risk and ensure that their benefit-risk profile remains positive. Components of local RMPs may include the issuance of educational materials for physicians and patients to highlight the safety concerns, the submission of periodic benefit-risk evaluation reports, as well as the strengthening of safety warnings in the package inserts.

In the year, RMPs for eight medicinal products — Opsumit, Gazyva, Remsima, Keytruda, Lemtrada, Hexaxim, Zydelig, and Entyvio — were implemented. HSA has also been monitoring the number of serious skin reactions since the implementation of an RMP for strontium ranelate in 2013 to mitigate the risk, which includes educating patients for early signs of serious skin reactions. As a result, we have not received any new reports of serious skin reactions with strontium ranelate since 2014.

We have also conducted 15 risk assessments in 2015, arising from health products found to contain adulterants or exceeding toxic heavy metal limits, as part of product quality surveillance and post-market surveillance activities. Regulatory actions taken include the seizure of affected products, including S Lion Juice and PUTIH GEBU KEKAL Pati Ibuputih, and the issuance of press releases for these products.

Surveillance of Local Product Defects

Product defect reports are submitted to HSA by local product registrants, and contain information on possible quality related problems such as deviations from the products' specifications, issues with packaging, labelling and dosing, product contamination, manufacturing deficiencies, and safety findings. Between April 2015 and March 2016, 58 product defect reports were submitted on chemical pharmaceutical products, biological products, cosmetic products, and health supplements.

Receiving Updates on Local Adverse Events

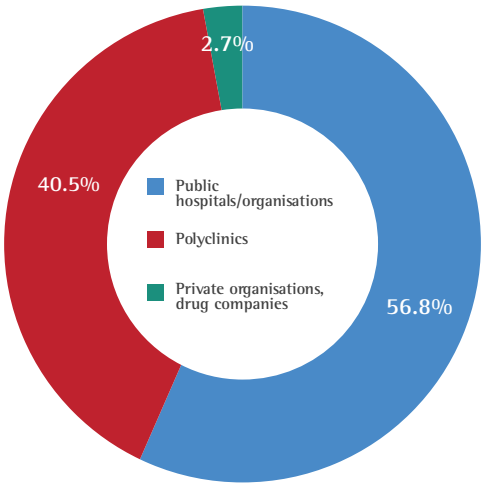
As part of its post-marketing risk detection approach to ensure health products and medical devices are safe for consumption or use, HSA receives regular reports on Adverse Events (AE) from healthcare professionals, manufacturers, dealers, and the product registrants. Monitoring of AE reports is one of the most important ways we keep track of the safety of a health product throughout its life cycle.

Adverse Event Reports on Health Products

Singapore retains its position on the World Health Organization (WHO) global Individual Case Safety Report (ICSR) database, ranking first in terms of the number of active individual case reports submitted per million inhabitants. We have maintained this position since 2011 with the support of vigilant healthcare professionals. HSA received a total of 26,930 local reports of AE suspected to be associated with health products (excluding medical devices) in FY 2015. Of these, 20,921 or approximately 78% of the total number received were captured into the national database as valid reports. Through our close monitoring and reviews of local AE reports, we identified the following significant drug safety signals locally:

- Risk of interstitial nephritis with omeprazole
- Risk of thrombotic microangiopathy with tacrolimus
- Risk of fixed drug eruption with etoricoxib

These safety signals were highlighted to healthcare professionals via the HSA Adverse Drug Reaction News Bulletin.



Source of AE reports for FY 2015

Adverse Event Reports on Medical Devices

HSA received 302 local reports of AE suspected to be associated with medical devices. Almost all the reports were contributed by dealers of the medical devices, who receive feedback on AE from hospitals and healthcare professionals.

Through our close monitoring of local AE reports and cooperation with device manufacturers and dealers, we are able to identify significant safety signals to be shared, and alert local healthcare professionals when necessary.

Vaccine Vigilance

In our efforts to maintain the safety of health products, HSA carries out active surveillance of adverse events (AE) reports from partners and stakeholders. For example, we work closely with KK Women's and Children's Hospital in the surveillance of suspected AEs after vaccination to ensure that potential safety signals are quickly detected and addressed.

From April 2015 to March 2016, 31,194 children were screened for AEs following vaccinations, and 221 cases of suspected AEs were further reviewed. We assessed the potential safety signals to ensure that the reports were within expected incidences listed in the product package inserts or in literature. Expert opinions were also sought to ensure that the benefit/risk profile of the vaccines remains favourable.

Lean Six Sigma Projects Undertaken

To improve processes, a number of Lean Six Sigma projects were initiated. These include:

- A review of the therapeutic products licence application process
- A review of the registration process for high risk medical devices
- Improving time taken on the follow-up on Change Notifications and Field Safety Corrective Actions for medical devices
- Improving stakeholder engagement and experience at the Health Products Regulation Group Connect Centre

Sharing HSA's Pharmacogenetics Initiative

As part of regulatory innovation, HSA's Pharmacogenetics (PGx) team is responsible for reviewing safety-related pharmacogenomics associations, recommending necessary product label changes, and communicating important pharmacogenomics associations to healthcare professionals. HSA's PGx initiative has been shared with local and international communities of academia, regulators and researchers on a number of occasions. Some of the key events are featured here.

Global Genomic Medicine Collaborative (G2MC) 2015 Symposium

Held in Singapore in November 2015, "G2MC 2015 Symposium: Implementing Genomic Medicine into Practice" aimed to identify and discuss regulations and policies that impact the implementation of genomic medicine, and to highlight best practices and lessons to enable others to effectively implement genomic medicine approaches.

Dr Mimi Choong, Chief Executive Officer of HSA, spoke about the evolution of genomic medicine and the broad principles of how personalised medicine could be regulated in Singapore. The audience was also updated on the impact of one of the regulatory recommendations to test for the HLA-B*1502 gene in all local patients of Asian ancestry starting on carbamazepine. This has reduced carbamazepine-induced serious skin rash from an average of 15 cases per year to no cases among patients screened since its implementation in April 2013.

Netherlands Medicines Evaluation Board

Guests from the Netherlands Medicines Evaluation Board (MEB), including its Executive Director, Mr Hugo Hurts, visited HSA in October 2015 to learn about HSA's pharmacogenetics initiatives. The meeting discussed the assessments of medicines and regulatory science, and emerging areas such as cell, tissue and gene therapy products and food-drug interphase products. Subsequently, MEB extended an invitation to HSA to give a presentation titled "Effective Surveillance through Screening of Patients at Risk for Serious Skin Rash in Singapore" at the Netherlands MEB Regulatory Science Day in Utrecht, Netherlands, in February 2016.

National University of Singapore

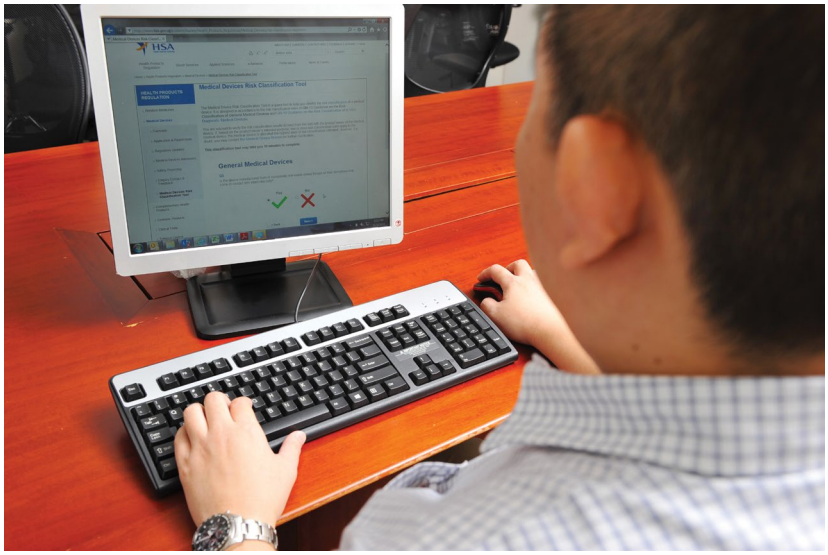
HSA's pharmacogenetics initiatives were presented to Professor Wolfgang Sadee, Felts Mercer Professor of Medicine, Chair of Department of Pharmacology at College of Medicine, Center for Pharmacogenomics at the Ohio State University. The visit which took place in November 2015 was hosted by the National University of Singapore's School of Pharmacy.

Building Infrastructure for Advancement

HSA constantly pushes for technological advancements and improvements to infrastructure to enhance its role as a regulator. With these advancements, we are able to provide timely and accurate delivery of information about the risk-benefit profile of health products, and have the knowledge to make sound regulatory decisions.

Creating the HSA Online Medical Device Risk Classification Tool

To help the trade identify the risk classification of a medical device, HSA has created the Medical Device Risk Classification Tool. This is a self-help query tool that allows users to quickly navigate the risk classification considerations electronically by answering a few questions, when trying to determine the risk classification of a medical device. This enables the enquirer to get immediate risk classification, compared to filling up the hardcopy enquiry form previously, thus saving time and resources. It has won the Pro-enterprise Award, presented by the Ministry of Trade and Industry, for its direct and positive impact on industry stakeholders.



Good Governance and Stewardship

Having good governance in our regulatory processes and operations is absolutely crucial. This encompasses being fair in dealings, and having transparency and clarity in our regulatory decisions. We work to be good stewards, ensuring judicious use of resources.

Interacting with the Industry

We meet regularly with industry stakeholders to share knowledge and expertise, so as to enhance their awareness in the regulatory processes, to assist in their regulatory submissions and post-market obligations. The interactions also help us to better understand their business models and obtain feedback to further enhance our regulatory policies and framework to reduce regulatory costs and burden, where possible, while safeguarding public health.

HSA Medical Device Regulatory Forum

International and local experts were invited to share innovative strategies and best practices in the medical device arena at the HSA Medical Device Regulatory Forum in September 2015. The forum aimed to create a platform for stakeholders to share the latest trends and technology for medical devices, share perspectives, and exchange ideas on how the industry and regulators can co-create solutions to further enhance the medical device regulatory framework, resulting in the advancement of public health. International medical device expert, Dr Michael Drues, from Vascular Sciences in the USA, explored the emerging trends, opportunities, and challenges of the future of the global medical device sector.

Medical Device Workshop

In February 2016, the medical device workshop "The Use of Standards in Medical Devices" was jointly organised by HSA, the Pharmaceuticals and Medical Devices Agency, Japan, and the Singapore Manufacturing Federation Standards Development Organisation. It was held to facilitate understanding of the current regulations on the use of standards, and provided a platform for regional regulators and regulatory affairs professionals to share recent developments in the regulatory frameworks in the ASEAN region.

TechInnovation and TechVenture 2015

TechInnovation and TechVenture 2015 brought together Singapore-based start-ups and introduced them to the global investment community. As part of the event, in September 2015, HSA conducted a sharing session for the technology accelerators, incubators, and participants to give them an overview of medical device regulatory controls and framework. This session was held to improve the awareness of regulatory strategic considerations necessary for budding innovators when navigating the local or international regulatory systems.

Trade Engagement Session with Tobacco Retailers

A ban on displaying tobacco products in the public's line of sight, or tobacco point-of-sale displays (POSD) — was passed by Parliament in March 2016. Prior to that in December 2015, in order to help retailers get on board with the new measures, HSA, the Ministry of Health, and the Health Promotion Board held a trade engagement session with tobacco retailers that was chaired by Dr Amy Khor, Senior Minister of State for Health, and Environment and Water Resources. Brochures of the implementation guidelines were distributed to tobacco retailers to assist them in complying with the POSD ban. HSA officers also explained the measures to retailers during visits to tobacco retail outlets, and shared the possible ways to store tobacco products away from the public's line of sight.

Eradicating Polio with WHO

Polio is a crippling disease that the World Health Organization (WHO) has worked to eradicate worldwide. A phased withdrawal of the trivalent oral poliovirus vaccine (tOPV) is needed to achieve this because of the risk of outbreaks due to circulating vaccine-derived polioviruses. As part of the WHO's Polio Eradication Plan, a globally synchronised withdrawal of tOPV and a switch to bivalent OPV (bOPV) began in April 2016, removing the type 2 poliovirus component from immunisation programmes. In support of this plan, HSA worked closely with medical companies to expedite the submission and approval process of the vaccine to ensure the availability of the bOPV vaccine for our local population. The vaccine was approved in February 2016, within a relatively short period of four months.

Our Enforcement Efforts

HSA partners with law enforcement agencies regularly in various joint operations to address the peddling of illegal health products and tobacco products.

Sexual Enhancement Drugs Wipeout

Joint operations between the Singapore Police Force (SPF) and HSA were conducted at Geylang, where more than 94,000 units of sexual enhancement drugs comprising 80 different types of illegal health products were seized. The seizure had an estimated street value of more than $200,000.

Operation White Rabbit

SPF and HSA launched Operation White Rabbit to target illegal peddlers of sex drugs in the red light district. During the operation, more than 60,000 units of drugs with a street value of more than $180,000 were seized and 17 people were arrested and repatriated.

Illegal Supply of Codeine Halted

Six doctors were among 10 individuals investigated for the illegal supply of codeine cough syrup to underground drug syndicates. Joint operations by HSA and SPF also led to the seizure of products with an estimated street value of over $200,000. The accused persons were charged and those found guilty were punished with fines and/or jail time.

