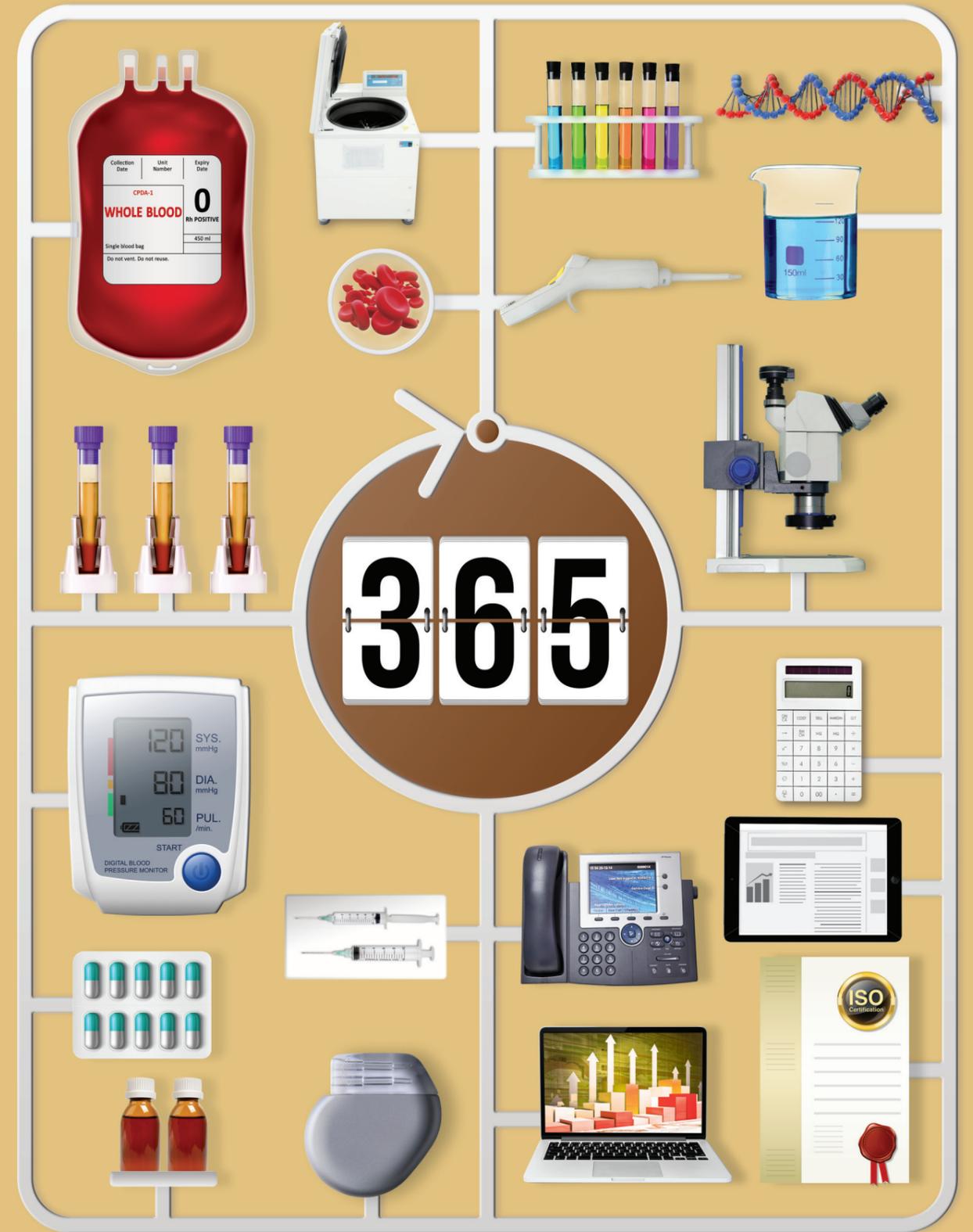




**HEALTH SCIENCES AUTHORITY**  
11 Outram Road Singapore 169078  
tel (65) 1800 213 0800  
fax (65) 6213 0839  
[www.hsa.gov.sg](http://www.hsa.gov.sg)  
[hsa\\_info@hsa.gov.sg](mailto:hsa_info@hsa.gov.sg)





### HSA is ready for today, tomorrow, and the future.

In the past 14 years, we have grown not only in size and stature, but also in our commitment to achieving our goals to ensure the health and safety of people in Singapore.

