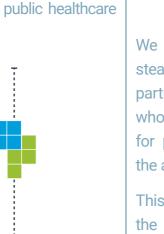
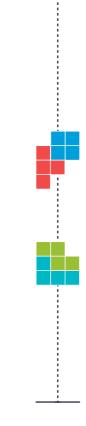


## SYNERGY

At HSA, we are greater than the sum of our parts. Our progress and success are anchored by the partnerships we have fostered, both within and outside of the organisation, locally and internationally.

We find strength and unity amidst the rich and diverse layers of interaction and cooperation amongst our staff. Tapping on each other's strengths and capabilities, we are empowered to safeguard and advance public healthcare in Singapore.





We are thankful to have the steadfast support of our partners and stakeholders who share the same passion for public health, safety and the administration of justice.

This annual report celebrates the synergy we have established over the years that spurs us on in making a difference every day. ANNUAL REPORT 2016/17

## Contents

VISION, MISSION & VALUES

OUR ACCOLADES

06 CHAIRMAN'S MESSAGE

> 08 CEO'S MESSAGE

> > 10 HSA BOARD

13 BOARD CHANGES

HSA EXECUTIVE COMMITTEE (EXCO)

CORPORATE GOVERNANCE STATEMENT

17 ORGANISATION CHART

PRINCIPAL OFFICERS

20
HEALTH PRODUCTS REGULATION GROUP

BLOOD SERVICES GROUP

APPLIED SCIENCES GROUP

CORPORATE SERVICES GROUP

OUR ACHIEVEMENTS IN FIGURES

FINANCIAL HIGHLIGHTS

## 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 CoreValues

#### **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

since 2014

#### The Public Service Milestone Award 2010

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

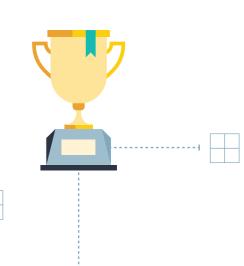
#### Singapore Service Class

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



#### **HEALTH PRODUCTS REGULATION GROUP** 1---

#### ISO 9001:2015

Tobacco Regulation Branch since March 2017

#### ISO 9001:2015

Vigilance & Compliance Branch since March 2017

#### ISO 9001:2015

**Enforcement Branch** since March 2017

#### ISO 9001:2008

Audit and Licensing Branch since October 2015

#### **Member of the Management Committee for** the International Medical Device Regulators Forum (IMDRF)

since September 2016

#### First Position in the World Health Organization (WHO) Global ICSR (Individual Case Safety **Report) Database Ranking**

Vigilance & Compliance Branch since 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 **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** 

**American Society of Crime Laboratory Directors/Laboratory Accreditation Board** (ASCLD/LAB)

since June 1996

**Pharmaceutical Division and 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 General European Official Medicines Control Laboratories Network (GEON)** 

since May 2014

**Member of the ASEAN Cosmetics Testing Laboratory Committee (ACTLC)** 

since November 2012

**Observer to the European Pharmacopoeia** Commission

since February 2012

**World Health Organization Collaborating Centre for Tobacco Testing and Research** 

since June 2009

**World Health Organization Collaborating Centre for Drug Quality Assurance** 

since February 1993

#### **Food Safety Division**

Member of the ASEAN Food Testing **Laboratory Committee (AFTLC)** 

since June 2011

**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









#### **BEING FUTURE-READY**

As a scientific organisation, HSA prides itself on being future-ready, keeping a finger on the pulse of trends and evolving to tackle challenges. We constantly upgrade our skills and knowledge in the pursuit of our vision to advance public health and safety.

#### COMMITMENT TO PUBLIC HEALTH

The Health Products Regulation Group (HPRG) approved Dengvaxia® - the first dengue vaccine. Given the public health concerns associated with dengue, our staff were dedicated to facilitating access to a safe and suitable dengue vaccine for Singapore. Working in close collaboration with a panel of healthcare experts, we completed the analysis of the scientific studies and approved the vaccine for marketing in Singapore. We could not have done it without our team of diligent and passionate staff.

I am also proud to share that HPRG's post-market cluster, including Vigilance & Compliance, Enforcement, and Tobacco Regulation, was awarded the ISO 9001:2015 certification with zero nonconformities, attesting to our rigorous frameworks and processes.

#### **ADVANCING OUR SCIENTIFIC EXPERTISE**

HSA also supports the administration

excellence, we seek innovative techniques to broaden our scope of investigations. Our Applied Sciences Group (ASG) has developed a faster and non-destructive technique to analyse metals and fake jewellery. The Cosmetics Laboratory has also expanded their scope of testing to include two new biocides, helping to ensure compliance in cosmetic products in Singapore.

Our laboratories undergo regular assessments by international accreditation bodies to ensure that our work processes are robust and match international standards. From 2016 to 2017, ASG went through the rigorous accreditation processes of the American Society of Crime Laboratory Directors/ Laboratory Accreditation Board (ASCLD/LAB) International Program, National Association of Medical Examiners (NAME) and Singapore Accreditation Council-Singapore Laboratory Accreditation Scheme (SAC-SINGLAS), and we retained our accreditations. The Forensic Chemistry & Physics Laboratory was also accredited in the 'Crime Scene' discipline for the first time.

The Blood Services Group has always been committed to ensuring the highest standards in blood safety and quality, transfusion medicine and tissue typing services. They were successful of justice. In our pursuit of forensic in their American Association of

Blood Banks (AABB) and American Society for Histocompatibility and Immunogenetics (ASHI) reaccreditation, retaining confidence in our blood and tissue products.

#### **ESTABLISHING AND NURTURING A RESEARCH** CULTURE

We promote a strong organisationwide research culture in HSA, as we believe that through inquiry and maintaining a keenness to learn and improve our work and processes, we can advance our knowledge, enhance our professional capabilities and better meet the needs of our stakeholders.

We have established HSA as a Research Institution and implemented a research governance framework to encourage, guide and support the researchers in our organisation. With new findings, we can improve the way we work and keep HSA at the forefront of our business.

With continued developments, I am confident that the years ahead will bring satisfying progress and rewards to HSA.

ANNUAL REPORT 2016/17
SYNERGY
ANNUAL REPORT 2016/17
SYNERGY



#### A SYNERGISTIC ORGANISATION

The landscape we are operating in is becoming increasingly volatile and complex, with more economic and geopolitical uncertainty. At the same time, we are seeing many more scientific and technological advances and new innovations coming into the healthcare space. These changes present challenges as well as opportunities for HSA in the future.

To help us be future-ready, HSA has a five-year strategic road map. Founded on a strong foundation of 'people and values', and the pillars of 'knowledge and innovation', 'technology and infrastructure', and 'governance and stewardship', the road map serves to guide a common organisational direction to achieve our mission.

HSA is a multi-faceted and dynamic organisation. Our core values, mission and vision are deeply ingrained in our staff. Together, our shared sense of service to our nation fuels us to fulfil our roles and responsibilities to secure and advance public health and safety.

In the past year, we crossed several milestones. The cooperation and synergy across the different Professional Groups in HSA, our close and strategic collaboration with external partners, and strong support for our stakeholders enable us to contribute towards Singapore's healthcare, safety and security.

#### STREAMLINING OUR REGULATORY CONTROLS

The Health Products Regulation Group (HPRG) oversaw the complex and extensive transfer of regulatory controls from the existing Medicines Act to the Health Products Act (HPA) in 2016. We successfully ported over the different regulatory controls for therapeutic products, clinical trials and oral dental gums under the umbrella of the HPA in November 2016.

The collaborative efforts and contributions of our stakeholders were invaluable in this process. Consultations were held with industry stakeholders to enable HPRG to understand their concerns and minimise impact to them in the course of the legislative transfer. We are also appreciative of the Whole-of-Government support of 14 government agencies, which enabled a smooth transition of the regulations to the HPA.

#### MITIGATING PUBLIC HEALTHCARE THREATS

When HSA first received news of a Zika outbreak in Brazil and other parts of the world, and the possibility of microcephaly in babies of infected pregnant women, we planned ahead and readied ourselves. The Blood Services Group's (BSG) partnership with the National Public Health Laboratory also enabled us to mitigate this external public health threat by building a stockpile of Zika-tested blood for pregnant women in under three months.

When Zika hit our shores in August 2016, we acted swiftly to implement mass blood screenings for Zika. BSG banded together with our colleagues from HPRG and the Corporate Services Group to make this a reality. Imports of the Zika test kits were expedited via the special authorisation route, the test kits were validated, and legal agreements were finalised. Working tirelessly under a tight timeline, our collective efforts led to the introduction of routine Zika screening of all blood donations at our blood banks in January 2017.

## WORKING IN TANDEM WITH OUR ENFORCEMENT COUNTERPARTS

Synergy within the Applied Sciences

Group (ASG) and the commitment to support our stakeholders through enhancing and broadening our work has been our strength and is evident in our work. In order to meet the emerging needs of our stakeholders due to the evolving environment, ASG has built up competencies in new areas such as interpretation of alcohol breathalyser results and detection of new psychoactive substances in seized drugs and biological specimens. The Shangri-La shooting case, which involved a vehicle attempting to drive through a police barricade that left one dead, clearly demonstrates our synergy and commitment. More than 60 of our forensic staff from six different laboratories within ASG analysed the evidence from the crime scene, which included chemicals, explosives, fibres, glass fragments, paint chips, and blood stain patterns, and worked round the clock to provide vital information and results to aid the investigation. This case also highlighted how we work in sync with our enforcement counterparts like the Singapore Police Force to shed light on the evidence found.

In 2017, we also conducted the first multi-agency clandestine drug laboratory investigation course with the Central Narcotics Bureau and the Singapore Civil Defence Force. We have also continuously introduced more efficient workflows and processes, and through these efforts, reduced the expected analysis turnaround times of some services.

#### **VALUING OUR PEOPLE**

HSA's unique line of work attracts individuals who are highly committed to our mission to secure national health and safety. Our staff are

our greatest asset and are key to ensuring we can continue to do our work well. We will carry on building this strong community of passionate and capable HSA-ians. Besides adopting a holistic approach of hiring and assessing staff based on their skills and competencies, we have also reviewed the Professional Development Career Tracks to clarify required competences and training needs as part of our efforts to develop a skills-based workforce that excels in their work

We are also looking beyond traditional recruitment channels to see how we can continue to attract talents for critical jobs. HSA is now offering pre-service nursing sponsorships to attract nursing diploma students to grow the number of registered nurses in HSA.

#### FUTURE SENSING FRAMEWORK

As a scientific organisation, we must continue to be forward-looking, develop new capabilities, innovate, and achieve more with our resources. We have also institutionalised a Future Sensing Framework to keep ourselves updated on the latest developments, trends and emerging issues that may impact HSA.

A core team comprising members across all four Professional Groups supports horizon scanning, strategic planning and risk management in HSA.

As we continue to maintain a keen eye on future trends and develop our people, I'm confident that HSA is prepared and ready for our journey ahead. We are united by our strong sense of purpose and passion, and will continue to leverage on and develop our synergies, within the organisation and with the external stakeholders we work closely with.

Mr Adam Abdur Rahman

Head of Corporate Affairs

Citi Singapore and ASEAN

Mr Lionel Yee Woon Chin, SC

Attorney-General's Chambers

Deputy Attorney-General

**Managing Director** 



**C**<sub>AS AT</sub> AUGUST 2017



10



2





4



5

#### **Professor Satkunanantham** s/o Kandiah

Chairman Health Sciences Authority

5

#### 6 Mrs Tan Li Lian

2

Mr Max Loh

Ernst & Young

Managing Partner

ASEAN and Singapore

**Executive Director** Contemporara Holdings Pte Ltd

### **Professor Freddy Boey**

Deputy President and Provost Nanyang Technological University

#### Mr Dileep Nair

Independent Director Keppel DC REIT Management Pte Ltd

#### 10

A\*STAR

3

Chair

Mr Tai Lee Siang

World Green Building Council

Value Addition

**Professor Alex Matter** 

Chief Executive Officer

Experimental Therapeutics Centre/Drug Discovery & Development

Chief Executive Officer

#### 11

Mr Alok Mishra Mr Jimmy Phoon

CEO & Chief Investment Officer Seatown Holdings International Pte Ltd



6



7





9



10



11

## HSA Board Committees

**F**AS AT **AUGUST 2017** 

#### **BOARD EXECUTIVE COMMITTEE**

Professor Satkunanantham Chairman s/o Kandiah

Mrs Tan Li Lian

Member

Mr Adam Abdur Rahman Member

Mr Alok Mishra Member

#### AUDIT AND RISK COMMITTEE

Mr Max Loh Chairman

**Professor Freddy Boey** Member

**Professor Alex Matter** Member

Mr Jimmy Phoon Member

#### **BUILDING DEVELOPMENT COMMITTEE**

Mr Tai Lee Siang

Chairman

World Green Building Council

Dr Choong May Ling, Mimi Chief Executive Officer

Co-Chairman

Member

Member

Member

Member

**Health Sciences Authority** 

Mr Lionel Yee Woon Chin, SC

Deputy Attorney-General Attorney-General's Chambers

Mr Dileep Nair Member

Independent Director Keppel DC REIT Management Pte Ltd

Mr Jeffrey Wong

**Group Director Corporate Services Group** 

Assoc Professor Sunil Sethi Member

**Group Director** 

**Applied Sciences Group** 

Assoc Professor Chan Cheng Leng Member

**Group Director** 

Health Products Regulation Group

Dr Ang Ai Leen Member

**Group Director Blood Services Group** 

Ms Elizabeth Quah

Group Director (Planning)

Ministry Of Health

Mr Loke Mun Sing Member

Director

Healthcare Infrastructure Projects

Ministry Of Health Holdings

**Health Sciences Authority** 

Mr Hoong Bee Lok

Visiting Consultant

Board Changes

HSA would like to express our deepest appreciation to Ms Serene Wee and Mr Clifton Tan, who ended their term on the HSA Board on 31 March 2017. They were two of HSA's longest serving Board members and have made many wideranging contributions to HSA over the years.



**ANNUAL REPORT 2016/17** 

Ms Serene Wee served as our Board member for nine years. HSA has benefited greatly from her wise counsel and she has guided us through several critical milestones. As the Chairman of the Audit Committee between 2009 and 2013, Ms Wee gave us invaluable advice to strengthen HSA's corporate governance, which helped to improve HSA's corporate performance and accountability. As a member of the Executive Committee since 2013, she has further enhanced our manpower strategy and performance management.





Mr Clifton Tan was our Board member for seven years. His guidance as a member of the Audit and Risk Committee has helped us to ensure that HSA has robust measures and controls put in place, thus enabling HSA to achieve high standards of corporate governance and transparency.

His insightful guidance has also enabled HSA to strengthen the framework for strategic risk monitoring and reporting.

> We wish them every success in the future.

> We welcome our new board members: Mr Dileep Nair, Mr Jimmy Phoon and Mr Alok Mishra who started their term on 1 April 2017. With their extensive experience in both the public and private sectors, we look forward to their insightful guidance.



## Executive Committee

#### **F**AS AT **AUGUST 2017**

#### Dr Choong May Ling, Mimi Assoc Professor Chan Cheng Leng

Chief Executive Officer

#### Dr Ang Ai Leen

**Group Director Blood Services Group** 

#### Mr Jeffrey Wong

**Group Director Corporate Services** Group

**Group Director Health Products** Regulation Group

#### **Assoc Professor Sunil Sethi**

**Group Director Applied Sciences Group** 

#### Dr Diana Teo

Chairman **Professional Board** Senior Consultant **Blood Services Group** 







2









## the public at large.

#### 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 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 meet every two to three months to Appointments Council (DCAC) set strategic directions, assume the 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.