Annual Operation Pangea VIII

The eighth instalment of Operation Pangea, a week of Internet-based enforcement operations coordinated by INTERPOL, was conducted internationally from 9 to 16 June 2015. During this operation, HSA seized more than 11,000 units of illegal health products with a total street value of more than $20,000. These illegal health products comprised Western medicines, slimming products, and contact lenses. 12 people are currently assisting HSA in investigations.

Vaporiser Offences

Two Singaporean males were prosecuted in August 2015 for the illegal online sale of vaporisers. They purchased the vaporisers illegally from overseas suppliers in Thailand and the United States on two websites. Both peddlers were convicted and fined a total of $31,000.

In another case, HSA shut down the operations of two peddlers selling vaporisers and vaporiser accessories after raiding their premises at Pasir Ris and Geylang in February 2016. More than 1,000 vaporiser supplies, with an estimated value of around $23,000 were seized. Both peddlers had sold their products on social media platforms.

Crackdown on Tobacco Offences

HSA coordinated with the Singapore Customs to jointly prosecute a recalcitrant tobacco wholesaler. The wholesaler was subsequently sentenced by the State Courts on 9 December 2015 to a fine of $63,900 for the unlicensed wholesaling of ang hoon tobacco or loose tobacco leaves, an offence under the Tobacco (Control of Advertisements and Sale) Act. He was also fined $955,000 and eight months' imprisonment for duty evasion, an offence under the Customs Act and the Goods and Services Tax Act.

In support of the national tobacco control policy against illegal sales of tobacco products to under-18 minors, a total of nine tobacco retail licences were suspended for 6 months and two tobacco retail licences were revoked for selling tobacco products to under-18 minors. Additionally, five tobacco retail licences were revoked for breaching licensing terms and conditions.

Developing an Educational Approach to the Sale of Medicinal Products

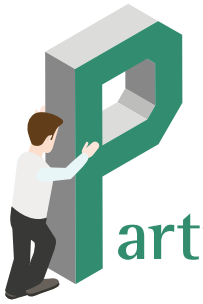
HSA regulates the sale of medicinal products in Singapore, ensuring that only registered products are sold at licensed retailers. When we received feedback about the sale of medicinal products at shops located at Peninsula Plaza, we carried out compliance checks and found that several stores styled as toiletry shops were selling products labelled to contain poisons such as ibuprofen, metronidazole and chlorpheniramine. These products included antibiotic tablets and creams, paracetamol tablets, ibuprofen tablets and antifungal creams. 14 shop owners were informed of regulations surrounding the sale of medicinal products and the offence of selling unregistered medicinal products, and these products were removed from the shelves. The shop owners were very receptive to this educational approach as it enabled them to learn more about the regulations governing medicinal products.

Ongoing Public Education on Dangers of Illegal Health Products

To educate the public on the dangers of illegal health products, HSA distributes a consumer advisory booklet on illegal health products at polyclinics and related events, and works with the Health Promotion Board to put up informative consumer articles on the HealthHub website.

Engaging Healthcare Professionals

HSA maintains close communication with healthcare professionals, keeping them up-to-date on the latest safety issues and regulatory decisions related to health products. As part of this effort, four Dear Healthcare Professional Letters (DHCPL) were issued from April 2015 to March 2016, and 47 DHCPLs issued by industry were vetted by HSA within the same period. The HSA ADR News Bulletin continued to receive accolades from healthcare professionals who view it as a staple source of safety information. Additionally, HSA communicated important safety issues to the public via 11 press releases. This included alerts on illegal, adulterated health products and harmful cosmetic products.



Partnering Local Organisations

HSA is constantly developing new partnerships while building on current relationships in order to ensure that health products in Singapore are safe for the public.

Study on Serious Skin Rash

HSA Pharmacogenetics (PGx) team completed the evaluation on the role of HLA-B*5801 genotyping prior to the initiation of allopurinol. HSA, together with the Ministry of Health (MOH), jointly issued a Dear Healthcare Professional Letter (DHCPL) in March 2016 to remind healthcare professionals of the risk of allopurinol-induced severe cutaneous adverse reactions, and inform on the role of genotyping prior to the initiation of allopurinol.

Study on Drug-induced Liver Injury

When regulatory actions like the withdrawal of marketing approval, post-marketing withdrawal and restrictions on prescriptions are taken, it is often because the medication in question has been found to cause drug-induced liver injury (DILI). To help uncover possible genetic associations behind serious adverse drug reactions, HSA embarked on a study with the Singapore General Hospital titled "Pharmacogenetics of Adverse Drug Reactions — Drug-induced Liver Injury (DILI)". Information from this study aims to help to reduce the incidence of DILI in Singapore.

Surveillance and Pharmacogenomics Initiative for Adverse Drug Reactions (SAPhIRE)

The SAPhIRE programme is a strategic partnership among the Genome Institute of Singapore (GIS), Translational Lab of Genetic Medicine (TLGM) and HSA to improve drug safety. HSA will lead the establishment of a national active surveillance network while GIS, TLGM and physician collaborators will work on discovery and validation of pharmacogenomic biomarkers and development of diagnostic tests of highest relevance to Asian populations in Singapore. Global experts including Dr Dukyoon Yong from Korea's Ajou University and Professor Jeff Brown from Harvard Pilgrim Health have also lent their expertise in this significant collaboration.

Pre-registration Pharmacist Training Programme

HSA conducted a 12-week pre-registration pharmacist training programme for four pre-registration pharmacists from Ng Teng Fong General Hospital from December 2015 to March 2016. The participants learnt about the specific roles and responsibilities of HSA staff in various areas of regulatory work and how we safeguard public health.

Graduate Certificate in Medical Devices Regulatory Affairs Programme

Established in 2014, this certification programme is a joint collaboration between the National University of Singapore's Department of Biomedical Engineering, and the Regulatory Affairs Professionals Society. Through an integrated learning approach, this programme provides an invaluable platform for participants, including regulators, to acquire professional knowledge of the regulatory practices and issues. Since its inauguration, four HSA staff members have participated, and graduated as part of the pioneer batch in 2015.

Partnerships Beyond Singapore

Developing working partnerships with overseas organisations helps HSA to stay up-to-date with the latest developments in health product regulation and health product industries, to enable us to better carry out our role to secure public health and safety.

Study Trip to Australia

A team of five HSA staff visited the Therapeutic Goods Administration (TGA) in Australia in November 2015. The study trip allowed the team to gain more in-depth knowledge of TGA's regulatory frameworks for medical devices and complementary medicines, the challenges posed by the regulatory regimes, regulatory impact assessments conducted by TGA, stakeholder engagement for their regulatory processes, and the ongoing government level regulatory reform initiative.

APEC Harmonisation Centre Pharmacovigilance Workshop and Training

HSA supported the APEC Harmonisation Centre Pharmacovigilance Workshop and Training Programme held in Seoul, South Korea, in September 2015. We delivered a presentation at the workshop and conducted training on Risk Communication — these were rated highly by participants, who gave feedback that they found the training very useful.

Sharing Learning Experiences

HSA was invited by agencies worldwide to speak in numerous international training sessions throughout the year. The subjects we spoke on include:

- Gene therapy product development at the International Pharmaceutical Regulators Forum in New Orleans, USA
- Cell Therapy in Singapore at the International Forum on Regulation of Cell Therapy in Taipei, Taiwan
- Regulatory experiences on plasma quality and plasma-derived medicinal products in Singapore at the International Plasma Fractionation Association Asia Pacific Workshop in Taipei, Taiwan

Pharmacovigilance Workshop

In collaboration with WHO and Uppsala Monitoring Centre (UMC), HSA jointly organised the WHO-UMC-HSA Inter-Regional Pharmacovigilance (PV) Training Workshop. This was held from September to October 2015 in Singapore, the third collaboration on PV training since the inaugural workshop held in 2010. We hosted over 50 local and international participants from ASEAN and the Asia Pacific region. We were also privileged to have guest speakers from Japan, New Zealand, Pakistan, Sweden and Switzerland.

The course received positive feedback from participants, many agreeing that it enabled them to learn useful tools for building a good pharmacovigilance system in their countries.

Healthcare Data Analytics Sharing Sessions

HSA hosted Professor Jeffrey Stuart Brown, MOH Health Manpower Development Plan Visiting Expert, in November 2015. Professor Brown played a pivotal role in developing the U.S. Food and Drug Administration's Mini-Sentinel pilot project with the objective of creating a national public health active surveillance system. This system was created to monitor the safety of regulated medical products, such as drugs, biologics and devices.

During his visit, Professor Brown met with participants from various healthcare and academic institutions, sharing his expertise on the details of the operational structure of the Sentinel Operations Centre. He talked about developing the necessary infrastructure, systems and methodologies, as well as collating and using existing healthcare data from various data partners in a distributed network by using a common data model. Professor Brown also gave valuable advice on how HSA could further enhance our current active surveillance system for better drug safety signal detection and verification.

Joint Projects between Malaysia and Singapore

The 4th Bilateral Meeting with the National Pharmaceutical Control Bureau (NPCB), Ministry of Health, Malaysia, and HSA, was held in July 2015. At the meeting, HSA and NPCB provided regulatory updates and progress on various cooperation projects.

Another focus of the meeting was to continue with work-sharing initiatives in the area of drug registration of generic products, and a prospective joint review of a generic product submitted to both agencies was carried out to achieve this. We believe this will enhance confidence building, deepen the understanding of each other's processes, and promote the convergence of technical requirements for product registration. Both agencies have agreed to continue information- and work-sharing initiatives in the various cooperation projects.

1st ASEAN Medical Device Committee Meeting

The ASEAN Medical Device Directive (AMDD) Agreement was signed in 2014 and would pave the way towards reducing economic barriers through establishing common interpretations and aligning definitions and documentation for ASEAN member states, developing pre- and post-market guidelines for medical devices, and more. Following the signing, the ASEAN Medical Device Committee (AMDC) was established in November 2015 to oversee the implementation of AMDD in member states, and held its first meeting in December 2015.

HSA is the first ASEAN member state agency to roll out medical device regulations, and we maintain a framework that is aligned with the framework by AMDD.

Bilateral Meetings with International Partner Agencies

HSA played host to a number of bilateral meetings with international partner agencies throughout the year.

Pharmaceuticals and Medical Devices Agency, Japan

Members of the Pharmaceuticals and Medical Devices Agency, Japan, including its CEO Dr Tatsuya Kondo, and Associate Executive Director (for International Programs) Dr Toshi Tominaga, visited in October 2015 to exchange regulatory updates and share their future plans and key strategies.

Therapeutic Goods Administration, Australia

A meeting in February 2016 with the Therapeutic Goods Administration, Australia, including its Deputy Secretary of the Regulatory Services Group at the Department of Health, Adjunct Professor John Skerritt, saw a discussion on a myriad of key topics such as the regulation of various therapeutic goods, and regulatory impact analysis.

Hosting and Sharing with International Guests

We were involved in a series of international events and meetings that were held in Singapore. The visits included the following:

- May 2015 – Dr Desmond Johns from the Institute for Regulatory Science, National Department of Health, Pretoria, South Africa, visited to share regulatory training framework and licensing regimes
- May 2015 – Delegates from the Chinese University of Hong Kong visited to share approaches on regulating medical advertisements
- July 2015 – Visitors from the Guangxi Food and Drug Authority met with HSA officials on a sharing session on the regulatory framework of drugs, cosmetics and healthcare products in Singapore and Guangxi
- July 2015 – Delegates from the Myanmar Food and Drug Administration visited to learn more about HSA's pharmacovigilance framework
- August to September 2015 – Members of the Ministry of Health and Sports, Mongolia, visited to share their regulatory practices
- December 2015 – Delegates from the Drug Administration of Vietnam visited to share their regulatory practices on Western medicines, cell therapy and gene therapy products, controls of cosmetic products, post-market surveillance for cosmetics, GMP and GDP inspections, and licensing requirements
- January 2016 – Cambodian Ministry of Health officials visited to discuss their regulatory practices and technical systems of Western drugs and medical devices
- January 2016 – Members of the Yunnan Food and Drug Authority, China, shared regulatory practices of drug evaluation and health products regulation, post-market surveillance, and incident crisis management
- February to March 2016 – Delegates from Japan's National Institute of Infectious Diseases visited to find out more about our Adverse Event Following Immunisation monitoring and surveillance system

WHO Informal Consultation on Regulatory Risk Assessment for Biotherapeutic Products

HSA was the Chair of an informal consultation with the WHO to discuss a new document on Regulatory Risk Assessment. This meeting led to a proposal to amend an existing WHO guideline on the quality, safety and efficacy of bio-therapeutic protein products prepared by recombinant DNA technology, instead of drafting a new WHO guideline. This recommendation was then made to the WHO Expert Committee on Biological Standardization for consideration.