Our team of dedicated staff is equipped with the expertise and passion to serve our nation 365 days a year. Our collaborative approach drives us to actively seek like-minded partners locally and globally to help us to do better today, so we can do more tomorrow.

Every day, HSAians champion our vision and mission. Working proactively and preemptively, we are prepared to serve the administration of justice, secure a safe and sustainable supply of blood for patients, and ensure that the public have access to health products that are safe for use and of good quality.

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## 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

#### ISO 9001:2008

Corporate Headquarters  
since June 2015

The Public Service Achievement Award  
2014

The Public Service Milestone Award  
2010

Singapore Quality Class Star  
March 2014

Singapore Quality Class  
since 2009

People Developer Certification  
since 2002

Singapore Innovation Class  
first public healthcare agency to be endorsed  
2003

Singapore Service Class  
March 2014

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

Public Service Award for  
Organisational Excellence  
2006

Meritorious Defence Partner Award  
since 2005

Meritorious Home Team Partner Award  
since 2008

Community Chest Awards  
since 2003

Singapore Family Friendly Employer  
Award  
2004

#### ISO 9001:2008

Information Management Department  
Corporate Headquarters  
since 2011



# Our Accolades

## Professional Excellence



### Health Products Regulation Group

#### ISO 9001:2008

Tobacco Regulation Branch  
since February 2011

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

Audit & Licensing Division  
since January 2000

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

since May 2013



### Blood Services Group

#### Compliance with PIC/S Good Manufacturing Practice Standard

Cell Therapy Facility was audited to acceptable GMP standard jointly by HPRG and Swissmedic  
August 2014

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

July 2013

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

August 2008

#### AABB Accreditation

first national blood service in Asia to be accredited  
May 2006

#### Certified On-the-Job Training Centre

December 2005

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

since 1992



### APPLIED SCIENCES GROUP

#### Forensic Medicine Division

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

first agency outside North America to be accredited

September 2005

##### Commendation for Significant Contribution in Helping Singapore Overcome SARS

March - May 2003

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

since 1999

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

##### Excellence for Singapore Award

1999

##### Accredited under American Society of Crime Laboratory Directors / Laboratory (ASCLD/LAB) Accreditation Board

since June 1996

##### Pharmaceutical Division & Food Safety Division

##### Public Service Award for Organisational Excellence

July 2003

##### Singapore Quality Class

since August 2002

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

since 1997

#### Pharmaceutical Division

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

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

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

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

#### Food Safety Division

ASEAN Reference Laboratory for Mycotoxins Analysis  
since June 2004

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

#### Chemical Metrology Division

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

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

# Q&A with Our Chairman

**This is your second year as Chairman of HSA. How has it been?**

It is my privilege and pleasure to be with HSA as its Chairman. The past year has been productive with many new developments, both within the organisation and in our engagements with our stakeholders.

Within the organisation, we have improved policies on staff assessment and schemes for re-employment of our older staff. Our engagements with our various stakeholders – the public, the industry, healthcare institutions and the judiciary – continue to grow as we expand the depth and range of our services. I have been impressed by the good work that HSA has done and I am confident that this is an organisation that is ever-ready to meet the challenges that come its way.

**What are HSA's key accomplishments in 2014 that will steer the organisation forward?**

One of the most outstanding achievements in the year has been within the HSA team – our persistence, our passion and our commitment to excellence.