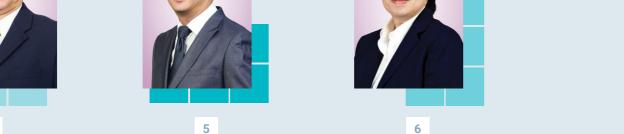


The HSA Board and Senior Management Team are committed

**ANNUAL REPORT 2016/17** 

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









## Organisation Chart

**AUGUST 2017 HSA BOARD INTERNAL AUDIT** 

**CHIEF** 

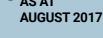
**EXECUTIVE** 

**OFFICER** 

**QUALITY** SERVICE **MANAGER** 

**PROFESSIONAL** BOARD

**F**AS AT



#### I ACCOUNTABILITY AND AUDIT

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

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

#### A. BOARD EXECUTIVE COMMITTEE

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

#### **B. AUDIT AND RISK COMMITTEE**

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

#### C. BUILDING DEVELOPMENT COMMITTEE

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

#### COMMUNICATION WITH **STAKEHOLDERS**

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

#### CODE OF **BUSINESS** CONDUCT



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

#### RISK MANAGEMENT

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

#### **HEALTH PRODUCTS** REGULATION GROUP

- Therapeutic
- Products Medical Device
- 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



#### 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









## Principal Officers

#### **CORPORATE HEADOUARTERS**

Chief Executive Officer Dr Choong May Ling, Mimi

#### **Professional Board**

Chairman Dr Diana Teo

#### **Quality Service Manager**

Director (Concurrent Appointment) Mr Adrian Chia

#### **Internal Audit**

Assistant Director Ms Adeline Ho

#### CORPORATE **SERVICES GROUP**

**Group Director** Mr Jeffrey Wong

Assistant Group Director Mr Adrian Chia

#### **Corporate Communications**

Director (Concurrent Appointment) Mr Adrian Chia

#### **Risk Management & Emergency Planning**

Deputy Director Mr Ho Cheng Choy

#### **Human Capital Management**

Director Ms Lily Goh

#### Legal

General Counsel Ms Linda Chen

### **AUGUST 2017**

#### **Legal Policy & Prosecution**

Director Ms Grace Lim

#### **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**

Acting Director Mr Gabriel Yeo

#### Safety & Quality

Acting Director Mr Yap Tien Siang

#### **HEALTH PRODUCTS** REGULATION **GROUP**

**Group Director** Assoc Professor Chan Cheng Leng

#### **GROUP DIRECTOR'S &** STAKEHOLDER ENGAGEMENT **OFFICE**

Director Ms Ling Boon Lee

#### **PRE-MARKET CLUSTER**

Assistant Group Director Ms Lee Hui Keng

#### **Clinical Trials Branch**

Director Mr Foo Yang Tong

#### **Therapeutic Products Branch**

Actina Director Ms Agnes Chan

#### **Medical Device 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**

Director Ms Annie Tan

#### Vigilance & Compliance **Branch**

Director Ms Jalene Poh

#### **Tobacco Regulation Branch**

Director

Mr Norman Chong

#### **AUDIT & LICENSING DIVISION**

**Division Director** Ms Jessica Teo

#### **Audit Branch**

Director Ms Jessica Teo

#### **Licensing & Certification** Branch

Director Dr Lai Weng Fai

#### **BLOOD SERVICES** GROUP

**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

#### **Quality & Accreditation**

Senior Manager Ms J Thilakavathi

#### **BLOOD RESOURCES**

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

#### **OUALITY**

Director Dr Chow Shui Tse

Director-Designate Dr Lui Chi Pang

#### FORENSIC MEDICINE

Chief Dr Paul Chui

#### Infrastructure Branch

Branch Director Dr George Paul

#### **Operations Branch**

**Branch Director** Dr Marian Wang

#### **Professional Practice Branch**

Branch Director Clinical Professor Gilbert Lau

#### **Technical Capabilities Branch**

Branch Director Assoc Professor Cuthbert Teo

#### **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**

**Division Director** Mr Lim Thiam Bon

#### **Illicit Drug Division**

Division Director Dr Angeline Yap

#### **ANALYTICAL SCIENCE**

Assistant Group Director Ms Low Min Yong

#### **Chemical Metrology Division**

Division Director Dr Lee Tong Kooi

#### **Food Safety Division**

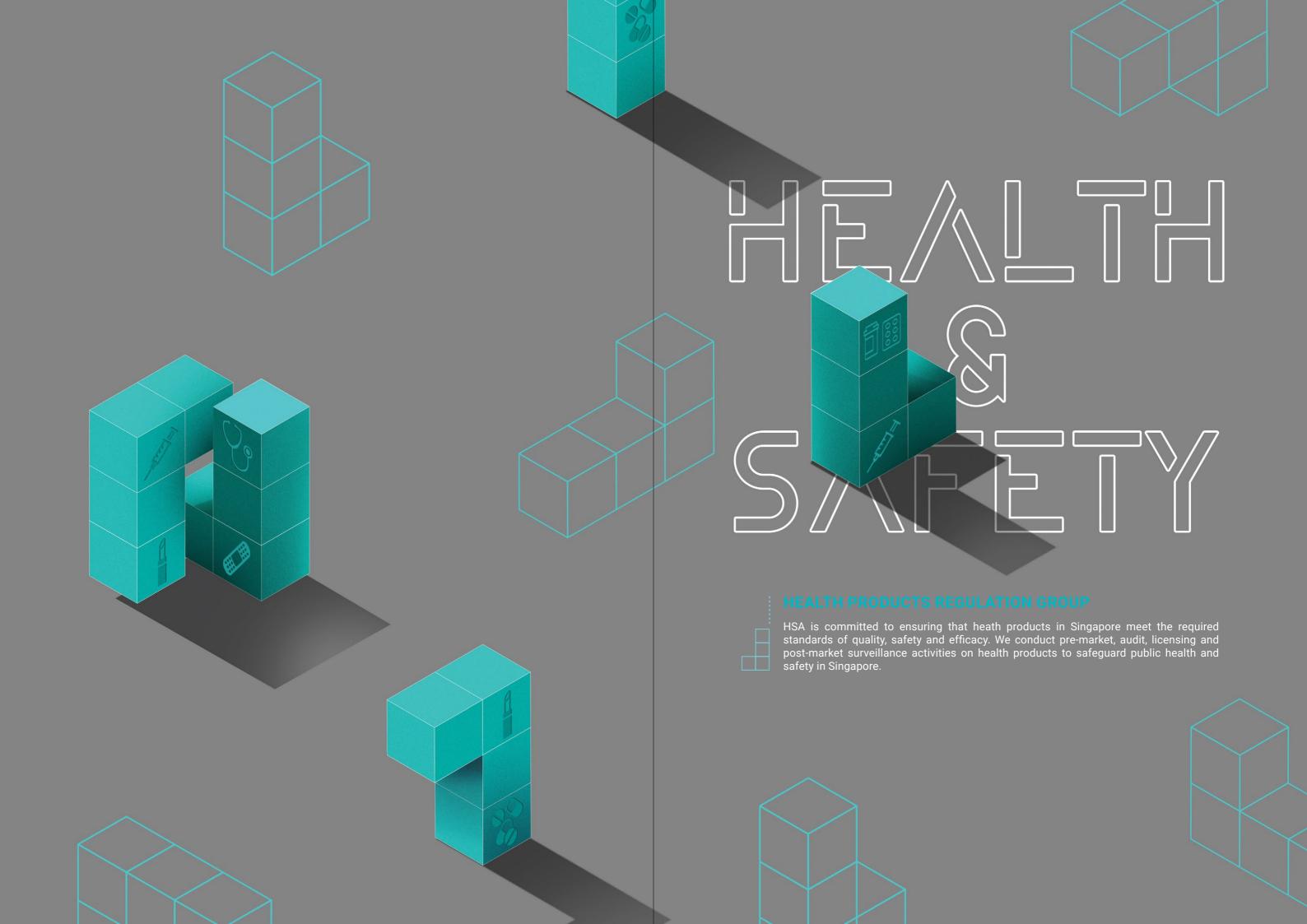
Division Director Ms Joanne Chan

#### **Pharmaceutical Division**

**Division Director** Ms Low Min Yong







J-----

## Knowledge and Innovation

At HSA, we strive for innovative ways to achieve our goals, fueling progress by reviewing frameworks that will facilitate the industry while placing public trust, health and safety as our priorities.

#### TRANSFERRING REGULATORY CONTROLS OF PHARMACEUTICAL PRODUCTS TO HEALTH PRODUCTS ACT

As of 1 November 2016, pharmaceutical products are regulated as "Therapeutic Products" (TP) under the Health Products Act (HPA), replacing existing controls under the Medicines Act (MA) and the Poisons Act (PA).

This TP port-over ensures that new regulations remain relevant to the evolving pharmaceutical development landscape, and are adequate to safeguard public health while facilitating timely access to TPs.

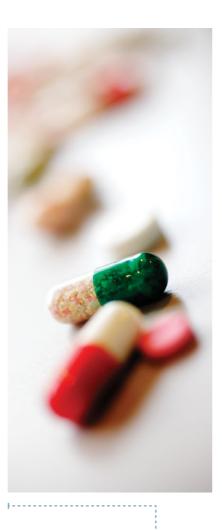
#### **ORAL DENTAL GUMS CONTROLS**

ANNUAL REPORT 2016/17

Controls of oral dental gums

#### **ENGAGEMENT WITH STAKEHOLDERS**

- Extensive consultation sessions, workshops and stakeholder meetings were conducted to prepare stakeholders for the port-over implementation
- Information related to the new legislation was shared through various channels, including:
- Email communications
- Dedicated TP port-over webpages
- Compilation of frequently asked questions
- A dedicated enquiry emai





#### THERAPEUTIC PRODUCT REGISTRATION, AUDIT AND LICENSING CONTROLS

- Licensing of Retail Pharmacies regulation on 1 November 2016
- More than 5,000 registered pharmaceutical products are now regulated as TPs
- An activity-based licensing Registrants who intend to import and/or wholesale registered TPs are required to hold an Importer's Licence (IL) and/or Wholesaler's Licence (WL) to import and wholesale their registered TPs
- Regulatory controls of TPs imported for the purpose of re-export, for non-clinical use, or for supply to vessels and aircraft (in accordance to other consignments imported for re-
- To streamline the dealer's licensing process, Form A required for dealings in **Pharmaceutical Ingredients** and veterinary products. Form A Poisons Licence is also not required for licensed manufacturers of TPs for the import of substances containing poisons (i.e. API manufacturing of their own TPs
- Importer's and Wholesaler's



Six new regulatory guidance documents were released on our website following the port-over of the clinical trial regulations and introduction of the Clinical Research Materials (CRM) regulations.

#### **Key Legislative Changes**

- Risk-based approach to the regulation of clinical trials introduced, which allows faster turnaround times for local registered products
- Clinical Research Materials (CRM) regulations, which replaces the import permit issuance system, was introduced to facilitate the importation and supply of CRM for use in local clinical research
- CRM notifications for trials have been made as part of the clinical trial application/ notification to HSA to further streamline the regulatory process and reduce the regulatory burden on stakeholders







### POST-MARKET CONTROLS

Enhancements were made on the following post-market controls:

- Timelines for reporting of serious adverse effects were aligned with the International Council for Harmonisation Of Technical Requirements For Registration Of Pharmaceuticals For Human Use E2D guidelines
- Post-marketing requirements for product registrants to carry out risk management plans and submit product benefit-risk evaluation reports
- Companies to report and maintain records on product defects to ensure greater accountability of post-market responsibilities for public safety



ANNUAL REPORT 2016/17

- Removal of the permit system for advertisements of TP to streamline regulatory controls. The rules and principles of advertisement controls are prescribed as requirements under the HPA and its subsidiary legislation, the Health Products (Advertisement of Therapeutic Products) Regulations. HSA will maintain oversight with its post-market efforts through surveillance and monitoring of published TP advertisements for compliance to the prescribed rules and principles
- Higher maximum penalties are imposed on offenders who are convicted for offences relating to advertisements of TP under the HPA which includes a maximum fine of up to \$20,000 or imprisonment of up to 12 months, or both

## APPROVAL OF FIRST DENGUE VACCINE

In October 2016, HSA issued its regulatory decision to approve Dengvaxia®, a vaccine that prevents dengue infection caused by dengue virus serotypes 1, 2, 3 and 4 in individuals aged 12 to 45 years. The approval was based on an indepth review of the clinical studies conducted by Sanofi Pasteur and in consideration of the application of the study findings to the local context.

Extensive consultations were also conducted with various expert groups, including HSA's Dengue Expert Panel comprising infectious diseases specialists, the Medicines of Advisory Committee, and the Ministry of Health. This has led to the conclusion that the subpopulation in Singapore most likely to benefit from the vaccine is the age group 12 - 45 years who have had a previous dengue infection. Given the public health concerns associated with dengue, the vaccine review was expedited and completed within six months.







## Streamlining Our Work Processes

At HSA, we are constantly reviewing and improving processes for our stakeholders and the public.



## AUDIT AND LICENSING DIVISION PROGRAMME REVIEW PROJECTS

#### RISK-BASED APPROACH TO GDP AUDITS

To enhance and optimise the efficiency of audit and licensing work processes, we conducted an in-depth study on the risk-based approach to Good Distribution Practice (GDP) audits.

We reduced the frequency of GDP audits of companies with good track records by using a risk-based approach. This will incentivise companies to demonstrate good compliance to the GDP standards.

#### SINGLE-LICENCE APPLICATION FOR THERAPEUTIC PRODUCT DEALERS AND REDUCED FEE STRUCTURE

The merger of applications for Therapeutic Products Importer's Licence and Therapeutic Products Wholesaler's Licence came into force on 1 November 2016, in conjunction with the implementation of the Therapeutic Products Regulations. Aimed at reducing the administrative burden to stakeholders by providing a single-licence application form for multiple licences, this initiative streamlined the application process and also reduced the cost of application with a bundled fee.



#### INTRODUCTION OF ELECTRONIC TOBACCO LICENCES

All hardcopy tobacco licences have been replaced with electronic licences which are issued via the online system. This paperless system has increased the efficiency of our processes. Applicants can also download and save soft copies of their licences for their safekeeping or easy reference.

## RECLASSIFICATION EXERCISE FOR THERAPEUTIC PRODUCTS

To enhance the accessibility of drugs over-the-counter for the convenience of consumers, ten active ingredients were reclassified from prescription-only medicines to medicines that can be supplied by a pharmacist without a prescription between April 2016 and June 2017. During this period, 30 active ingredients were also reclassified from Pharmacy Only to General Sale List under specified conditions.





#### REVIEW OF REQUIREMENTS FOR SINGAPORE QUALITY OVERALL SUMMARY

In response to industry's feedback on the requirement of the Singapore Quality Overall Summary (SQOS) as part of therapeutic products registration applications, HSA worked with the Singapore Association of Pharmaceutical Industries and Singapore Pharmaceutical Trade Organisation/Singapore Pharmaceutical Manufacturer's

Council to streamline the submission process. The required information under the SQOS was simplified and incorporated into the application screening checklist rolled out in November 2016. This initiative enables pharmaceutical companies to save time and effort in preparing their application dossiers, allowing earlier submissions.



## STREAMLINING REQUIREMENTS FOR GENERIC DRUG APPLICATION (GDA)

The HSA-Industry Generic Drugs Workgroup comprising HSA and industry representatives worked on issues pertaining to generic drug applications. The workgroup's discussions led to further clarification of the guidance document on therapeutic product registration, particularly on the requirements pertaining to bioequivalence

study design, Biopharmaceutics Classification System-based biowaiver, Comparative Dissolution Profile (CDP) testing requirements and reference product selection to facilitate GDA submissions. In addition, we implemented a reduction in CDP testing requirements while ensuring consistency with international practices.



## Governance and Stewardship

HSA is committed to exercising good governance in our regulatory processes and operations. Our efforts include ensuring fairness in dealings and transparency in our regulatory decisions.

## UPDATED POST-MARKETING RISK MANAGEMENT REQUIREMENTS

In May 2015, the post-marketing risk management requirements for therapeutic products were revised to further strengthen the vigilance framework of products registered for use in Singapore.