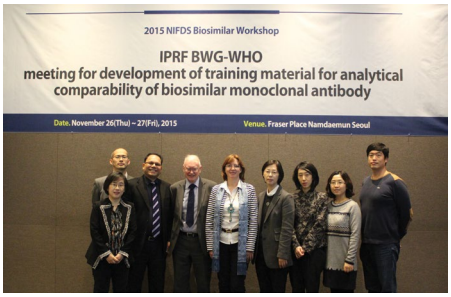
WHO Expert Committee on Biological Standardization

The WHO Expert Committee on Biological Standardization is responsible for establishing recommendations and guidelines for the manufacturing, licensing, and control of blood products, cell regulators, vaccines and related in vitro diagnostic tests. HSA was involved in discussing and finalising recommendations in the areas of:

- WHO reports and updates
- International guidelines, recommendations and other matters related to the manufacture and quality control of biologicals
- International reference materials for virus, vaccines and related substances
- International reference materials for biotherapeutics
- International reference materials for blood products and related substances
- International reference materials for in vitro diagnostic devices and reagents
- International reference materials for antibiotics

International Pharmaceutical Regulators Forum – WHO Meeting

HSA participated in a meeting between the International Pharmaceutical Regulators Forum (IPRF) Biologics Working Group and WHO. The goal of this meeting was to develop a manual for regulatory reviewers on "Analytical tools for comparability of biosimilar monoclonal antibodies", which would support WHO's global implementation of training activity on biosimilars.



1st and 2nd International Generic Drug Regulators Programme Meeting

The International Generic Drug Regulators Programme (IGDRP) was formed in 2015 after a three-year pilot phase, and works to promote collaboration and convergence in generic drug regulatory programmes. This move will help to address the challenges posed by increasing workloads and complexity of scientific issues.

HSA participated in the first and second IGDRP Meeting which was held in Pretoria, South Africa in May 2015 and in Seoul, South Korea in November 2015 respectively.

Discussions on 21st Century Innovative Regulations

In September 2015, Professor Peter J. Pitts, Partner and Director of Global Health Care at Porter Novelli, visited HSA to share insights on the urgency of quality and innovation in 21st century medicine regulation. Professor Pitts had also served as the US FDA's Associate Commissioner for External Relations, where he acted as senior communications and policy adviser to the Commissioner.

Industry Training from Singapore Manufacturing Federation

In March 2016, the Singapore Manufacturing Federation's Medical Technology Industry Group (SMF-MTIG) assisted to bring overseas experts to help train and enhance the regulatory skills of HSA staff. Some of these trainings included: (i) Implementing Design Control Requirements and Best Practices for Medical Devices, (ii) ISO13485 Lead Auditors Training, and (iii) Workshop on Human Factors Engineering for Medical Devices.

Annual Storm Enforcement Network Meeting

The Storm Enforcement Network serves as a platform for different enforcement agencies to collaborate and cooperate to fight pharmaceutical crime in the ASEAN region. In June 2015, the Annual Storm Enforcement Network Meeting took place in Singapore. The two-day meeting gathered representatives from the Customs, Police and Drug Regulators from 10 ASEAN countries. HSA's enforcement officers' investigations into the illegal supply of codeine cough syrup were showcased at this meeting.

Following the meeting, INTERPOL and HSA conducted a two-day training session for participants. This was necessary because of the increasing complexity of pharmaceutical and trans-border crimes, as well as the involvement of drug syndicates and even healthcare professionals in pharmaceutical crime. Participants were taught and equipped with the know-how in combating these new challenges.

Sharing Singapore's Experience in Enforcing Tobacco Control

HSA had the opportunity to share its enforcement best practices with a delegation team led by the Philippines Government in July 2015. Delegates were introduced to our enforcement against the use of tobacco by minors under 18 years of age and errant tobacco retailers, and learnt more about the administration of the tobacco licensing system.

Recognition for High Standards

HSA has been recognised for its numerous accomplishments through numerous awards and achieving international accreditations.

Awards Presented by the Ministry of Home Affairs

In recognition and appreciation of the role they played in successfully tackling the problem of Romilar and Milam tablets, HSA's enforcement officers were presented with Certificates of Appreciation by Mr K Shanmugam, Minister for Home Affairs and Law, in November 2015. A total of 16 people were arrested and 10 charged through this operation, and the number of peddling cases of these drugs has been significantly reduced. The joint operation is an excellent example of successful collaboration between different law enforcement agencies in Singapore, and the positive impact it has on deterring illegal activities.

ISO 9001:2008 Surveillance Audit on Tobacco Regulation Branch

HSA's Tobacco Regulation Branch (TRB) has achieved ISO 9001:2008 certification since 2011. TRB passed the external surveillance audit conducted in February 2015 successfully. This was done to assess our administration and enforcement of the Tobacco (Control of Advertisements and Sale) Act and its subsidiary legislation, as well as its compliance with the standard(s) requirement under ISO 9001:2008.

ISO 9001:2008 Certification for Audit and Licensing

The Audit & Licensing Division of HSA was certified to the ISO 9001:2008 standard in October 2015, with no major or minor non-conformities. This accreditation highlights the consistency of our audit, licensing and certification processes which will lead to increased confidence in our stakeholders in the effectiveness and efficiency of the organisation.

Mrs Tan Shook Fong – PSS Innovation and Scientific Research Award 2015

HSA's Pharmacogenetics (PGx) Team was awarded the inaugural "Mrs Tan Shook Fong – PSS Innovation and Scientific Research Award 2015", in recognition for the significant impact their work had on pharmacy practice and pharmaceutical sciences in Singapore.

One shining example of the PGx Team's achievements is its ability to detect an increased risk of serious skin reactions in locals taking the anti-epileptic drug carbamazepine. PGx initiated clinical research studies to investigate genetic associations behind such serious drug-induced adverse reactions — this uncovered evidence of a strong association between the HLA-B*1502 gene and carbamazepine-induced serious skin reactions in the local population. As a result, testing for the HLA-B*1502 gene in all new patients of Asian ancestry who are starting on carbamazepine has been established as the standard of care in Singapore, and is subsidised at restructured hospitals and institutions funded by the Ministry of Health.

BLOOD

We are Bolstering Efforts to Save Lives

BLOOD SERVICES GROUP

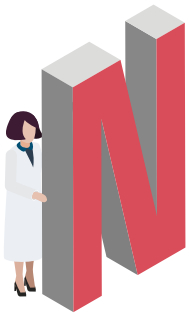
HSA safeguards Singapore's national blood supply, working hard to ensure that patients always have access to a safe and sustainable blood supply in their time of need. From refining our protocols to ensure the safety of blood supplies; to making blood donation more convenient, we are dedicated to our mission.

Thanking Our Blood Donors

The success of the National Blood Programme depends on the contributions of donors, who give their time – and blood – to help others. Every year, we honour our blood donors for their precious gift of life.

Celebrating the Achievements of Blood Donors

HSA and the Singapore Red Cross recognised over 1,500 blood donors — out of which 542 were Champion Blood Donors — for their selfless contributions at the 12th World Blood Donor Day 2015 celebrations on 6 June 2015. The event was held at the Singapore Discovery Centre and graced by Guest of Honour, Minister for Health, Mr Gan Kim Yong. A total of 16,700 visitors attended the event and enjoyed fringe activities like band performances, carnival snack stations, and photo-taking sessions with the adorable Blood Buddy mascots.



Nurturing Talents

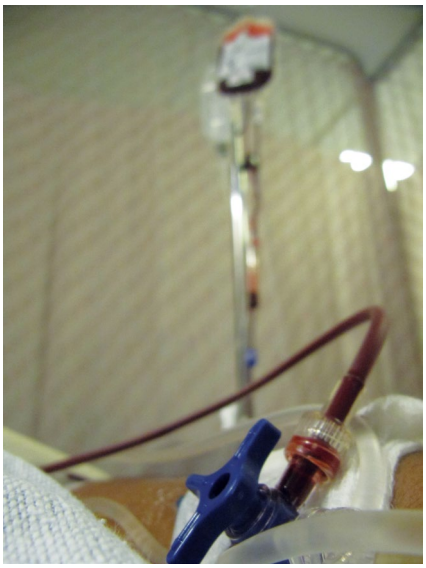
Our staff play an integral part in maintaining Singapore's blood supply, and HSA is dedicated to providing them with attractive career and advancement opportunities.

Charting a More Defined Career Path

In line with recommendations made by the National Nursing Taskforce in 2014, HSA has set up a distinct career progression structure for their nurses. One of the more notable changes is the addition of an Assistant Nurse Clinician role — this provides nurses who have the required experience and aptitude with the opportunity to take up leadership roles.

Upgrading Professional Qualifications

In a move to train a core of resident doctors with clinical expertise in transfusion medicine, HSA has set up the Staff Registrar Scheme Diploma in Transfusion Medicine. This two-year post-graduate diploma was developed in partnership with the Chapter of Haematologists at the College of Physicians and the Academy of Medicine, and aims to raise the national standard of transfusion medicine and blood components, while raising the professional standing of transfusion medicine in Singapore.



Putting Knowledge to Good Use

The Blood Services Group (BSG) is responsible for the smooth running of HSA's four blood banks and the organisation of mobile blood drives, to encourage regular blood donation. We also put new technology and expertise to use to improve the donor experience, enhance the safety of Singapore's blood supply, and educate medical professionals.

Updating Methods

An evaluation study into alternative methods of freezing red blood cells (RBCs) to extend their shelf life and lower discard rates was carried out in January 2016. In the past, RBCs were frozen manually via an open system, limiting the shelf life of thawed RBCs to 24 hours. In January 2016, an evaluation study was performed and completed, where a universal closed system was utilised to freeze RBCs and a red cell additive solution (AS-3) was used, resulting in an increased shelf life of 14 days. A longer shelf life allows for more flexibility in blood inventory management and a better ability to mitigate shortages in months of low blood collection. The new system was successfully implemented in March 2016.

Exploring New Inventory Methods

HSA is always looking for more efficient ways to utilise blood products. In May 2015, we kick-started an initiative to establish an on-site inventory for Fresh Frozen Plasma (FFP) for private hospitals, a temperature-sensitive product that needs to be stored at minus 18 degrees Celsius. Doing so allows FFP to be stored on-site for the next patient, instead of being returned to HSA as had been previously done.

This FFP can then be issued directly to patients with a confirmed blood group. Faster delivery of FFP to patients helps to maintain the integrity of the frozen blood product and necessary clotting factors for the benefit of patients, and provides a contingency FFP supply for emergency situations.

Clearer Labels, Safer Transfusions

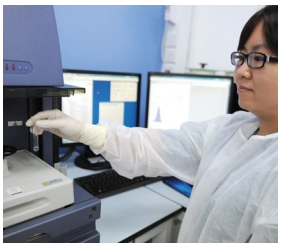
Any blood meant for transfusion is issued with an attached recipient label, which includes information critical for transfusion like the patient's particulars and blood group. The compatibility of issued blood meant for specific patients is only valid for three days from the sample drawn date. Furthermore, hospital wards where the blood is transfused have always had difficulties keeping track of the validity period as samples could be drawn by different departments or clinics.

To solve this problem, the expiry date of compatibility testing is now included on the recipient label. This provides clarity in the decision-making process when transfusions or operations are postponed, and reduces ambiguity for all hospital staff involved in the transfusion. It is also an assurance of better compliance to international transfusion practices for both HSA and public hospitals. Most importantly, stricter adherence to safety standards will mean safer transfusions for patients.

Implementing HLA-DQB Typing for Better Matches

Human leukocyte antigen (HLA) typing is required to match patient and donor HLA in bone marrow transplants. In the past, we carried out HLA-ABC and HLA-DRB typing via sequenced-based typing (SBT). But from September 2015, we have also begun typing the HLA-DQB allele at high resolution — this provides a more accurate HLA match between patient and donor, which improves bone marrow transplant outcomes for patients.

Establishment of CD34 Enumeration Capabilities



The Cell Therapy Facility (CTF) is responsible for processing haematopoietic progenitor cells (HPCs) collected by bone marrow or by apheresis, supporting several stem cell transplant programmes in various hospitals. As an extension of routine HPC processing, CTF has introduced CD34 enrichment as a new treatment option for patients with severe haematologic malignancies undergoing allogenic transplantation, and for autologous transplantation in patients with autoimmune diseases. We have performed 14 CD34 enrichment processes since its introduction in March 2015.

Passing CAP 2015 for CD34 Enumeration and Platelet Serology Testing

We have validated and developed the capability to perform CD34 enumeration testing internally to generate faster and more accurate results. Our Tissue Typing & Platelet Reference Laboratory (TTPR) has also passed the College of American Pathologists (CAP) 2015 Proficiency Test for CD34 enumeration testing.

New Ideas to Maximise Resources

We completed three Lean Six Sigma projects in 2015, each working to improve efficiency, reduce errors and increase productivity in its processes. Two of these projects were selected for poster presentations in the International Society of Blood Transfusion (ISBT) conference in Dubai. Team members will also be sharing their completed work with colleagues at quarterly staff meetings.

The projects completed are:

Reducing Laboratory Report Transcription Errors

Transcription errors in laboratory reports can affect patient treatments. To reduce such errors, the team made recommendations such as having non-urgent reports generated after 3pm checked the next morning, and creating a 'HLA phenotype' field in the Access Database for staff to select the serological typing.

Better Workflow Efficiency in Processing Packed Red Blood Cells

The team set a goal to reduce the processing turnaround time for red blood cells, in order to process all whole blood collected within the day of collection. After validation and evaluation of their suggested process, they found that it was sufficient to let blood products from whole blood rest for two hours to meet the required specification, instead of the current QC parameter of four hours.

Increasing Effectiveness of Appointment Scheduling

Aiming to increase the number of appointment bookings, and to improve appointment turn-ups based on appointment slots, the team recommended that appointment bookings through the Singapore Red Cross and Donor Care system be combined. They also suggested re-designing the Donor Care Appointment system to forecast blood type requirements, and re-designing the appointment information pamphlet to make it more reader-friendly.