I would like to congratulate HSA for achieving one of the highest accolades in organisational excellence by being awarded the Singapore Quality Class Star for its 4-in-1 Certification. This includes the Singapore Quality Class, People Developer, Singapore Innovation Class, and Singapore Service Class. The results of these key institutional health checks are a testament to the highest standards that HSA has in driving organisational excellence.

Our professional groups continue to be benchmarked against international best practices and standards. Namely, the American Association of Blood Banks (AABB), the American Society for Histocompatibility and Immunogenetics (ASHI) and the Joint Accreditation Committee - International Society for Cellular Therapy and European Group for Blood and Bone Marrow Transplantation (JACIE) for the Blood Services Group; the National Association of Medical Examiners (NAME), American Society of Crime Laboratory Directors/Laboratory (ASCLD/LAB) Accreditation Board, Singapore Accreditation Council – Singapore Laboratory Accreditation Scheme (SAC-SINGLAS), and the International Organization for Standardization ISO/IEC 17025 for the Pharmaceutical Division and Food Safety Division; as well as ISO 9001:2008 for the Tobacco Regulation Branch and most recently, ISO 9001:2008 for the Corporate Services Group. These accreditations are recognitions of our standing as a credible, reliable and highly efficient regulatory authority.

Additionally, I am particularly proud that our Applied Sciences Group's Pharmaceutical Division Laboratories became the first and only organisation from Asia to be granted the Associate Membership to the General

European Official Medicines Control Laboratories (OMCL) Network (GEON) of European Directorate for the Quality of Medicines. GEON provides an important scientific platform for technical exchange in the fields of pharmaceutical testing and counterfeit drugs analysis.

Not to rest on our laurels, our Professional Groups constantly stay connected to regional and international networks – to upgrade our scientific and technical proficiencies and keep abreast of the latest developments. We participate actively in international groups such as the World Health Organization, Asian Forensic Sciences Network, Association of Southeast Asian Nations, Asia-Pacific Economic Cooperation and INTERPOL. Our strong ties with these partner organisations will allow us to leverage on their expertise and knowledge, as well as share ours.

We believe that our people are the heart of HSA's success. That is why I am particularly proud that our manpower strategy focuses on attracting, developing and retaining the best and right people. In 2014, we reviewed and implemented a competency framework, and enhanced the career tracks of our professional and technical staff. We will continue to do our best to provide an appropriate work environment to motivate, empower and enable HSAians to give their best in all that they do, for today and the future.

**What are the key challenges in HSA's future?**

Science and technology are developing at a rapid pace, which means that the spectrum of our services, which impact public health and the justice system, will continue expanding.

HSA therefore needs to enhance and broaden its existing services, stay abreast of new scientific and technological challenges, and develop faster and more accurate ways of analysis and testing. It is essential that we evolve to better serve the needs of the public and the industry and be ahead, both in knowledge and expertise. We also need to continue to fortify existing partnerships and formulate new key strategic links. This will allow us to work with and learn from the best, and tap on expertise that can bring meaningful change to our science and processes.

To ensure continued success, we require a good team competent in their areas of expertise. We need to be resilient, versatile and rise to meet challenges, and manage the escalation of workload while maintaining a lean workforce. We need people with the integrity, expertise, professionalism, and right values. They need to be passionate about HSA's mission and vision, and find the work in HSA meaningful and fulfilling. Once we recruit these talents, we will help them realise their full potential by providing them with support, training and development opportunities.

**There have been some key leadership movements in the HSA Board. How will these impact HSA's future?**

I would first like to express my sincere appreciation to Professor K. Ranga Krishnan, who stepped down after serving on the Board for four years. He was an invaluable member of the Board who drew from his rich scientific and regulatory expertise, and experience to provide strategic guidance to HSA. Professor Ranga was instrumental in refining the business plan for the HSA Academy and helped to build a stronger scientific and risk management foundation.

