



#### **HEALTH SCIENCES AUTHORITY**

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The theme for this year's annual report – Live Innovation, is something close to our hearts as a science-driven organisation. For HSA, innovation is key to advancing and achieving our goals, and highlights our culture of continual improvement.

Innovation is something that we try to live out each and every single day. By tapping on new technologies and digitalisation, we are able to streamline our work processes and improve our service delivery, thereby offering greater value to the public and stakeholders.

As we continue to live innovation in the many years to come, we look forward to more new and efficient ways to protect and advance national health and safety.

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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 Core Values -



#### **SERVICE TO THE NATION**

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

#### **PASSION FOR EXCELLENCE**

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

#### **DEVELOP OUR COMMUNITY**

We value our people and build trusted teams.

#### **INSPIRE TRUST**

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

#### **LIVE INNOVATION**

We seek constantly to improve and transform.

## Our Accolades

#### ORGANISATIONAL EXCELLENCE

SINCE 2014	The Public Service Achievement Award
2010	The Public Service Milestone Award
MARCH 2014	Singapore Quality Class Star
SINCE 2009	Singapore Quality Class
SINCE 2002	People Developer Certification
2003	Singapore Innovation Class First public healthcare agency to be endorsed
MARCH 2014	Singapore Service Class
2012	Singapore H.E.A.L.T.H. Platinum Award
	2014 2010  MARCH 2014  SINCE 2009  SINCE 2002  2003



## Our Accolades

#### PROFESSIONAL EXCELLENCE

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

SINCE MARCH 2017 ISO 9001:2015

Tobacco Regulation Branch

2017

ISO 9001:2015

Vigilance & Compliance Branch

2017

ISO 9001:2015

**Enforcement Branch** 

SINCE OCTOBER 2015

ISO 9001:2008

Audit & Licensing Division

2016

**Member of the Management** Committee for the International **Medical Device Regulators** 

Forum (IMDRF)

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

2000

**Accession to Pharmaceutical Inspection Co-operation** Scheme (PIC/S)

Audit & Licensing Division

2013

**Member of the Management Committee for the International Coalition of Medicines** Regulatory Agencies (ICMRA)



#### **BLOOD SERVICES GROUP**

AUGUST 2014 Compliance with PIC/S Good **Manufacturing Practice** Standard

Cell Therapy Facility was audited to acceptable GMP standard jointly by HPRG and Swissmedic

2013

**Joint Accreditation Committee** - International Society for Cellular Therapy and European **Blood and Bone Marrow Transplantation (JACIE)** 

AUGUST 2008

**American Society for** Histocompatibility and Immunogenetics (ASHI)

2006

**AABB Accreditation** 

First national blood service in Asia to be accredited

2005

**Certified On-the-Job Training** Centre

1992

**World Health Organization Collaborating Centre for Transfusion Medicine** 

#### APPLIED SCIENCES GROUP

#### FORENSIC MEDICINE DIVISION

2005

**National Association of** Medical Examiners (NAME)

First agency outside North America to be accredited

2003

Commendation for Significant Contribution in **Helping Singapore Overcome** 

1999

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

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

1999

**Excellence for Singapore** Award

SINCE

1996

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

#### **PHARMACEUTICAL DIVISION & FOOD SAFETY DIVISION**

2003

**Public Service Award for Organisational Excellence** 

SINCE AUGUST

**Singapore Quality Class** 

Scheme (SAC-SINGLAS)

2002 SINCE

1997

ISO/IEC 17025 Accreditation under Singapore Accreditation Council - Singapore **Laboratory Accreditation** 

#### PHARMACEUTICAL DIVISION

2014

**Associate Membership to the General European Official Medicines Control Laboratories** 

**Network (GEON)** 

SINCE NOVEMBER 2012

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

FEBRUARY 2012

**Observer to the European** Pharmacopoeia Commission

SINCE 2009 **World Health Organization Collaborating Centre for Tobacco Testing and Research** 

SINCE FEBRUARY 1993

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

#### **FOOD SAFETY DIVISION**

2011

Member of the ASEAN Food **Testing Laboratory Committee** 

(AFTLC)

SINCE JUNE 2004

**ASEAN Reference Laboratory** for Mycotoxins Analysis

SINCE JULY 1992 **World Health Organization Collaborating Centre** for Food Contamination

Monitoring

#### **CHEMICAL METROLOGY DIVISION**

SINCE NOVEMBER 2014

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

JANUARY 2014 Member of the Joint Committee for Traceability in **Laboratory Medicine (JCTLM)** 

SINCE AUGUST 2013 **Accredited as a Proficiency Testing Provider under ISO/** IEC 17043 by the Singapore **Accreditation Council** 

2008

**Full Member of the Asia Pacific** Metrology Programme (APMP)

### 7

## Chairman's Message

We embraced with renewed vigour our commitment to protect public health and safety, maintain a constant supply of blood products, and boost our scientific capabilities to support the work of our stakeholders.

Guided by our core value, "Live Innovation", we explored methods and resources to improve processes and achieve higher standards of work. We encouraged creative thinking for better results as we believe that in doing so, there is much to be gained by our staff as well as by the public and our stakeholders.

Some of our major achievements over the year include:

#### Refining Our Regulatory Framework

The Health Products Regulation Group recently launched two new schemes for medical devices. The Priority Review Scheme is a proenterprise and industry-friendly initiative that provides companies with an option for faster registration and market entry of their products, potentially reducing the processing time by 40 days or more. This is especially relevant for innovative medical devices targeting national healthcare priorities or unmet clinical needs.

The Pre-market Consultation Scheme offers medical device developers, manufacturers and suppliers regulatory advice concerning a new product. The advice can be sought during the various stages of development, from conception to product registration.

Another notable change in our regulatory framework is the lifting of the ban on the herb Corydalis Yanhusuo, which contains the naturally occurring substance tetrahydropalmatine or THP. This comes after a comprehensive review, which indicates that such products when manufactured and used appropriately pose no major safety concerns.

### Safeguarding the National Blood Supply

As part of our ongoing efforts to improve the safety of our blood supply, the Blood Services Group (BSG) introduced a new initiative to use male-only plasma products for transfusion. This decision was based on studies which showed that the risk of transfusion-related acute lung injury is more than halved with plasma products derived only from male donors. This reduction may be related to the lower incidence of anti-human leukocyte antigen (HLA) antibodies in males compared to female donors.

Additionally, BSG implemented a process to automatically transmit pre-transfusion test results obtained from laboratory equipment directly into the computer database system. This eliminates errors from manual entry.

#### New Scientific Capabilities

A key challenge faced in analysing exhibits from female victims in sexual assault cases is that the male perpetrators' DNA is often masked by the victim's DNA. To overcome this obstacle, the Applied Sciences Group developed a novel analysis method

that targets the Y chromosome, found only in the DNA of males. This allows for specific detection of the male perpetrator's DNA, helping to generate potential investigation leads for law enforcement.

Our Food Safety Laboratory has developed four new analytical methods to test for new and emerging harmful substances found in food. These substances include tropane alkaloids found in cereals and cereal-based food, and amatoxin from mushrooms. These substances affect the heart rate and the central nervous system, and can result in fatality.

In the area of toxicology drug screening, I am pleased to say that our customised commercial solution known as Toxtyper, implemented in April 2017, has so far helped us to cut processing time significantly. The higher sensitivity of this instrument allows us to detect more drugs, including plant poisons and previously undetectable synthetic cannabinoids.

#### **Enhancing Career Pathways**

As our committed and capable staff add value to HSA's work, we also strive to add value to their lives. One of the ways we do this is by ensuring that they find fulfilment and meaning in their job through our continued review of their career tracks and roles.

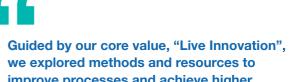
A review of the minimum educational qualification requirements was recently concluded and greater emphasis given to competency requirements. Staff with the newly defined minimum educational

qualification requirements and appropriate accreditation or professional certification of competence can be considered for specific positions for which they could not be considered before. This increased focus on competencies ensures that the skills and knowledge of our staff are kept relevant to current needs.

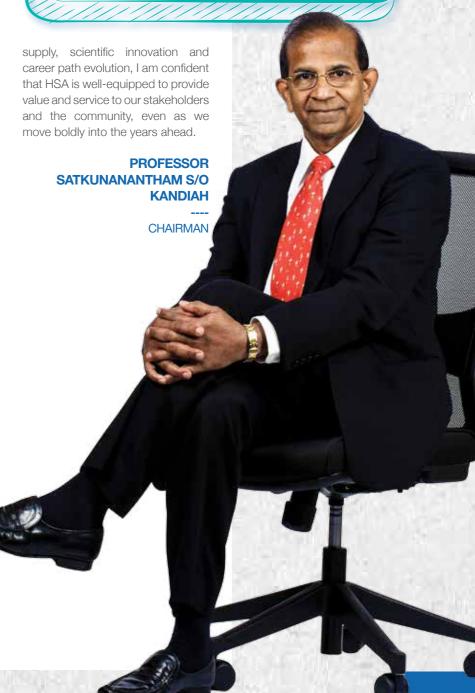
We are also expanding the roles of our blood donation nurses who play a key role in blood collection. HSA aims to prepare selected nurses to take on the role of Clinical Nurse Leaders through training. Additionally, some nurses were given scholarships to pursue the Advanced Diploma in Medical-Surgical Nursing. These newly-defined roles will contribute to enhancing donor safety and blood supply safety in areas such as predonation screening, and handling of post-donation adverse events.

The importance and value of our staff cannot be emphasised enough. Their passion and commitment not only help us to remain at our most efficient, but are, ultimately, the driving force in our vision to protect and advance national health and safety.

Through all these exciting developments in regulation, blood



we explored methods and resources to improve processes and achieve higher standards of work. We encouraged creative thinking for better results as we believe that in doing so, there is much to be gained by our staff as well as by the public and our stakeholders.



## CEO's Message

#### **Our Changing World**

Science and technology are fast evolving, bringing great change to our world and impacting the way we live. As the leading authority in the field of health sciences, we are feeling the full force of these disruptions.

Many new products such as telehealth devices, 3D printed drugs and cell therapy are entering the global market at an accelerated pace. These innovative products bring with them new benefits to patients and new regulatory challenges. Smart yet disruptive technologies, such as artificial intelligence (AI), internet-ofthings and robotics, are increasing our efficiency and productivity, but are also requiring us to pick up new skills and adopt new ways of doing things. Even the demands of consumers are evolving; many are demanding faster responses and greater convenience.

#### **Our Transformation Plans**

To be future-ready, we need to speed up our transformation journey. We have placed greater emphasis on research and innovation to revolutionise our services and processes. We are also reviewing our existing regulatory frameworks to meet current needs, and developing new ones to meet evolving and future needs. Our initiatives include:

#### Implementing Transformation

To drive strategic transformation across the organisation, we have set up a Transformation Working Group (TWG). It will help to identify areas of synergy, and streamline efforts and initiatives across HSA. TWG will also play a vital role in helping to future-proof our workforce by identifying the critical competencies needed

to support new technologies and growth areas.

### Reviewing Our Regulatory Frameworks

As an enabler and a gatekeeper, HSA needs to strike a balance between allowing faster access to life-saving therapies and products, while ensuring that public health and safety are not compromised.

Cell, tissue and gene therapy products (CTGTPs) such as cellular immunotherapies, cancer vaccines and stem cell therapies are a novel class of health products that can bring about better outcomes or even cures for certain diseases. There is a rich research pipeline and many are now being developed commercially for clinical use. We are thus developing a new CTGTP regulatory framework that is forward-looking and fit for purpose.

Digital technology is another area that has advanced rapidly. To ensure transparency and clarity to players in the telehealth field, we have published a set of guidelines to help them identify which types of products are regulated as medical devices, as well as provided relevant advisory statements to be included for products not intended for medical purposes.

A good example of HSA's dynamic and astute approach to regulation can be seen from our assessment of the first dengue vaccine. We were the sole regulator recommending sero-testing to identify patients who had never had a previous dengue infection, as they would be at higher risk of severe dengue if vaccinated. Eighteen months post-approval, new data from the company confirmed

this assessment, and sero-testing is now recommended by the company in all countries where the vaccine has been approved.

#### Adopting Automation

Automation and robotics are helping us to mitigate resource challenges by improving staff productivity, reducing manpower needs and enhancing the quality of our products.

For example, through the implementation of a fully robotic system for sample preparation and instrument analysis, our Applied Sciences Group's (ASG) Analytical Toxicology Laboratory has managed to cut down the process of detecting monoacetylmorphine (a biomarker for heroin consumption) in urine from two days to three hours.

Another area where automation made a difference is in the dissolution of illicit drug samples for quantitation. By adopting an automated syringe dispenser into the process, we have managed to improve the accuracy of results and increase efficiency five-fold.

Our Blood Services Group (BSG) is also working with the Nanyang Technological University to build an automated system for blood processing, testing, distribution and inventory management.

#### Implementing Digitalisation

To spearhead our digitalisation journey, we have set up a steering committee to coordinate and drive digitalisation projects within HSA.

These projects include the use of artificial intelligence by the Health Products Regulation Group. Through this pilot project, we are

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To be future-ready, we need to speed up our transformation journey. We have placed greater emphasis on research and innovation to revolutionise our services and processes. We are also reviewing our existing regulatory frameworks to meet current needs, and developing new ones to meet evolving and future needs.

experimenting with chatbots for round-the-clock handling of email queries, as well as machine learning to match a user's query with draft answers in the database.