Building Solid Infrastructure

We look at improving and upgrading our existing infrastructure to make blood donation more convenient and more pleasant for blood donors; and are always seeking opportunities to implement new technologies to allow us to perform at our highest capabilities.

Opening of Bloodbank@Westgate Tower

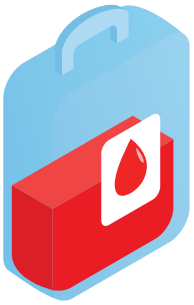
Bringing donation centres closer to donors and the community helps to encourage regular blood donation. The new Bloodbank@Westgate Tower is part of a joint effort by HSA and the Singapore Red Cross to attract residents and workers staying and working in Jurong, as well as nearby estates, along with the many companies working in the vicinity of Westgate Tower. The donation centre has the capacity to collect 100 units of blood daily to help meet national blood demand. It was officially opened in June 2015 by Deputy Prime Minister and then-Minister for Finance Mr Tharman Shanmugaratnam, with special guests Minister for Culture, Community and Youth Ms Grace Fu, and Minister of State (Ministry of Health) Dr Lam Pin Min.

Besides targeting the 18,000 blood donors currently living in the West, the Singapore Red Cross is working with partners such as Yuhua Community Club, Jurong Town Council, Nanyang Technological University, M1, ExxonMobil and other organisations to encourage new donors to give blood at the new blood bank.

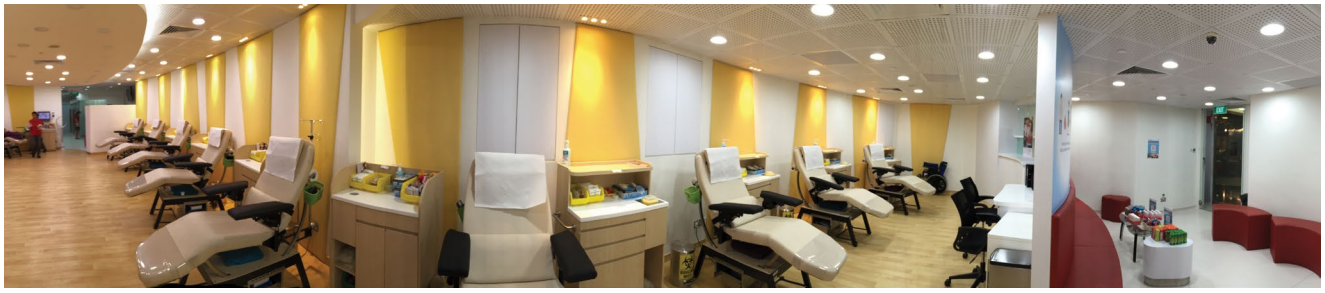
Expansion of Bloodbank@Dhoby Ghaut

Thanks to its convenient location, Bloodbank@Dhoby Ghaut (BB@DG) has been a popular blood donation centre, especially among youths and working adults, since it opened in September 2012.

Between January to November 2015, blood collection at BB@DG increased by 10% as compared to the same period in 2014.



BB@DG was expanded by adding one interview room and three beds. Renovations were completed in November 2015. The expanded BB@DG can now accommodate more donors, and provide them with a more conducive environment for blood donation. Expansion works have helped to shorten the waiting time during peak periods, and has created a bigger and dedicated post-donation resting area for donors.

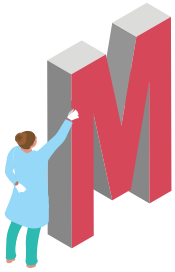


Web-based Portal for Updating Patient Transfusion Records

To streamline the work process of electronic updates of patient transfusion records from restructured hospitals and ensure the confidentiality of patient records, we implemented a Web-based Secured File Transfer Protocol (SFTP) with two-factor authentication. This ensures secure and efficient transfer of data from hospitals to HSA.

Increasing Efficiency with X-ray Irradiator

Patients with the risk of transfusion-associated graft-versus-host disease (TA-GVHD) require stocks of irradiated blood components. We replaced the gamma irradiator with an X-ray irradiator in October 2015. This X-ray irradiator increases workflow efficiency, as up to six products can be irradiated simultaneously in one cycle and overall processing time is reduced from 6 min/unit to 1.4 min/unit. Staff are also less exposed to radiation risks as no radiating source material is used in X-ray irradiators.



Maintaining Strict Protocol

HSA works hard to ensure that all procedures carried out are to the highest international standards, and have strict protocols in place to provide both patients and healthcare professionals with the assurance of access to safe blood products.

Formal Management Protocol for Suspected TRALI Cases

In April 2016, we introduced to all hospitals, a formal system of reporting and documenting suspected cases of Transfusion-Related Acute Lung Injury (TRALI) — an uncommon but serious complication of blood transfusion. Having a formal reporting structure facilitates timely reporting of all suspected TRALI cases to the blood bank, allowing rapid quarantine of affected blood products and early initiation of appropriate investigation of affected blood donors. This will further safeguard the quality of the blood supply, improve blood recipient and transfusion safety, and simplify the reporting process for clinicians and hospital laboratory staff.

Partners Beyond Borders

We welcomed groups of medical professionals to our blood banks, both locally and in the region, showing them what goes on behind the scenes.

International Training in Transfusion Medicine

The Blood Services Group is a World Health Organization (WHO) Collaborating Centre in Transfusion Medicine. As part of these efforts, we had the opportunity to share our expertise with fellow medical professionals and the WHO.

March 2015

Delegates from Japan's Ministry of Health, Labour and Welfare made a study trip to discuss the blood safety policy for transfusion transmissible HIV in the Singapore Blood Service.

April 2015

The Australian Red Cross Blood Service visited to find out more about our current research programmes, donor recruitment and retention strategies and marketing tools, and toured our blood bank and blood processing laboratories.

September 2015

The Jakarta Blood Centre came for a pooled platelet production training attachment.

The Hong Kong Red Cross Blood Transfusion Service came for a study visit at our Cell Therapy Facility.

November 2015

A doctor from a medical college in Bangalore, India, was attached to the Human Leukocyte Antigen (HLA) Laboratory to learn more about blood bank support to a haematopoietic stem cell transplantation unit.

A doctor from Sri Lanka joined us for an observership in HLA typing.

December 2015

The Japanese Red Cross Tokyo Blood Centre participated in a training attachment on donor recruitment and retention programmes.

Sharing Our Knowledge

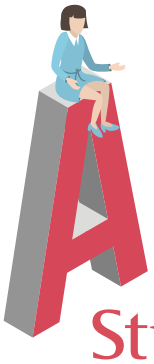
HSA is a training centre for the SingHealth Haematology Senior Residency Program and we are actively involved in educating haematology specialists-in-training from the SingHealth cluster. In addition, we regularly provide short training attachments in transfusion medicine for physician trainees from Tan Tock Seng Hospital and the National University Hospital under the Staff Registrar Scheme Diploma in Haematology and the National University Health System Haematology Senior Residency Program.

Site Visits

A group of Haematology/Oncology consultants, registrars and newer blood bank staff from the KK Women's and Children's Hospital visited the blood banks in November 2015. The visit was organised to help them gain a better understanding of blood product collection, processing and distribution in Singapore. A group of doctors, nurses and executives from Khoo Teck Puat Hospital also visited the blood bank in December 2015 to learn about safety and quality in handling blood products.

Helping out in Yangon

A specialist team of volunteers from HSA headed to Yangon in August 2015 to conduct training for 23 senior management staff in Myanmar, with the goal of developing management and leadership capabilities and to centralise the management of Myanmar's National Blood Programme. This programme was sponsored by the Singapore International Foundation, at the request of the National Blood Centre in Yangon.



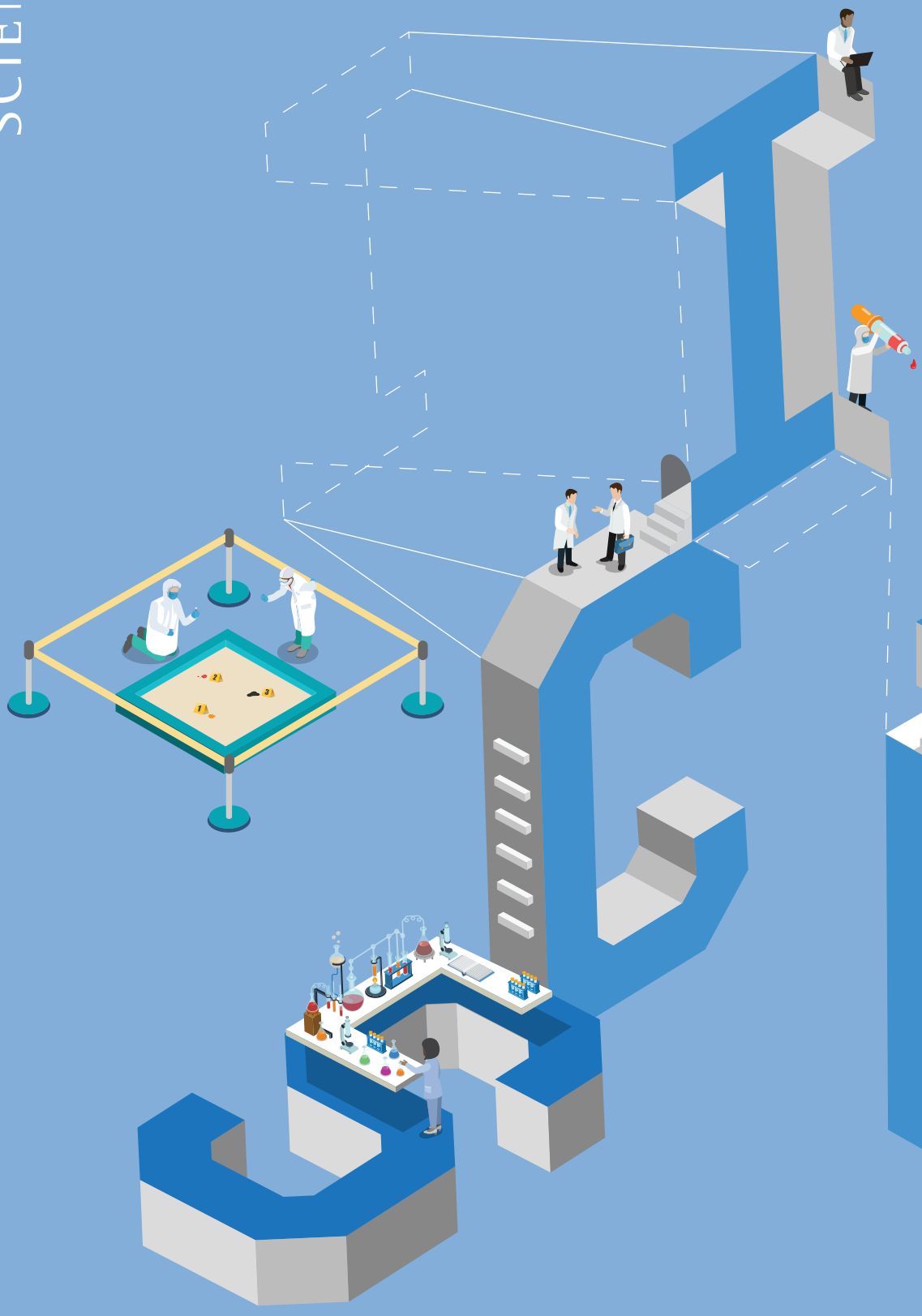
lways Striving for the Highest Standards

We aim to ensure that all our facilities attain the highest international certification, and we have gained both regional and international recognition for our accomplishments.

Maintaining ASHI Accreditation in 2015

The Tissue Typing and Platelet Reference Laboratory (TTPR) has once again passed the American Society for Histocompatibility and Immunogenetics (ASHI) 2015 self-inspection, and remains accredited by ASHI. This gives our clients confidence in our services. TTPR has also gained more recognition from regional clients, and has received an increase in test requests from neighbouring countries.

SCIENCE



We are Advancing Our Capabilities in Science

APPLIED SCIENCES GROUP

HSA provides varied and invaluable scientific expertise to law enforcement agencies, regulators and the judiciary in the administration of justice, and the safeguarding of public health. We seek to continuously deepen our competencies through innovation and research, to offer the most effective solutions grounded firmly on scientific rigour.

Raising Capabilities

We constantly strive to keep our scientific knowledge and expertise up-to-date so as to continue developing solutions and innovative processes to meet the needs of our stakeholders.

Expanding Our DNA Capabilities

There is much information that can be revealed by a single drop of blood beyond a mere DNA profile. The Biology Division is now developing forensic intelligence capability through DNA analyses to estimate the age and ethnicity of an individual from a blood sample, with further work ongoing to predict the appearance of the individual. Referred to as DNA intelligence or predictive DNA testing, these technologies will help the police narrow down their search for the perpetrator.

We are now also able to use fluorescence-labelled antibodies and laser micro-dissection — a new instrumentation platform. This allows more accurate detection of human spermatozoa, even in the presence of excess epithelial cells and microfloral contamination, making it a useful tool to identify offenders in sexual assault cases.

Looking out for Adulterants

Detection of new and unpermitted drug substances can be difficult as they cannot be identified by routine analytical testing methods, and require a high level of vigilance and scientific expertise. We detected a new compound, lorcaserin, in two samples of seized health supplements during a routine screening. Lorcaserin was first reported as an adulterant in a slimming dietary supplement in 2014. The compound has since been added to the adulterants screening library, further strengthening and expanding our analytical testing capabilities in such analyses.