This year, we extend a warm welcome to three new board members. Professor Freddy Boey, Professor Alex Matter and Mr Lionel Yee bring with them well-regarded expertise and knowledge. Their perspectives and insights will help enrich our strategic plans and clarify the goals that the HSA Board and Senior Management will work towards.

“ We believe that our people are the heart of HSA's success. That is why I am particularly proud that our manpower strategy focuses on attracting, developing and retaining the best and right people. ”



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

“ I am very impressed by my team's strong professionalism, passion and pursuit of scientific excellence and rigour. They believe in being the best that they can be and are indeed committed to securing public health and safety, 24/7, 365 days a year. ”



**Dr Mimi Choong**  
Chief Executive Officer

**You came on board as the CEO of HSA on 1 July 2014. How has the experience been like so far?**

HSAians have been very warm, welcoming and supportive. It has been a busy and exciting year, as well as meaningful and fulfilling to have joined such a professional and dynamic organisation with such varied scientific functions that protect and advance public health and safety, and serve the administration of justice.

I am very impressed by my team's strong professionalism, passion and pursuit of scientific excellence and rigour. They believe in being the best that they can be and are indeed committed to securing public health and safety, 24/7, 365 days a year. I am also struck by HSAians' innovative spirit. They seize opportunities and show resilience in overcoming challenges. It is my privilege and honour to work with so many highly committed and motivated individuals whose actions and decisions are defined and guided by HSA's core values. It is precisely their passion and sense of responsibility that have allowed us to discharge our national responsibilities well, and to continue advancing HSA as a leading scientific and regulatory organisation.

I am constantly reminded of our unique national roles and responsibilities. The work that we do is essential to our nation's healthcare, justice and economy. It is also deeply satisfying to know that we are helping to safeguard lives through health product regulation, securing the nation's blood supply, and serving the administration of justice.

Our strong international reputation and high professional standing is clearly evident whenever I meet our overseas counterparts and witness our interactions with our international partners. We have signed numerous Memoranda of Understanding and Cooperation Agreements worldwide, and have been appointed to several international panels and committees. In addition, we are among the founding members of professional networks such as the Asia Pacific Blood Network and the Asian Forensic Sciences Network.

At home in Singapore, our professional expertise is well-respected by the many stakeholder groups we interact with, and we are growing our engagements with these communities. Within HSA, the various Professional Groups work well together. For instance, the Applied Sciences Group recently developed the capability to test antimicrobial preservatives in cosmetic products and developed a new testing methodology to analyse structurally-similar stereoisomers of yohimbine. Capabilities like these support the function of our Health Products Regulation Group.

**What are some of HSA's key highlights in the past year?**

My fellow HSAians have a strong sense of responsibility and professionalism in supporting the needs of our stakeholders,

# A Round-up with Our CEO

and we have further strengthened our working relationships with them over the past year.

We secured our first Service Level Agreement with the Agri-Food and Veterinary Authority (AVA) in food safety testing. This is a significant milestone that underscores AVA's confidence and commitment in our scientific and analytical expertise.

To support the investigative needs of the Home Team, our Forensic Chemistry and Physics Laboratory has expanded its knowledge and expertise, and enhanced its range of scientific services, particularly in crime scene and traffic accident reconstruction. The laboratory has also embarked on structured cross-training, and implemented multi-functional case management teams to allow for flexibility in staff deployment to handle complex and urgent cases.

The medical devices industry will benefit from our enhancement to the change notification routes for existing registered medical devices undergoing Field Safety Corrective Actions. The streamlined and risk stratified process will now allow product registrants to risk-manage the use of medical devices by existing users for the safety of their patients.

The Blood Services Group's Cell Therapy Facility attained the global Pharmaceutical Inspection Cooperation Scheme (PIC/S) certification for our human cell and tissue-based therapeutic products (CTT) in August 2014, which qualifies it as a GMP facility to manufacture or produce cells/tissues under very stringent, sterile conditions. We are the first in the region to attain this certification, and we can look forward to more potential new CTT projects in the years ahead.