For BSG, the experience of blood donors is being improved through the 3E initiative – e-Registration, e-Rebooking and e-Feedback. Donors are now able to book medical appointments, as well as provide feedback conveniently using e-portals and self-help kiosks.

Digitalisation has also enabled ASG's Pharmaceutical Division to conveniently retrieve data on demand, and do away with manual printouts. Using LabX 2017, the efficiency and traceability of their daily work processes have been greatly enhanced.

### Leveraging on Data Analytics and Behavioural Insights

To better inform our decision making, our Data Analytics Core Team (DACT) is helping to equip our officers with data analytics and behavioural insights (BI) skills. To date, DACT has already completed a few pilot projects, with more on the way. Starting with simple data analysis and visualisations, we are now steadily progressing towards more complex predictive analytics.

A BI Working Group has also been formed to champion the use of BI.

DR CHOONG MAY LING, MIMI

CHIEF EXECUTIVE OFFICER

One notable project was the redesign of the blood donor health assessment questionnaire. The result is a smoother and easier form-filling experience for our donors.

#### **Our Future Ahead**

There are many exciting developments that we can look forward to – one is the upcoming launch of our revamped website. Using user experience and design thinking, we are adopting the perspective of our stakeholders to come up with a more functional and user-centric website, complete with self-help tools and chatbots to help people find answers quickly and easily.

The rate of change is only going to get faster from here on. Nonetheless, I'm confident that HSA is well-prepared for the road that lies ahead. By living innovation, digitalisation and transformation, we can realise many opportunities to ensure the highest standards for health and safety in Singapore.



## HSA BOARD

As at August 2018



**Professor** Satkunanantham s/o Kandiah Chairman Health Sciences Authority



Mr Max Loh Managing Partner ASEAN and Singapore Ernst & Young



Mr Tai Lee Siang Chair World Green Building Council



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



Mrs Tan Li Lian Executive Director Contemporara Holdings Pte Ltd



**Professor Freddy Boey** Senior Vice President Graduate Education and Research Translation National University of Singapore



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



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



Mr Dileep Nair Independent Director Keppel DC REIT Management Pte Ltd



Mr Alok Mishra Chief Executive Officer Value Addition



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

## HSA Board Committees

As at August 2018

#### **Board Executive Committee**

#### Chairman

Professor Satkunanantham s/o Kandiah

#### Members

Mrs Tan Li Lian Mr Adam Abdur Rahman Mr Alok Mishra

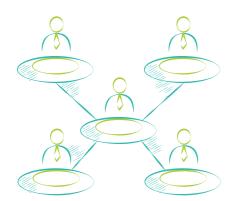
#### **Audit and Risk Committee**

#### Chairman

Mr Max Loh

#### **Members**

Professor Freddy Boey Professor Alex Matter Mr Jimmy Phoon



## Building Development Committee

#### Chairman

Mr Tai Lee Siang Chair World Green Building Council

#### **Co-Chairman**

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

#### **Members**

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

#### Mr Dileep Nair

Independent Director Keppel DC REIT Management Pte Ltd

#### Mr Jeffrey Wong

Group Director Corporate Services Group

#### Assoc Professor Sunil Sethi

Group Director
Applied Sciences Group

#### Assoc Professor Chan Cheng Leng

Group Director

Health Products Regulation Group

#### Dr Ang Ai Leen

Group Director Blood Services Group

#### Ms Elizabeth Quah

Group Director (Planning)
Ministry of Health

#### Mr Loke Mun Sing

Directo

Healthcare Infrastructure Projects Division Ministry of Health Holdings

#### Mr Hoong Bee Lok

Visiting Consultant

Health Sciences Authority

# HSA Executive Committee (EXCO)

As at August 2018



Dr Choong May Ling, Mimi Chief Executive Officer



Assoc Professor Chan Cheng Leng Group Director Health Products Regulation Group



Dr Ang Ai Leen Group Director Blood Services Group



Assoc Professor Sunil Sethi Group Director Applied Sciences Group



Mr Jeffrey Wong Group Director Corporate Services Group



Dr Diana Teo
Chairman
Professional Board
Senior Consultant
Blood Services Group

## Corporate Governance Statement

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

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

#### **The Board**

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

## **Board Members'**Remuneration

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

#### Notice and Declaration of Directorships and Interest in Shares and Debentures

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

#### **Accountability and Audit**

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

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

#### (a) Board Executive Committee

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

#### (b) Audit and Risk Committee

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

#### (c) Building Development Committee

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

## Communication with Stakeholders

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

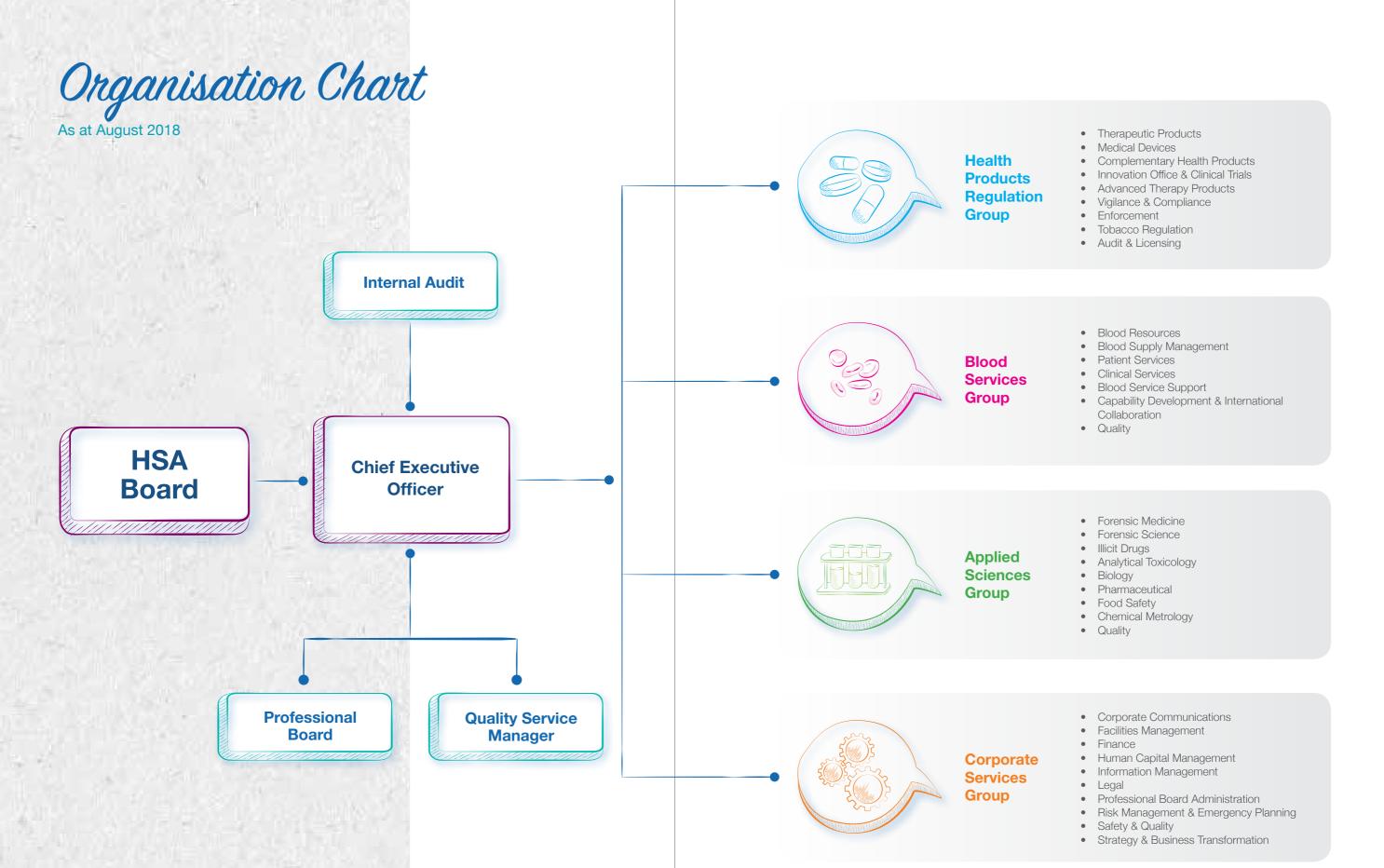
#### Code of Business Conduct

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.

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## Principal Officers As at August 2018

### CORPORATE HEADQUARTERS

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

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

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

### MEDICINAL PRODUCTS PRE-MARKET CLUSTER

Assistant Group Director Ms Lee Hui Keng

### Innovation Office & Clinical Trials Branch

Acting Director Dr Lisa Tan

#### **Therapeutic Products Branch**

Director
Ms Agnes Chan

### Complementary Health Products Branch

Director

Ms Hui Foong Mei

### Advanced Therapy Products Branch

Acting Director

Dr Kellathur Nadathur Srinivasan

### VIGILANCE, COMPLIANCE & ENFORCEMENT CLUSTER

Assistant Group Director Dr Dorothy Toh

#### **Enforcement Branch**

Director Ms Annie Tan

#### Vigilance & Compliance Branch

Director
Ms Jalene Poh

#### **Tobacco Regulation Branch**

Director

Mr Norman Chong

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

Division Director Ms Jessica Teo

#### **Audit Branch**

Director
Ms Jessica Teo

#### Licensing & Certification Branch

Director

Dr Lai Weng Fai

#### **MEDICAL DEVICES CLUSTER**

Acting Assistant Group Director Ms Wong Woei Jiuang

#### **Medical Devices Branch**

Acting Director
Dr Sethuraman Rama

### 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**

Acting Division Director
Ms Sally Lam

#### **PATIENT SERVICES**

Immunohaematology & Cell Therapy Support Laboratory Director Dr Marieta Chan

#### **CLINICAL SERVICES**

Vacant

## APPLIED SCIENCES GROUP

Group Director
Assoc Professor Sunil Sethi

#### QUALITY

Director, Quality
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 Drugs 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
Asst Professor Joanne Chan

#### **Pharmaceutical Division**

Division Director

Ms Low Min Yong

## Professional Board Updates

The Professional Board (PB) advises CEO on policy and management issues relating to professional matters in HSA. PB looks at the professional development of staff and initiatives to promote a research and innovation culture.



## Professional Career Tracks and Training Roadmaps

#### **Career Track for Scientists and Regulatory Specialists**

We reviewed and updated the minimum educational qualification requirement in alignment with the government's move to focus on competency requirements. Now, staff with the appropriate accreditation or professional certification can be considered for specific positions. This focus on competencies ensures that the skills and knowledge of our staff are kept relevant to current needs instead of educational qualification that was attained in the past.

#### **Career Track for Technical Staff**

In support of the merger of the Health Sciences Professional and Technical Executive Schemes, we developed and implemented the Career Track for Technical Staff, which states the competencies requirement for each grade of Technical Staff.

#### **Professional Actualisation Training (PAT) Roadmaps**

We rolled out PAT roadmaps for staff to plan the training required for the competencies of their current and next grade. In this way, staff are empowered to manage and meet their career aspirations. There are four categories of trainings:

- Professional / Technical Training
- Management Training
- Overseas / Local Attachments
- Continuing Education

PAT roadmaps for professionals such as nurses, forensic pathologists, transfusion medicine specialists and non-specialists were launched between September 2016 and 2017.

#### **Professional Critical Skills Identification Exercise**

This exercise was mooted by PB to ensure that there are sufficient numbers of trained professionals in areas critical for business continuity and sustainability. New Learning & Development key performance indicators were tracked over the year-in-review and linked to the acquisition of Professional Critical Skills.

#### **Professional Leadership Development Programme (PLDP)**

We developed an in-house programme, "Channelling Leadership" to give selected candidates an opportunity to realise their leadership potential with adequate guidance. PLDP consists of management training sessions, project work and informal coaching. This modular management training consists of three modules. A pilot run consisting of 20 promising officers from our four Professional Groups was launched in the first quarter of 2018.



#### **Continuing Professional Education Programmes**

#### **Science and Innovation Day 2017**

June 2017

The objective of this half-day event was to promote the culture of research and innovation in HSA, facilitate exchanging of scientific information and innovative ideas, and showcase and recognise staff who have contributed to research and innovation projects in HSA.





#### **Event Highlights**



staff participated



abstracts accepted



projects awarded under the oral presentations category



best posters selected from each of the Research & Innovation categories

#### **Professional Education Lecture Series** February 2017 - March 2018



This is the start of a new programme of educational lectures that focuses on important aspects of professional practice that staff will find useful in their work.

#### Collaborations between HSA and Nanyang Technological **University (NTU)**

May 2017

Organised by HSA and NTU, the inaugural Research Collaboration Workshop was co-chaired by Dr Choong May Ling, Mimi, CEO of HSA, Prof Russell Gruen, Executive Director of HealthTech NTU and Prof James Best, Dean of Lee Kong Chian School of Medicine. The event was attended by close to 50 leaders and researchers from both institutions, who came together to discuss areas of mutual research interest, such as Robotics and Automation, Artificial Intelligence, Health Services Outcomes Research, Phenomics and Nuclear Magnetic Resonance applications.



#### August 2017

HSA and NTU followed up with the signing of a Memorandum of Understanding (MOU). This MOU creates many opportunities for further scientific knowledge exchange and potential research collaborations between the two institutions. The ultimate goal is to be able to leverage on each other's expertise to develop innovative solutions that will benefit national health and safety.