Partnering the Police

To provide better support to the law enforcement agencies, we undertook a joint project with the Forensic Division (FD) of the Singapore Police Force on dust analysis. In the study, we evaluated different dust collection media and methods and also analysed the dust composition in various floors of a building. The results will help FD officers in collecting evidence, in particular for fall-from-height cases.

Broadening Testing Capabilities

A myriad of chemical compounds is used in cosmetic products. To bolster support for the Health Product Regulation Group's administration of the cosmetic products regulations, we have expanded our testing capabilities to test for hydrogen peroxide, a compound used in hair bleaching, oral antiseptics, hair relaxers and tooth bleaching products.

In response to the prevalent use of nail polishes, we have also expanded the testing scope of formaldehyde content to include nail polish and also hair care products. Formaldehyde is commonly used as a preservative in cosmetics and added in nail hardeners for its specific cross-linking functionality with keratin.

Boosting Food Testing Support

One of our key customers in food testing is the Agri-Food and Veterinary Authority of Singapore (AVA), and we have added seven new analytical services to better support them as well as other commercial customers. Our new services include analysis of artificial sweetener Advantame in food products and the fluorescent whitening agent Tinopal CBS-X in rice-based products.

A Lean Six Sigma Project with the objective of increasing effectiveness in expiry date monitoring and traceability was also carried out.

Participating in International Research Projects

Firearms that are manufactured consecutively are known to exhibit similar sub-class characteristics, and as such, their identification may present a challenge to examiners. Our forensic scientists, the first participants in South East Asia, joined 600 firearm examiners from over 30 countries to take part in a project to see if a set of unknown bullets could be correctly associated with 10 rifle barrels which were manufactured consecutively. Thanks to the intensive training they received and the continual exposure to cases, the scientists correctly identified all firearms that were used to fire the bullets.

Photo credit: Dr James Hamby

Our participation in the European Hair and Textile Scientific Working Group's fibre collaborative exercise was another chance to benchmark our expertise with the international communities. We were pleased with our performance in the exercise, and also appreciated the opportunity to learn from the different practices and protocols of our counterparts.

Contributing to Quality ISO Standards

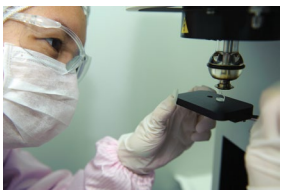
ISO standards are quality standards that are adopted internationally, and we are actively involved not just in the attainment, but the development of these standards. We have been engaged in the preparation of various international documents, including the ISO standards ISO/DIS 18385.2 (Minimising the risk of human DNA contamination), which aims to create global standards for manufacturers of forensic products used for DNA forensic analysis. We are one of 20 member countries deliberating on forensic-specific standards, which will subsequently become ISO standards.

Benchmarking against International Standards

Vitamin D metabolites in human serum

We completed eight international comparisons in 2015, which demonstrated that our laboratory's measurements are accurate and comparable to those of established national metrology institutes and expert laboratories. The eight comparisons were:

- Determination of mass fraction of benzoic acid, methyl paraben and n-butyl paraben in soy sauce (organised by the Chemical Metrology Lab)
- Trace elements in drinking water
- Determination of arsenic species and total arsenic in brown rice flour
- Peptide purity of synthetic human C-peptide
- Vitamin D metabolites in human serum
- Elements in infant formula
- Purity assessment of folic acid
- HbA1c Measurement (RELA)



Purity assessment of folic acid

Raising Measurement Standards in Local Laboratories

Since 2011, we have organised the External Quality Assessment (EQA) Programme in clinical chemistry as a part of HSA's metrology efforts to enhance the accuracy of local clinical measurements. In the second cycle of the 2015 HSA EQA Programme, two new analytes — LDL-cholesterol and HDL-cholesterol — were included. A total of 15 clinical analytes were covered in the programme.

We organised an EQA Symposium for the participating laboratories of the programme in January 2016. The event provided a forum for an in-depth discussion of results with the participating laboratories, and for the sharing of follow-up activities undertaken by HSA to address the feedback provided by participants of the 2015 programme. A simple approach for the estimation of measurement uncertainty in clinical chemistry was also presented at the symposium.

We also organised Proficiency Testing (PT) schemes to enhance the accuracy of local chemical measurements. In 2015, we organised two PT schemes — Artificial Sweeteners in Fruit Juice, and Mass Fraction of Heavy Metals (As, Pb and Hg) in Cosmetic Cream for our local chemical testing laboratories.

Maintaining Excellent Quality Management

We also continue to demonstrate reliability in our analyses and have received excellent results in the following PT schemes in pharmaceuticals and cosmetics:

- (i) Assay by liquid chromatography; (ii) identification using Infrared Absorption Spectrophotometry; and (iii) pH measurement by the European Directorate for the Quality of Medicines & HealthCare (EDQM)
- (i) Dissolution testing on metronidazole tablets, and (ii) pH measurement by ASEAN Bureau of Drugs and Narcotics (BDN)
- (i) Assay by liquid chromatography; (ii) melting point determination; and (iii) pH measurement by Royal Dutch Association for the Advancement of Pharmacy
- Hydroquinone assay in cream samples by the Bureau of Cosmetics and Hazardous Substances, Department of Medical Sciences, Ministry of Public Health, Thailand
- Determination of mass fraction of heavy metals (arsenic, lead and mercury) in cosmetic cream samples by the Chemical Metrology Laboratory (CML), Singapore

Toxic elements in cosmetic cream

Expanding the Certified Reference Materials Production Programme

CML produces Certified Reference Materials (CRMs) for use as calibrants, quality controls and for validation of methods. We have now expanded the CRMs' production programme to include:

- Saccharin and sodium cyclamate in fruit juice
- Acesulfame potassium
- Sucralose
- L-Isoleucine
- L-Phenylalanine
- Inorganic analytes (calcium, iron, potassium, magnesium and sodium) in frozen human serum
- Toxic elements (arsenic, lead and mercury) in cosmetic cream

Participating in EU Method Validation

There are many different international food safety tests, and our laboratories are always working to achieve validations of these tests to safeguard food safety in Singapore. We participated in a number of EU method validations:

- Inter-laboratory validation of the method for determination of phomopsin A in lupin seeds by LC-MS-MS by Rikilt, Netherlands
- Inter-laboratory validation of the method for determination of deoxynivalenol, zearalenone aflatoxin B1, T2 and HT2 toxins, fumonisins B1 and B2
- Ochratoxin A in animal feed by LC-MS-MS by EURL-IRMM

Researching Chinese Medicinal Materials

We supported a pilot project initiated by the Health Products Regulation Group (HPRG) on Chinese Medicinal Materials (CMM), to study the authenticity, pesticide residue and heavy metal contents of selected CMM sold in the local market. The project was completed with more than 30 samples of 11 different types of CMM assessed in both raw powder and decoction form. This has enabled HPRG to better assess the quality of CMM products retailing in Singapore and would serve as a reference in setting CMM standards.

Training in the Region

It is an honour for HSA to work with and share knowledge with partners through attachment and training programmes in the region. Some of these included:

- Vietnam Metrology Institute (VMI) for Inorganic Isotope Dilution Mass Spectrometry (IDMS) training from June to August 2015
- Research Centre for Chemistry-Indonesian Institute of Sciences (RCChem-LIPI) for Organic IDMS training from August to October 2015
- Department of Chemistry, Malaysia, for Statistics in Certification of CRMs training, August 2015

Upgrading Skills and Knowledge

Firearms training with Mr Malcolm Griffiths

Through learning from the best, we can enhance our skills. We invited overseas experts Dr James Hamby and Mrs Patricia Hamby to conduct intensive in-house training on firearms. Mr Malcolm Griffiths from the British Coatings Federation also joined us to conduct in-house training. Professor Bruce Budowle, a world authority on forensic DNA analyses, was also invited to conduct a one-week workshop on DNA mixture interpretation, Y-chromosome and kinship analysis.

Improving Infrastructure with Technology

Having up-to-date facilities allows HSA to complete its many roles, whether in assisting the police in investigating crimes, or testing the safety of food.

Enhancements at the Mortuary

We completed renovations at the mortuary to provide a larger and more conducive waiting area for next-of-kin. We also continued to strengthen our operational readiness and capabilities in carrying out examinations on deaths suspected to be due to highly infectious diseases, in our unique patented Mobile Containerised Bio-Safety Level 4 Autopsy Suite.

Technologies for Traffic Accident Reconstruction

The Forensic Chemistry and Physics Laboratory harnesses the latest technologies to reconstruct traffic accident scenes to assist in investigations.

In traffic accident reconstruction, our Reflectorless Total Station helps us take measurements over an extended range of distances. Together with the 3D laser scanner, we can map out blind zones for vehicles and plot sketches of the accident scene.

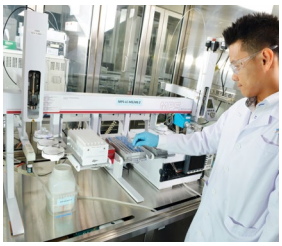
Improved Fibre Analysis Sensitivity

The newly acquired CRAIC PV2020 microspectrophotometer allows forensic scientists to analyse the colours of trace material in a more objective manner. The instrument was first used in fibre casework in December 2015. Its discriminating power helped us to solve an otherwise challenging case where we had to examine fibres of almost the same colour.

Smoother Screening for Drugs

To facilitate reliable and efficient urine drug screening workflow, the Analytical Toxicology Laboratory has successfully integrated chemistry analysers with IT solutions. Automatic information flow is achieved through the use of a middleware to interface sample and test request information from the Laboratory Information Management System to the analyser software. Using the barcode labels on the sample tubes, the analysers track and test samples automatically, eliminating the need for manual entry and reducing possible transcription and positioning errors at the analysers. This improves the efficiency of the screening process.

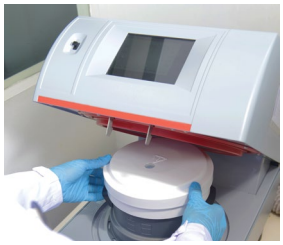
Faster Drug Analysis



The full automation of the analysis of ketamine and its metabolites in urine has been implemented using the online automated disposable pipette extraction on a Gerstel Multisampler system coupled to a LC-MS/MS in December 2015. This new workflow allows both automated analysis of amphetamines and ketamine to be performed concurrently within a single batch of samples. The total processing time for a batch of 30 samples has been reduced from two days to about five hours.

Quicker Identification of Drugs

The Illicit Drugs Laboratory has acquired a handheld Raman spectrometer to facilitate faster screening of exhibits for drug identification. The spectrometer can test a sample directly through a variety of materials like glass or plastic without the need for any sample pre-treatment. It is easy to use and non-destructive. Using the results from the spectrometer, officers are able to better triage exhibits and select appropriate methods of analysis to confirm the presence of controlled drugs.



New Food Testing Methods

Fast and accurate testing of food is essential to protect public health, and we have introduced new and advanced analytical techniques such as high-resolution mass spectrometry (TOF-MS). This enhances baseline service delivery to the Agri-Food & Veterinary Authority for rapid, precise and accurate confirmation of preservatives and mycotoxins in food. In a single analysis, TOF-MS is able to provide precise identification, physical separation and quantitation of regulated substances in complex food matrices. This represents a game-changer in food testing within HSA as it strengthens our reports and provides a good platform to train officers to take on added responsibilities on advanced data interpretation.

In addition, a high-efficiency microwave digestion system for faster sample preparation in the laboratory was also installed — this provides a 50 percent increase in throughput, with a lighter weight and smaller footprint.

Building Strong Relationships

Working closely with partners and stakeholders allows us to achieve our mutual goals of safeguarding Singapore.

Inking New Partnerships

In order to build new partnerships with local organisations, HSA signed a number of Memoranda of Understanding (MOUs) in 2015.

SPRING Singapore

Photo credit: Singapore Accreditation Council

HSA and SPRING Singapore signed a Collaboration Memorandum on 13 August 2015 to collaborate in the areas of supporting national standards and conformance infrastructure, and strengthening the dissemination of metrological traceability to local laboratories.

As part of the partnership, the Chemical Metrology Division partnered the Singapore Accreditation Council to co-organise two training courses each on Method Validation for Chemical Testing, and Measurement Uncertainty Made Easy, in May and November 2015. They also co-organised the Asia Pacific Laboratory Accreditation Cooperation (APLAC) PT Scheme on Determination of Acesulfame Potassium and Sucralose in Cake Mix Flour for laboratories nominated by accreditation bodies.

Ministry of Home Affairs

The analytical labs embarked on a three-year MOU with the Ministry of Home Affairs on the testing of controlled drugs in food, supplements and cosmetics for the Central Narcotics Bureau on 1 January 2016.

Strengthening Stakeholder Engagement

To strengthen our working relationship with the Traffic Police, we conducted a month-long trial where forensic scientists were on standby to be activated to suitable traffic accident scenes. This exercise enabled better engagement and exchange between the scientists and scene investigators on matters regarding traffic scene investigation.

Working with More Local Partners

Service level agreements were signed with local organisations, strengthening their collaborations with HSA.

- The Analytical Toxicology Laboratory signed a service level agreement with the Department of Laboratory Medicine, National University Hospital.