We have also provided assistance beyond our shores. In response to the AirAsia flight QZ8501 incident on 28 December 2014, our forensic experts were part of the Disaster Victim Identification team led by the Singapore Police Force that went to Surabaya, Indonesia.

**How is HSA equipping itself to be future-ready?**

Being future-ready requires us to plan ahead and anticipate changes, opportunities and challenges. Collectively, we have to ensure scientific rigour and excellence in all that we do. This involves recruiting and developing the right and best people.

To maintain our scientific and technical proficiencies, we will need to be attuned to the latest scientific developments worldwide, and participate in international conferences and programmes.

At the same time, we must continue building and strengthening our networks, both locally and globally, and leverage them for information, learning and work sharing. With this strategy in place, we can make the best scientific decisions across all our professional groups, and maintain

HSA's position as a credible, reputable and leading scientific and regulatory authority.

In an ever-changing scientific landscape, we need to always be ahead of the game. Apart from making continuous refinements, we must identify and develop new capabilities that we require. For example, our Applied Sciences Group has acquired 3D laser scanning capabilities that will allow investigators to present virtual crime scenes in court for a more accurate visualisation.

Productivity and innovation are key to enabling us to do our job more effectively and efficiently. We seek to boost our skills, expertise and competencies, think innovatively, develop new methods, and streamline work processes. We will also undertake R&D work that can, with time, enhance our scientific and regulatory value and contributions to society.

Given our diverse national responsibilities, we need to identify and mitigate the many risks we face. Our response is crucial, and we have implemented an HSA-wide risk register, and a risk reporting and governance framework. We have enhanced our response and escalation system to ensure that sentinel events are managed promptly and appropriately. We are also developing HSAians' capabilities to anticipate and deal with the potential risk exposures they face in their work and operating environments.

On the regulatory front, we recognise that engaging our stakeholders early in the policy-making process enables us to consider their feedback, and solicit their buy-in. This also helps us to strike the right balance between the need to protect public health and safety, and the demands for a more business-friendly environment with fewer, yet more transparent rules and regulations. It is pro-enterprise, and facilitates our own regulatory work. It is win-win.

This year, we welcomed Associate Professor Sunil Sethi as Group Director of the Applied Sciences Group, and Mr Jeffrey Wong as Group Director of the Corporate Services Group. With their wealth of experience and expertise, I am confident that they will help HSA to effectively deliver on our mission and vision. We would also like to express our appreciation to Dr Mok Ying Jang for his contributions to HSA over the past four years. He has driven strategic initiatives and organisational reviews that have enhanced corporate support to our Professional Groups. I wish him all the very best in his future endeavours.

With a strong leadership team and the support of committed and professional staff, I am confident that HSA is well-positioned to meet the needs of Singapore today, tomorrow and in the future.

# HSA BOARD

As at August 2015



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



**Mr Max Loh**  
Managing Partner, ASEAN and Singapore  
Ernst & Young



**Mr Tai Lee Siang**  
Group Managing Director  
ONG&ONG Pte Ltd



**Ms Serene Wee**  
Chief Executive  
Senate Secretary  
Singapore Academy of Law



**Professor Freddy Boey**  
Deputy President and Provost  
Nanyang Technological University



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



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



**Mr Clifton Tan**  
Director  
Pembroke Investments Pte Ltd



**Mrs Tan Li Lian**  
Director  
Contemporara Holdings Pte Ltd



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

# HSA Board Committees

As at August 2015

## Board Executive Committee

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

## Board Updates



We would like to express our deep appreciation to Professor K. Ranga Krishnan for his dedicated service and wide-ranging contributions as a member of the HSA Board for the past four years. Professor Ranga has helped to position and prepare HSA to be better structured and equipped to manage current and future regulatory challenges. We wish him success for the future.