#### **Event Highlights**



lectures on topics such as research ethics and behavioural insights

Renowned speakers: Prof Alastair Campbell, Ms Rebecca Chew and Dr Serene Koh



attendees per session

#### **Tea-time Tidbits** February 2018



**HSA Professional Staff Sharing Sessions** 

Theme: DNA Across HSA

Topics included: Biology in Crime Investigation, Molecular Testing for Infectious Disease and Clinical Applications of Gene Editing



# Knowledge and Innovation

At HSA, we constantly review and update our regulatory frameworks and regulations so that they stay relevant and forward-looking.



#### **Updating Regulations on Chinese Proprietary Medicines (CPM)**

Corydalis Yanhusuo and CPM containing the naturally occurring substance tetrahydropalmatine (THP) have been disallowed for sale since 1995 due to overseas reports that they could cause liver toxicity when consumed.

In June 2018, the ban on THP products was lifted following a review conducted by HSA and its expert panel.

Results of the review indicated that THP-containing herbs posed no major safety concerns when used appropriately.

Nevertheless, to ensure the safety of consumers, HSA will continue to monitor the safety and quality of CPM that contain these herbs by implementing cautionary labelling and dosing restrictions on these products.



#### **Dengvaxia Update**

When HSA approved the world's first dengue vaccine application in 2016, it was recommended that sero-testing be done to determine whether a patient has had a past dengue infection before vaccination. This was based on HSA's assessment that there is a postulated risk of a higher incidence of severe dengue following vaccination in individuals who do not have previous dengue infection.

One year post-approval, new data from Sanofi confirmed HSA's earlier assessment that there was indeed an increased risk of severe dengue in individuals without prior dengue exposure. The recommendation for sero-testing, which was previously only in place in Singapore, has been adopted by other countries where the vaccine is approved.

#### **Adding Clarity to Telehealth Product Regulations**

In September 2017, HSA published guidelines to provide clarity on the types of telehealth products that are regulated as medical devices. These guidelines will greatly facilitate the development of new and innovative high quality telehealth products, whilst safeguarding public health.

#### **Notable Medical Products Approvals**

#### 1. Zika Diagnostic Tests

HSA has approved three diagnostic tests which will assist healthcare providers in managing the infection and spread of the Zika virus. Applications for these tests were first received in 2016 and 2017, when information on the epidemic was still maturing.

#### 2. Glucose Monitoring System

In 2017, HSA approved a first-in-class wearable flash glucose monitoring system for the management of diabetes mellitus.

#### **Supporting the Development of New Medical Devices**

Two new schemes were introduced in 2017 to support the development and early market entry of novel medical devices:

#### 1. Priority Review Scheme

Implemented in August 2017, this new scheme allows for faster registration of new medical devices to facilitate timely access to safe and quality medical devices in Singapore. As of December 2017, HSA received a total of six applications.

#### 2. Pre-market Consultation Scheme

Implemented in October 2017, this scheme allows stakeholders to seek early regulatory advice from HSA during the process of device development up to the pre-registration phase. As of December 2017, HSA received a total of seven consultation requests.



# Streamlining Our Work Processes

Over the year-in-review, we made the following changes to our work processes to facilitate the regulatory filing process for our stakeholders.

#### **Simplification of Cosmetic Products Notification**

We simplified the online notification form for cosmetic products to only require essential information needed for product traceability purposes. Other information relating to product supply and technical aspects could be submitted later, where necessary.



Self-Help Tool

#### **Streamlined Process for Transfer of Licensed Dealer**

A streamlined process was introduced to facilitate the transfer of CPM ownership from one licensed dealer to another. For products where there is no change of the manufacturer, dealers now only need to submit the list of products to be transferred, instead of having to submit a new listing application for each affected product.

#### **Easier Search for Class A Medical Devices (MD)**

An online searchable database has been set up on HSA's website to capture all non-sterile Class A MDs that are supplied by licensed importers and manufacturers in Singapore. This database allows consumers to search for licensed importers and manufacturers, as well as their associated Class A MDs.



An interactive MD dealer online enquiry tool was launched as a trial project to help enquirers search for MD dealers, and locate the appropriate licences and regulatory requirements of different MDs. This self-help tool provides enquirers with quick and timely responses, while reducing the number of enquiries.

**Increased Efficiency through** 

#### **Facilitating the Filing** of Therapeutic Product **Dossiers**

A self-checking screening form was introduced to facilitate the applicants' compilation and filing of their product registration dossiers. In addition, the screening process was further streamlined through capping the number of rounds of screening queries at HSA's end and giving applicants a set period of time to respond to inquiries.



#### **Review of Processes to Reduce Investigation Time**

To enhance and optimise the efficiency of investigations into various regulatory contraventions, the Lean Six Sigma team conducted a thorough data analysis and studied measures to reduce the median time taken to resolve feedback and complaints by 20%. We have adopted some of the measures, which would enhance timely resolution of complaints.

#### **Faster Regulatory Approval** of Changes to Registered **Therapeutic Products**

HSA successfully implemented a new filing route - MIV-1 (minor variation-1) verification application route - for drug companies to file post-approval variation applications for registered therapeutic products. This initiative would improve process efficiency through greater leveraging of reference agencies' assessments and minimise duplication of effort. The processing timeline for these variation applications was reduced from 120 to 90 working days.



# New and Developing Partnerships

To keep up-to-date with the latest developments in regulatory sciences, we continued to forge and strengthen partnerships with other governments and industry players.

#### **International Harmonisation Efforts**

HSA is a member of the Management Committee of the International Medical Device Regulators Forum (IMDRF) - a voluntary group of regulators from around the world who have come together to facilitate international medical device regulatory harmonisation and convergence. We are involved in the following harmonisation workgroups:

#### **Patient-Specific**

Developing guidance to facilitate progress of novel technology and clinical approach towards patientspecific clinical strategies



#### **Good Regulatory Review Practices**

Reviewing the essential principles for safety and performance of medical devices cornerstone quidelines



#### **Standards**

Developing guidance and strategies on improving international standards for regulatory purposes



#### **Regulated Product Submission**

Developing guidelines, such as common data elements from device life cycle, for an electronic submission system



#### **Supporting the Drive Towards Standardisation**

In April 2017, HSA was appointed Deputy Chair of the Biomedical and Health Standards Committee. Together with other representatives from the public and private sectors, we will be assisting the Singapore Standards Council in identifying, developing and promoting critical standards for the biomedical and healthcare clusters in Singapore.

#### Adverse Events (AE)

Developing guidance on AE terminology and system to enhance AE management systems



#### **Unique Device Identifier (UDI)**

Developing application guidance to facilitate UDI implementation globally



#### **Real World Evidence**

Developing guidance on important considerations for real world data gathering for use in supporting regulatory functions



#### **Partnership Development Highlights** Generic Medicines Work Sharing Trial

In March and April 2017, the Australia-Canada-Singapore-Switzerland (ACSS) Generic Medicines Work Sharing Trial (GMWST) completed the review of the first generic application via a work-sharing process.

In December 2017, HSA published the GMWST Expression of Interest package on its website to invite new submissions to the trial.

#### MOU to Formalise Programme for Pharmacy Students

In April 2017, HSA signed a Memorandum of Understanding (MOU) with the National University of Singapore (NUS) to formalise the Pre-Employment Clinical Training (PECT) programme for pharmacy students' professional training in indirect patient care.

#### Appointment of First Pharmaceutical Inspection Co-operation Scheme (PIC/S) Chairman from Asia

In September 2017, Mr Boon Meow Hoe from HSA became the first (PIC/S) Chairman to be elected from Asia. He will serve from 1 January 2018 to 31 December 2019.



#### Accepted as Regulatory Member

In November 2017, HSA was accepted as a regulatory member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). We now join the ranks of established regulators such as US Food and Drug Administration (FDA) and EU European Medicines Agency (EMA) to influence decisionmaking in pharmaceutical product development and registration.

#### Improving Inspection Convergence

As Chair of the ASEAN Joint Sectoral Committee on GMP inspection, HSA has actively driven the pharmaceutical inspection convergence between Korea Ministry of Food and Drug Safety (MFDS) and ASEAN. Korea MFDS will continue to organise the annual Korea-ASEAN Good Manufacturing Practice (GMP) Conference as well as the on-going Korea-ASEAN Pharmaceutical Inspectors Training Program, These two activities are expected to improve inspection convergence between ASEAN and Korea MFDS.

#### Recognised as Comparable Overseas Regulator (COR)

In January 2018, HSA was recognised as a COR by the Therapeutic Goods Administration (TGA), Australia. This is part of TGA's new shortened process for the evaluation of prescription medicines by leveraging assessments by COR partners that have been selected for their scientific robustness and evaluation methodology.

# Local Outreach Programmes

Throughout the year-in-review, we reached out to local healthcare professionals and the public to strengthen our partnerships and heighten public awareness.



#### **Health Products Regulatory Conference 2017**

The role of HSA is increasingly evolving from that of a gatekeeper to becoming an "enabler" for innovation. Engagement and partnerships with stakeholders enable us to share our regulatory approaches and philosophy as well as understand the perspectives of the industry.

The Health Products Regulatory Conference was held in May 2017 with the theme, "Enabling innovations through collaborations in advancing healthcare" at SingHealth Academia. HSA, together with Duke-NUS Centre of Regulatory Excellence (CoRE) jointly organised the event which was attended by more than 370 participants from the public sector, private sector and academia.

Through this conference, we successfully brought together various experts, stakeholders and collaborators from numerous fields to share their expertise and perspectives on regulation and advances in the fields of therapeutic products, advanced therapies and medical devices. Participants also benefitted from getting the latest updates on developments in Singapore's biomedical industry.



#### Focus Group Discussions on Cell, Tissue and Gene Therapy **Products (CTGTP)**

From April to September 2017, we organised 10 focus group discussions, which were attended by more than 150 people representing the different sectors dealing with CTGTP. They include the healthcare institutions, professional associations, government agencies, tertiary institutions, research institutions, stakeholders from pharmaceuticals, biotech and medical device industries. The objective was to seek feedback on the proposed regulatory framework for CTGTP under the Health Products Act.

#### **Trade Engagement Sessions** on Raising of the Minimum Legal Age (MLA) for Tobacco **Products**

Over three days in June and July 2017, HSA, in collaboration with the Ministry of Health (MOH) and Health Promotion Board (HPB), held engagement sessions with tobacco retailers and key trade associations.

The aim of these sessions was to explain the policy and implementation of raising the MLA for the sale, purchase, use and possession of tobacco products from 18 to 21 years old, as well as to gather feedback from our stakeholders.



#### **Dialogue Sessions with Medical Device Associations**

In February 2018, the Singapore Manufacturing Federation's Medical Technology Industry Group (SMF-MTIG) and the Asia Pacific Medical Technology Association (APACMed) held a dialogue session with HSA to discuss challenges and explore potential solutions. Topics discussed include pre-market and Change Notification processes, proposed regulatory amendments, and the developments in ASEAN and the International Medical Device Regulators Forum (IMDRF).

#### **Pharmacogenomics Workshop - Clinical Implementation Strategies & Pharmacists' Roles**

In February 2018, HSA shared our clinical implementation strategies and public health impact with healthcare professionals and industry at the Pharmacogenomics Workshop organised by the Department of Pharmacy, National University of Singapore.

#### **Creating Awareness** for Pharmacovigilance and Adverse Event (AE) Reporting

Over the past year, we organised various awareness programmes covering topics such as pharmacovigilance, risk communication, adverse event reporting and dangers of illegal health products. These programmes were targeted at undergraduates, healthcare professionals and the public.

In addition, we also developed an educational video for healthcare professionals on how to assess and report adverse events. This video was published on our website as well as video-sharing sites in March 2018.



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#### **Educating the Public on Adverse Drug Reactions and Dangers** of Purchasing Health Products from Dubious Websites

A consumer guide on the risk of allopurinol was published in October 2017 to raise public awareness about rare but potentially lifethreatening adverse drug reactions.

We also collaborated with final-year Singapore Polytechnic students to develop ideas on how best to educate young people on the dangers of buying health products from dubious websites.

## Keeping Alert

We keep a watchful eye on safety issues and breaches that can jeopardise the health and safety of patients and consumers.

#### **Maintaining Close Communications with Healthcare Professionals**



#### **Surveillance of Local Product Defects**

12% 105 48% therapeutic products and traditional medicine defects 8% were reported by companies. They consist of: Quality-related issues Labelling and product packaging issues Manufacturing

Subsequent regulatory actions were taken. These include:



deficiency issues

Other issues



labelling and packaging corrections

The other cases of product defects were evaluated to ensure that appropriate corrective and preventive actions were taken by their companies to mitigate impact on the safety and quality of future batches.



35

Dear Healthcare Professional Letter (DHCPL) was issued



Company DHCPLs were reviewed



Product safety press advisories were issued



Safety updates were published on the HSA website



HSA adverse drug reactions news bulletins were disseminated to all registered healthcare professionals

#### **Local Adverse Event (AE) Reports**

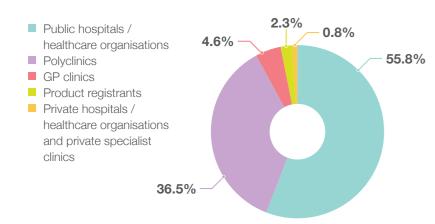
HSA receives AE reports from healthcare professionals and companies as part of our post-marketing surveillance programme. These reports are reviewed and closely monitored to ensure that drug safety signals are detected in a timely manner.

HSA also partners with the KK Women's and Children's Hospital (KKH) to carry out active surveillance of AEs after vaccination in children to ensure the benefit/risk profile of the vaccines remains favourable.