Submission of Risk Management Plan (RMP) documents, which includes the Singapore-Specific Annex (SSA) that describes the proposed local RMP, is required for all New Drug Application (NDA)-1 and biosimilar applications. For other application types, such as NDA-2/3, major variation application or GDA, the submission of RMP documents may be requested on a case-by-case basis. Under the Health Products (TP) Regulations

2016 that was enacted in November 2016, companies may be required to implement RMPs under the direction of HSA so as to ensure the benefitrisk profile of the TP remains optimal throughout its lifecycle.

To provide greater transparency and access to the new requirements, the updated Guidance for Industry on Postmarketing Vigilance Requirements was published on HSA's website, along with a list of Frequently Asked Questions on the revised post-marketing risk management requirements.

To date, SSAs for 33 products have been submitted to HSA at the point of product application for registration.

#### ADAPTING TO CHANGES IN THE BUSINESS ENVIRONMENT

We reviewed the legislative control and provided for the supply of General Sale List medicines by retail sale vending machines under the Health Products (TP) Regulations. A guidance document was published to provide stakeholders with clear instructions and conditions related to this new provision.



## Keeping Alert

HSA is always on the lookout to protect the health of patients and consumers through surveillance and vigilance work.

#### VIGILANCE UPDATES ON LOCAL ADVERSE EVENTS

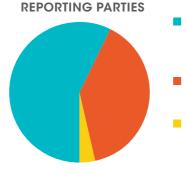
As part of our post-marketing risk assessment approach to ensure health products are safe for consumption and use, HSA closely monitors Adverse Events (AE) reports received from healthcare professionals and companies to keep

tabs on the safety of a health product throughout its marketed life.

Singapore retains its position as the first in the World Health Organization (WHO) Global Individual Case Safety Report (ICSR) database ranking in terms of the number of active individual case reports submitted per million inhabitants per year. We have maintained this position since 2011 with the support of vigilant healthcare professionals.







■ 57.3%
Public hospitals

Public hospitals / healthcare organisations

■ 39.3% Polyclinics

3.4%

Private hospitals, clinics, retail pharmacies and pharmaceutical companies

As a result, the following significant drug safety signals were identified:



Risk of uterine rupture with gemenrost



Risk of placenta abruption with dinoprostone 10mg vaginal delivery system



Risk of Stevens-Johnson Syndrome and toxic epidermal necrolysis with pembrolizumab

#### UPDATE ON PRODUCT RISK MANAGEMENT ACTIVITIES

Local Risk Management Plans (RMPs) were implemented for TPs to ensure the benefits outweigh the risks.

#### 9

RMPs for TPs were implemented

85

Safety signals associated with TPs were assessed

#### 10

Risk assessments were conducted arising from health products found to contain adulterants or exceeding toxic heavy metal limits

#### **Actions Taken:**

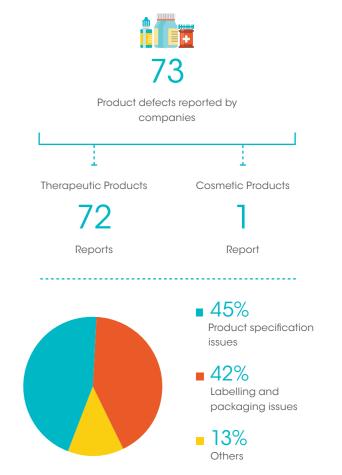
#### Local RMPs include:

- Issuance of notification letters
- Distribution of educational materials to physicians and patients
- Routine submission of periodic benefit-risk evaluation reports to HSA

#### Regulatory actions include:

- Amendment of local package inserts for affected TPs
- Communication with healthcare professionals to raise awareness of safety concerns and to encourage the reporting of local adverse reactions.
- Issuance of press releases to warn public about the danger o harmful products

## SURVEILLANCE OF LOCAL PRODUCT DEFECTS



Regulatory actions taken for







Issuance (

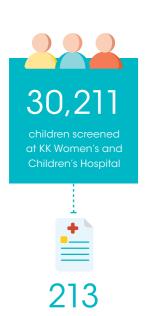
Dear Healthcare
Professional Letters

Other cases were evaluated to ensure that the companies had implemented appropriate corrective and preventive actions to mitigate impact on the safety and quality of future batches.

## UPDATE ON VACCINE VIGILANCE



**ANNUAL REPORT 2016/17** 



suspected of AEs identified for further review

#### **Actions Taken:**



Detailed assessment of potential safety signals were conducted

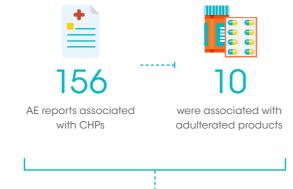


Expert opinions were sought to ensure that the benefitrisk profiles of the vaccines remain favourable



## OATE ON

## UPDATE ON VIGILANCE OF COMPLEMENTARY HEALTH PRODUCTS (CHPS)



#### **Actions Taken:**

4

press releases issued via the various media channels to alert the public

# 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:

#### VISITS BY REGULATORY AGENCIES AND ASSOCIATIONS

#### **JUNE 2016**

**Purpose:** To understand the drug registration system and harmonisation initiatives in ASEAN.

**Guests:** A delegation from the Indian Council for Research on International Economic Research.

#### **JUNE 2016**

Purpose: Provide training and expert advice to HSA on data analytics using electronic medical records to detect adverse drug reactions as well as refinement of quantitative data mining tools for the analysis of spontaneous adverse event reports. A talk was given on the importance of data representation in research studies, jointly organised by HSA and the Saw Swee Hock School of Public Health, National University of Singapore.

**Guest:** Professor Stephen Evans, London School of Hygiene and Tropical Medicine.

#### **SEPTEMBER 2016**

**Purpose:** To understand the regulatory framework of Singapore and also share an overview of Switzerland's Healthcare Ecosystem.

**Guests:** A delegation from Switzerland organised by the Swiss Association for Health Economics.

#### **OCTOBER 2016**

**Purpose:** To gain insights and learn best practices from the European Medicines Agency (EMA).

**Guest:** Professor Guido Rasi, the Executive Director of EMA.

#### **NOVEMBER 2016**

**Purpose:** To facilitate mutual exchange of information and expertise on the teaching, practice, regulation and research of TCM between China and Singapore.

**Guests:** A delegation from China's State Administration of Traditional Chinese Medicine.

#### **DECEMBER 2016**

**Purpose:** To deepen cross-agency collaboration and share learning experiences.

**Guests:** A team of officers from Korea's Ministry of Food and Drug Safety.





# Communicating with Local Stakeholders and the Public



We organised events and initiatives to deepen partnerships and educate both healthcare professionals and the public on how they can help to keep our health products safe.

#### REACHING OUT TO HEALTHCARE PROFESSIONALS

We continued to forge close partnerships with healthcare professionals in pharmacovigilance through the education sessions in hospitals and polyclinics. An overview of the pharmacovigilance framework, how adverse drug reaction reports are managed after submission to HSA and case studies were shared.

#### ENGAGING OTHER STAKEHOLDERS

We also met our key stakeholders to engage them early in the policy development phase. We met the Singapore Traditional Chinese Medicine Organisations Committee in August 2016, and the Health Supplements Industry Association of Singapore in March 2017.

## REACHING OUT TO STUDENTS

We reached out to healthcare-professionals-in-training to engage them in ensuring the continued safety of health products. For instance, we spoke to students of the TCM College (S) Pte. Ltd. to increase the awareness among future Traditional Chinese Medicine (TCM) practitioners on the safety monitoring of complementary medicines, as well as undergraduates of Nanyang Technological University and National University of Singapore (NUS) to introduce the importance of adverse event reporting and risk communication.

We conducted a lecture on risk communication to share the importance of public health messaging with NUS students, as part of their Public Health Communication module with the Saw Swee Hock School of Public Health. The students were also given the opportunity to work on case studies to enhance their learning.





#### ENGAGING HEALTHCARE PROFESSIONALS AND THE PUBLIC

We maintained close communications with healthcare professionals to alert them on safety issues and regulatory decisions related to health products.

#### **OUR EFFORTS INVOLVED:**

Writing and issuing



Dear Healthcare
Professional Letters



press releases



website updates



Publishing



3

issues of HSA Adverse Drug Reaction News Bulletin

## EDUCATIONAL GUIDE ON SCAR

Severe cutaneous adverse reactions (SCAR) are the most common cause of Adverse Drug Reactions (ADR) locally. Often associated with significant morbidity, they usually lead to hospitalisation. As such, HSA has been promoting awareness and the importance of reporting SCAR among healthcare professionals through a variety of communication channels.

In December 2016, HSA published a guide on SCAR to highlight the key features of various forms of SCAR, the drugs that are most commonly associated with each form of SCAR as well as the risk factors associated with the two drugs commonly associated with SCAR locally: allopurinol and carbamazepine.

CENTRE FOR
HEALTHCARE
ASSISTIVE
AND ROBOTICS
TECHNOLOGY
(CHART) EVENT

## CRIMEWATCH PRODUCTION

Issuing

In collaboration with the National Crime Prevention Council and Mediacorp, we re-enacted one of the enforcement operations electronic vaporisers into a Crimewatch episode. The episode illustrated HSA's Tobacco Regulation Branch's efforts in identifying such illegal activities through online surveillance, careful planning of operations and thorough investigations. The production was aired in late October 2016, and reached out to around 800,000 viewers, educating the public on the prohibition against the sale of electronic vaporisers, the harms of such products as well as to send a deterrent message to wouldbe peddlers.

The Medical Device Branch participated in the CHART seminar, which was part of the Singapore Service Robotics Visit Programme in April 2016 organised by the Singapore Economic Development Board at Changi General Hospital. An overview of the medical device regulations



in Singapore was presented to the robotics and assistive technology companies and communities, to showcase the collaborative efforts in realising these integrations by using good quality and safe strategies.



# New and Developing Partnerships

We worked with agencies and organisations to stay up-to-date with the latest developments in the health sciences.

#### LOCAL EVENTS

In November 2016, HSA and A\*STAR jointly organised the Regulatory Framework on Medical Device Development: 2016 Seminar. The seminar highlighted the various approaches to tackling quality, safety and efficacy challenges of healthcare solutions through the sharing of experiences and insights by expert speakers from the research and development field, innovative companies, multinational companies, as well as standards and regulatory affairs professionals.

We also shared insights at the Centre of Regulatory Excellence Biosimilars Workshop, the Chemistry, Manufacturing and Controls Workshop, the International Society of Pharmaceutical Engineering Singapore Conference and the Singapore Manufacturing Federation's Medical Technology Industry Group's Medical Device Seminar.

#### OVERSEAS EVENTS

#### **JULY 2016**

Pharmaceutical Inspection Cooperation Scheme Committee meeting in Manchester, United Kingdom

#### **MAY AND AUGUST 2016**

HSA chaired the Complementary Health Products Working Group, which was set up to work-share on safety assessment of CHP ingredients and discuss emerging regulatory issues with CHP. The group has completed the safety assessment for seven ingredients since its inception in 2015.

#### **MAY AND OCTOBER 2016**

HSA met with its global International Generic Drug Regulators Programme at the 3<sup>rd</sup> and 4<sup>th</sup> meeting.





#### **AUGUST 2016**

The 5<sup>th</sup> Bilateral Meeting of HSA and the National Pharmaceutical Regulatory Agency, Ministry of Health, Malaysia



#### 2016 REGIONAL INITIATIVES — ASEAN

HSA contributes actively towards the ASEAN integration initiatives to remove the technical barriers affecting trade, through the harmonisation of standards and technical regulations of specified healthcare products — pharmaceuticals, medical devices, traditional medicines, health supplements and cosmetic products. In this regard, the various health product workgroups came together to converge the regulatory requirements for these products.

#### ASEAN AGREEMENT ON MEDICAL DEVICE COMMITTEE

\_\_\_\_\_

#### May and December 2016

**Key Topics Covered** 

**SEPTEMBER 2016** 

Management Committee.

**SEPTEMBER 2016** 

**SEPTEMBER AND** 

**DECEMBER 2016** 

HSA participated in the Western

Pacific Regional Forum for the

Harmonisation of Herbal Medicines

Singapore's regulatory control of CHPs

at the 14th Standing Committee FHH

HSA presented on the regulation of

generics products in Singapore at the

4<sup>th</sup> China — ASEAN Drug Cooperation

and Development Summit Forum held

Meeting in Nanning, China.

**DECEMBER 2016** 

in Nanning, China.

HSA became the first ASEAN regulator

to join as a member of the International

Medical Device Regulators Forum

HSA spoke at the 2016

APEC Harmonization Center

Pharmacovigilance Workshop and

CoE Pilot held in Seoul, Korea.

- Development of common interpretations of the ASEAN Agreement on Medical Device Directive (AMDD), post-market guidance documents and capacity building activities
- Regulatory post-market guidelines to support the AMDD

#### (FHH) Subcommittee III Meeting in Chengdu, China. We also presented on PRODUCT WORKING GROUP

#### August 2016

**Key Topics Covered** 

- Providing a framework for bioequivalence (BE) studies conducted by listed BE Centres in ASEAN
- Convergence-related issues and concerns in medicinal product regulations across the region



#### TRADITIONAL MEDICINES & HEALTH SUPPLEMENTS PRODUCT WORKING GROUP

#### May, June, November, December 2016

**Key Topics Covered** 

- Plans to finalise the ASEAN Agreement on Regulatory Framework for Traditional Medicines and the ASEAN Agreement on Regulatory Framework for Health Supplements
- Training proposals for various technical standards, in which the training modules for ASEAN GMP Guidelines for Traditional Medicines and Health Supplements were developed and finalised by the end of October 2016

#### **ASEAN COSMETIC COMMITTEE**

#### May and November 2016

**Key Topics Covered** 

- Key performance indicators, progress and emerging issues arising from the implementation of the ASEAN Cosmetic Directive (ACD)
- Proposal to develop an ASEAN joint opinion statement for ingredients that are of public interest
- Scientific discussion on new ingredients, restricted cosmetic ingredients or allowable colouring agents, preservatives or UV filters under the ACD

\_\_\_\_\_\_



## Enforcement **Operations**

We continued our partnerships with enforcement agencies in various joint operations to address the peddling of illegal health products and tobacco products.



#### CLAMPING DOWN ON PEDDLING OF SEXUAL ENHANCEMENT DRUGS (SED) IN GEYLANG

Operations against SED Peddlers in FY 2016: 206



376,365



\$891,637

#### **Partner Agencies**

- Singapore Civil
- Singapore Customs
- Land Transport

Inter-Agency Taskforce led by the **Singapore Police Force** 

#### THWARTING THE ILLEGAL SUPPLY OF COUGH SYRUP AND SLEEPING TABLETS





codeine syrup and sleeping tablets



Joint operations with Bedok Police Division and Central Narcotics Bureau against sellers operating in the back alleys of Geylang and coffee shops







Suspects investigated

#### FIGHTING CRIME GLOBALLY

#### 29 May to 7 June 2016

Operation Pangea, a week-long series of Internetthe INTERPOL.

customs agencies on the global stage, we focused on apprehending online sellers of various health products, as well as taking down websites advertising or peddling health products such as and drugs for infertility and weight loss.

-----



Participating

agencies



Countries involved



25,000 Health products seized











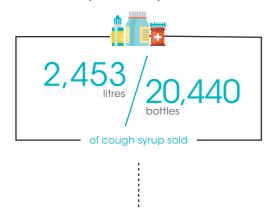




### PROSECUTION OF PHARMACIST FOR EXCESSIVE CODEINE SUPPLY

A pharmacist was investigated for selling excessive amounts of codeine cough syrup to abusers in contravention of Poison Rules governing the retail sale of such preparations.

#### May 2013 to April 2015





## PROSECUTION OF GENERAL PRACTITIONER FOR ILLEGAL CODEINE SUPPLY

A medical doctor was found to be selling codeine syrup without keeping a proper record of sales.