We would also like to thank Mr Colin Lim for his contributions as a Board Member.

We warmly welcome three new board members to the HSA family – Professor Freddy Boey and Professor Alex Matter with effect from 1 April 2015; and Mr Lionel Yee with effect from 1 August 2015. We look forward to their insightful guidance in advancing HSA as a reputable and high-performing scientific and regulatory authority.

## Audit and Risk Committee

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

## Building Development Committee

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

# HSA Executive Committee (EXCO)

As at August 2015



**Dr Mimi Choong**  
Chief Executive Officer



**Assoc Professor Sunil Sethi**  
Group Director  
Applied Sciences Group

## Asst Professor Raymond Chua

Group Director  
Health Products Regulation Group  
Principal Director  
HSA Academy



**Mr Jeffrey Wong**  
Group Director  
Corporate Services Group



**Dr Diana Teo**  
Chairman  
Professional Board  
Senior Director  
Blood Services Group



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



**Dr Ang Ai Leen**  
Deputy Group Director  
Blood Services Group

We would like to thank Dr Mok Ying Jang for his invaluable contributions as Group Director, Corporate Services Group, from 1 June 2011 to 10 July 2015.

# Corporate Governance Statement

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

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

## The Board

The Board comprises the Chairman and its members, who are appointed by the Minister for Health for a 2-year or 3-year term. It aims to meet every two to three months to set strategic directions, assume the role of monitoring and reviewing of policies leading to HSA's improved management and performance.

## Board Members' Remuneration

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

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

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

## Accountability and Audit

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

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

### (a) Board Executive Committee

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

### (b) Audit and Risk Committee

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

### (c) Building Development Committee

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

## Communication with Stakeholders

The Professional Groups conduct regular consultations with the industry and their clients, seeking to keep them informed of new directions and regulations, and to listen to their concerns. HSA publishes an annual report to meet statutory requirements and provide information to our stakeholders.

In addition, regular updates on matters of interest to our stakeholders are posted on our Internet website. Our Quality Service Manager ensures that the organisation's professional quality standards are maintained.