#### **Health Products**

There were **22,404** AE reports related to health products, of which **96.5%** were associated with pharmaceutical drugs.

These reports were contributed by:





### Complementary Health Products (CHP)

There were 149
AE reports associated with CHPs



were associated with adulterated products

## Actions taken to remind consumers to be cautious



Press releases were issued to the media



MediaCorp News carried an in-depth feature story, advising the public not to buy health products from unfamiliar sources

#### **Product Risk Management**

Safety reviews were conducted to ensure that the benefits for therapeutic products outweigh the risks throughout the product's life cycle. Safety reviews were also conducted to assess the risk of adulterated health products detected post-market.



risk management plans were reviewed



benefit-risk assessments were tabled for Product Vigilance Advisory Committee discussion



benefit-risk assessments were conducted

#### **Product Recalls**

In FY17/18, there were 190 medical device recalls overseen by HSA and performed by medical device product owners to address device quality, safety or performance related issues. HSA worked with the respective product owners to ensure that the appropriate actions were completed. This included three consumer-level recalls for peninjectors, contact lens and multi-purpose contact lens solution.



# Enforcement Operations

Leveraging our scientific expertise, we worked with other enforcement agencies in various joint operations to clamp down on illegal activities relating to health and tobacco products.

#### **Dealing with Tobacco-related Infringements**

In support of the national tobacco control policy against illegal sales of tobacco products to under-18s, the following actions were taken:





- A total of 27 tobacco retail licences were suspended for 6 months
- 1 tobacco retail licence was revoked



- A 32-year-old male was prosecuted for illegally importing close to **5,000** sachets of chewing tobacco
- The seized tobacco had an estimated street value of around \$9,200
- Sentenced to 4 weeks' imprisonment



- An individual and his company was convicted of selling shisha on 7 occasions without a valid tobacco retail licence
- He was fined a total of \$12,300

#### **Prohibition on Display of Tobacco Products**

The Point-of-Sale (POS) display ban on tobacco came into effect in August 2017. All tobacco retailers are required to keep their tobacco covered or in drawers. As of April 2018, HSA has not come across any non-compliant retailers during our surveillance activities.

#### **Cracking Down on Illegal Health Products**

#### Cough Syrup and Sleeping Tablets

We continued our crackdown on the illegal supply of codeine syrup and sleeping tablets.





Total number of seizures:



**118,000** units of assorted medicines and 213 litres of cough syrup



Street value \$181,000



Number of suspects investigated 24

#### Operation Pangea X

In September 2017, HSA participated in Operation Pangea - an Internet-based enforcement operation of illegal health products, coordinated by INTERPOL.



A total of 197 participating agencies from **123** countries worldwide were involved

This was the 10<sup>th</sup> time HSA participated



More than **39,000** health products such as anabolic steroids and sleeping pills were seized



Worth an approximate street value of **\$133,000** 

> 2<sup>nd</sup> largest haul since the operation began in 2008

#### **Getting Tough on Sexual Enhancement** Drugs (SEDs) in Geylang

#### Largest Seizure of SEDs in 5 Years

Acting on an alert from Immigration & Checkpoints Authority (ICA) about the import of illegal SEDs, HSA conducted a raid at a private apartment in Geylang. About 300,000 units of assorted SEDs, worth more than \$700,000 were seized.



Number of crackdown operations against SED supply 357



Units of SEDs seized 316,000



Street value \$790,000

For its contribution, HSA was awarded the Ministry of Home Affairs Ops Excellence Award in September 2017.

## Knowledge Exchange

We collaborated with partners and stakeholders, both locally and abroad, to raise global standards in the regulation of health products.

#### **Guest Speakers to HSA**

## EMA and PMDA's Experiences in Implementing CTGTP Regulations

May 2017

Guests: Dr Paula Salmikangas, from Finnish Medicines Agency, Finland representing European Medicines Agency (EMA), and Dr Yoshiaki Maruyama, representing Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Key Topics Covered:

Experiences and challenges in the implementation of CTGTP regulations in their respective jurisdictions



#### Biomedical Informatics Sessions

May 2017

Guest: Professor Robert Carroll,
Department of Biomedical
Informatics at Vanderbilt
University School of Medicine

Key Topics Covered:

Overview of the eMERGE Network, methodologies for detecting and characterising potential adverse events from electronic medical records, as well as standardising different clinical terminologies and mapping tools



#### Regulatory Sciences and Strategy for CTGTP

November 2017

Guest: Dr Patrick Celis, Head of the Committee for Advanced Therapies Secretariat at EMA

Key Topics Covered:

Insights from the EMA's approach and the challenges faced in implementing Advanced Therapy Medicinal Products regulations in Europe

#### Maximising the Potential of Electronic Medical Records January 2018

Guests: Professor Park Rae Woong, Dr You Seng Chan and Dr Shin Dahye, Department of Biomedical Informatics at Ajou University School of Medicine, South Korea

Key Topics Covered:

Overview of the Korean healthcare and electronic health record (EHR) system, and Korea's experience in converting EHRs into the common data model



#### **Hosting Overseas Guests**

### Visit by Food and Drug Administration Philippines June 2017

The Department of Health, Food and Drug Administration (FDA), Philippines, with representatives from the World Health Organization (WHO) Regional Office of Philippines, The Union and Bureau of International Health Cooperation visited HSA to study our tobacco and cosmetic regulatory functions. The delegation was led by Deputy Director General, Attorney Ronald de Veyra.



### Visit by Saudi Food and Drug Authority February 2018

Delegates made a study visit to HSA to better understand the role of HSA and the regulatory controls for health products and tobacco products. The seven delegates were led by their Chief Executive Officer, Dr Hisham Aliadhev.

#### Nepal Study Visit on Tobacco Control Measures in Singapore July 2017

14 delegates led by Director General, Department of Health Services, Dr Rajendra Pant visited HSA to learn about the tobacco control policies in Singapore.

## Study Visit by China Delegates on Regulatory Controls for Health Products September 2017

Delegates from Changsha visited HSA to better understand the regulatory controls for health products and tobacco products.

#### **International Events and Alliances**

#### APEC RHSC Pilot CoRE Advanced Therapies Workshop July 2017



The Asia Pacific Economic Cooperation (APEC) Life Sciences Innovation Forum Regulatory Harmonization Steering Committee (RHSC), the APEC Harmonization Center and the Duke-NUS Centre of Regulatory Excellence (Duke-NUS CoRE) organised an Advanced Therapies Workshop to provide a platform for international regulators, industry and academia to share their challenges in regulating CTGTP. HSA was invited as the programme committee member and speaker for the workshop.

#### APEC Pharmacovigilance Centre of Excellence Pilot Program September 2017

Korea

We were invited to speak at the APEC Pharmacovigilance Centre of Excellence Pilot Program on Effective Risk Communications, and the Singapore perspective on Partnership in Pharmacovigilance.

## **ISPE Singapore Conference** 2017

August 2017

HSA participated in the Regulators Panel Discussion at the International Society for Pharmaceutical Engineering (ISPE) Singapore Conference 2017. Panellists included regulators and experts from the UK Medicines and Healthcare Products Regulatory Agency (MHRA), the European Medicines Agency (EMA), and the Thailand Food and Drugs Administration (Thai FDA), ASEAN.

#### 13th ACSS Work Group Meeting October 2017 Brasilia, Brazil



HSA chaired the 13th Australia-Canada-Singapore-Switzerland (ACSS) Generic Medicines Working Group Meeting, which discussed the next steps to advance and promote the Generic Medicines Work Sharing Trial (GMWST) to encourage more submissions.

## Asia Pacific Cities Alliance for Tobacco Control September 2017

The International Union Against Tuberculosis and Lung Disease invited HSA to share about our experience in enforcing tobacco control at the Asia Pacific Cities Alliance for Tobacco Control (AP-CAT) Meeting. Participating countries included Malaysia, Indonesia, Laos, Vietnam, Nepal, Philippines, Cambodia and Timor Leste.

## 15<sup>th</sup> FHH Standing Committee Meeting

October 2017 Tokyo, Japan

At the 15<sup>th</sup> Standing Committee Meeting, Forum for the Harmonization of Herbal Medicines (FHH) members discussed the latest developments on herbal medicines covering areas of technical standards development, regulation and pharmacovigilance.

#### Featured in Regulatory Science 2017 Edition November 2017

HSA's experience and opinion in pharmacogenomics and regulatory science were featured in the November 2017 edition of Regulatory Science issued by the Netherlands Medicines Evaluation Board (MEB) at www.regulatoryscience.nl.

#### **ASEAN Regional Initiatives**

#### 1st ASEAN Medical Device Technical Committee (AMDTC) Meeting April 2017

Siem Reap, Cambodia

At the first AMDTC meeting, important areas such as risk classification system and grouping of medical devices for product registration were discussed.

#### ASEAN Cosmetic Committee (ACC) Meetings May 2017 Cambodia

At the 26<sup>th</sup> ACC and ASEAN Cosmetic Scientific Body (ACSB) meetings, officers from the European Commission, Brussels, as well as experts from the cosmetics industry shared about EU cosmetics regulation and the experience of implementing the regulation.

#### May 2017 Indonesia

At the 27<sup>th</sup> ACC and ACSB meetings, a Q&A document was finalised to provide clarity on the ASEAN Cosmetic Directive (ACD), and to ensure that implementation is in line with technical requirements and the intended philosophy.

#### ASEAN Traditional Medicines & Health Supplements Product Working Group (TMHSPWG) Training

April 2017 Bangkok, Thailand

HSA participated in training on the ASEAN guiding principles on safety substantiation on traditional medicines and health supplements for regulators and small and medium-scale enterprises.

### 27<sup>th</sup> and 28<sup>th</sup> ASEAN TMHSPWG Meetings

May 2017, Vietnam October 2017, Brunei Darussalam

Matters related to the finalisation of the draft ASEAN Agreement on Regulatory Framework for Traditional Medicines and ASEAN Agreement on Regulatory Framework for Health Supplements were discussed.

#### Train-the-Trainers Sessions for ASEAN Guidelines on TMHS May 2017

HSA provided training at the "Train the Trainers" sessions for Good Manufacturing Practice (GMP) inspectors from ASEAN Regulatory Authorities and members of the ASEAN industry associations.

# 24th ASEAN Pharmaceutical Product Working Group (PPWG) Meeting July 2017 Thailand

During the meeting, current international developments in GMP as well as requirements for product quality, including variations, and requirements for biological products were reviewed.

Prior to the Meeting, the 1st ASEAN Educational Workshop was conducted by GaBi (Generics and Biosimilars Initiative) on the Regulation and Approval of Similar Biotherapeutic Products, including Biosimilars.

## **DUKE-NUS CoRE Regional Training Workshop on Pharmacovigilance**

August 2017
Lao PDR and Cambodia

HSA participated as a trainer in the inaugural in-country CoRE Regional Training workshop on Pharmacovigilance.



#### 5<sup>th</sup> ASEAN Medical Device Committee (AMDC) Meeting October 2017 Surabaya, Indonesia

At the 5<sup>th</sup> AMDC meeting, the committee oversaw AMDTC's discussion topics of risk classification and borderline products, and looked into interpretations on ASEAN Agreement on Medical Device Directive (AMDD) Labelling Requirements. Approaches to the Guidelines on Post Market Surveillance were also finalised.

# New Awards and Accreditations

We collaborated with partners and stakeholders, both locally and abroad, to raise global standards in the regulation of health products.

#### **Pro-enterprise Ranking Survey 2017 Results**

The Pro-enterprise Ranking (PER) survey is an annual survey conducted by the Ministry of Trade and Industry on business customers of government regulatory agencies. In the 2017 survey, we were awarded "Top 3 Most Improved Agencies" for significantly improving our rankings from 19<sup>th</sup> in the previous year to 10<sup>th</sup>.

#### Re-assessment for PIC/S membership

In September 2017, HSA successfully completed the re-assessment for its Pharmaceutical Inspection Co-operation Scheme (PIC/S) Participating Authority (PA) membership. The re-assessment team, comprising senior Good Manufacturing Practice (GMP) inspectors from France, Australia, New Zealand and Malaysia, concluded that HSA was compliant with the PIC/S GMP regulatory compliance scheme.

### ISO Surveillance Audit and Certifications

In October 2017, HSA's Audit and Licensing Division (ALD) successfully passed the ISO 9001:2008 surveillance audit with zero non-compliance. ALD's next goal will be working towards achieving the ISO 9001:2015 certification. This transition journey will include internal technical training, and review of Quality Manuals, SOPs and processes.

In February 2018, the postmarket cluster branches, namely Enforcement Branch, Tobacco Regulation Branch and Vigilance & Compliance Branch, successfully obtained renewal of the ISO 9001:2015 certification.





# Enhancing the Blood Donation Experience

Through educating blood donors and by improving their donation experiences, we strive to turn onetime donors into repeat donors.



#### **Using IT to Improve Donor Experience at Our Blood Bank**

From September 2017 to March 2018, we implemented the 3e (e-Registration, e-Rebooking and e-Feedback) project to improve the experiences of our blood donors.

With these new features, we are able to provide a faster and more pleasant donation experience. Besides raising our productivity, they also enable us to obtain valuable donor feedback to improve our services.

#### What's new:

- Donors can update their particulars and print questionnaires at their
- Ability to check their donation records
- Donors can book new appointments and give feedback readily
- Group booking function



#### **Increased Engagement with** the Public

Donors can now check their donation milestones on the interactive wall at our satellite blood banks. Members of the public can also tap on the interactive panels to get useful information about blood donations.