#### VAPORISER OFFENCES

Two males and one female were convicted in Court between May and July 2016 for the illegal online sale of electronic vaporisers.

They had purchased the vaporisers from overseas suppliers and sold them illegally on various social media and e-commerce platforms. The three peddlers were fined a total of

\$28,500



### \$\$50,000

worth of vaporisers was seized in a raid at Serangoon North in November 2016 — HSA's largest raid to date, in terms of its seizure value and the scale of the peddler's business.

The suspect, a 30-year-old Singaporean male, was identified for his peddling activities through our online surveillance and investigations. Transaction records revealed that he had sold



worth of vaporisers and vaporiser accessories on



1 ------

online platforms.





### CRACKING DOWN ON TOBACCO OFFENCES

In support of the national tobacco control policy against the illegal sales of tobacco products to under-18 minors:



31 tobacco retail licences were suspended for



tobacco retail licence was revoked

A 19-year old male and three friends were nabbed for selling cigarettes without a tobacco retail license.

The four had stolen



from a supermarket and attempted to resell them online.



## New Awards and Accreditations

HSA is proud to have achieved these new milestones over the year.

#### **ISPE LIFETIME** AWARD

Adjunct Associate Professor Sia Chong Hock, Senior Consultant, Audit & Licensing Division/Director, Quality Assurance, received the ISPE Lifetime Award for his lifelong contributions to the field of pharmaceutical regulatory practices. This took place during the 16th ISPE Singapore Conference in August 2016.



#### BEST SUGGESTION (SUPPORTING AGENCY) 2016 AWARD

HSA won the Best Suggestion (Supporting Agency) 2016 Award at the annual Pro-Enterprise Panel-Singapore Business Federation Awards Ceremony in November 2016, for the implementation of the sale of over-the-counter products via vending machines. With this implementation, businesses benefit

from having another option to sell such medicines, and consumers benefit from the convenience of being able to purchase the medicines anytime while appropriate safeguards are put in place to ensure that the safety and quality of these medicines are not compromised.



#### **PUBLIC SECTOR PRO-ENTERPRISE INITIATIVES BRONZE AWARD** 2016

HSA's project on "Simplification of system and product codes to be declared for health products in TradeNet" was awarded the Public Sector Pro-Enterprise Initiative Bronze Award for 2016 at the annual Pro-Enterprise Panel-



Singapore Business Federation Awards Ceremony, held at Suntec Convention Centre in November 2016.

#### 2016 PRO-**ENTERPRISE** PANEL -**SINGAPORE BUSINESS FEDERATION AWARDS**

In November 2016, HSA received the Public Sector Pro-Enterprise Initiative Bronze Award at the Pro-Enterprise Panel-Singapore Business Federation Awards. The award was given in recognition for the "Medical Device Risk Classification Tool", an online self-help tool. Launched in the fourth quarter of 2015, it improves productivity by giving industry stakeholders immediate responses to their medical device risk classification queries instead of going through each rule in the guidance documentation, raising overall productivity.



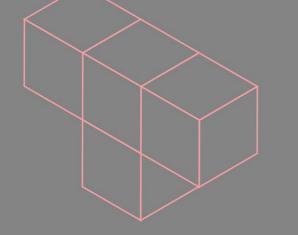
#### ISO 9001:2015 **CERTIFICATION**

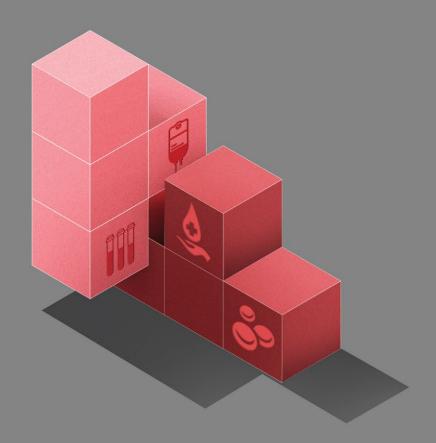
In March 2017, HSA's Vigilance & Compliance, Tobacco Regulation and Enforcement Branches successfully obtained the ISO 9001:2015 certification for their quality management systems. This was done in support of operating an effective and efficient quality management system that fulfils HSA's mission to regulate health products and safeguard public health. The Audit & Licensing Division also obtained the renewal of its ISO 9001:2008 certification in October 2016 with the intention to move towards ISO

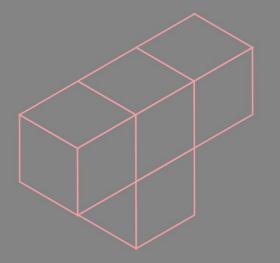


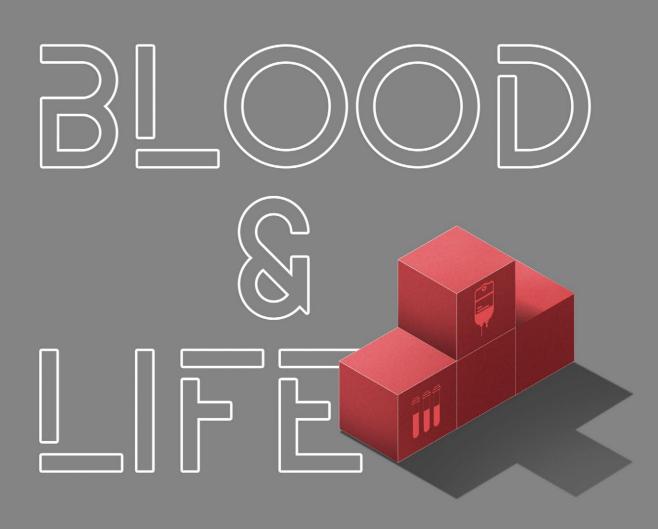






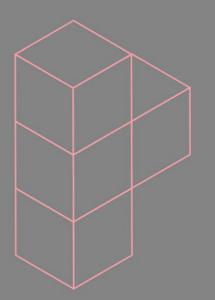






#### BLOOD SERVICES GROUP

Blood is life. To ensure that patients in Singapore always have access to safe blood, HSA strives to strengthen the safety and sustainability of our blood supply.





## Showing Our Appreciation to Blood Donors

Blood donors bring hope and save lives in times of need with their altruistic contributions. HSA strives to make the donation process as smooth and comfortable as possible, to encourage more to give the gift of life.

#### GOING DIGITAL

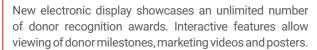
To enable us to continuously recognise the efforts of more blood donors, we have gone digital to accommodate more donor recognition awards on an electronic display outside the Bloodbank@HSA.



Names of champion donors on mini plaques displayed on donor recognition boards.







#### MORE ENTERTAINMENT CHOICES FOR APHERESIS DONORS

Apheresis donors spend a longer time in donation suites than regular blood donors. To provide them with a better donation experience, we added four new Cable TV channels to their existing entertainment system line-up of free-to-air TV and radio channels.



## THANKING OUR BLOOD DONORS

Twelve thousand donors and guests gathered at the Singapore Sports Hub on 4 June 2016 to celebrate the 13<sup>th</sup> World Blood Donor Day. Graced by Minister of Culture, Community and Youth Ms Grace Fu, and Member of

Parliament Ms Tin Pei Ling, the year's theme was "Blood Connects Us All" — representing how blood can link the members of the community together. Six hundred and seventy-nine donors were recognised for their contributions to the National Blood Programme, out of which 18 were awarded the Medal for Life and 19 for Champion of Champions.



#### BOOST TO QUALITY AND EFFICIENCY FOR MOBILE DONATION DRIVES

From December 2016, we replaced the traditional manual blood-weight monitors used in mobile blood donation drives with user-friendly, automated blood monitors. Equipped with electronic data recording, audible alarm systems and a self-rocking feature to mix collected blood with anticoagulants continuously, this new system optimises staff efficiency by taking over the technical aspects of monitoring the collection process, helping them to better focus on other aspects of donor care. This also improves the quality of blood collected.



#### ENHANCED TRACKING AND CONFIDENTIALITY FOR CALL-BACKS

In the past, staff had to answer calls from blood donors who called the Blood Services Group for enquiries or to retract their donations. We have introduced an automated call-back system that allows more convenience and better tracking of calls from donors. The new system enables 24/7 services, so that donors can get information whenever they need to.



## Maintaining a Consistent Blood Supply

We strive to maintain a safe and sustainable blood supply, so that patients in Singapore always have access to blood when the need arises.

### **TOWARDS** A HIGHER RETURN RATE

In a move to increase return rates while enhancing convenience for donors, blood donation centres have embarked on an initiative to achieve 100% re-booking of appointments. Donors are encouraged to make their next appointment after their blood donation session. Bloodbank@ Westgate Tower started the ball rolling in January 2016, followed by other centres across the island. We are happy to note a gradual but positive change in donor preferences.



ANNUAL REPORT 2016/17

## DEMAND-BASED BLOOD INVENTORY SYSTEM

HSA is always looking for ways to improve our systems. Together with the Singapore Red Cross (SRC), we set up an Inventory Response healthy daily national blood stock with minimal fluctuation. Monitored proactively by the team on a daily basis, the inventory system, upon detecting downward trends for blood

supply, will prompt SRC to initiate blood donor recruitment activities to replenish the supply. This demandbased system has ensured an Team in an effort to maintain a adequate and stable daily national blood stock and allowed hospitals to hold a higher blood stock on site throughout the year. It has also minimised transportation needs from hospitals to collect blood from HSA.

#### TACKLING THE **ZIKA VIRUS**

The Zika virus was first detected in Singapore in May 2016. Amidst the outbreak, HSA took swift action to reduce the risk of the virus entering our blood supply.







#### **JUNE 2016:** ZIKA-TESTED BLOOD FOR PREGNANT **PATIENTS**

In partnership with the Ministry of Health's National Public Health Laboratory, we provisioned a smal inventory of Zika-tested negative blood for pregnant patients.



#### **JANUARY 2017:** ZIKA-TESTED **BLOOD FOR ALL**

We implemented universal Zika Nucleic Acid Test Screening on all blood donations.

- Ensures that all blood donations are screened for the virus



## Gunning for Better Outcomes

We constantly look at how we can refine our processes, adopt new ones and find solutions to improve our efficiency and produce better results.

#### FACILITATING INVESTIGATIVE PROCEDURES

We implemented the C1q assay, an investigative procedure to identify and distinguish complement-fixing antibodies that could be significant in solid organ transplant rejection. With the C1q assay, more complement-fixing antibodies can be detected, compared to the current historical complementdependent cytotoxicity (CDC) method which is less sensitive and specific. This assay is offered as a routine test for the solid organ transplant programmes in Singapore and regional countries, ensuring that patients have access to clinically relevant results and improving transplant outcomes.

We also completed the evaluation of red cell genotyping kits for the common antigens. To keep up with current and leading trends in immunohaematology, we are aiming to offer red cell genotyping to hospitals. This capability will complement complex serological investigations as it can help to resolve cases involving patients who have received multiple transfusions recently and who have other donors' red blood cells in their body. This strengthens our engagement with hospitals, enabling us to forge sustainable and collaborative partnerships by better understanding their transfusion needs.



ANNUAL REPORT 2016/17



## FINDING SOLUTIONS WITH LEAN SIX SIGMA

In 2016, we completed two Lean Six Sigma projects. They are:





Background	Objective	Recommended Solutions
Incorrect input of patient residential status leads to over-charging or under-	To reduce the unnecessary changes of patient	Clarify discrepancies in residential status during daily bill checking
charging of fees	residential status due to incorrect	<ul> <li>Request hospitals to provide patients' nationality information on the forms</li> </ul>
Such discrepancies also cause inconveniences, where blood products have	information given by hospitals	Implement a new system that enables BSG to check and confirm residential statuses to reduce errors
to be amended in the blood bank computer system —		

### ENHANCING INVENTORY MANAGEMENT OF PHENOTYPED RED BLOOD CELLS (RBC)

with invoice adjustment

forms raised before the

the hospital

Finance department bills

Background	Objective	Recommended Solutions
A readily available phenotyped blood	To reduce the shortfall of phenotyped RBC	<ul> <li>Set guidelines for Blood Inventory Officers to standardise the arrangement criteria</li> <li>Make use of the newly one-time phenotyped blood to top-up the shortfall by having the phenotypes printed on their blood bags</li> <li>Simplify storage system by removing overlapping categories for a more accurate stock level count</li> </ul>



## Empowering Our People

HSA recognises our staff's efforts in keeping the nation's blood supply safe. We believe in investing in our people by providing ongoing learning and career opportunities, so that they can be at their best.

ANNUAL REPORT 2016/17





#### ADVANCING CAREER PATHWAYS

To gear our Blood Professional Assistants (BPAs) towards career progress, the Blood Services Group introduced more digitisation and automation. This facilitates our BPAs' move towards higher-level responsibilities and more complex tasks, uplifting their confidence and career mobility.

We also revamped the career development pathways of our Blood Inventory Control Officers (BICO) and BPA in blood processing and inventory laboratories to give them more opportunities and enhance their skillsets. As part of a strategy to transition to automated work processes in blood component processing and inventory management of the national blood supply, this move will also increase productivity and streamline processes to provide a safe and high-quality blood supply.

# Committed to Cell Therapy Research

Our Cell Therapy Facility (CTF) has worked with various partners to develop cellular therapies for the treatment of diseases.

#### ENHANCING UMBILICAL CORD BLOOD (UCB) ENGRAFTMENT

A three-way collaboration project to boost engraftment of UCB during transplantation has taken off with the CTF, Singapore-MIT Alliance for Research and Technology (SMART) and Singapore General Hospital (SGH). A customised microfluidics sorting device has been designed by SMART for the selection of a specific Mesenchymal Stromal Cells (MSC) sub-population (known as Biophysically-derived Pro-angiogenic Mesenchymal Stromal Cells). These cells, through experimental evidence, have been found to be able to foster a tissue environment conducive for engraftment and haematopoiesis. CTF will manufacture these cells under Good Manufacturing Practices (GMP) conditions to use in the phase I/II trial conducted in the SGH to determine the efficacy of this process.



#### HOPE AGAINST GvHD AND AUTOIMMUNE DISEASES

BSG also worked with the SGH Haematology Department on using MSCs for steroid refractory Graft versus Host Disease (GvHD) and autoimmune disorders. MSCs derived from bone marrow have been shown to have immunosuppressive and immunoregulatory properties. CTF has been engaged to culture and cryopreserve these bone marrow-derived MSCs under GMP conditions as an alternative treatment avenue for patients with refractory GvHD and autoimmune diseases.



## Our Awards and Accreditations

#### On-site inspection of the Tissue Typing and Platelet Reference Laboratory

We passed the inspection by the American Society for Histocompatibility (ASHI) with zero non-compliance.

#### What this means for patients:

**ANNUAL REPORT 2016/17** 

- Good quality services to support the various transplant programmes
- The ability to maintain compliance with international standards



#### **JACIE Interim Audit**

The Cell Therapy Facility continued to maintain JACIE accreditation in passing the interim audit.

#### What this means for our stakeholders:

 Our ability to maintain compliance with international standards remains valid

#### **On-site FACT Audit**

We received accreditation from the Foundation for the Accreditation of Cellular Therapy (FACT), enabling us to be a back-up facility for the National University Hospital for cellular therapy.

#### What this means for our stakeholders:

 Additional assurance that we are able to meet international standards in cellular therapy



#### **Cell Prothera On-site Audit**

CTF was cleared by a private company as its contract manufacturing facility for the provision of expanded stem cells

### What this means for our stakeholders:

- An expanded CTF product range, as well as better capabilities
- More support for a collaborative project with the National Heart Centre



#### **AABB Re-assessment**

We were granted accreditation by the AABB accreditation programme.

#### What this means for donors and patients:

- We offer the highest quality of care for patients and donors in our transplant programmes
- Proven ability to comply with international standards

# Hosting Local and International Visitors

HSA had the opportunity to share our expertise and work with fellow medical professionals, both from Singapore and around the world.