## Code of Business Conduct

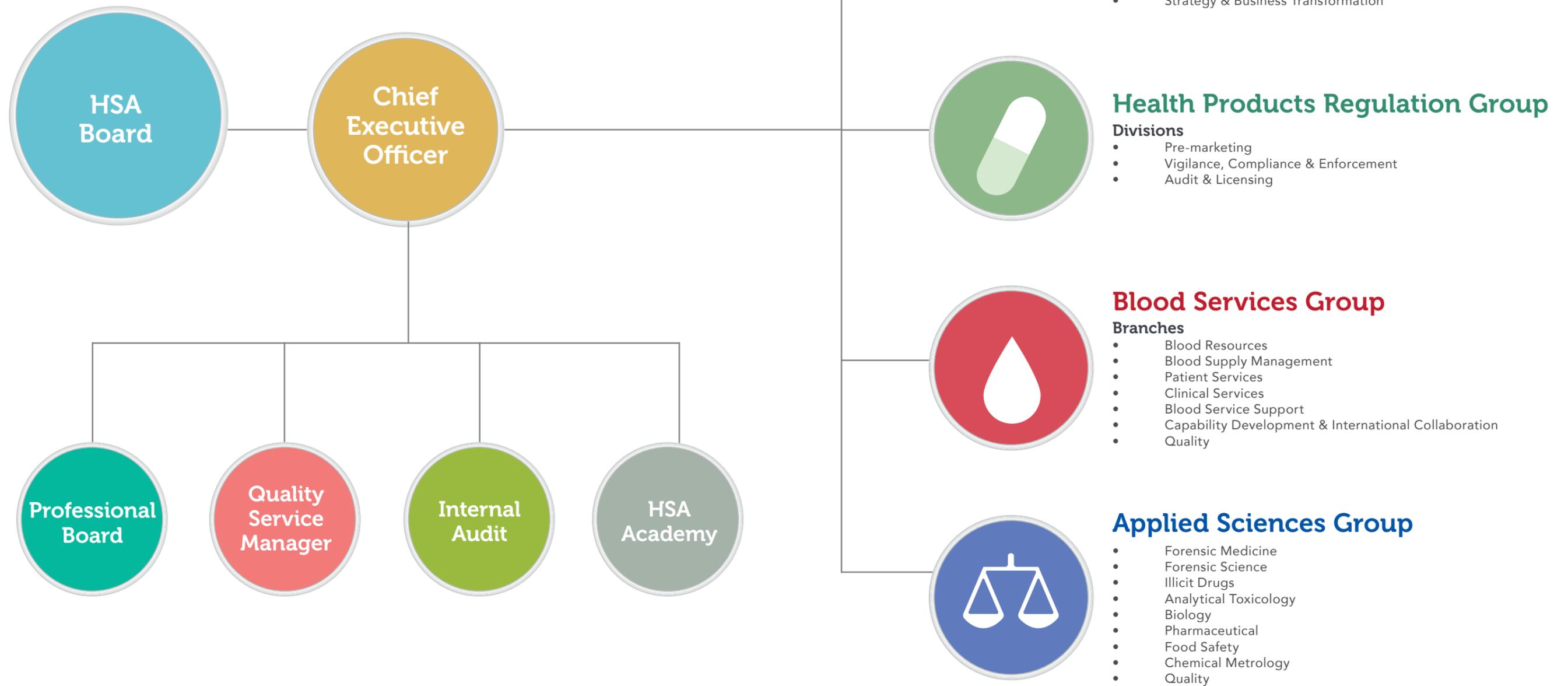
The Board, officers and employees are required to observe and maintain high standards of integrity, and be compliant with the law, government regulations, organisation policies, and best corporate practices.

## Risk Management

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

# Organisation Chart

As at August 2015



# PRINCIPAL OFFICERS

As at August 2015

## CORPORATE HEADQUARTERS

Chief Executive Officer  
Dr Mimi Choong

**Professional Board**  
Chairman  
Dr Diana Teo

**Quality Service Manager**  
Director  
Professor Bosco Chen  
Bloodworth

**Internal Audit**  
Assistant Director  
Adeline Ho

**HSA Academy**  
Principal Director  
Asst Professor Raymond Chua

Senior Director  
Dr Christina Lim

## CORPORATE SERVICES GROUP

Group Director  
Mr Jeffrey Wong  
(with effect from 15 July 2015)

**Corporate Communications**  
Director  
Mr Adrian Chia

**Risk Management & Emergency Planning**  
Director  
Mr Axel Chan

**Human Capital Management**  
Director  
Ms Lily Goh

**Legal & Prosecution**  
General Counsel  
Ms Linda Chen

**Finance**  
Director  
Ms Grace Chan

**Facilities Management**  
Director  
Ms Lynette Goh

**Information Management**  
Director  
Mr Manoj Abraham

**Strategy & Business Transformation**  
Director  
Mr Prashant Dharmi

**Safety & Quality**  
Director  
Professor Bosco Chen  
Bloodworth

## HEALTH PRODUCTS REGULATION GROUP

Group Director  
Asst Professor Raymond Chua  
Deputy Group Director  
Assoc Professor Chan  
Cheng Leng