- The Food Safety Laboratory (FSL) started cyanotoxins testing in reservoir waters under a two-year service level agreement with the Public Utilities Board from 1 January 2015.

- The FSL was engaged by the National Environment Agency to conduct a survey on the safety and quality of cooking oils in Singapore under a six-month service level agreement from January 2016.

Working on Better Victim Identification

HSA and the Singapore Police Force (SPF) are longstanding partners in law enforcement on many fronts — both domestic and foreign. In late April 2015, HSA's Chief Forensic Pathologist, Dr Paul Chui, was part of the Home Team's 126-strong contingent that flew to Nepal in support of the Disaster Victim Identification team, and the search and rescue effort. The deployment was completed on 9 May 2015.

The Forensic Medicine Division also worked with the Ministry of Health, State Coroner and SPF to streamline work processes and the exchange of data across multiple agencies relating to Coroner's cases and death certification.

Photo credit: Singapore Police Force

Strengthening Ties Worldwide

We take our responsibilities as part of a wider, global community seriously, and continually work to improve relationships with international organisations.

Active Involvement in the Asian Forensic Sciences Network

We are actively involved in the Asian Forensic Sciences Network (AFSN), a grouping of national forensic institutes in Asia that allows for knowledge sharing and regional advancement of forensic science.

Establishing an Explosives Database

Teaming up with Thailand's Central Institute of Forensic Science, the Forensic Chemistry and Physics Laboratory has pioneered the establishment of an explosives database. The database will include photos, analysis parameters and results of cases involving pre-blast explosives, post-blast explosives, and fireworks encountered by AFSN member countries. This will help create better awareness of explosives found in this region, provide a platform for the exchange of know-how in explosives analysis, and strengthen the AFSN Trace Evidence Workgroup network, benefiting all members of the AFSN.

DNA Inter-Laboratory Collaborative Exercise

The DNA Profiling Lab organised the first DNA Inter-Laboratory Collaborative Exercise for member institutions in the AFSN in early 2015 to compare the efficiency of DNA extraction methodologies. This was followed by a second exercise in late 2015 on the interpretation of DNA mixtures. Both exercises drew participation from member institutions in China, Indonesia, Malaysia, Mongolia, Philippines, South Korea and Thailand. The results of the exercises were shared with AFSN members at the 7th Annual AFSN Meeting in Kuala Lumpur in November 2015, and were invaluable in driving discussion, benchmarking and the development of best practices amongst AFSN members.

Working with the World Health Organization

As a Collaborating Centre of the World Health Organization (WHO), our laboratories have been actively supporting WHO's activities.

Ensuring Quality Assurance in Medicines

The Pharmaceutical Laboratory (PL) was involved in a number of WHO activities as a Collaborating Centre in the areas of medical quality assurance, tobacco testing and research, and food contamination monitoring.

- ### Training Programmes

  The Pharmaceutical and Cosmetics Laboratories provided a one-week training programme on the role and responsibilities of Singapore's national regulator testing laboratory to a WHO fellowship trainee from the National Drug Quality Assurance Laboratory in Colombo, Sri Lanka, in November 2015.

- ### Monograph Development

  The PL has successfully completed the development of two monographs — ceftriaxone sodium and ceftriaxone — for injection for the International Pharmacopoeia. We also continued to support WHO in the review of a tetracycline hydrochloride monograph, and the elaboration of a new draft for pyrimethamine tablets in the coming year.

- ### Consultation and Technical Contributions

  A Senior Analytical Scientist was appointed as a WHO Temporary Advisor in the Consultation Meeting on Screening Technology, Sampling and Specifications for Medicines. This event was held at the WHO Headquarters in Geneva, Switzerland, in April 2015.

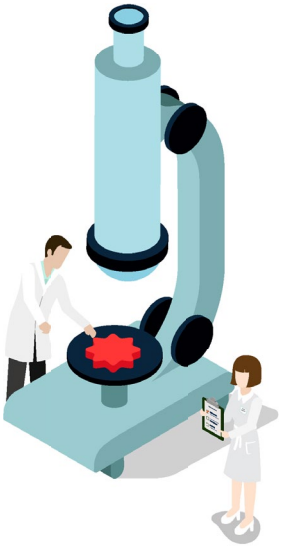
Re-designation as a Collaborating Centre

The Cigarette Testing Laboratory was successfully re-designated as a WHO Collaborating Centre (WHO CC) for Tobacco Testing and Research in June 2015 for a four-year term.

As the co-Chair to the WHO Tobacco Laboratory Network, we participated in a three-day meeting with WHO Collaborating Centres on Tobacco Product Testing and Research. This meeting explored and mapped out the activities of both current and potential WHO CC's areas of future collaboration, and took place in the WHO Western Pacific Regional Office in Manila, Philippines, in September 2015.

Helping with Food Contamination Monitoring

The Food Safety Laboratory continues as a WHO Collaborating Centre for Food Contamination Monitoring, and participated in the WHO meeting on strengthening the International Food Safety Authorities Network (INFOSAN) in Asia, and national food safety systems in Hong Kong in November 2015.



Activities in ASEAN

Apart from being active on the international arena, we were also involved in numerous events in ASEAN.

Hosting the 5th ASEAN Cosmetic Testing Laboratory Committee

In collaboration with HSA's Cosmetics Control Unit, the Cosmetics Laboratory hosted the 5th ASEAN Cosmetic Testing Laboratory Committee (ACTLC) Meeting, which was held in May 2015. The meeting was chaired by a Medical Scientist from the Department of Medical Sciences, Thailand, and co-chaired by a Senior Analytical Scientist from the Cosmetics Laboratory. Bringing together regulators and scientists from ASEAN member states, the committee discussed various aspects of cosmetic regulation, analytical testing, the latest developments on economic integration, and other decisions impacting the cosmetic sector. It also witnessed the handing over of the position of Chair from Thailand to Singapore.

Singapore was appointed as Chair of the ACTLC in November 2015. This committee is dedicated to tackling challenges faced when dealing with complex cosmetics matrices and how the committee can cooperate to handle evolving complexities in cosmetics analysis.

Testing for Mycotoxins

As the ASEAN Reference Laboratory (ARL) for mycotoxin analysis, the Food Safety Laboratory (FSL) organised the 2015 ASEAN Proficiency Test on Aflatoxins B and G in Nutmeg Powder. 19 laboratories from nine ASEAN countries participated in this round of proficiency testing.

FSL also conducted a training workshop on mycotoxins analysis for the Ministry of Health, Brunei, in September 2015 as part of its role as the ARL for mycotoxins in August 2015.

Boosting Clinical Metrology Capability

A collaboration memorandum was signed between HSA and France's Laboratoire national de metrologie et d'essais (LNE) in the area of clinical metrology. The collaboration enabled the exchange of scientific information and reference materials related to clinical and peptide/protein chemistry. This has accelerated our capabilities-building in clinical chemistry. In 2015, the areas of collaboration included measurements in LDL-cholesterol, HDL-cholesterol, calcium, potassium, sodium and chloride in human serum.

European Network of Forensic Science Institutes (ENFSI)

We have been accepted as an associate member in five different workgroups of the ENFSI. They are:

- DNA Working Group
- Firearms/Gunshot Residue Working Group
- Forensic International Network for Explosive Investigation
- European Document Experts Working Group
- European Network of Forensic Handwriting Experts

The DNA Profiling Laboratory also participated in the European DNA Profiling Work Group's age prediction by DNA methylation analysis exercise phase 1.

Forensic Isotope Ratio Mass Spectrometry (FIRMS) Network

HSA served as a Steering Group member on the FIRMS Network, contributing to the development of the scope of stable isotope techniques in forensic applications.

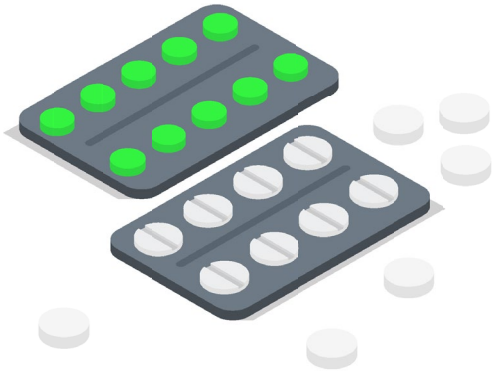
Providing Our Inputs on DNA Analysis to INTERPOL

HSA was invited to be a member of the INTERPOL DNA Monitoring Expert Group (MEG). This MEG consists of 10 to 12 DNA experts who act as an advisory body to the INTERPOL General Secretariat on DNA policies and projects. The MEG also provides recommendations on the use of DNA in crime investigation, national DNA databases, and procedures for mass fatality victim identification, which have been adopted by almost all countries. HSA's representative is the first from an ASEAN country since the inception of the MEG in 1998.

United Nations Office on Drugs and Crime (UNODC)

HSA was appointed as an UNODC International Forensic Expert for 2016 to 2018. As part of our role, our representative will sit on the International Panel of Experts, which oversees:

- Guidance and support in addressing relevant quality issues and oversees the implementation of International Collaborative Exercises
- Provision of expertise in the development of forensic best practices and review of guidelines, manuals and other publications
- Assistance and advice on forensic assessments and training
- Support to the establishment of links with professional associations and relevant research activities



Asia-Pacific Economic Cooperation (APEC)

HSA participated in an APEC conference in Taiwan in May 2015, and also gave an oral presentation titled "Development of LC-MS/MS determination method of T2 toxins and its glucosated and acetylated derivatives for estimating the contamination of total T2 toxins in staple flour" at the 13th Fusarium Seminar in Italy in May 2015. These were amongst six oral presentations and three poster presentations made at international conferences. In addition, HSA published three articles in international scientific journals.

European Pharmacopoeia Commission

HSA was also invited to attend a meeting on the Benefits of the European Pharmacopoeia Network of Observers, which was held in March 2016. This meeting provided the observers and the European Directorate for the Quality of Medicines and Healthcare (EDQM) a unique opportunity to dialogue directly, and to exchange and share ideas on possible cooperation opportunities. This will help to advance regulatory compliance testing in the field of pharmaceuticals and cosmetics. Representatives from more than 20 countries attended this 2016 special meeting, which was especially organised by the European Pharmacopoeia Commission for non-European community stakeholders.

Official Medicines Control Laboratories Network

As an associate member of the Official Medicines Control Laboratories (OMCL) Network, the Pharmaceutical Laboratory was invited to join the 20th Annual Meeting of the OMCL Network, which was held in June 2015 in Brussels, Belgium. A presentation was made on the key activities related to this network during this meeting.

International Atomic Energy Agency (IAEA)

We contributed to the IAEA coordination project on the authentication of rice and authentication of milk and attended an IAEA coordination meeting in Vietnam in July 2015.

Playing Host

HSA opened its doors to many local and international visitors, who were keen to find out more about our processes, regulations and more.

Myanmar delegation visit

Mongolia delegation visit

Guangxi delegation visit

Iran delegation visit

Forensic Chemistry and Physics Laboratory

Our Forensic Chemistry and Physics Laboratory and the Central Narcotics Bureau Forensic Response Team hosted laboratory visits and two rounds of bilateral exchanges, where officers were attached to each other's laboratory for a day. These initiatives enabled us to better understand each other's roles and capabilities, and to strengthen our partnership.

Pharmaceutical Division

The Pharmaceutical Division (PD) hosted a number of visitors in 2015.

- In July 2015, the PD hosted a delegation led by Dr Than Htut, Director General of Myanmar's Foreign Economic Relations Department, Ministry of National Planning and Economic Development, along with officials from Myanmar's Food and Drug Administration.

- Dr Bayar Oyun, Director of Health Policy Implementation Coordination Department of Mongolia's Ministry of Health and Sports, visited the PD laboratories in September 2015. The delegation was given an overview of Singapore's national policy and governance of medicine in a regulatory compliance framework.

- A delegation from the Food and Drug Authority in Guangxi Province, China visited in July 2015. The delegation was led by Ms Zhao Zhuang, Associate Director of the Guangxi Institute for Food and Drug Control and comprised six delegates from the Chemical and Food Divisions.

Cigarette Testing Laboratory

- Officials from the national focal point for the WHO Framework Convention on Tobacco Control, and the University of Medical Sciences of the Islamic Republic of Iran, visited the Cigarette Testing Laboratory (CTL) in July 2015. The visit gave the delegates insights into the setting up of a regulatory testing laboratory for tobacco products.

- A delegation from the Philippines Department of Health Food and Drug Administration visited the CTL in September 2015. Jointly hosted by HSA's Tobacco Regulation Branch, and the Health Promotion Board, the aim of the visit was to introduce the work of Singapore's National Tobacco Control Programme.

CORPORATE

We are Strengthening Our Core for Organisational Excellence

CORPORATE SERVICES GROUP

Our corporate team works cohesively and collaboratively across departments to support our Professional Groups. Through continued development and training, we enhance productivity and create greater value for our organisation and HSAians.

Culture of Empowerment

Our people drive the progress and performance of HSA. We constantly seek to evolve our practices and policies and discover new ways to meet the needs of our stakeholders and at the same time motivate, inspire and empower all HSAians to grow – as individuals and as an organisation.