#### LEARNING FROM THE EXPERT

HEALTH MANPOWER
DEVELOPMENT PLAN
(HMDP) EXPERT
PROGRAMME ON RED CELL
IMMUNOHAEMATOLOGY
Date: January 2017

Our visitor: HMDP Visiting Expert
Adjunct Assistant
Prof Sandra Nance

Senior Director for Immunohaematology Reference Laboratories for the American Red Cross

Adjunct Assistant Professor at the University of Pennsylvania



The programme aimed to enhance Singapore's diagnostic capabilities in Red Cell Immunohaematology, as well as improve red cell transfusion support of patients with rare blood groups and complex red cell alloantibodies and/or autoantibodies.

During her visit, Professor Nance delivered lectures and conducted discussion sessions with blood bank laboratory officers from various hospitals and the Blood Services Group, haematologists and postgraduate trainees. She also visited the immunohaematology labs at HSA, National University Hospital and Tan Tock Seng Hospital, and made insightful recommendations on improving the services, infrastructure and manpower developments in the labs.



### **SHARING** OUR EXPERTISE

MAY

ANNUAL REPORT 2016/17

Purpose: Two-week training attachment in immunohaematology on performing investigations of red cell abnormal antibodies present in patient samples

Guests from: Tan Tock Seng Hospital

**Purpose:** To have an overview of our Cell Therapy Facility and discuss possible collaborations

Guests from: Sydney's Royal Prince Alfred Hospital



**Purpose:** Study visit to the Blood Services Group (BSG) laboratories to better understand blood product collection, processing and distribution in Singapore

**Guests from:** Changi General Hospital

Purpose: Study visit to BSG laboratories to study our work processes in blood component processing, donor testing and cross-matching

Guests from: Thai Red Cross Society

### JUNE -JULY

**Purpose:** Training attachment to better understand how patients in Singapore receive top quality and safe blood

Guests from: KK Women's and Children's Hospital

**Purpose:** Training attachment in Transfusion Medicine

**Guest from:** All India Institute of Medical Sciences





#### **AUGUST**

Purpose: Study visit on:

- Blood collection processes
- Information technology and system integration processes

Guests from: Thai Red Cross Society

Purpose: Observership in Human Leukocyte Antigen (HLA) typing

**Guest:** Trainee doctor from the National University Hospital

### **OCTOBER**

**Purpose:** To gain more insights from our blood bank

Guests from: Ho Chi Minh City, Vietnam's 175 Military Hospital

#### **NOVEMBER**

Purpose: Study visit on donor recruitment

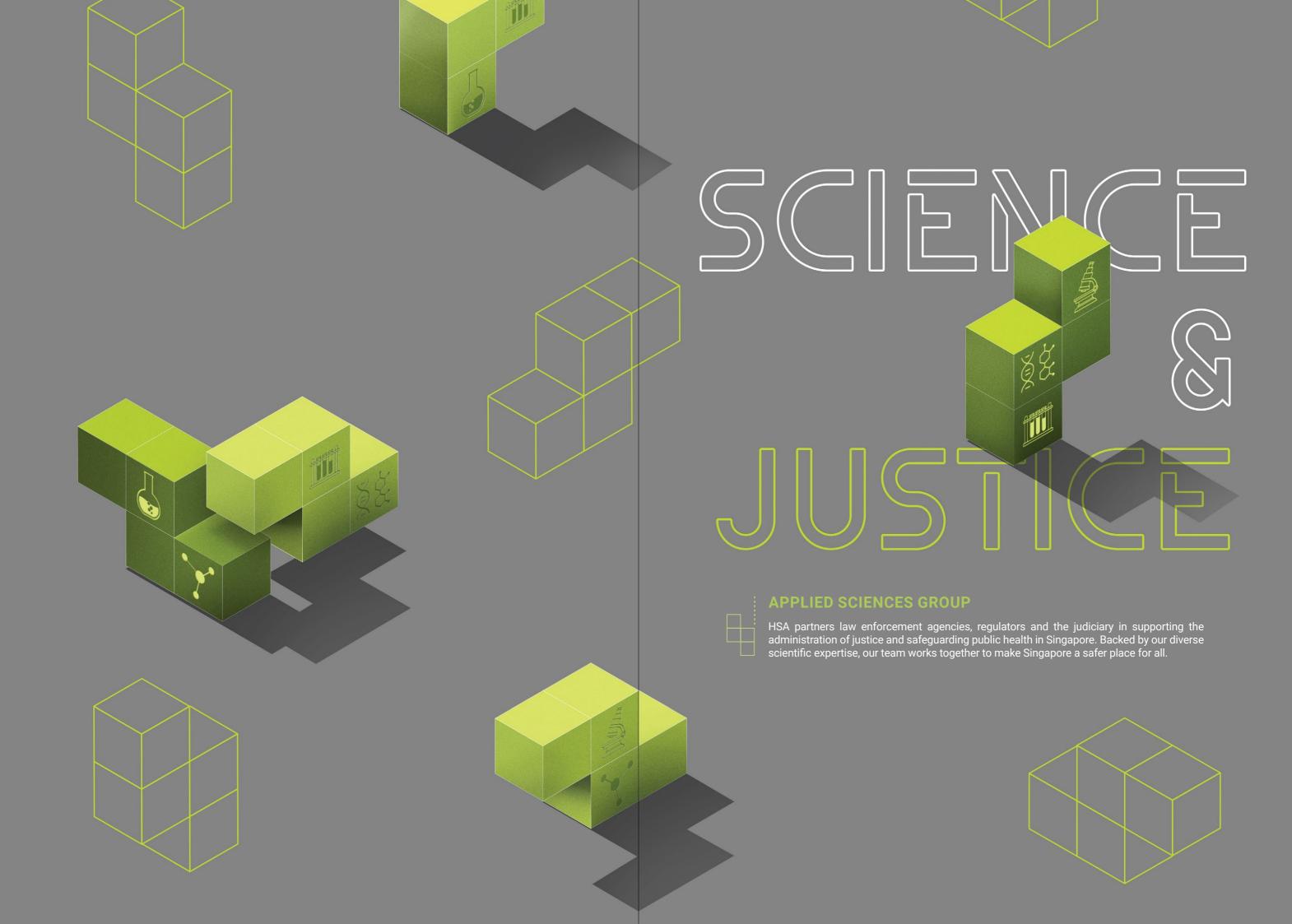
**Guests from:** Japanese Red Cross

**DECEMBER** 

**Purpose:** Training attachment for the "Donor Recruitment, Retention, Donor Care and Organising Blood Donation" campaign

Guests from: Sri Lanka Blood Transfusion Services







## Building Our Capacity

We strive to acquire new expertise and solutions to serve the nation.

#### MAKING COSMETICS **EVEN SAFER**

chloro methyl isothiazolinone - in

our accredited testing scope for We successfully added two new cosmetics. These additions enable isothiazolinone-type biocides us to analyse commonly used - methyl isothiazolinone and biocides which include triclosan and triclocarban.

ANNUAL REPORT 2016/17

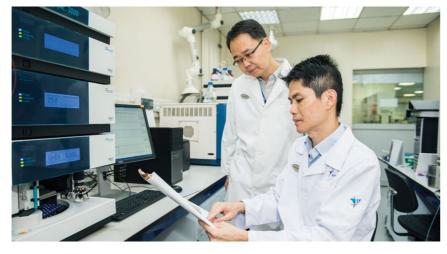


#### **MORE EFFECTIVE SHARING OF DNA RESULTS AMONG COUNTRIES**

Throughout the world, different regions use varying sets of DNA markers for analysis in criminal investigations. This is why an increased set of markers is especially essential in borderless crimes, where international comparison of DNA profiles are required to identify the perpetrators who are often part of a larger syndicate. As of November 2016, we have validated and implemented the use of 24 DNA markers, up from 16. This will result in greater harmonisation and more effective sharing of DNA results among countries.

#### **NEW FINDINGS** FOR SEXUAL HEALTH **SUPPLEMENT**

A new sildenafil analogue (3,5-dimethylpiperazinyl dithiodesmethylcarbodenafil) was discovered from a health supplement for sexual enhancement. The identity of the analogue was determined using advanced analytical instruments including high-resolution mass spectrometry (HRMS) and nuclear magnetic resonance spectrometry (NMR). The findings were published in the Journal of Pharmaceutical and



further safeguard public health, by

Biomedical Analysis in January 2017, helping them to look out for this new and will help drug control authorities structurally modified adulterant in their routine screening processes.

#### **INVESTIGATING** HIT-AND-RUN **ACCIDENTS**

Started in 2008 in collaboration with the Singapore Police Force's Bomb and Explosives Investigation Department, the Vehicle Paint Database is an investigative tool that narrows down possible makes of unknown samples in hit-and-run traffic accident cases. In the last two years, we have expanded our database of 1,500 samples to include paint samples from taxis. With this database, we were able to identify the taxi operator of a hit-and-run case in April 2016.

#### **EXPANDING CERTIFIED REFERENCE MATERIALS**

Certified Reference Materials (CRMs) are used as calibrants, quality controls and for validation of methods. This year, we have expanded our CRM production programme to include L-proline, and trace elements (Al, As, Cd, Ca, Cu, Cr, Pb, Mo and Ni) in drinking water.





#### PAVING THE WAY FOR MORE ACCURATE TRAFFIC ACCIDENT **INVESTIGATIONS**

Drag factor is an important parameter when reconstructing traffic accidents. The Traffic Accident Reconstruction team currently relies on studies done overseas for a range of values for drag factor. In 2016, the team collaborated with the Traffic Police to organise skid tests to determine the drag factor of roads in Singapore. As a result, a smaller range catered to the local context can be used, resulting in more accurate estimation. We will continue our efforts in 2017.

#### TESTING NEW **WATERS**

We have set up a dedicated water testing facility and expanded our water testing capabilities for ultra-trace analyses, to provide new or enhanced testing services to stakeholders.





## Refining Our Techniques

We constantly improve our work processes by implementing new technologies that can enhance our efficiency.



#### ANALYSING RESIDUE FROM EXPLOSIVES

Post-blast samples can come in different types of matrices. This requires a range of equipment and involves different sample preparation for the analysis. In 2016, we developed a simple sample preparation process to streamline analysis procedures. This ensures that the samples are cleaned up and prepared to cater to the needs of a wide range of equipment.

We have also completed the validation and application of the X-ray diffraction technique for the analysis of explosive compounds and unknown solid substances. This non-destructive technique prevents samples from being permanently altered after analysis, making them usable for further tests and analysis.

#### ANALYSING THE ACTIVE INGREDIENTS IN PEPPER SPRAY AND CHILLI POWDER

Chilli powder and pepper spray have been used in assault cases where suspects attempted to irritate the victim's eyes to incapacitate his/her sight.

Previously, only gas chromatographymass spectrometry (GCMS) was used to analyse the active ingredients of samples, but the liquid chromatographymass spectrometry (LCMS) method was later developed with better detection limits. When used together (GCMS and LCMS), higher conclusion levels for the detection of these active ingredients can be achieved.



#### ANALYSING METALS AND FAKE JEWELLERY

HSA has validated and adopted a better screening technique for metals and fake jewellery. Using inert air instead of water, it prevents the formation of water bubbles with rough surfaces — which may result in inaccuracy — while making it suitable for non-waterproof products. Lastly, being non-destructive and much faster than previous techniques, this new technique produces results that are more reliable and reproducible in a shorter timeframe.

## Meeting Global Standards

At HSA, we are committed to benchmarking our expertise internationally, and raising local and regional testing standards.

#### HONING OUR DNA AGE PREDICTION CAPABILITIES

In January 2016, HSA participated in a collaborative exercise on age prediction that was organised by the European DNA Profiling Group. This exercise saw the participation of 15 laboratories from Denmark, Austria, Netherlands, USA, France, Australia, UK, Spain, Germany, Norway and Switzerland. HSA did well in estimating the age of an unknown individual from a blood sample, which is of value to law enforcement in narrowing down possible perpetrators.

#### SETTING THE BENCHMARK FOR FOOD SAFETY STANDARDS

In June 2016, we participated in the inter-laboratory comparison of phomopsin in lupin organised by Wageningen RIKILT. Through this collaboration, we reinforced our technical competence against international standards as well as expanded our analytical know-how in upholding the safety of food.

#### ENSURING THE ROBUSTNESS OF DNA TESTING

HSA organised the third DNA Inter-Laboratory Collaborative Exercise in mid-2016 to compare the robustness of the DNA testing system and the mixture interpretation approaches among the Asian Forensic Sciences Network member institutions. The exercise saw the participation of 14 member institutions from China, Indonesia, Malaysia, Mongolia, the Philippines, South Korea and Thailand.







#### ALIGNING STANDARDS

HSA is actively involved in international comparisons and proficiency testing programmes to ensure that our laboratories' capabilities are comparable to other countries worldwide.

#### 1. INTERNATIONAL COMPARISONS



Polycyclic aromatic hydrocarbons in acetonitrile

HSA completed three international comparisons:

Low-polarity analytes in a botanical matrix: polycyclic aromatic hydrocarbons in tea leaves

Ethanol in aqueous matrix

#### It also organised three international comparisons:

High polarity analytes in biological matrix: determination of urea and uric acid in human serum



Comparison of Certified Reference Materials and value-assigned quality controls: urea and uric acid in human serum or plasma [co-organised with the National Institute of Standards and Technology USA]

Elements (sodium, chloride, copper, selenium, phosphorus) in human serum

## 2. EXTERNAL QUALITY ASSESSMENT (EQA) AND PROFICIENCY TESTING (PT) PROGRAMMES

We continued to organise an accuracy-based EQA and PT programmes for the local clinical laboratories, and chemical testing laboratories, respectively. The analytes covered in the EQA programme included clinical markers of chronic diseases affecting the Singapore population such as diabetes mellitus and lipid disorders.

#### **External Quality Assessment**



ANNUAL REPORT 2016/17

17 clinical analytes covered



2

new analytes

creatinine and albumin in urine were included in Cycle 2 of the programme

#### **Proficiency Testing Programmes**

- Asia Pacific Laboratory Accreditation Cooperation PT programme co-organised with the Singapore Accreditation Council on the determination of acesulfame potassium and sucralose in cake mix flour
- PT programme on oil and grease in water
- PT programme on trace elements in water for local water-testing laboratories.

#### 3. EXTERNAL BENCHMARK PROFICIENCY TESTING PROGRAMMES

We achieved excellent results in the benchmark PT programmes during the year:

#### Pharmaceutical Laboratory

- Semi-micro determination of water by volumetric titration by the European Directorate for the Quality of Medicines & HealthCare (EDQM)
- Assay of gemfibrozil by high-performance liquid chromatography, (ii) pH measurement on sodium ascorbate and (iii) dissolution testing on gemfibrozil tablets by the ASEAN Bureau of Drug and Narcotic
- pH and melting point measurements of vanillin and sulfapyridine by the Dutch Association for the Advancement of Pharmacy
- Assay of octyl gallate and testosterone by UV-VIS Spectrophotometry organised by EDQM

#### Cosmetics Laboratory

- Assay of hydrogen peroxide in tooth whitening products by EDQM
- Assay of parabens in lipsticks by EDQM



## Bolstering Strong Relationships

Working alongside local and global partners and stakeholders enables us to support our vision of safeguarding public health and serving the administration of justice in Singapore.

#### MEMORANDUM OF UNDERSTANDING (MOU) TO TEACH FORENSIC SCIENCE

HSA signed an MoU with the Singapore University of Social Sciences (SUSS) on 4 April 2017 to teach the forensic science introductory course in the School of Law.



#### COLLABORATION MEMORANDUM WITH LABORATOIRE NATIONAL DE METROLOGIE ET D'ESSAIS (LNE)

The Memorandum of Collaboration (MoC) between HSA and LNE in France was renewed for another three years in May 2016. This MoC will enable the Chemical Metrology Laboratory and LNE to continue exchanging scientific information and reference materials relating to clinical and peptide/protein chemistry.