#### **Revised Criterion for Male Blood Donors**

Sufficient iron stores in blood donors' body would help regenerate red blood cells removed during blood donation. In response to the growing concern that regular male donors were at risk of depleting their body iron stores and developing anaemia, HSA raised the minimum predonation haemoglobin (Hb) criterion to 13.0g/dL in January 2018, in order to protect their health. The change does not affect female donors as the current Hb criteria of 12.5g/dl for females is aligned with international practices and guidelines in blood banking.



To minimise the deferral rate of our regular male donors, the following measures were adopted:

- Education through pamphlets and posters at donation venues on how to improve body iron stores through food intake
- The course of oral iron supplements provided was increased from 10 tablets to 20 tablets
- Regular male donors were notified of this change through postal mail; an advisory and FAQs were also posted on the HSA website

#### 14th World Blood Donor Day

The 14th World Blood Donor Day was held at the Singapore Sports Hub in June 2017 to recognise the contributions of dedicated blood donors and to raise awareness on the need for regular blood donations. The event was graced by Minister for Health Mr Gan Kim Yong as the Guest of Honour for the morning ceremony, and Member of Parliament for Mountbatten, Mr Lim Biow Chuan, as the Special Guest for the afternoon ceremony.





people attended the event



13 donors received the Medal

for Life, 24 received the Champion of Champions award

In total, 1,262 donors were

# Safeguarding Our Blood Supply

We continually fine-tune our processes to ensure that the blood supply for our patients is maintained at the highest possible standards of safety.

#### **Reviewing Our Infectious Diseases Blood Screening Tests**

As dengue is endemic to Singapore and there were also reports that immunity-suppressed recipients of blood infected with Hepatitis E virus (HEV) were at risk of developing chronic liver diseases, we have decided to perform a prevalence study for these two infections in our local donor pool. Both studies employ Nucleic Acid Testing (NAT) to help us assess the need to introduce dengue and HEV screening tests for blood donations.

#### **Reducing the Risk of Transfusion-related Complications**

To reduce the risk of transfusion-related acute lung injury (TRALI), HSA has made the move to use male-only plasma products for transfusion. This is because studies have shown that the risk of TRALI is more than halved when the plasma supply is switched to a predominantly maledonor source, possibly because male donors have a lower incidence of anti-human leukocyte antigen (HLA) antibodies than female donors.

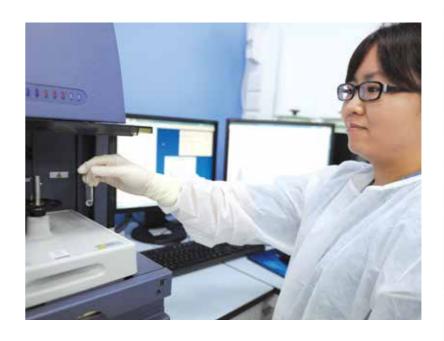


### Minimising Errors from Manual Entry of Pre-transfusion Test

To improve work-flow processes and minimise transcription errors from manual entry of data, we have implemented a system that automatically transmits results from the laboratory testing equipment into the computer database system.

#### Safeguarding the Quality of Cell Therapy Facility (CTF) Products

We have expanded the capabilities of our transplant support lab to perform immunophenotyping tests. This test, which was previously done externally, is required before CTF products can be used on patients. Through this initiative, we are now able to meet all the necessary testing requirements within a shorter period of time, which in turn reduces the time for clinicians to make patient management decisions.



# Emergency Preparedness at the National Level

In today's increasingly uncertain environment, it is important to always be prepared for the unexpected. This is why we put into place policies and safety checks, as well as run emergency drills to ensure emergency preparedness is maintained at the highest level.



#### **Evaluating Major Threats to Blood Supply**

In April 2017, HSA officially implemented a Risk-Based Decision Making Framework, modelled after the one developed by the international Alliance of Blood Operators. This structured and comprehensive framework helps us to critically evaluate major threats to blood safety and adequacy in Singapore and select the most appropriate mitigating measure, proportionate to the risk level. The main principles of the framework are:

- Optimising the safety of blood supply within reasonable standards
- Balancing risks against benefits
- Allocating resources in proportion to the risk and potential opportunity cost
- Considering socio-economic and ethical factors that may affect decisions.



In April 2017, we also held our first-ever emergency blood exercise involving all the public hospitals (PHs) in Singapore. This exercise tested our readiness in ensuring timely blood supply during a civil emergency, where there may be many casualties requiring intensive blood support.

The successful exercise yielded many useful learning points for both the PHs and HSA. Through the lessons learnt, we were able to update our respective Standard Operating Procedures to enhance emergency preparedness at the national healthcare level.

## Investing in Our People

A critical part of the mission of keeping blood supply safe is our people. We invest in our staff at HSA by providing continuous learning and career opportunities to help them reach their fullest potential.

#### **Expansion of Nurses' Role**

Nurses currently play a key role in blood collection, managing daily blood bank operations, as well as ensuring donors' post-donation well-being. HSA aims to further expand their role through training and the development of a more streamlined career progression. To prepare selected nurses to take on the role of Clinical Nurse Leaders, they were:

- Trained to handle predonation screening, manage donors' adverse events, and counsel those with low haemoglobin levels
- Sent for a three-day theory and clinical attachment at the Emergency Department of Ng Teng Fong General Hospital to learn how to triage patients and manage clinical events
- Given scholarships to pursue the Advanced Diploma in Medical-Surgical Nursing





#### **Applying Lean Six Sigma for Continuous Improvement**

To raise productivity, we sent 14 staff in 2017 on an Operations Management Innovation (OMNI-LITE) course, where they were exposed to business strategy integration, operations management and systematic productivity improvement concepts. They also picked up skills in implementing Lean Six Sigma methodologies and solving real-life problems.



#### **Continuous Improvement Projects**

1. Redesigning Manpower Allocation in the Blood **Donation Room** 



**Objectives** 

Improve staff productivity by 20%

Reduce annual complaint rate in the donation room to zero

Improve staff working attitudes using pre- and posttrial survey trial survey comparisons on 35 staff



**Improvement Steps** 

Redesign the work flow to cut waste and increase staff productivity

Reduce unnecessary walking and level out the workload

Empower staff with necessary skills and capabilities in phlebotomy

Conduct pre- and post-trial survey comparisons on **35** staff



Results

Achieved higher efficiency and effectiveness in improving staff morale

OMNI method to be applied in future improvement projects



2. Streamlining Inventory **Management Processes** 



**Objectives** 



**Improvement Steps** 

Ensure inventory status in the lab is accurately maintained

Reduce repetitive recording of test kits or reagents' information

Ensure effective communication

Improve efficiency and increase productivity



Reduce the number of manual entry forms

Make reagent information readily available in database

Create visual board where delivery information of reagents is readily available



Results

Average turnaround time spent on managing inventory of lab supplies improved by

**34%** from 5.4 minutes to 3.6 minutes per reagent

#### **Training Courses**

Throughout the year, some of our staff attended the following courses:

- Monocyte Monolayer Assay Training Philadelphia, USA Assist physicians to better decide on transfusion risks when compatible blood is unavailable
- CliniMACS Prodigy T-Cell-Transduction User Training Germany CliniMACS Prodigy is an automated system for the generation of Chimeric Antigen Receptor T (CAR-T) cells

## Knowledge Sharing with Local and Overseas Counterparts

We believe that through knowledge sharing, we are doing our part to help raise the standard of blood services globally. Throughout the year, we conducted training courses and hosted overseas visitors.

#### May 2017

Hosted a clinical fellow in Bone Marrow Transplant from Mumbai, India, who came to learn about the basic methodology of HLA tests and how to search for unrelated donors for transplantation.

#### June 2017

Hosted a study attachment for eight delegates from the Thai Red Cross Society, Thailand, on Information Management System and Smart Applications.



#### September 2017

Hosted a team from National Blood Centre, Malaysia led by its Director Dr Noryati Bte Abu Amin. The objective of their visit was to learn more about the areas of donor management, blood collection, quality management and IT.



#### September 2017

Conducted a blood bank tour for a Regional Medical Laboratory Scientist from the Embassy of the United States of America. He came to learn more about transfusion medicine practices in Singapore.

#### September 2017

Hosted a study visit for two senior nursing staff from the Hong Kong Red Cross Blood Transfusion Service. Their objective was to learn ways in which they could strengthen the organisation and management of their national blood programme, in order to improve the safety and availability of blood supply in Hong Kong.

#### January 2018

Hosted a study visit for an overseas delegation from Zhejiang Blood Centre in China. The delegation, which was led by their deputy director, was interested in blood donation, donor recruitment, quality management, blood donation testing and blood service management.

#### March 2018

Singapore Polytechnic and HSA signed a training collaboration agreement to equip medical laboratory technologists with immunohaematology knowledge.





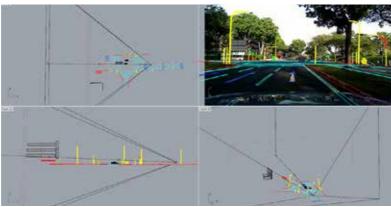
## Building Capabilities

We are committed to continually enhancing our expertise to better serve the nation.

### **Using 3D Technology to Enhance Efficiency of Traffic Investigations**

Our Traffic Accident Reconstruction team developed a new "camera matching" method to examine accident sites. This method allows forensic scientists to determine the position of a car or pedestrian in a video using 3D laser scans of the accident site.

The technology can be applied to cases involving the calculation of the speed of vehicles, as well as those involving the determination of a driver's field of view. It also helps minimise the need for extended road closures.





## New Image Analysis Technique for Forensic Document Examination

We adopted a new image analysis technique for comparing paper products based on repetitive patterns created during the paper manufacturing and handling process. Using a technique called Fast Fourier Transform, these repetitive patterns are converted into spectrums, which can then be compared and analysed.

In the area of ink analysis, differentiation of ink can now be done using the digital images of questioned handwritten entries. The technique is useful in detecting altered entries on documents such as cheques and in enhancing faded, erased and obliterated entries.

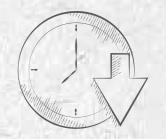


This year, the Pharmaceutical Division completed the implementation of LabX 2017 software for the measurement of weights, and its integration with the titration analysis to enhance the efficiency and traceability of our daily work processes.

Through this digitalisation process, data is now automatically stored on the server and can be conveniently retrieved on demand, doing away with the need for hard copy printouts. This digitalisation effort also paves the way for future digitisation of laboratory records by enabling the auto-population of electronic data.

#### **Automation of Opiate Testing in Urine**

Following the successful implementation of full automation for tests involving amphetamines and ketamine, we are now also able to fully automate the process for testing of monoacetylmorphine (MAM) in urine. This new method, implemented in February 2018, utilises a fully automated robotic system to perform sample preparation and instrumental analysis, doing away with the need for further human intervention after initial sample loading.



From 2 days to 3 hours – the new time it takes to process a batch of 20 urine samples for drug testing



### **DNA** Analysis of Urine Samples

Urine samples are commonly analysed in cases involving suspected illicit drug consumption. In certain circumstances, DNA analysis of urine samples can be useful when there are allegations of sample mishandling as it allows for the donor's identity to be verified.

We have developed a new method that enables us to analyse DNA from small volumes of urine samples. With this, HSA can assist law enforcement agencies in resolving allegations of urine sample mishandling.

#### **Targeting the Y Chromosome to Solve Sexual Assault Cases**

One of the problems faced in analysing exhibits from female victims in sexual assault cases is that the male perpetrator's DNA is often masked by the victim's DNA. To overcome this obstacle, we developed an analytical method to target Y chromosomes that are only found in males. This allows for specific detection of the male perpetrator and can help in generating potential leads for law enforcement.



#### **Ensuring Safer Food with New Testing Methods**

Four new analytical methods were developed specially for the Agri-Food & Veterinary Authority of Singapore (AVA). These new methods enable the testing of new and emerging harmful substances present in foodstuff including natural toxins such as tropane alkaloids and amatoxins.

#### **Enhanced Testing for UV Filters in Sunscreen**

A new multi-screening method using reversed-phase high-performance liquid chromatography (HPLC) on 10 UV filters in cosmetic products in Singapore has been successfully validated. This method will be used to test various sunscreen products for compliance with safety requirements.

# Fine-tuning Work Processes

In the pursuit of greater efficiency, we are always looking out for new technologies that can improve our workflow and processes.

### Enhanced Workflow to Identify New Psychoactive Substances (NPS)

The constantly evolving chemical structures of NPS, which are commonly used as drugs of abuse, are posing analytical challenges for laboratories around the world. We have therefore come up with a comprehensive analytical workflow that combines the use of two or more techniques including gas chromatography mass spectrometry, liquid chromatography with photodiode array detector, and nuclear magnetic resonance (NMR) to help us differentiate between close structural analogues, and to accurately identify NPS.

#### **Faster and More Comprehensive Toxicology Screening**

To increase work efficiency of toxicology drug screening, we implemented and customised a commercial liquid chromatography ion-trap mass spectrometry (LC-MSn) solution known as Toxtyper in April 2017. Enhancements include the expansion of the default library, as well as customising the analytical report to automate and simplify data interpretation and performance checks.