EXSA 2015
3 Silvers
9 Golds
7 Stars

OSCA 2015
20 Service Advocates
15 Service Leaders
5 Service Champions
5 Team Awards

RISE and Shine

HSA strives to always go above and beyond to meet the needs of both customers and fellow colleagues. We believe that helping HSAians achieve personal and team success impacts positively on customer service. To facilitate this, the organisation celebrated its 7th HSA Customer Service Day with the theme "Rising Above". The event held in March 2016, had speaker Ramesh Muthusamy sharing the concept of RISE — Resilience, Ideas, Support & Energy. This provided useful insights to HSAians on how to achieve personal and team success that could lead to better performance and service.

During the event, HSAians were recognised for their excellent service with the presentation of 19 Excellent Service Awards (EXSA) and 45 Outstanding Service to Customers Awards (OSCA).

Highly Satisfied Customers

The first HSA Internal Customer Satisfaction Survey has found that nine out of 10 Corporate HQ internal customers were satisfied with our services. The purpose of this survey was to seek feedback from the various professional groups on their working experience with Corporate HQ over the past year. In addition to measuring the level of satisfaction of the respective departments' internal customers, the exercise also evaluated Corporate HQ's strengths and identified possible areas of improvement.

Living Our Core Values

A new series of customised Core Values Team Building Workshops was conducted as part of the orientation programme for new staff. Through experiential activities, these workshops aimed to enhance the network and synergy among staff of different functional units across the organisation. The activities further promote a better understanding of HSA's Core Values, to help them transform the values into personal beliefs, enabling them to live the Core Values.

Balancing Home and Work Life

Good work-life balance is known to reap benefits like lower absenteeism, improved staff morale, and improved customer satisfaction. HSA is constantly creating opportunities to help members of the HSA family maintain a healthy work and home life.

Empowering Staff with Skills Enhancement

Quarterly lunchtime talks were held to help staff better manage their interpersonal relationships and time in and out of the workplace. The topics ranged from communication techniques to conflict management and caring for caregivers, to suit different staff audiences.

Children's Day Out in the Office

We held the inaugural 'Bring Your Kids to Work' Day in September 2015, where the little ones joined their parents at the office. This fun-filled day offered the children an insight into their parents' work life. There were art and craft workshops, games, and a tour of the premises to keep the children entertained. The day ended with a bang at the Gardens by the Bay where the fun continued with an outdoor picnic.

Picnic at Gardens by the Bay

Strength in Unity

Building stronger bonds between colleagues, forming friendships that go beyond the office walls, we create opportunities to forge a stronger HSA identity.

Getting to Know You

A myriad of staff bonding activities were held over the course of the year for HSAians to mingle with each other. These included the Staff Forum, New Year's Gathering, HSA Public Service Week Observance Ceremony, and HSA National Day Observance and Celebration Day. A special Staff Bonding Durian Trip to Johor Bahru was also held in July to provide a relaxing and fun opportunity for staff from different groups to bond and get to know each other better.

National Day Observance and Celebration Day

Celebrating SG50

HSA celebrated the nation's 50th birthday with a series of corporate-wide activities that brought staff from different groups together, including learning journeys to the Peranakan Museum, Philatelic Museum and Singapore Discovery Centre. We also took time to thank HSA's Pioneer Generation members with an Appreciation Lunch, where retirees and long-serving colleagues with over

Lunch with our pioneers

40 years of service were invited to celebrate with us. Other staff engagement activities were the 'HSA Appreciation Week' to encourage colleagues to thank one another at work, the 'HSA SG50 Selfie/Wefie Photo Competition', and the 'Uniquely HSAians Awards' — all in the name of fostering greater staff engagement and cohesiveness.

Lunchtime Learning

New initiatives were piloted over lunchtime to further engage staff across the workplace. These included the HSAians READ! and Chat programme, as well as weekly first-aid sharing sessions held in collaboration with Staff Volunteer Facilitators during the months of July and August.

Understanding NEWater

HSAians visited the NEWater Visitor Centre in July 2015, where they learnt about Singapore's high-grade reclaimed water and Singapore's water sustainability strategy, and how they can conserve, value and enjoy this precious commodity.

Enhanced Benefits for HSAians

Discussions for the Collective Agreement (CA) with the Amalgamated Union of Statutory Board Employees (AUSBE) were concluded in 2015.

Effective from 1 November 2015 to 31 October 2018, this new improved CA includes the following enhanced benefits for all staff:

- Introduction of a Special Appreciation Award for re-employed staff in recognition of their continued contributions to HSA, effective from 1 January 2016
- Expansion of the Flexible Benefits scheme to include outpatient claims from registered TCM clinics
- Increased scope of representation to include HSP Grades 13 & 12, in support of AUSBE's efforts to represent more HSA employees

Active Employment for Older HSAians

The GRACE (Graceful and Active Employment) Programme was implemented to establish the guidelines for re-employment of HSA employees beyond the age of 67. This programme, which took effect from 1 April 2015, also provides them work flexibility in their golden years, as well as to ease them into retirement.

Paying It Forward

HSA is always looking for ways to contribute towards improving the lives of fellow Singaporeans. Through activities organised under the Corporate Social Responsibility Framework, CARE (Community Action, Responsible for our Environment), we take joy in giving a helping hand to those in need.

Journeying with the Kids of APSN Katong School

It was a heart-warming sight as HSA volunteers accompanied the special needs students of APSN Katong School on a learning journey to HealthZone at the Health Promotion Board (HPB) in May 2015. The life-sized exhibits of the human jaw and eyes fascinated the ever-curious students. They also experienced hands-on learning activities and interactive games at the different thematic sectors.

HSA volunteers for the APSN Katong School learning journey

An Afternoon with Our Elders

HSAians got into action at the annual "HSA CARE-in-action through Sponsoring, Packing and Distributing" initiative. This year, staff increased the contribution by sponsoring a total of 202 CARE bags, up from 170 in 2014. Filled with household items, the CARE bags were presented to the seniors affiliated to the Lions Befrienders Centre at Mei Ling Street in December 2015. HSA volunteers also spent quality time with the seniors, playing games and chatting with them.

Spending time with our elders

Raising $18,000 for Cancer

23 brave HSAians, including three female colleagues, stepped up and went bald for a good cause. Together, they raised $18,244 for the Children's Cancer Foundation at the Hair for Hope satellite event held at the HSA Outram office in June 2015. The event was organised to promote awareness of childhood cancer.

Doing Our Part to Raise Awareness

HSA serves the public and our work is dedicated to keeping them informed of health product risks and our efforts in protecting and advancing public health and safety.

Being Mindful of Our Role to Alert and Educate

Unscrupulous manufacturers sometimes add prohibited substances to health products, errant peddlers sell banned vaporisers online for profit, and retailers close an eye to underage smokers. HSA plays an important and active role to alert and warn the public swiftly of the dangers of consuming and using products that could be harmful to their health. We also undertake the responsibility of educating and warning the public against actions that could contravene the law.

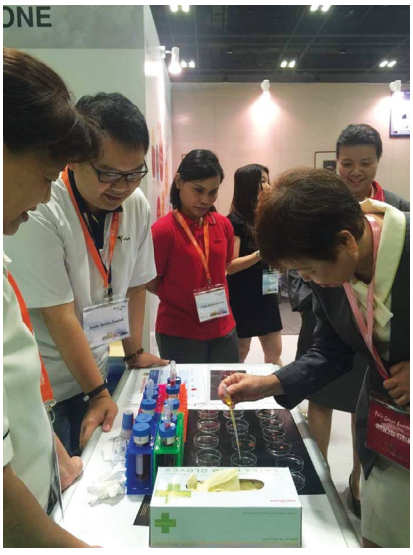
To this end, HSA issued timely press releases on health product alerts, errant tobacco retailers, and vaporiser peddlers.

HSA works closely with the Singapore Red Cross and our Blood Services Group to drive awareness on the importance of regular blood donation through media stories, an annual marketing campaign and the World Blood Donor Day event. Last year, we also planned and rolled out the Bloodbank@Westgate Tower opening and blood donation exhibition at Jurong East MRT successfully, which raised the prominence of the new blood bank and generated interest in blood donation.

We also played a significant role in supporting our forensic laboratories when they were featured on the Channel U programme, *I am Sherlock Holmes*, as well as on Crimewatch collaborations. We also worked with the Public Service Division to profile HSA staff and their work across the three professional groups.

Giving the Community a Glimpse of How Blood Donation Works

Visitors to the HSA's Experential Zone of the Public Service Festival — an outreach activity held in October 2015 in collaboration with Science Centre Singapore and the Singapore Red Cross — spent time role-playing as blood donors and nurses in a typical blood donation process. The booth, which was manned by HSA and Singapore Red Cross staff, also gave visitors a chance to simulate blood-typing activities using basic chemicals. Information cards and souvenirs were distributed to create awareness of the blood donation process, eliminate common myths related to it and reinforce the national need for blood to save lives.



ooking Ahead with New Technology

HSA works hard to constantly improve our infrastructure to enhance productivity, raise service standards, and provide peace of mind to all our stakeholders with regard to health, the environment and our IT infrastructure.

A Role Model in Energy Efficiency

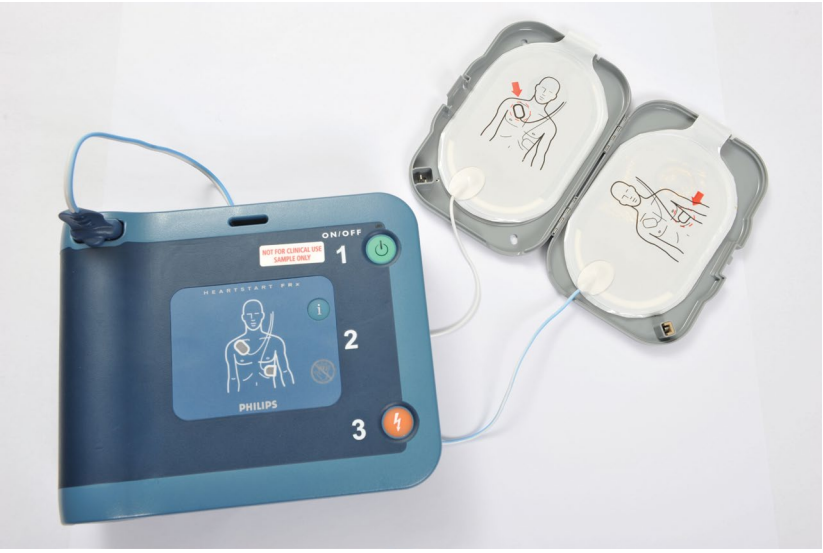
A lower score in tests for Power Usage Effectiveness (PUE) indicates better energy efficiency, and HSA is proud to have achieved a low PUE score that was far below the government's benchmark for data centres and was attained ahead of the target date of end-FY2016 for government agencies. HSA was invited by the Infocomm Development Authority (IDA) to share its success story with other government agencies in March 2016.

Innovations for Stakeholders

To enable a quick search on the licence status of health products, HSA has engaged a team to develop a proof-of-concept (POC) mobile application that can eventually be developed into a health product-centric mobile service for citizens and the healthcare industry. The team was chosen from the National Hackathon (Hackathon@SG) organised by IDA in July 2015. Through this event, HSA was able to leverage on innovative ideas from participating teams.

Equipped for Cardiac Emergencies

Staff at HSA Outram are now prepared for cardiac emergencies, with the installation of an Automated External Defibrillator (AED) at the premises, as well as the implementation of a staff-training programme to ensure a sufficient number of first-aid volunteers who are equipped with life-saving skills. From mid-2016, these volunteers will be given access to HSA's AED through the 'myResponder' mobile app. This means that any volunteer within 400 metres of the AED will be notified of any cardiac emergencies. The AED can also be accessed during HSA's operating hours on weekends. This initiative is a collaboration between HSA, and our external partners from the Singapore Heart Foundation and Singapore Civil Defence Force.