## AGREEMENT WITH FORE FRONT TEST CO LTD

We signed an agreement with Fore Front Test Co Ltd, Korea, appointing the company as the exclusive distributor of our CRMs in the Republic of Korea for a period of two years from October 2016.



# COLLABORATION WITH THE U.S. CENTERS FOR DISEASE CONTROL (CDC) AND PREVENTION

HSA collaborated with the U.S. CDC on the measurement of two clinical markers for lipid disorders (LDL-cholesterol and HDL-cholesterol) in human serum. The serum materials were measured by both institutions and the results obtained were found to be comparable.



## WORKING WITH THE POLICE

We worked closely with the Singapore Police Force to examine evidence from the high-profile shooting case that took place near Shangri-La Hotel in 2015. The Forensic Chemistry & Physics Laboratory provided multidisciplinary examinations (chemical analysis of unknowns, explosive analysis, glass, paint, vehicle speeds, textile damage, firearms, gunshot residue, trajectory, bloodstain pattern analysis and crime scene reconstruction) and issued a total of six forensic reports. Three of our experts testified at the Coroner's Inquiry held in 2016.

#### SUPPORTING THE AGRI-FOOD AND VETERINARY AUTHORITY OF SINGAPORE (AVA)

ANNUAL REPORT 2016/17

Five new analytical testing services were launched in support of AVA. The tests included anthraquinone in food contact materials, pyrrolizidine alkaloids in flour and spices, multiple mycotoxins in beer and liquors, bisphenol A, BADGE, BFDGE and derivatives by ultra fast liquid chromatography in food contact materials and authentication of pine nuts.



#### SHARING ON EQA RESULTS AND MEASUREMENT UNCERTAINTY

In February 2017, we organised an EQA Programme Sharing Session. The sharing session provided a platform for an in-depth discussion of results from the 2016 EQA programme, and to share on the approaches to estimating measurement uncertainty using data from EQA Programmes.

#### COLLABORATING WITH THE NATIONAL ENVIRONMENT AGENCY (NEA)

We took on a joint project with NEA from January to April 2016 to check the safety of cooking oil used in eateries across the country. The project aimed to investigate contaminants present in cooking oil as well as the fraudulent use of gutter oil. With more than 100 samples tested, NEA was able to use the results to work with hawkers on ensuring the safe use of cooking oils.



## INVESTIGATING FUNGICIDES

Fungicides, if present in food, are detrimental to health. To help safeguard public health, HSA embarked on a one-year joint research agreement with Shimadzu Asia Pacific (Pte) Ltd on a project to explore a rapid determination of fungicides. The project involved a new technology, SFE-LC/MS/MS for food contact material testing and was titled "Single laboratory method validation of a method for the determination of fungicides in food simulants from disposable wooden cutlery". It was completed and presented at the Food Science 2016 Conference in November.

## Training Our Staff

To boost our capabilities, we sent our staff for training to ensure that they acquire new knowledge and improve their skillsets.

#### MANAGING BIOLOGICAL THREATS

HSA maintains an operational readiness programme in training staff to work safely in a Biosafety Level 4 (BSL4) environment. It successfully carried out Exercise Andromeda V, which saw the field deployment of the mobile BSL4 containerised autopsy facility offsite in Yio Chu Kang as part

of ensuring operational readiness to conduct autopsies of suspected potentially highly infectious cases.

The exercise was carried out in collaboration with the Singapore Civil Defence Force (SCDF) to enhance response to emergencies at the facility. Going forward, we will work on developing capabilities to meet challenges in responding to Chemical, Biological, Radiation, Nuclear and Explosive scenarios.





## LEARNING FROM THE EXPERTS

HSA staff attended the Singapore Academy of Law Expert Witness Course and met experts such as Queen Counsel Ms Alison Pople from Cloth Fair Chambers, UK, a Prosecutor, Defence Counsel, Judge and Coroner. Held in March 2017, the course saw the experts sharing their perspectives on the roles forensic experts play in the criminal justice system.



#### SHARING OUR KNOWLEDGE

We welcomed an engineer from the Shanghai Food and Drug Packaging Material Control Centre, for a three-week training on laboratory quality management systems and the analysis of western medicines.

#### SPECIALIST TRAINING BY OVERSEAS EXPERTS

**ANNUAL REPORT 2016/17** 





#### BOOSTING KNOWLEDGE IN TOXICOLOGY

HSA invited Professor Dr Hans H. Maurer, leading expert in analytical toxicology and in-vitro / in-vivo toxicokinetics studies, to conduct a training session for its staff in August 2016. Aimed at strengthening staff knowledge in drugs metabolism, the training comprised nine lectures, and included topics such as sewage epidemiology and the applications of high-resolution mass spectrometry and ion trap mass spectrometry.



In September 2016, HSA staff attended the Technical Crash Investigation and Reconstruction Advanced Course by Dr Shane Richardson from the Society of Automotive Engineers Australasia. The course introduced new technologies and gave more in-depth insights into analysis methods such as the use and analysis of the event data recorder and modelling and simulation.

In October 2016, two experts from the Major Incidents Forensics Group in the Transport Research Laboratory in UK, Dr Richard Lambourn and Mr James Manning, conducted a five-day customised training and consultancy on traffic reconstruction for HSA staff. Participants gained valuable insights, especially in incorporating new technologies.

Also in October 2016, HSA staff attended the Forensic Knot Analysis Review by expert and author Mr Robert Chisnall, who shared with them knowledge from his 40 years of experience in the area of forensic knots analysis.

#### BUILDING CAPACITY FOR PROVIDING EXPERT OPINION ON ALCOHOL-BREATHALYSERS TEST RESULTS

We engaged Professor Edmund Lee Jon Deoon, Professor of the Department of Pharmacology, National University of Singapore to provide training for the scientists to build up their capability in providing expert opinion in alcohol interpretation. Furthermore, two scientists also attended the Robert Borkenstein Course on Alcohol, and Highway Safety: Testing, Research and Litigation at the Indiana University, Center for Studies of Law in Action, USA in May 2016.

#### ANALYSING COMPLEMENTARY HEALTH PRODUCTS

Our scientist was attached to the Hong Kong Government Laboratory for a benchmark study on the process, scope and methodologies used in the analysis of complementary health products. The study took place from February to March 2016 and provided opportunities for technical exchange, sharing of good laboratory practices as well as strengthening work processes in the analysis of



complementary health products. Through the study, we were also able to enhance our analytical capabilities in investigating adverse drug reactions associated with consumption of herbal health products.

#### JOINING HANDS IN MANAGING CLANDESTINE LABORATORY INVESTIGATIONS

With support from the Drug Enforcement Agency (DEA), United States Department of Justice, we conducted a seven-day training course and exercise on clandestine laboratory investigation in May 2016.

Conducted by three DEA instructors and two DEA agents, the course attracted 32 participants including officers from Central Narcotics Bureau and SCDF. The course enabled participants to acquire the necessary knowledge and skills in handling clandestine laboratory investigation and helped built inter-agency rapport. Following the positive feedback, the three agencies will take turns to organise a joint exercise biennially to maintain the competencies of officers and coordination between agencies.





ENHANCING OUR KNOWLEDGE IN ANALYSING ANABOLIC STEROIDS

In recent years, bodybuilding and performance-enhancing supplements have been gaining popularity. To stay abreast with technological advancements in testing for such products, in March 2017, a scientist went on a week-long attachment to

the Forensic Chemistry Center of the U.S. Food and Drug Administration to gain insights on methodologies used in the analysis of anabolic steroids in bodybuilding supplements.

## Training Our Counterparts

We also worked with our partners to accelerate progress in forensic and analytical sciences across the world.

#### ENHANCING FOOD SAFETY STANDARDS

We provided technical training to an Assistant Government Analyst from the Department of Agriculture, Sri Lanka in November and December 2016. Training areas included analytes such as ochratoxin A, deoxynivalenol, aflatoxins B & G and artificial sweeteners.





We ran a course in October 2016 to help criminal lawyers understand the basics of the science and the application of forensic science in crime investigations. During the course, participants also visited the forensic laboratories to gain first-hand insights into many state-of-the-art equipment and instrumentation used in the analysis of evidence. In addition, participants had the opportunity to experience hands-on microscopic work and test their understanding of bloodstain pattern analysis.

#### SPEAKING AT THE UNITED NATIONS OFFICE ON DRUGS AND CRIME'S (UNODC) WORKSHOP

In August 2016, the UNODC South Asia office invited HSA to conduct a workshop held in New Delhi, India. The workshop aimed to help law enforcement officers and forensic experts understand New Psychoactive Substances (NPS) and their analytical methods.

#### SPEAKING AT THE NATIONAL POLICE UNIVERSITY OF CHINA'S (NPUC) FORUM

HSA spoke on drug control strategies and techniques at a three-day forum on "International Forum on Drug Control Strategy and Techniques" held in Shenyang, China. The event took place in September 2016 and saw forensic experts from China as well as international speakers exchange views on issues concerning drug control strategies and techniques in their provinces/countries.



## Going Beyond Our Shores

We participate in global and regional events, workgroups and meetings so that we can share and gain new knowledge from our partners around the world.





## PARTICIPATING IN THE ASEAN REFERENCE SUBSTANCES PROJECT

We continued our active involvement in the ASEAN Reference Substance Project – a project that establishes ASEAN secondary drug reference standards by providing an important source of reliable drug reference substances for use in ASEAN member countries. In 2016, HSA led the establishment of an ASEAN Reference Substance (PARS), trimethoprim with Indonesia, Malaysia, Myanmar and Philippines, and participated in the inter-laboratory collaborative study of PARS. It also participated in the inter-laboratory study of amlodipine besilate led by Thailand.

#### ORGANISING THE ASEAN PROFICIENCY PROGRAMME

We organised the annual ASEAN Proficiency Programme on aflatoxins B & G in rice to enhance capacity-building of the ASEAN government laboratories. Twenty-four official laboratories participated in the programme.

## WORKING WITH THE FOOD AND DRUG ADMINISTRATION (FDA) MYANMAR

We provided technical assistance to FDA Myanmar in the investigation of aflatoxins B & G in cooking oils at their local retail market. This move was intended to support FDA Myanmar in building their capability in the analysis of aflatoxins B & G.

#### ASEAN

#### INVOLVEMENT IN ASEAN ACTIVITIES

HSA participated in the Inaugural Meeting of the ASEAN Reference Material Network in July 2016 as one of its founding members together with the National Institute of Metrology, Thailand and the Department of Chemistry, Malaysia with support from the National Metrology Institute of Malaysia.

The Cosmetics Laboratory, as Chair to ASEAN Cosmetics Testing Laboratory Committee, attended meetings in Vietnam and Brunei Darussalam. In 2016, the laboratories embarked on inter-laboratory comparison studies on cosmetic methods to establish and strengthen the competencies of national laboratories in ASEAN.

We also participated in two ASEAN inter-laboratory comparison studies. This included determination of diethylene glycol, a residual contaminant and alpha hydroxyl acids (AHAs) compounds. AHA is a popular ingredient permitted for use by up to 10% in skincare products. When used in excess, it can cause skin irritation and hyperpigmentation.

#### CENTRAL INSTITUTE OF FORENSIC SCIENCE (CIFS)

In September 2016, we were invited by the CIFS, Thailand to conduct a pre-assessment on the management and technical operations of the laboratory for conformance with the American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB)-International accreditation programme.



#### BEYOND ASEAN

#### REVIEWING BEST PRACTICES

HSA reviewed three best practices on the subjects of Alterations, Stamps and Stamp Impressions and Examination of Inkjet Printed Documents for the European Document Experts Working Group of European Network of Forensic Science Institutes.

More than 10 best practices have been developed by the workgroup, and they are mainly used by various forensic science institutes in Europe.

#### **INTERNATIONAL FORENSIC STRATEGIC ALLIANCE (IFSA) ANNUAL MEETING**

HSA represented the Asian Forensic Sciences Network as a Board Member of the IFSA and participated at the IFSA Annual Meeting which was held at Lyon, France in conjunction with the INTERPOL International Forensic Science Managers Symposium in October 2016.

#### **UNODC EXPERT CONSULTATION** ON FORENSIC TOXICOLOGY AND DRUG CONTROL

We participated in the UNODC Expert Consultation on Forensic Toxicology and Drug Control meeting in Vienna in June 2016. Participants discussed the development of a platform for sharing NPS-related toxicological data amongst the forensic toxicology community and other relevant stakeholders, as well as improving the prioritisation of NPS for national/international action.

#### UNITED STATES **PHARMACOPOEIA**

United States Pharmacopoeia (USP) continued to collaborate with HSA to establish the dissolution reference range for the new lot of USP Prednisone tablets, which would be used as the calibrator for performance qualification of Dissolution Apparatus. In 2016, our results were used by USP in establishing the reference range on Prednisone Tablets.

#### **OFFICIAL MEDICINES CONTROL LABORATORIES (OMCL) ACTIVITIES**

HSA was invited to join the 21st Annual Meeting of the OMCL Network held in May 2016, in Paris, France. Representatives from 61 OMCLs across 38 countries exchanged latest technical information and discussed emerging pharmaceutical analysis on issues relating to health and dietary supplements.



#### **OFFICIAL COSMETICS CONTROL** LABORATORIES OF EDOM

HSA was invited to speak at the 1st Symposium of the Network of Official Cosmetics Control Laboratories (OCCL) which took place in June 2016 at the headquarters of European Directorate for the Quality of Medicines and Healthcare (EDQM), Strasbourg, France.



#### PREVENTING FOOD FRAUD

In April 2016, we participated in the International Atomic Energy Agency (IAEA) Rice Project, with a meeting held in Beijing. The project aimed to prevent food fraud as a result of false declaration of rice geographic origin for economic gains. It also served to build technological capacity for food traceability and food safety control systems through the use of nuclear analytical techniques.



#### ISO STANDARDS ON FORENSIC SCIENCE

HSA staff were accepted as members of the National Mirror Working Group (NMWG) for ISO/TC 272 Forensic Sciences, a multi-agency workgroup looking after the development of international standards for forensic science. One of them was also appointed as the deputy convenor of the NMWG, where he represented Singapore in the ISO/TC 272 meetings.



#### **INTERPOL FORENSIC MEETINGS**

Over the year, we participated in meetings with INTERPOL:

INTERPOL forensics meeting on Assessing the Forensic Capabilities in Southeast Asia and the Pacific, INTERPOL Global Complex for Innovation, Singapore.

#### WHEN: 19 - 20 APRIL 2016

INTERPOL Training to Enhance the Forensic Capabilities in ASEAN Member States, where we hosted the ASEAN participants to a laboratory tour.

#### WHEN: 28 NOVEMBER TO 2 **DECEMBER 2016**



## Maintaining Ties with WHO

During the year, we continued to actively participate in World Health Organization (WHO) activities.

#### **IMPROVING FOOD SAFETY STANDARDS**

The current term held by HSA as the WHO Collaborating Centre has been renewed for another four years. This exemplifies HSA's contribution in providing valuable and continual input in health matters and food security on the global stage.

We continued to support meetings organised by WHO. These meetings seek to address some of the gaps identified in the strategic plan from 2013 to 2022 and help to improve communication between WHO, its partners and stakeholders. "First Meeting of WHO Collaborating Centres in Food Safety and Other Stakeholders" was held in Geneva, 2. CONSULTATION WORK AND Switzerland in May 2016.

In November 2016, a poster titled "Collaborating Centre for Food Contamination Monitoring" presented at the Second Regional Forum of WHO Collaborating Centres held in Manila, Philippines.

#### WHO COLLABORATING CENTRE FOR DRUG QUALITY ASSURANCE

HSA continues to actively support WHO activities under its Terms of Reference as its Collaborating Centre. Activities conducted during the year include:

#### 1. MONOGRAPH **DEVELOPMENT WORK**

The Pharmaceutical Laboratory has successfully completed the development of two draft monographs on Pyrimethamine and Pyrimethamine tablets for inclusion to the International Pharmacopoeia. The laboratory has also developed an additional TLC Identity Test for the draft monographs on Ceftriaxone sodium and Ceftriaxone for Injection.