Expanded the default library from **900** to **1,200** with compounds relevant to Southeast Asia, including NPS



**Higher sensitivity** of the instrument allows us to detect more drugs, including plant poisons and previously undetectable synthetic cannabinoids



Processing time has now been cut by **12 hours** for a batch of 30 samples



In 2017, we identified a total of NPS

#### **Automating the Process for Dissolution of Drug Samples**

To improve the efficiency of the dissolution of illicit drug samples for quantitation, we implemented an automated syringe dispenser for the addition of suitable amounts of solvent.



#### Reducing the Time Needed for Analysing Cannabis Samples

A new method which combines the use of a weighing balance with a heating element has drastically reduced the time needed to determine moisture content in cannabis exhibits for major cases. Previously, this used to take weeks using the conventional oven drying method. This step now takes less than an hour, reducing the overall time needed to analyse cannabis exhibits.



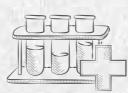
With the implementation of the automatic syringe dispenser:



Time-consuming filtration step is **removed** 



Accuracy of results is **improved** 



Sample throughput is **boosted** 



Total efficiency is increased **5-fold** 

#### **Faster Screening of Illicit Drugs**

A handheld Fourier Transform Infra-Red (FTIR) Detector has been introduced to facilitate faster screening of illicit drugs. This not only speeds up laboratory analysis, but is critical in today's environment where highly toxic opioids have begun to surface in other countries.

#### Age and Ethnicity Prediction

Studying the DNA in cells has enabled us to develop methods in ethnicity prediction, and improve on our age prediction capability. The results of both cutting-edge studies have been published in Forensic Science International: Genetics – the top ranked journal for forensic biology, and its supplemental series respectively.

90% – the accuracy in which an individual's ethnicity can be predicted using bio-geographic ancestry DNA markers, which also allows for individuals with mixed parentage to be identified.

 $\pm$  5 years – the current accuracy of our age prediction method based on epigenetic changes to DNA, an improvement over our earlier method that gives  $\pm$  8.6 years accuracy on liquid blood. Furthermore, this method is effective for both fresh and aged bloodstains.



### Rapid Homogenisation of Drug Samples



Replacing the traditional mortar and pestle with a multi-sample grinder to homogenise drug samples has resulted in a **30-fold improvement** in process efficiency



Up to **16 samples** can now be homogenised in 15 minutes



Additionally, the closed vessel of the grinder also creates a **safe environment** protecting the user from the potential presence of toxic drugs

# Protecting Public Health

An important part of our work involves ensuring that public health and safety is maintained through product testing.



#### Presence of Aristolochic Acids and Heavy Metals in **Health Products**

We conducted a survey on 179 calcium-containing health supplements. These supplements were tested for the presence of heavy metals such as mercury, lead, arsenic and cadmium.

We also conducted a follow-up survey to our 2015 survey of Chinese Medicinal Materials (CMM). For this survey, 20 Radix Et Rhizoma Asari roots were surveyed for aristolochic acids, and 10 Cordyceps and 10 Bulbus Lilii and 17 finished products containing Cordyceps or Bulbus Lilii were tested for heavy metals.

The results of these baseline surveys help the Health Products Regulation Group (HPRG) with relevant scientific data to make policy and regulation decisions regarding health supplements and CMMs.

#### **Cosmetic Products** Surveys

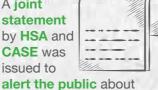
We supported Consumer Association of Singapore (CASE) in a series of three consumer product surveys conducted on a total of 63 skin whitening, oral hygiene and sunscreen products.

These findings enabled CASE to assess the quality and safety of cosmetic products retailed locally and online.

The results:

Out of 21 skin whitening products tested. 1 contained excessive amounts of mercury

A joint statement by **HSA** and **CASE** was issued to



this product All 20 oral hygiene

products surveyed were found to be compliant for Fluoride and Diethylene Glycol (DEG) content

UV filters for the 22 surveved SPF++ sunscreen products were also found to be within authorised limits

# Benchmarking Our Standards

**HSA** is committed to benchmarking our standards internationally, as well as raising local and regional testing standards.

#### **Pharmaceutical Division**

The laboratories achieved excellent results in external benchmark Proficiency Testing (PT) programmes conducted by the Dutch Association for the Advancement of Pharmacy (KNMP), ASEAN Bureau of Drug and Narcotics (BDN), European Directorate for the Quality of Medicines & HealthCare (EDQM), Bureau of Cosmetics and Hazardous Substances, Department of Medical Sciences, Ministry of Public Health, Thailand, and Dienstleistung Lebensmittel Analytik GbR (DLA), Germany.

#### **Food Safety Division**

Our staff participated in various regional and international proficiency tests, organised by the ASEAN Reference Laboratories, Food Analysis Performance Assessment Scheme (FAPAS) in UK, WHO-TAMU (World Health Organization-Texas A&M University) and International Atomic Energy Agency (IAEA).



#### **Forensic Chemistry & Physics Laboratory**

HSA participated in:

- European Network of Forensic Science Institutes (ENFSI) European Paint and Glass Working Group Glass Elemental Analysis Collaborative Exercise 2016/17
- Quality Assessment Trial Examination Questioned Documents and Inks 2017
- 2017 European Network of Forensic Science Institutes (ENSFI) Textile Hair Group Meeting and Collaborative Exercise

**Chemical Metrology** Division

Completed 8 international comparisons covering veterinary drugs and toxic elements

Expanded our list of Certified Reference **Materials** (CRM)



Conducted an accuracybased **External** Quality **Assessment Programme** 



for local clinical laboratories

Conducted a PT scheme on inorganic elements and arsenic species in brown rice flour



**HSA** embarked on various partnerships and collaborations to raise our capabilities.

#### **Food Safety Research Project with Shimadzu**

Under a joint research agreement, the Food Safety Division embarked on research projects with Shimadzu. We completed a project focused on the exploration of more efficient analyses and greener technology in October 2017.

#### **Research Agreement with NUH**

An agreement was signed with the National University Hospital (NUH) to develop a method for the measurement of the diabetic marker, haemoglobin (Hb) A1c in human blood samples, and to embark on a commutability study on CRMs of HbA1c as long-term quality controls for local clinical laboratories.

#### **Knowledge Sharing Exercise and Collaboration with SPF**

In December 2017, HSA collaborated with the Special Tactics Advisory Team (STAT) from the Operations Department of the Singapore Police Force (SPF) to record bullet trajectories using a high-speed camera.

This experience provided our examiners with the opportunity to observe the trajectory of bullets that were shot through vehicle parts, and examine bullet impact areas - both potentially useful areas of knowledge for reconstructing shooting incidents.

We also collaborated with the Criminal Investigation Department's (CID) Forensic Division to assess the evidential value of dust particles when associating a deceased person who had fallen from a building to a particular floor of a block.

In this exercise, we evaluated the chemical compositions and the occurrence of specific dust particles on parapets of a HDB block as well as the results from the transference experiments of such particles from parapets to hands. This joint collaboration serves as a useful platform for CID officers and HSA to exchange knowledge on trace evidence collection and analysis.

#### **Performance Qualification of Dissolution Apparatus**

In July 2017, we completed a collaborative study with the United States Pharmacopoeia (USP) to establish the dissolution reference range for a new lot of USP Prednisone Tablets. This reference range acts as the calibrator for performance qualification of Dissolution Apparatus.



In April 2017, the Forensic Medicine Division conducted a Mass Fatality Incidents (MFI) table-top exercise to review DVI operations at our mortuary. Gaps were identified in the workflow, while plans were made to improve processes and procedures.

In October 2017, we had a chance to showcase our DVI capabilities at Exercise Northstar X, which was attended by Deputy Prime Minister Teo Chee Hean.

In November 2017, SPF and the Royal Brunei Police Force held their third joint post-blast investigation exercise (Ex-Solarwind III).

An HSA team of forensic DNA scientists also participated in the exercise to evaluate the recovery of DNA from exhibits recovered from post-blast scenes such as laptops and mobile phones.

Additionally, HSA forensic pathologists set up temporary autopsy station to examine the remains from the post-blast recovery.







## External Engagement

To maintain and raise our level of engagement with external partners, we signed partnership agreements, hosted visits and conducted training sessions.



#### June 2017

Visit by Philippines Food and Drug Administration to learn about Singapore's cosmetics and tobacco regulatory framework.



### July 2017

Visit by Shanghai Institute of Food and Drug Control to learn about Singapore's regulatory framework on pharmaceutical products.

### January 2018

Visit by Singapore Armed Forces
Military Police Command to the
Forensic Laboratories.

### Partnership with National Institute of Metrology (NIM), China

HSA and China's NIM signed a Partnership Agreement to cooperate on a project entitled "Research and Application of Measurement Standard and Technical System in Agro-Product Safety". Two of our scientists will be attached to NIM for an accumulated period of nine months.

#### **Visits**

HSA hosted visitors, both locally, around the region, and beyond to share knowledge and best practices.

### January 2018

Visit by Government Laboratory, Hong Kong to exchange knowledge on the various methods of analysing tobacco products.





### January 2018

Visit by Indonesia's Department of Police Medicine to learn about our experience in ISO 17025 accreditation in the fields of forensic biology, post-mortem toxicology, and in DNA analysis.

### January 2018

Visit by senior officials of the Abu Dhabi Judicial Department to discuss topics relating to Forensic Science and Forensic Medicine.

### **Training Sessions**

In doing our part to raise global standards, we provided training sessions to the following partners:



### National Quality Control Laboratories, Food and Drug Administration (FDA), Myanmar June 2017

We hosted two trainees from FDA, Myanmar, who came to train in Western Medicine analysis.



### National Public Health Laboratory (NPHL), Malaysia July 2017

As a WHO Collaborating Centre for Tobacco Testing and Research, we organised a technical exchange programme for an NPHL scientist to learn more about the analysis of tobacco.



### Ministry of Food and Drug Safety, Korea July to September 2017

We hosted a senior scientific officer from the National Institute of Food and Drug Safety Evaluation (NIFDS). This was a technical exchange on general analytical testing workflow, as well as the analysis of illegal health products.



## Food and Drug Administration (FDA), Myanmar September 2017

A two-week technical training session on mycotoxins analyses was conducted for two staff from Myanmar's FDA.



### Scientific Laboratory Services, Ministry of Health, Brunei Darussalam December 2017

We provided an on-site customised training on basic statistical tools, method validation and measurement uncertainty to staff from Brunei's Scientific Laboratory Services, Ministry of Health.



We provided training on the use of Raman handheld devices at a three-day workshop conducted for five Central American and Caribbean Countries in Panama City as part of UNODC's request to set guidelines and training on field identification of narcotics drugs, drug precursors, as well as NPS.

### Local and International Events

Throughout the year, our staff have been active in attending and organising industry related events both here and abroad.

### 9th Asian Forensic Sciences Network (AFSN) Annual Meeting and Symposium

Together with the AFSN Board and Ngee Ann Polytechnic, HSA organised the 9th AFSN Annual Meeting and Symposium, which was held from 4 to 8 September 2017. Mr Desmond Lee, then-Minister in the Prime Minister's Office and Second Minister for Home Affairs and National Development was the Guest of Honour for the symposium. Themed, "Advancing Forensic Science in a Rapidly Changing World", the event was attended by more than 600 overseas and local participants from 21 countries and 83 institutes.



### Some of the programme highlights include:

### **DNA Workgroup**

HSA organised a successful DNA Workgroup programme attended by 14 foreign institutions from 8 countries. Five renowned experts from the United States, Australia and New Zealand lectured on various topics such as Massively Parallel Sequencing (MPS), the latest revolutionary technology in forensic DNA testing. At this meeting, we also shared the results of the AFSN Inter-Laboratory DNA Exercise organised by HSA.

### **Toxicology Workgroup**

Dr Dimitri Gerostamoulos, Head of Forensic Science and Chief Toxicologist at the Victorian Institute of Forensic Medicine (VIFM) conducted a workshop on NPS. Topics covered included issues and challenges in forensic toxicology, methods for NPS detection and interpretation of NPS toxicity.

### **Illicit Drugs Workgroup**

Mr David Love and Mr Chad Esch, from the Drug Enforcement Administration (DEA) of US, conducted a workshop on clandestine laboratory investigation.

The objective of this workshop was to equip the participants with the knowledge and skills in clandestine laboratory investigation as well as analysis of the evidence collected.

### **Soil Forensic Workshop**

Professor Fitzpatrick conducted a three-day soil forensic workshop to showcase the value of soil evidence in linking questioned exhibits to particular locations. During the workshop, attendees were introduced to procedures for gathering useful information from soil samples. This was followed by a hands-on lesson at a pit dug within the HSA compound to better understand the techniques discussed.



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### **Quality Assurance & Standards Committee**

We invited three experienced professionals to conduct the Quality Workshops, including Ms Ilini Ng to talk on "Building an Effective Training Framework", Mrs Anja Einsein to highlight the important changes in the "Revision of ISO/IEC 17025", and Mr John Mario to present "The William A. Hinton State Institute Drug Analysis Laboratory Investigation".



### **Sharing Session on Drug Control**

Dr Justice Tettey, Chief of United Nations Office on Drugs and Crime (UNODC) Laboratory and Scientific Section, shared on the various international drug control efforts by UNODC.



First International Conference of Forensic Science, Interforensics May 2017 Brasilia, Brazil

HSA was invited to share our experience in quality assurance and accreditation in forensic science, and on developments in the field of forensic DNA analysis.

### 2017 Meeting of the UNODC International Panel of Forensic Experts May 2017 Vienna, Austria

This meeting saw two important manuals on testing methodologies being reviewed, as well as the prospective creation of a new manual for the analysis of fentanyl and its analogues being discussed.