Our Achievements in Figures

Blood Services Group

Key Statistics as at end-December 2015

71,277
Blood Donors

112,713
Whole Blood Donations

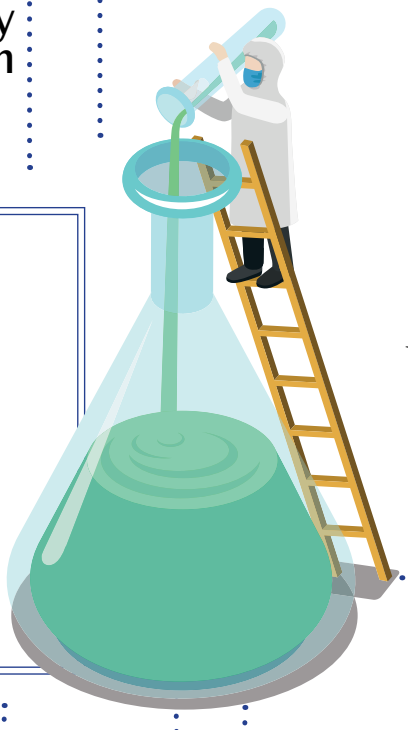
365,979
Blood Components Processed

9,335
Apheresis Donations

1,170,004
Laboratory Tests Conducted

Applied Sciences Group

Key Statistics as at end-March 2016



Forensic Medicine Divison

4,150 Coroner's Cases

1,342 Coroner's Autopsies

Food Safety Divison

37,938 Analytical Tests for Laboratory Samples

4,068 Analytical Cases

Pharmaceutical Division

14,812 Analytical Tests for Laboratory Samples

2,887 Analytical Cases

Forensic Science Division

295 Forensic Cases

1,055 Forensic Exhibits

Analytical Toxicology Divison

20,506 Forensic Cases

37,815 Forensic Exhibits

Biology Divison

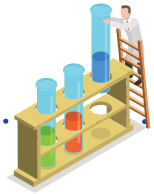
24,431 Forensic Cases

30,771 Forensic Exhibits

Illicit Drugs Divison

2,586 Forensic Cases

6,471 Forensic Exhibits



Medicinal Product Licences Approved

90
Medicinal Product Licences (New Innovator Drugs) Approved

117
Medicinal Product Licences (Generics) Approved

9
Number of Medicinal Products Approved under Priority Review

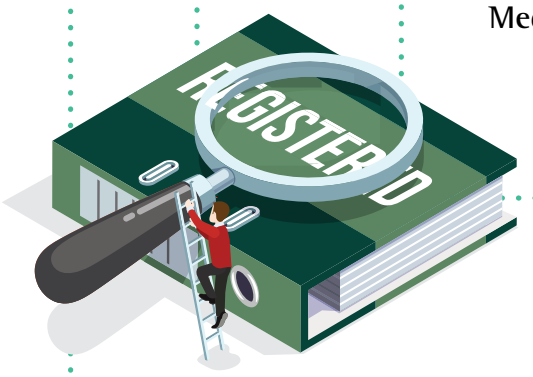
272
Clinical Trials Certificates Granted

1,201
Medical Device Product Listings Approved (Class A, B, C & D)

16,026
Approved Products on the Singapore Medical Device Register

1
Number of Biosimilars Registered

5,463
Number of Registered Medicinal Products



14
Number of First Generics Registered

53
Number of Reclassified Medicinal Products

20,921
Spontaneous Adverse Drug Reaction Reports Captured

3,108
Medical Advertisement Permits Approved

10,804
Total Number of Chinese Proprietary Medicines Listed

778
New Chinese Proprietary Medicines Listed

163,658
Total Number of Cosmetic Products Notified

43,470
New Cosmetic Products Notified

389
Site Audits Conducted for Good Manufacturing & Good Distribution Practices and Pharmacies

621
Number of Field Safety Corrective Action Reporting for Medical Devices Received

Health Products Regulation Group

Key Statistics as at end-March 2016

8,811
Number of Electronic Cigarettes Cases Referred to HSA

4,850
Total Number of Licensed Tobacco Retail Outlets

607
Tobacco Retail Licences Approved

2,672
Applications for Import of Medicinal Products for Personal Use Processed

Applications Approved

Applications for Licences/Certificates for Manufacturers of Health Products Approved	379
Applications for Licences/Certificates for Importers of Health Products Approved	3,489
Applications for Licences/Certificates for Wholesalers of Health Products Approved	1,431
Registration of Retail Pharmacies Approved	338
Applications for Licences/ Certificates for Exporters of Health Products Approved	622

Financial Highlights

Balance Sheet

	FY15/16 $'000	FY14/15 $'000	Increase / (Decrease) $'000	%
Property, Plant & Equipment	84,094	86,023	(1,929)	(2)
Intangibles	2,556	2,310	246	11
Current Assets	141,297	137,306	3,991	3
Total Assets	**227,947**	**225,639**	2,308	1
Equity	**135,507**	**127,428**	8,079	6
Long-Term Loans	17,290	18,200	(910)	(5)
Other Non-Current Liabilities	7,651	9,376	(1,725)	(18)
Current Liabilities	67,499	70,635	(3,136)	(4)
Total Equity and Liabilities	**227,947**	**225,639**	2,308	1

Income & Expenditure Statement

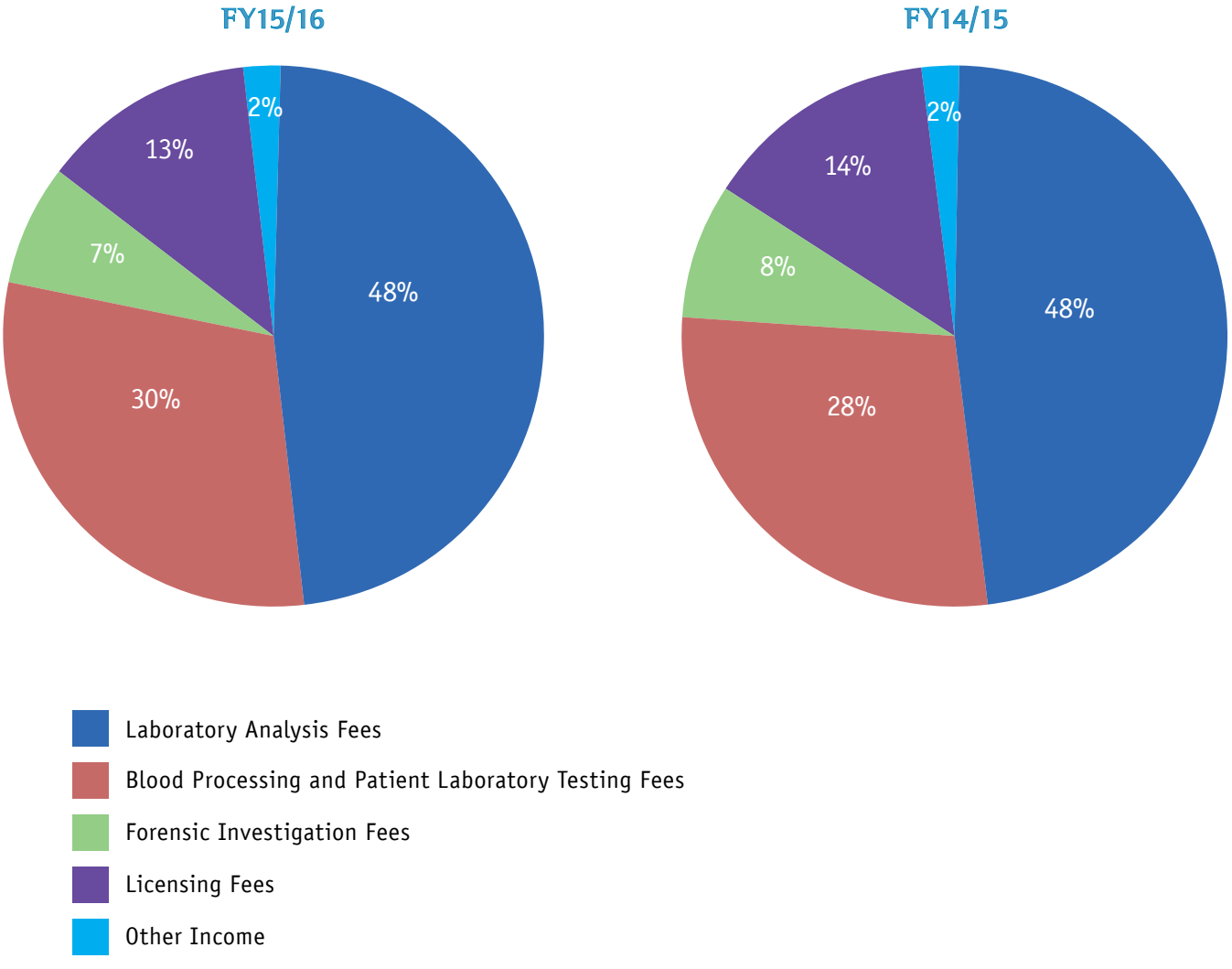
The Authority has achieved an overall net surplus of $8.0m for FY15/16.

	FY15/16 $'000	FY14/15 $'000	Increase / (Decrease) $'000	%
Operating Income	132,403	121,899	10,504	9
Operating Expenditure	(198,827)	(195,441)	3,386	2
Deficit before Government Grants	**(66,424)**	**(73,542)**	(7,118)	(10)
Government Grants	76,398	80,490	(4,092)	(5)
Surplus before Contribution to Consolidated Fund	**9,974**	**6,948**	3,026	44
Contribution to Consolidated Fund	(1,696)	(1,181)	515	44
Net Surplus	**8,278**	**5,767**	2,511	44
Other Comprehensive Income	(231)	(537)	(306)	(57)
Contribution to Consolidated Fund	-	(24)	(24)	100
Net Comprehensive Income	**(231)**	**(561)**	(330)	(59)
Net Surplus and Comprehensive Income for the Year	**8,047**	**5,206**	2,841	55

Operating Income

The Authority earned a total operating income of $132.4m in FY15/16, an increase of $10.5m (9%) over FY14/15's revenue of $121.9m.

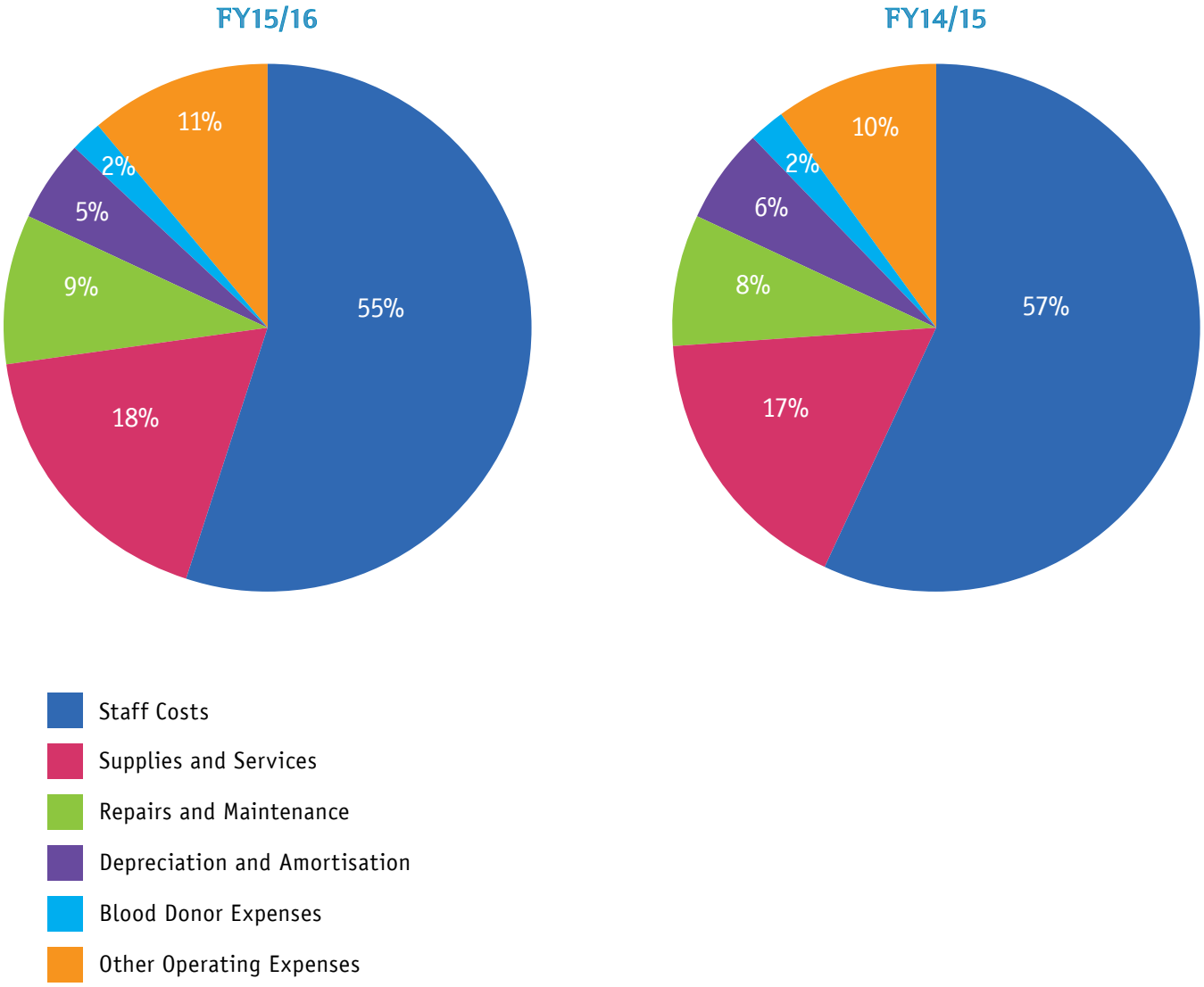
	FY15/16 $'000	FY14/15 $'000	Increase / (Decrease) $'000	%
Laboratory Analysis Fees	63,486	57,945	5,541	10
Blood Processing and Patient Laboratory Testing Fees	39,090	34,556	4,534	13
Forensic Investigation Fees	9,647	9,547	100	1
Licensing Fees	17,042	17,024	18	0
Other Income	3,138	2,827	311	11
Total Operating Income	**132,403**	**121,899**	**10,504**	**9**



Operating Expenditure

The Authority incurred a total operating expenditure of $198.8m in FY15/16, an increase of $3.4m (2%) over FY14/15's expenditure of $195.4m.

	FY15/16 $'000	FY14/15 $'000	Increase / (Decrease) $'000	%
Staff Costs	110,317	112,079	(1,762)	(2)
Supplies and Services	35,276	33,716	1,560	5
Repairs and Maintenance	18,307	16,169	2,138	13
Depreciation and Amortisation	10,272	11,469	(1,197)	(10)
Blood Donor Expenses	3,756	3,536	220	6
Other Operating Expenses	20,899	18,472	2,427	13
Total Operating Expenditure	**198,827**	**195,441**	**3,386**	**2**



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