#### **TECHNICAL CONTRIBUTIONS**

Where: WHO Headquarters in Geneva, Switzerland When: May 2016

HSA attended the Consultation Meet on Quality Control Laboratory Tools and Specifications for Medicines Screening Technology, Sampling and Specifications for Medicines as a WHO Temporary Advisor.

#### 3. SECOND REGIONAL FORUM **OF WHO COLLABORATING CENTRES (WHOCC) IN THE WESTERN PACIFIC**

Where: Western Pacific in Manila. Philippines

When: November 2016

We attended the Second Regional Forum of WHO Collaborating Centres, together with other WHOCC representatives from the Health Promotion Board, National University of Singapore, Ministry of Health as well as NEA. We presented on the activities conducted by the Cigarette Pharmaceutical and Testing Laboratories.





#### CIGARETTE **TESTING LABORATORY**

We continue to actively support WHO activities under its Terms of Reference as its Collaborating Centre. Activities conducted during the year are as follows:

#### WHO TOBACCO LABORATORY **NETWORK (WHO TOBLABNET)**

HSA was named Chairman to WHO TobLabNet at the Sixth WHO TobLabNet meeting in Maastricht, The Netherlands in May 2016. As the Chairperson to WHO TobLabNet, we were invited to the WHO Strategizing Meeting on Tobacco Product Regulation held in September 2016 in Montreux, Switzerland. The meeting discussed the policy and global tobacco regulatory needs which will help shape WHO's future tobacco product regulation activities.

#### **TECHNICAL SUPPORT TO WHO**

We spoke at the 1st WHO Technical Consultation and Capacity Building on Tobacco Product Testing and Disclosure, jointly organised by the Government of India and WHO in Delhi, India in April 2016. This meeting focused on our capabilities in the provision of analytical support and expertise in setting up regulatory laboratories to countries within the region in the field of tobacco testing.

We were invited as Temporary Advisor to WHO's Prevention of Non-Communicable Disease Department to provide technical support to WHO at the 7th Session of the Framework Convention on Tobacco Control held in New Delhi, India in November 2016. During the session, we presented on the application of validated methods in monitoring toxicants in tobacco products for regulatory setting purposes.



# Participating in International Events



During the year, our staff took part in international events where we visited and hosted partners with the aim of exchanging expertise. Through these efforts, we strengthened global ties as well as improved our technical knowledge.

#### MEDICINES (ILFCM) We participated in the ILFCM annual meeting in Paris, France in May 2016. At the forum, participants

exchanged technical information on new PDE-5 inhibitors analogues and synthetic stimulants detected in complementary health products.

They also shared their experiences in testing illegal peptides and proteins, marijuana for medical use, medical devices and smart drugs as well as new technologies such as 3D printing and its application in the pharmaceutical industry.



INTERNATIONAL LABORATORIES

FORUM ON COUNTERFEIT

#### **SHARING INFORMATION ON TRADITIONAL CHINESE** MEDICINES (TCM)

HSA hosted a delegation of six visitors from China's State Administration of Traditional Chinese Medicine in November 2016. The visit was aimed at facilitating mutual exchange of information and expertise on the teaching,

practice, regulation and research of TCM between China and Singapore. The event provided the visitors with a good overview of HSA's regulatory and testing framework of complementary health products in Singapore.

## Continually Surpassing Standards

At HSA, we strive to uphold the highest certifications and accreditations. Our achievements in this area attest to the quality standards we set for ourselves.

#### ASCLD/LAB RE-ACCREDITATION

#### **FORENSIC LABORATORIES**

In January 2017, over a thousand documents were examined by a team of international assessors across various disciplines and categories of testing for the ASCLD-LAB reaccreditation. The accreditation reflects on the forensic laboratories' excellence in complying with stringent standard operating procedures that will withstand legal challenges in court. We are proud to have done well and pleased to have earned accreditation in the "Crime Scene" discipline for the first time.

#### NAME ACCREDITATION 2. Cigarette Testing Laboratory

#### **FORENSIC MEDICINE DIVISION**

Reaccredited with the National Association of Medical Examiners (NAME) Accreditation programme for another five years.

#### ISO/IEC 17043 **ASSESSMENT**

#### **CHEMICAL METROLOGY** DIVISION

#### **Chemical Metrology Laboratory** (September 2016)

Successfully underwent the surveillance assessment by SAC-SINGLAS with the current accreditation scope.

#### ISO/IEC 17025 ASSESSMENT

#### PHARMACEUTICAL DIVISION

Three laboratories achieved full compliance to ISO/IEC17025 in the SAC-SINGLAS annual assessment:

#### 1. Pharmaceutical Laboratory (April 2016)

Successfully accredited two test methods:

- Analysis of active pharmaceutical ingredients in cough mixture
- Identification of cannabinoids in herbal products

#### (April 2016)

Successfully underwent the surveillance assessment with the current accreditation scope.

#### 3. Cosmetic Laboratory (April 2016)

Successfully accredited two test methods:

- Determination of isothiazolinones in cosmetic product by HPLC-DAD
- Identification of cannabinoids in cosmetic products

#### **FOOD SAFETY DIVISION**

Two laboratories achieved compliance to ISO/IEC17025 in the SAC-SINGLAS annual assessment:

#### 1. Food Safety Laboratory (April 2017)

Successfully accredited four test methods:

- Malachite Green, Leucomalachite Green, Crystal Violet and Leucocrystal Violet in seafood by LC-MS-MS
- Pyrrolizidine alkaloids in honey by LC-MS-MS
- Sulphur dioxide by iodine titration
- 4-methylimidazole in sauces by LC-MS-MS

#### 2. Water Testing Laboratory (April 2017)

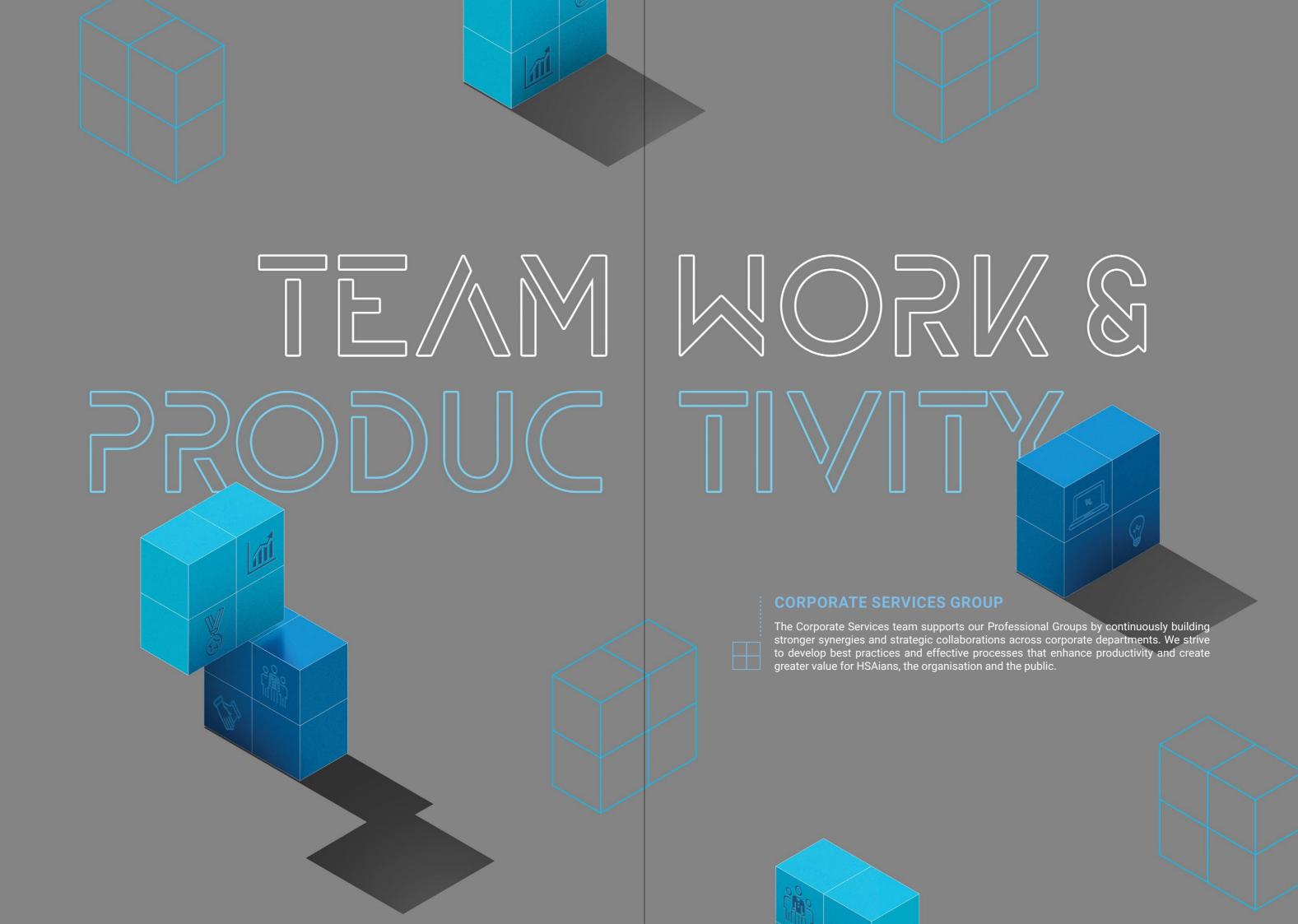
Successfully accredited one test method:

· Acrylamide in water by LC-









# People and Values

At HSA, nurturing our people to reach their best potential is at the heart of everything we do. Through advocating continual learning and development, we empower our people to maximise their potential and develop their talents. At the same time, we strive to inspire a workforce of individuals who are not just driven by success, but also by compassion.

### SERVING WITH EMPATHY

We pride ourselves on doing the best for our customers and staff. In March 2017, we held our 8<sup>th</sup> Customer Service Day with the theme "Empathy — At the Heart of All We Do". The event saw international speaker and behavioural scientist Mr Nick Jarvis Tan sharing insights on how great organisations, locally and around the globe, harness

the power of empathy to drive innovation, foster excellent customer service and create great workplaces.

At the event, we also recognised staff who displayed stellar service standards. Thirty-three of our staff achieved the national Excellent Service Award (EXSA) 2016 and 47 received the HSA Outstanding Service to Customers Award (OSCA) 2016.





#### BUILDING A SKILLS-BASED WORKFORCE

In 2016, in line with the Public Service Division's move beyond academic qualifications to focus more on skills and competencies, we merged our Health Sciences Professional and Health Sciences Technical Executive schemes to enhance the career prospects of non-graduates visar-vis their graduate counterparts. This ensures that our staff are assessed, and progress based on their competences, performance and potential.

We also took on the same direction in our recruitment of staff, which is aligned to the ASPIRE Committee's aim of providing more opportunities for Singaporeans to realise their full potential and progress in life.

We now offer pre-service nursing sponsorships to attract local nursing diploma students to take up Staff Nurse positions at our blood banks, to build a strong pipeline of registered nurses for the Blood Services Group.

We also reviewed our Corporate Professional Development Career Track. This will keep our staff upto-date on the competencies and training needs they are required to fulfil in building their careers with us.



A good balance between work and personal life brings along advantages such as better health and wellbeing, improved productivity and a happier workforce. HSA is always working on initiatives with HSAians to achieve the fine balance.

#### **LUNCHTIME BOOSTERS**

To nourish body, mind and spirit, we conducted quarterly Work-life Balance Talks during lunchtime. In all, five talks were organised for different groups of staff members on various topics such as parenting, good financial management for families and smart Internet usage.



#### CHILDREN'S DAY OUT

HSAians and their little ones participated in the "Bring-Your-Kids-To-Work" Day in September 2016. The fun-filled event saw the children touring HSA facilities to understand their parents' work better — they also got to visit interesting places like the laboratories and the Bloodbank@HSA. The day ended at East Coast Park, where everyone bonded over cycling and a scavenger hunt.

#### RECOGNISING OUR UNSUNG HEROES

In February 2017, we organised an Appreciation Lunch to thank staff working under our outsourced vendors for their role in keeping HSA clean, comfortable and safe. This was done in support of the "NTUC — APPRECIATING U Movement". Health Support Officers, cleaning staff, security officers and technicians — the Unsung Heroes of HSA — were invited to a well-deserved treat.



#### SINGAPORE'S NATURE CONSERVATION JOURNEY

In land-scarce Singapore, proper waste management is crucial to both the environment and people's quality of life. In November 2016, over 40 HSAians visited the Semakau Landfill for an educational tour. There, they witnessed how Singapore's environmental protection and nature conservation efforts have created a landfill thriving with rich marine biodiversity as well as a place for nature-based recreational activities.





## Giving Back to Society

HSA is committed to improving the lives of those in our community through our Corporate Social Responsibility Framework, CARE (Community Action, Responsible for our Environment).





#### ES GROUP



To get our public health messages and warnings out to a larger audience, and to educate the public on HSA's role, we reached out to them via a variety of platforms.



#### HEIGHTENING PUBLIC AWARENESS

We launched Singapore's first ever Missing Types Campaign in August 2016, an international campaign held together with 21 countries. The goal was to highlight the importance of blood donation by getting organisations to drop the As, Bs and Os from their websites, social media pages and branding.

- Close to 60 organisations participated
- Blood collection over the last two weeks of August increased 16% over the same period in 2015

HSA also enjoyed positive media publicity as our forensic personnel were featured prominently in the Lianhe Wanbao and Shin Min Daily News forensic series, creating greater awareness of our scientific capabilities.

• Eight forensic specialisations featured in 15 articles

Together with the Tobacco Regulation Branch, we partnered the National Crime Prevention Council and the Singapore Police Force to produce an episode of Crimewatch. This helped to give the public a glimpse of how we shut down illegal vaporiser operations and warn others against committing such offences.

Attracted around 800,000 viewers





**ANNUAL REPORT 2016/17** 

Information Technology (IT) is an important part of everything we do at HSA. This is why we are constantly working on improving our processes to build a more effective and efficient organisation. During the year, our IT department rolled out various initiatives to enhance convenience for our blood donors, licensees and staff.



#### KEEPING UPDATED ON THE GO

Through a handy new feature added to the Health Hub app, blood donors can now keep track of their blood donation appointments with ease.



#### SMOOTHER LICENSING PROCESSES

Tobacco licensees can download their licenses via the one-stop government business portal instead of having to write to HSA to request for additional copies.

.....



#### INFO AT A TOUCH

Finding a nearby blood bank or registered pharmacy is now easier than ever. These useful information have been added to our interactive map on Health Hub.

......



#### A SAFER IT NETWORK

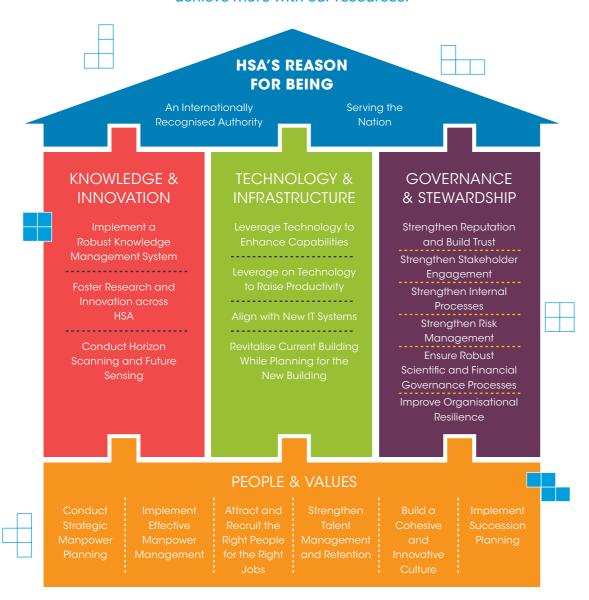
We successfully implemented Internet Separation — the separation of Internet from computers and devices linked to our internal network. This move is part of a nationwide government initiative to protect highly classified work email and files from cyber attackers and prevent malware from infiltrating IT systems.