### 3<sup>rd</sup> ASEAN Reference Material Network Meeting July 2017 Singapore

HSA hosted six metrology institutes from Thailand, Philippines, Malaysia and Singapore to confirm the Terms of Reference for the network, and to discuss joint activities on Proficiency Testing programmes and CRM production.

### 22<sup>nd</sup> Annual Meeting of the Official Medicines Control Laboratories (OMCL) Network May 2017 Budapest, Hungary

The meeting provided an opportunity for OMCLs to exchange the latest technical information and discuss emerging issues related to pharmaceutical analysis of counterfeit drugs and illegal health products.

## APEC Conference on Management and Related Scientific Detection Technology for Adulteration of Dietary Supplements with Drugs and Drug Analogs June 2017 Taipei, Taiwan

HSA gave an oral presentation on the "Singapore Pharmacovigilance Framework and Its Role in Combating Illegal Complementary Health Products".



### MEDEA Workshop on Production of Certified Reference Materials (CRMs) August 2017 Singapore

Attended by 10 metrology institutes, the Metrology – Enabling Developing Economies in Asia (MEDEA) workshop helped to strengthen the capability of the institutes in the Asia Pacific Metrology Programme.



### 16<sup>th</sup> Official Cosmetics Control Laboratories (OCCL) Network Meeting November 2017 EDQM Headquarters, Strasbourg, France

We shared on HSA's efforts in exchanging scientific and technical expertise in the field of cosmetics testing.

### First International Symposium of Forensic Drug Testing Lab Directors December 2017 Cancun, Mexico

This meeting saw laboratory directors and toxicologists from 17 countries coming together to establish the concept of a global toxic adulterant database.



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### WHO Activities

As WHO's Collaborating Centre, we actively supported numerous activities throughout the year in review.

### **Monograph Development Work**

We successfully developed a new related substances test for the draft monographs on Pyrimethamine and Pyrimethamine tablets, as well as two draft monographs on Ceftriaxone Sodium and Ceftriaxone for injection. We also developed a high-performance liquid chromatography assay test for the draft monograph on Tetracycline Hydrochloride.

### WHO Consultation Meet May 2017 WHO Headquarters, Geneva, Switzerland

We attended the WHO Consultation Meet on Quality Control Laboratory Tools and Specifications for Medicines as a WHO Temporary Advisor.

### 17<sup>th</sup> World Conference on Tobacco or Health (WCTOH) March 2018 Cape Town, South Africa

Organised by the International Union Against Tuberculosis and Lung Disease, the event brought together experts and professonals from more than 100 countries working on all aspects of tobacco control.



Technical Meeting on Testing and Regulating Electronic Cigarettes and Novel Tobacco Products December 2017 Hong Kong SAR, China

Graced by Professor Sophia Chan, Hong Kong's Secretary for Food and Health, the meeting covered discussions on emerging tobacco products, such as e-cigarettes and heat-not-burn tobacco products.

### **International Chemical Reference Substances (ICRS)**

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

# Involvement in ASEAN Activities

We continue to be actively involved with our ASEAN counterparts through various platforms that facilitate knowledge sharing.

ASEAN Food Testing Laboratory Committee Meeting (AFTLC) March 2017, Siem Reap, Cambodia November 2017, Luang Prabang, Lao PDR

HSA scientists participated in the 10<sup>th</sup> and 11<sup>th</sup> AFTLC meeting which was attended by representatives from 10 ASEAN countries. The members discussed the policies and processes involved in setting up new ASEAN Food Reference Laboratories in emerging areas of need, as well as updated on upcoming technical trainings and proficiency testings to strengthen the competency and capacity of food safety testing in ASEAN.

### ASEAN Reference Substances Project

The ASEAN Reference Substances Project establishes and provides reliable secondary drug standards for ASEAN member countries. In 2017, Singapore together with Laos, Malaysia and the Philippines established a proposed ASEAN Reference Substance – Clotrimazole. We also participated in the Interlaboratory Collaborative Study of Lansoprazole, led by Vietnam.

### ASEAN Cosmetics Testing Laboratory Committee (ACTLC) May 2017, Siem Reap, Cambodia November 2017, Bandung, Indonesia

As the chair of ACTLC, we continued our active involvement. The laboratories within ACTLC embarked on comparison studies of cosmetic methods to strengthen their competency in supporting the regulatory requirements for cosmetic products.





## International Laboratories Forum on Counterfeit Medicines (ILFCM) May 2017 South Carolina, United States

HSA scientists participated in the annual ILFCM meeting, where members shared on a range of counterfeit medicine topics. Speakers from pharmaceutical industries also shared about analytical characterisation of biologics and biosimilars, and combating counterfeit biologics.

## Keeping Our Staff Equipped

To keep our staff up-to-date, we ensured that the highest standards of training were provided.

### **Biosafety Training**

We have been developing our staff in the area of biosafety management. This includes local training by the Asia-Pacific Biosafety Association in the Biological Agents and Toxins Act (BATA) and Workplace Safety and Health Act (WSHA) components, as well as overseas certification by International Federation of Biosafety Associations (IFBA). Currently, we have two staff certified by IFBA in biorisk management and biological waste management.

### Analytical Toxicology December 2017

Professor Marilyn Huestis, a renowned toxicologist in the field of clinical pharmacology of drugs of abuse, conducted training on drugs metabolism.

Dr Michael Smith – an experienced toxicologist in urine drug testing, also shared about the defence challenges for drugs of abuse testing in urine and hair.





### Human Factors for Traffic Crash Reconstruction Course December 2017

Dr Jeffrey Muttart, an expert in Human Factors for Crash Reconstruction, shared about his in-depth knowledge and scientific approach to human capabilities in the context of vehicular accidents and emergency manoeuvres for various collision configurations and environmental conditions.

### Toolmarks and Quantitative Consecutive Matching Striae (QCMS) Course March 2018

Bruce Moran and John Murdock, both experts in firearms and toolmarks examination, organised a training course for HSA. The course consisted of toolmarks examination, and QCMS – a criteria designed to produce more objective interpretations.



Trainees who attended the course would subsequently be authorised to carry out toolmarks examination. In addition, HSA also has plans to adopt the QCMS criteria for firemarks and toolmarks examination, as well as assess its suitability for manufacturing marks examination.

### Advanced Textile Interpretation Course March 2018

Pamela Bauer, Scientific Lead for Hairs, Fibres and Damage in Cellmark, conducted a course on textile damage.

The training session provided staff with knowledge on how to interpret damage caused by implements with similar gross morphologies, as well as gave them new insights.





### Mitochondrial DNA Analysis Workshop January 2018

Professor Walther Parson, an authority in mitochondrial DNA (mtDNA) from the Institute of Legal Medicine, Medical University of Innsbruck, Austria, conducted a 1-week course on mtDNA analysis. The workshop equipped staff with knowledge on mtDNA sequencing and its applications, haplogrouping and phylogenetic analysis, statistical calculations and court reporting.

# Setting High Standards

At HSA, we are constantly striving to be the benchmark of our industry. Our accreditations are testament to this.

#### ISO/IEC 17043 Accreditation

We successfully renewed our accreditation as a PT/EQA Provider by the Singapore Accreditation Council based on the requirements of ISO/IEC 17043. We remain the only accredited facility in Singapore for such programmes.

### ISO/IEC 17025 Accreditation

We achieved full compliance to ISO/IEC17025 in the SAC-SINGLAS annual surveillance assessment:

- 1. The Pharmaceutical Laboratory successfully added six new methods into its accreditation scope:
  - Identification of common drugs using LTQ Orbitrap XL FTMS
  - Identification of chiral drugs using HPLC-DAD
  - Identification of common drugs using LC-MS-MS
  - Identification of Sildenfail, Tadalafil and Vardenafil using LC-MS-MS
  - Identification of common drugs using GC-MS
  - Determination of Diphenoxylate in herbal products using
- 2. The Cosmetics Laboratory successfully added three new methods into its accreditation scope:
  - Screening of Hydroquinone in skincare products using
  - Screening of Diethylene Glycol in oral hygiene products using
  - Determination of Hydrogen Peroxide in oral hygiene products using HPLC-DAD







- 3. The Cigarette Testing Laboratory successfully underwent assessment with the current accreditation scope.
- 4. Food Safety Laboratory successfully added five new methods into its accreditation scope:
  - Tropane alkaloids in infant cereals by LC-MS-MS
  - Screening of Amatoxins and Phallotoxins in mushrooms by LC-MS-MS
  - Screening of 12 Ergot alkaloids in rye and rye products by LC-MS-MS
  - Screening of Metanil Yellow and Acid Red 52 by LC-MS-MS
  - Deoxynivalenol, Zearalenone, Fumonisins B1 and B2 by LC-MS-MS
- 5. The Water Testing Laboratory successfully added two new methods into its accreditation scope:
  - Aroclors by GC-MS
  - Bromide and Nitrite by IC



## Developing Our People

At HSA, we believe in nurturing our people to reach their potential. We do this by creating an environment which not only supports continual learning and development, and recognising excellent customer service, but also encourages the development of a strong and cohesive HSA family.



### **Supervisory Training Framework**

A supervisory training framework was developed as part of our inhouse Professional Development Leadership Programme to groom and develop future leaders in HSA by equipping them with the required supervisory competencies.

### Review of Performance Appraisal Forms

In 2017, we reviewed our performance appraisal forms to make them simpler and easier to use. Supervisors and staff can now better focus on having meaningful appraisal conversations rather than completing lengthy appraisal forms. These new forms are being used from April 2018 onwards.

### 9<sup>th</sup> HSA Customer Service Day

HSA held its 9<sup>th</sup> Customer Service Day in March 2018 with the theme, "Smart Nation – Service in the Age of Disruption". Guest speaker Dr Narinder Kaur, Chief of Organisational Excellence and Quality Service Manager at the National Library Board (NLB), shared about NLB's service innovation journey.



### 2017 Outstanding Service to Customers Award (OSCA)

In 2017, we created a new award, the Star Award, to give special recognition to officers who exemplify strong customer service, champion service quality initiatives, and encourage staff engagement.





### In total, 54 awards were presented, comprising:















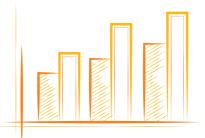






### Innovation at Work

To be future-ready, we need to fully embrace the digital age. This means creating an environment where technology and innovation are second nature to us.





### **2018 HSA Makeathon Challenge**

Our inaugural 2018 Makeathon provided a platform to engage HSA staff in collective ideation and solutioning. At the event, participants were divided into three work-streams to discuss Innovation, Digitalisation, and Data Analytics & Behavioural Insights. These are the areas that have been identified as critical in helping HSA transform to become future-ready.

### **Our Makeathon 2018 Scorecard**

- Our 2018 Makeathon Challenge spawned a total of **85 ideas**, which are now being considered for implementation.
- 21 ideas were generated from the Innovation workstream, including one to showcase innovative HSA projects on the intranet.
- The **most productive** workstream was **Digitalisation** with **37 ideas** generated. These ideas include creating an app for leave management/purchasing/meeting room bookings, as well as using Artificial Intelligence to assist with product classification.
- The most popular idea, which garnered 69 votes, came from the Data Analytics & Behavioural Insights workstream. This idea involves using data and text analytics to analyse frequent customer queries.



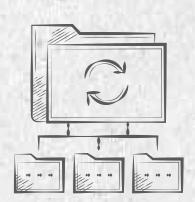




### **Getting Ready for Digitalisation**

A Digitalisation Steering Committee has been set up to oversee the harmonisation of digitisation and digitalisation efforts of HSA, and drive the organisation forward as part of the Public Sector Transformation initiatives to build a future-ready Singapore.

We are enhancing the capabilities of our officers in the area of data analytics. Recently, we engaged software industry partners to train our officers in using Business Intelligence (BI) software. This has resulted in increased operational efficiency as more insightful reports for decision making can be generated. The BI software tool has been installed as a standard software for all HSA staff.



# Prioritising Work-life Balance

HSA believes in fostering a healthy and thriving work environment where staff are able to effectively manage daily life and work demands. Here are some of our supporting initiatives.

### **Quarterly Work-life Balance Talks**

Lunchtime talks were held on the following topics:

- March 2017 Strategies for Family Bonding
- June 2017 -Non-violent Communication
- September 2017 Beating Burnout
- November 2017 Caring for the Caregiver of Seniors

### **Bring-your-kids-to-work Day**

Taking advantage of students' day-off during Teachers' Day in August last year, we organised a Bring-your-kids-to-work day at HSA. Although this was the third time the event was held, it was still much anticipated and well attended by staff and their children.

Throughout the day, the kids had the opportunity to make new friends, play games, watch movies, dabble in arts and crafts, as well as learn more about their parents' work through a tour of HSA's facilities, including the laboratories and the blood bank. The event ended with an HSA Active Day at the Singapore Botanic Gardens.





### **HSA Family Day**

In March 2018, the HSA Recreation Club organised a very well-received Family Day at ORTO. It was a fun-filled Saturday where staff and their family members got to enjoy a day of leisure prawning, longkang (drain) fishing, drift karting, trampolining and feasting.

## Giving Back to the Community

HSA is committed to giving back to the society through our Corporate Social Responsibility (CSR) framework, known as CARE - "Community Action, Responsible for our Environment". This was reflected in our active involvement throughout the year with various initiatives to help the needy. Through our giving, we also learnt the values of empathy and kindness.



### **Hair for Hope**

HSA and Children's Cancer Foundation jointly organised a satellite event at our Outram office in June 2017 to raise awareness for childhood cancer.



### **Befriending Our Mei Ling Street Seniors**

In September 2017, a group of HSA volunteers treated needy seniors from the Lions Befrienders at Mei Ling Street to a shopping trip and tea reception.



### **Reading Together for Charity**

In support of the National Reading Movement, HSAians participated in a special Read for Books charity drive sponsored by the National Library Board. The event helped to nurture the love of reading among HSAians, and encourage everyone to do their part for the needy.



### volunteers,

including 1 female HSA colleague shaved their heads

We raised a total of \$20.800



Volunteers helped seniors to choose healthier items

Each senior

During the tea reception, HSA staff entertained the seniors with performances



was given a \$30 voucher to shop for necessities



sessions were held over 2 lunch breaks in July 2017 at the

For every 10

persons

that read together

for 15 minutes, a book

was donated to charity



00

**HSAians** took part

# Keeping the Public Informed

Part of what we do at HSA includes educating the public on issues that concern their safety and well-being.



### **Risks of Buying Health Products Online**

We launched an online campaign to raise consumer awareness on the risks of buying health products from dubious online sources.





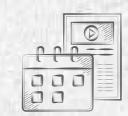
### **Target audience:**

Consumers searching for health products using keywords such as "burn fat", "pain relief medicine" and "health supplements"



### **Online platforms:**

Online Ads on YouTube, Google Display Banners and Google Search



### What we did:

- Ran an awareness campaign for 6 weeks from January to March 2018
- Put up 300 posters and screened an awareness video at various polyclinics



The YouTube video garnered over 775,000 views within 6 weeks



Photo credit: Tan Tock Seng Hospital

### **Our Media Report Card**



We continued to **showcase** HSA's work and expertise through interviews and news stories on various media platforms including TV, print and social media



We sent out 25 press releases during the year in review



12 HSA updates regarding safety alerts, public health warnings and enforcement messages were shared with the public



These efforts garnered

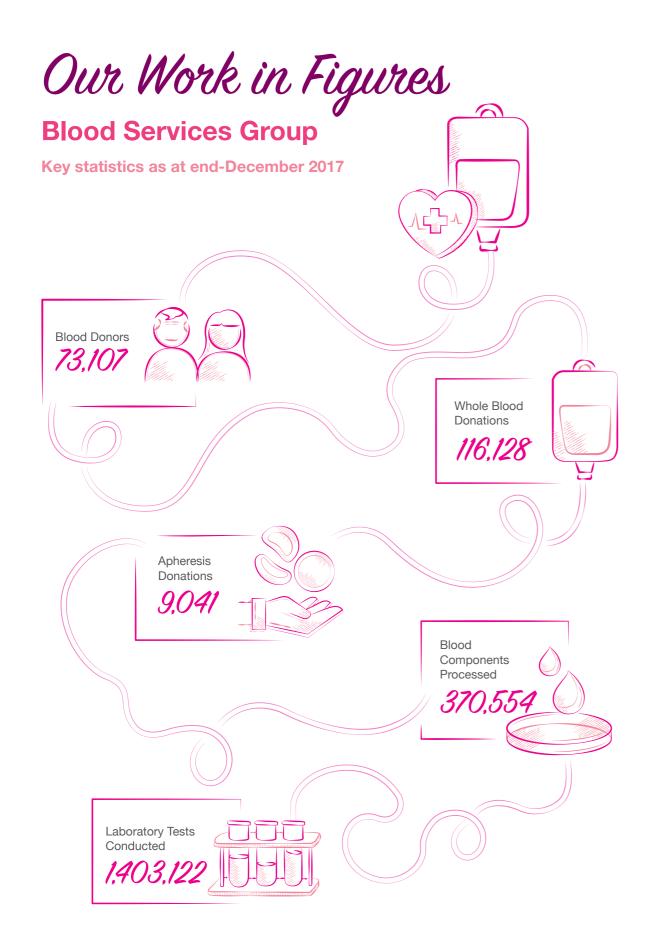
### Missing Type Campaign

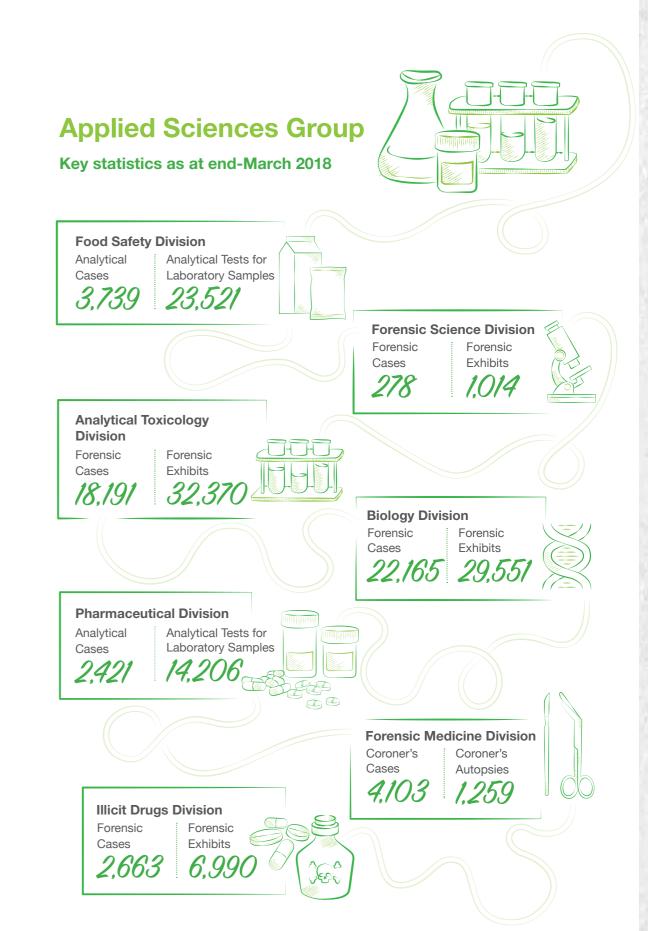
In July 2017, we ran our second campaign to raise awareness on the importance of blood donations. Almost 80 organisations showed their support by removing the blood type letters "A", "B" and "O" from their signage. In addition, Tan Tock Seng Hospital, Nanyang Polytechnic and many others also showed their support by organising blood donation drives.

### **How We Fared**

- We received strong support from government agencies, hospitals, schools, media, local brands and retailers. Some of the notable brands who partnered us include: BreadTalk IHQ, Carousell and Soup Spoon.
- Singapore Botanic Gardens, Swiss Cottage Secondary School and the Singapore TransportAid Red Cross were among those who altered their physical signage.







Approved Products on the Register of Therapeutic Products

5.467

Number of Reclassified Therapeutic Products

21

Number of Therapeutic Products Variation Applications 4.587

Tobacco Retail Licences Approved

589

Number of Electronic Vaporiser Cases Referred to HSA

1.744

Site Audits Conducted for Good Manufacturing & Good Distribution Practices and

Pharmacies

Total Number of Cosmetic **Products Notified** 172,606

> New Cosmetic Products Notified 51,612

Contravention of

Health Product

Legislation)

2.667

**Applications** Approved

Applications for Licences/Certificates for Manufacturers of Health Products Approved

430

Applications for Licences/Certificates for Importers of Health Products Approved

2.772

Applications for Licences/Certificates for Wholesalers of Health Products Approved

1.753

Applications for Licences for Retail Pharmacies Approved

352

Applications for Licences/Certificates for Exporters of Health Products Approved 501

2,688

Medicines Listed 11,297

**Total Number** of Chinese

Proprietary

**New Chinese** Proprietary Medicines Listed 566

Applications for Import of Therapeutic Products for Personal Use Processed

**Clinical Trial Applications** 

Number of New Trials Approved

123

Number of New Trials Processed 136

Number of Medical Device Change Notification Applications

95

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

1,507

Approved Products on the Singapore Medical Device Register

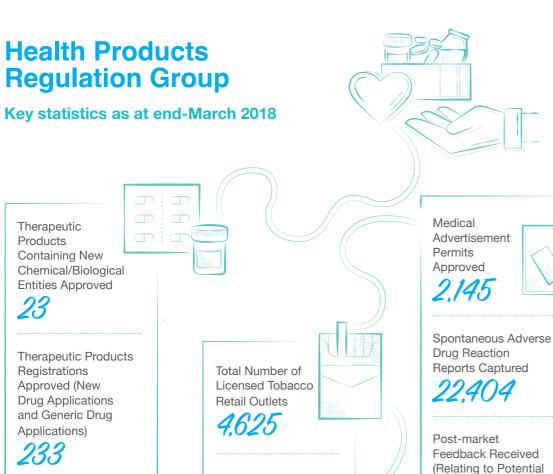
17.994

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

468

Number of Adverse Events (Local) Reporting for Medical **Devices Received** 





## Financial Highlights

### **Balance Sheet**

	FY17/18	FY16/17	Increase / (Decrease)	
	\$'000	\$'000	\$'000	%
Property, Plant & Equipment	88,224	80,351	7,873	10
Intangibles	8,547	4,038	4,509	112
Current Assets	161,009	154,446	6,563	4
Total Assets	257,780	238,835	18,945	8
Equity	159,892	147,481	12,411	8
Long-Term Loans	15,470	16,380	(910)	(6)
Other Non-Current Liabilities	7,406	6,734	672	10
Current Liabilities	75,012	68,240	6,772	10
Total Equity and Liabilities	257,780	238,835	18,945	8

### **Income & Expenditure Statement**

The Authority has achieved an overall net surplus of \$12.2m for FY17/18.

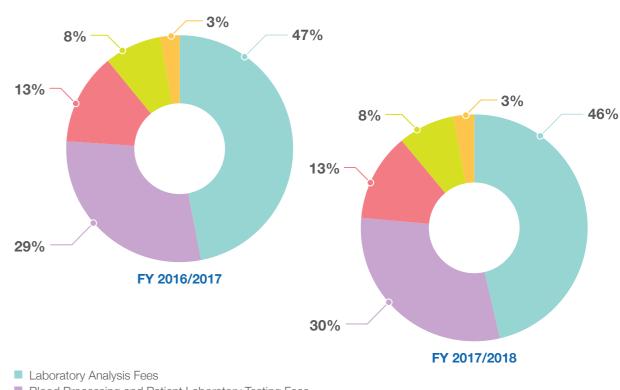
	FY17/18	FY16/17	Increase / (Decrease)	
	\$'000	\$'000	\$'000	%
Operating Income	142,995	138,378	4,617	3
Operating Expenditure	(212,634)	(203,019)	9,615	5
<b>Deficit before Government Grants</b>	(69,639)	(64,641)	4,998	8
Government Grants	84,370	78,661	5,709	7
Surplus before Contribution	14,731	14,020	711	5
to Consolidated Fund				
Contribution to Consolidated Fund	(2,504)	(2,383)	121	5
Net Surplus	12,227	11,637	590	5
Other Comprehensive Income	8	16	(8)	(50)
Net Surplus and Comprehensive	12,235	11,653	582	5
Income for the Year				

### **Operating Income**

The Authority earned a total operating income of \$143.0m in FY17/18, an increase of \$4.6m (3%) over FY16/17's revenue of \$138.4m.

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	FY17/18	FY16/17	Increase / (Decrease)	
	\$'000	\$'000	\$'000	%
Laboratory Analysis Fees	66,240	65,059	1,181	2
Blood Processing and Patient	42,982	40,308	2,674	7
Laboratory Testing Fees				
Licensing Fees	18,069	17,955	114	1
Forensic Investigation Fees	11,518	11,272	246	2
Other Income	4,186	3,784	402	11
Total Operating Income	142,995	138,378	4,617	3



■ Blood Processing and Patient Laboratory Testing Fees

Licensing Fees

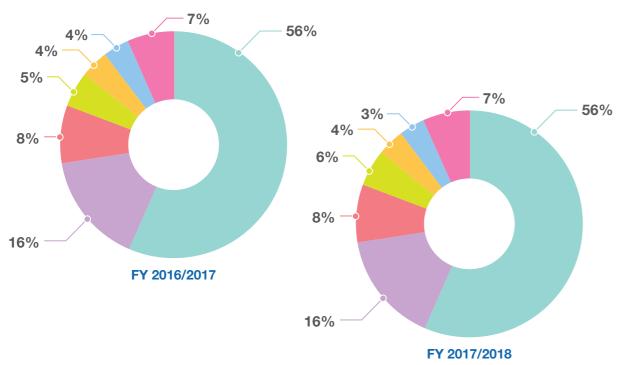
Forensic Investigation Fees

Other Income

### **Operating Expenditure**

The Authority incurred a total operating expenditure of \$212.6m in FY17/18, an increase of \$9.6m (5%) over FY16/17's expenditure of \$203.0m.

	FY17/18	FY16/17	Increase / (Decrease)	
	\$'000	\$'000	\$'000	%
Staff Costs	119,842	114,833	5,009	4
Supplies and Services	33,318	32,041	1,277	4
IT Services and Maintenance	16,816	16,535	281	2
Depreciation and Amortisation	12,215	10,712	1,503	14
General Repairs and Maintenance	7,858	7,956	(98)	(1)
Rental of Premises and Equipment	7,497	7,265	232	3
Other Operating Expenses	15,088	13,677	1,411	10
Total Operating Expenditure	212,634	203,019	9,615	5



Staff Costs

Supplies and Services

■ IT Services and Maintenance

Depreciation and Amortisation

General Repairs and Maintenance

Rental of Premises and Equipment

Other Operating Expenses

### **Editorial Team**



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