, }-----



## HSA Strategic Road Map

In an increasingly complex and evolving operating environment, it is important for HSA to be forward-looking and continuously develop new capabilities, innovate and achieve more with our resources.



Launched in April 2016, the HSA Strategic Road Map was jointly developed by staff across all four Professional Groups through a process of horizon scanning, brainstorming and discussions with our stakeholders. Built on a strong foundation of *People and Values*, and three key strategic pillars — *Knowledge and Innovation, Technology and Infrastructure* and *Governance and Stewardship*, the road map will provide strategic guidance for HSA in the next lap of our journey towards becoming the leading innovative authority protecting and advancing national health and safety.

# Promoting the Culture of Research and Innovation

As a scientific and knowledge-driven organisation, we strongly believe that research and innovation are key to bettering ourselves and the services we provide to our stakeholders.

#### DEDICATING OUR TIME TO RESEARCH

In line with the requirements of the Human Biomedical Research Act, HSA will be designated as a Research Institution. Our Professional Board was tasked to develop and implement a research governance framework. This will ensure that the work we do complies with national regulations.

They formulated the main Research Governance Policy and Standard Operating Procedures to guide HSA's research work. These include guidelines on research administration, implementation, monitoring of research and compliance checklists which were drafted by the Research Programme Workgroup.

A Research Advisory Committee comprising renowned experts from the public sector hospitals and senior staff from our Professional Groups was set up. They will review and evaluate HSA research proposals on their scientific merits and value, provide independent opinion on the ethical acceptability, research integrity and legislative consideration and provide advice on proposals to be approved and future trends in the fields of speciality.

Under the Continuing Professional Education Programme, a series of



informative lectures on research topics by experts in the field has also been planned for the year.

#### RESEARCH SEED GRANT

The HSA Research Seed Grant Scheme was launched in September 2016 with the objectives of encouraging and supporting HSAians on their research journey and promoting the research culture in HSA.

- Up to \$100,000 worth of research grants will be set aside each year
- In the first year, 10 applications were received.

#### ACTIVE LEARNING AND ENGAGEMENT

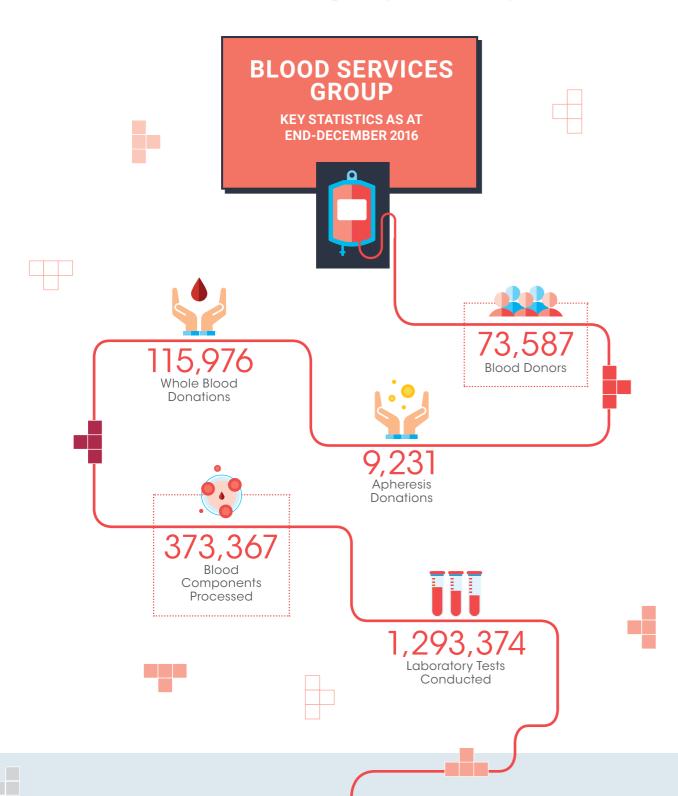
The HSA Innovation Festival was held from 4 November to 7 December 2016. It started with the HSA Innovation Day where Dr Kirpal Singh gave an insightful lecture.

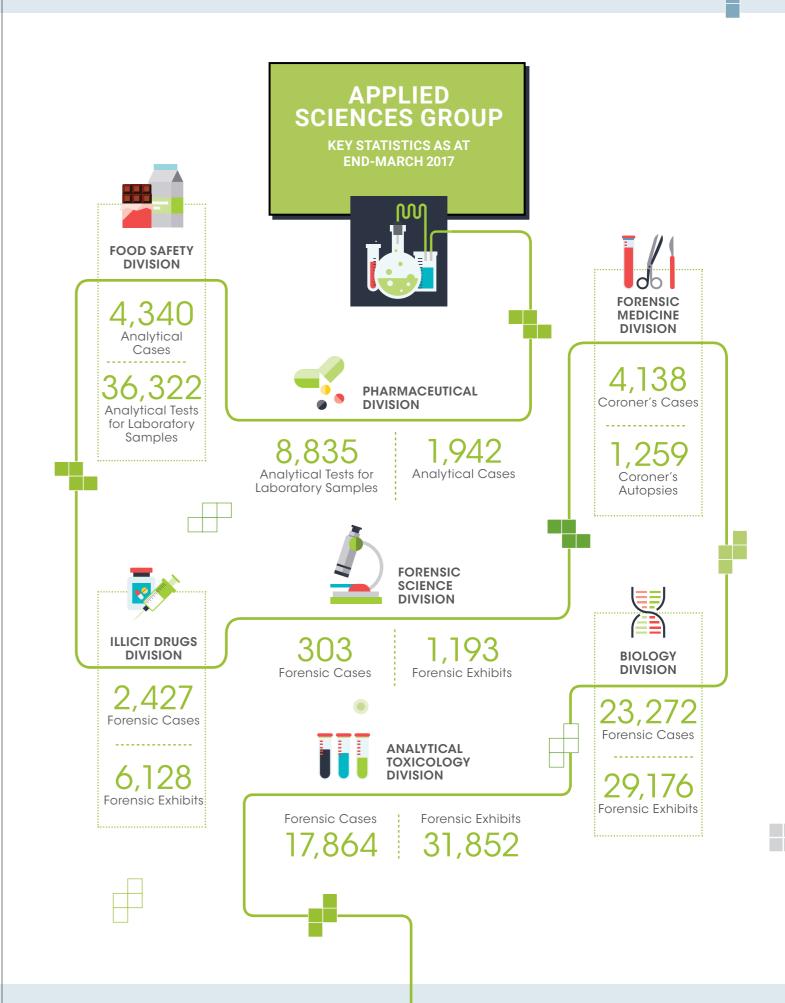
The festival featured a series of events to give HSAians opportunities to learn and collaborate with each other and 'Live Innovation'. Highlights of the festival included two Innovation Lab Workshops by Lego® Education; an innovation learning journey to the Infinite Studios and the HSA Marketplace Day where staff worked in teams to start small businesses in an "Innovative Entrepreneur Game" to raise funds for charity and more.

A series of informative lectures on research topics has also been planned for the year.

# **ACHIEVEMENTS** IN FIGURES

ANNUAL REPORT 2016/17





4,661 Number of 26 Therapeutic Products Containing 230 Therapeutic Products Variation New Chemical/ **Applications Biological Entities** Therapeutic Approved Products Registrations 0 0 0 Approved (New Drug **Applications** 5,476 40 and Generic Drug Number of Approved Products Applications) on the Register Reclassified of Therapeutic Therapeutic Products **Products** 1,361 Medical Device Product Listings Approved (Class A, B, C & D)

ANNUAL REPORT 2016/17

HEALTH PRODUCTS REGULATION **GROUP** 

**KEY STATISTICS AS AT END-MARCH 2017** 

16,833 Approved Products on the Singapore Medical Device Register 579 Number of Field Safety Corrective Action Devices Received

Reporting for Medical

358 Number of Adverse Events (Local) Reporting for Medical

2,666 Medical Advertisement Permits Approved

21,542

Spontaneous Adverse **Drug Reaction Reports** Captured

1,845

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



10,887

Total Number of Chinese Proprietary Medicines Listed

\_\_\_\_\_

561 New Chinese Proprietary

Medicines Listed



166,469 otal Number of Cosmetic Products Notified

45,324 Notified



**APPLICATIONS APPROVED** 

1,719 Applications for Licences/Certificates for Wholesalers of Health Products

Approved

-----

440

Applications for Licences/Certificates for Manufacturers of Health Products Approved

333

-----

Applications for Registration of Retail Pharmacies Approved

-----

3,398

Applications for Licences/Certificates for Importers of Health Products Approved

-----

496

**Applications** for Licences/ Certificates for Exporters of Health Products Approved



403

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



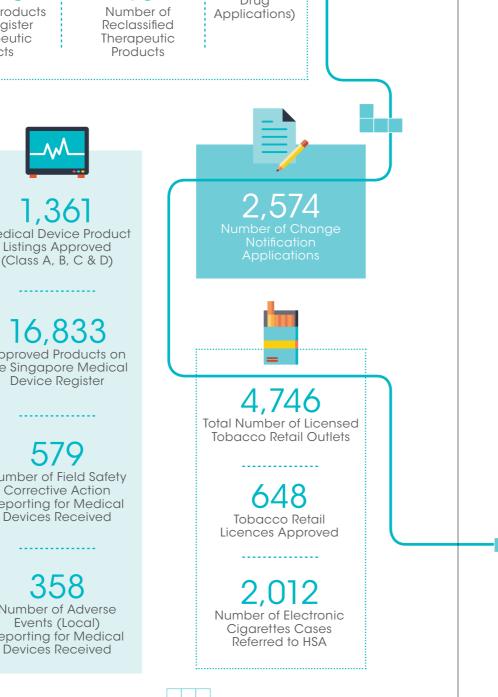
3,161

Applications for Import of Medicinal Products for Personal Use Processed



**CLINICAL TRIAL APPLICATIONS** 







	FY16/17	FY15/16	INCREASE	/ (DECREASE)
	\$'000	\$'000	\$'000	%
Property, Plant & Equipment	80,351	84,094	(3,743)	(4)
Intangibles		2,556	1,482	58
	154,446	141,297	13,149	
Total Assets	238,835	227,947		
Equity	147,481	135,507	11,974	
Long-Term Loans	16,380	17,290	(910)	
Other Non-Current Liabilities			(917)	
Current Liabilities		67,499	741	
Total Equity and Liabilities	238,835	227,947		

## INCOME & EXPENDITURE STATEMENT

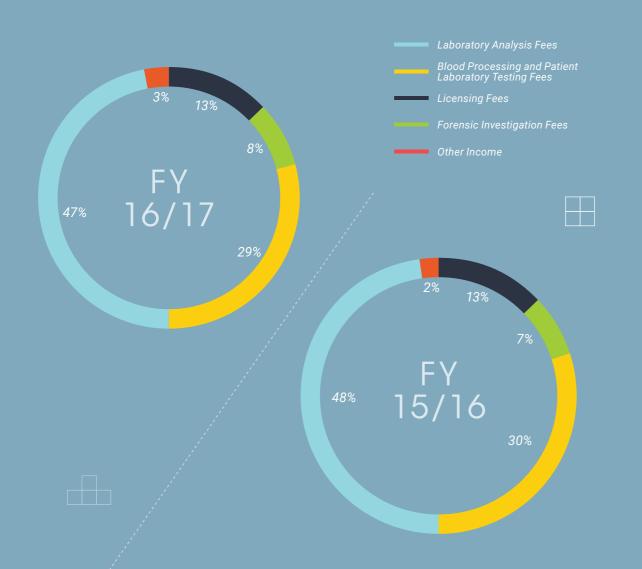
	FY16/17	FY15/16	INCREASE	/ (DECREASE)
	\$'000	\$'000	\$'000	%
Operating Income		132,403	5,975	5
Operating Expenditure	(203,019)	(198,827)	4,192	2
Deficit before Government Grants	(64,641)	(66,424)		
Government Grants	78,661	76,398	2,263	
Surplus before Contribution to Consolidated Fund	14,020	9,974		
Contribution to Consolidated Fund	(2,383)	(1,696)	687	41
Net Surplus	11,637	8,278		
Other Comprehensive Income		(231)	247	
Net Surplus and Comprehensive Income for the Year	11,653	8,047		



#### OPERATING INCOME



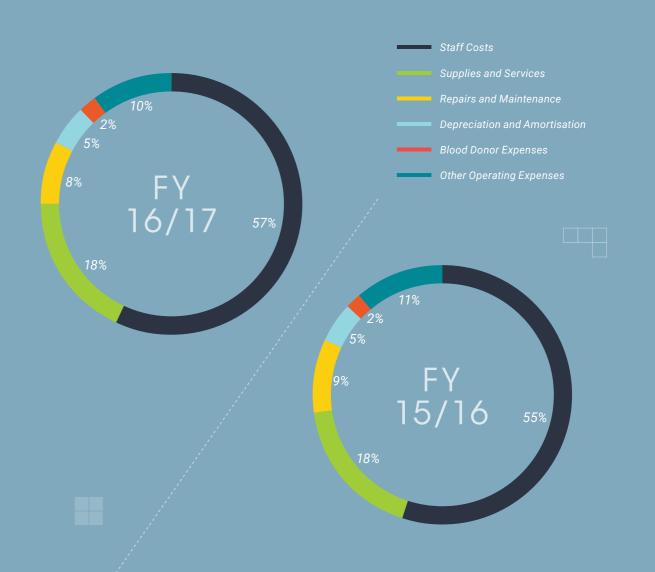
FY1		FY15/16	INCREASE	/ (DECREASE)
	\$'000	\$'000	\$'000	%
Laboratory Analysis Fees	65,059	63,486		
Blood Processing and Patient Laboratory Testing Fees	40,308	39,090		
Licensing Fees	17,955	17,042		
Forensic Investigation Fees		9,647	1,625	
Other Income	3,784			
Total Operating Income	138,378	132,403	5,975	



## OPERATING EXPENDITURE

The Authority incurred a total operating expenditure of \$203.0m in FY16/17, an increase of \$4.2m (2%) over FY15/16's expenditure of \$198.8m.

	FY16/17	FY15/16	INCREASE	/ (DECREASE)
	\$'000	\$'000	\$'000	%
Staff Costs	114,833			
Supplies and Services	36,324		1,048	
Repairs and Maintenance	17,098	18,307	(1,209)	
Depreciation and Amortisation			440	
Blood Donor Expenses	3,810	3,756		
Other Operating Expenses	20,242	20,899	(657)	
Total Operating Expenditure	203,019	198,827	4,192	2





92 ANNUAL REPORT 2016/17 SYNERGY

## Editorial Team

#### ADVISOR

Dr Choong May Ling, Mimi

#### EDITORS

Ms Valencia Seah

Ms Estelle Koh

Ms Michelle Chen

Mr Adrian Chia







#### MEMBERS

Ms Florence Teo

Dr Joe Yap

Ms Joyce Heng

Ms Joyce Nang

Ms Koh Geok Tin

Dr Marieta Chan

Ms Peck Li Fung

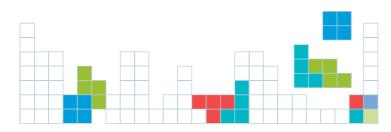
Ms Regina Hong

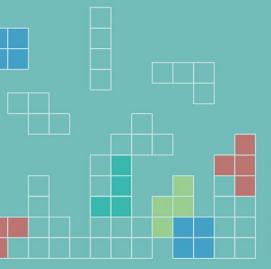
Mrs Sarojini Padmanathan

Ms Sandra Ng

Mr Tan Yeo Kwang

Mr Toi Shean Hoon







#### HEALTH SCIENCES AUTHORITY

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