**GROUP DIRECTOR'S OFFICE**  
Director  
Ms Ling Boon Lee

**PHARMACOECONOMICS & DRUG UTILISATION UNIT**  
Deputy Director  
Mr Benjamin Ong

## PRE-MARKETING

Assistant Group Director  
Ms Lee Hui Keng

**Scientific Advisory Office**  
Director  
Ms Agnes Chan

**Clinical Trials Branch**  
Director  
Mr Foo Yang Tong

**Therapeutic Products Branch**  
Director (Clinical)  
Ms Jalene Poh

Director (Quality)  
Dr Dinesh Khokal

**Medical Devices Branch**  
Director  
Ms Wong Woei Jiuang

**Complementary Health Products Branch**  
Director  
Ms Hui Foong Mei

**Advanced Therapy Products Unit**  
Head  
Dr Kellathur Nadathur Srinivasan

**VIGILANCE, COMPLIANCE & ENFORCEMENT**  
Acting Assistant Group Director  
Dr Dorothy Toh

**Enforcement Branch**  
Director  
Ms Ruth Lee

**Vigilance and Compliance Branch**  
Director  
Dr Dorothy Toh

**Tobacco Regulation Branch**  
Director  
Mr Norman Chong

**AUDIT & LICENSING**  
Assistant Group Director (covering)  
Ms Lee Hui Keng

Deputy Division Director  
Ms Jessica Teo

**Audit Branch**  
Director  
Ms Jessica Teo

**Licensing & Certification Branch**  
Director  
Dr Lai Weng Fai

**BLOOD SERVICES GROUP**  
Group Director (covering)  
Dr Mimi Choong

Senior Director  
Dr Diana Teo

Deputy Group Director  
Dr Ang Ai Leen

Assistant Group Director (Operations)  
Dr Tan Hwee Huang

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

**GROUP DIRECTOR'S OFFICE Blood Service Support**  
Director  
Ms Koh Geok Tin

**Capability Development & International Collaboration**  
Senior Manager  
Ms Leou Kwee Kim  
Ms Wong Wai Cheng

**Quality**  
Senior Manager  
Ms J Thilakavathi

**BLOOD RESOURCES**  
Branch Director  
Mr William Sim

**BLOOD SUPPLY MANAGEMENT**  
Laboratory Director  
Ms Sally Lam

**PATIENT SERVICES Immunohaematology & Cell Therapy Support**  
Laboratory Director  
Dr Marieta Chan

## APPLIED SCIENCES GROUP

Group Director  
Assoc Professor Sunil Sethi

**QUALITY**  
Director  
Dr Chow Shui Tse

**FORENSIC MEDICINE**  
Chief  
Dr Paul Chui

**Infrastructure Branch**  
Branch Director  
Dr George Paul

**Operations Branch**  
Branch Director  
Assoc Professor Cuthbert Teo

**Professional Practice Branch**  
Branch Director  
Assoc Professor Gilbert Lau

**Technical Capabilities Branch**  
Branch Director  
Dr Marian Wang

**FORENSIC SCIENCE**  
Assistant Group Director  
Dr Angeline Yap

**Analytical Toxicology Division**  
Division Director  
Dr Yao Yi Ju

**Biology Division**  
Division Director  
Assoc Professor Christopher Syn

**Forensic Science Division**  
Division Director (covering)  
Dr Chow Shui Tse

**Illicit Drugs Division**  
Division Director (covering)  
Dr Angeline Yap

**ANALYTICAL SCIENCE**  
Assistant Group Director  
Ms Low Min Yong

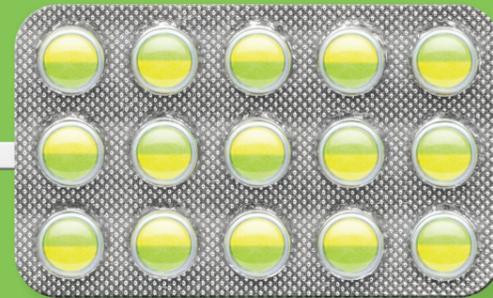
Senior Scientific Advisor  
Professor Bosco Chen  
Bloodworth

**Chemical Metrology Division**  
Division Director  
Dr Lee Tong Kooi

**Food Safety Division**  
Division Director  
Ms Joanne Chan

**Pharmaceutical Division**  
Division Director (covering)  
Ms Low Min Yong

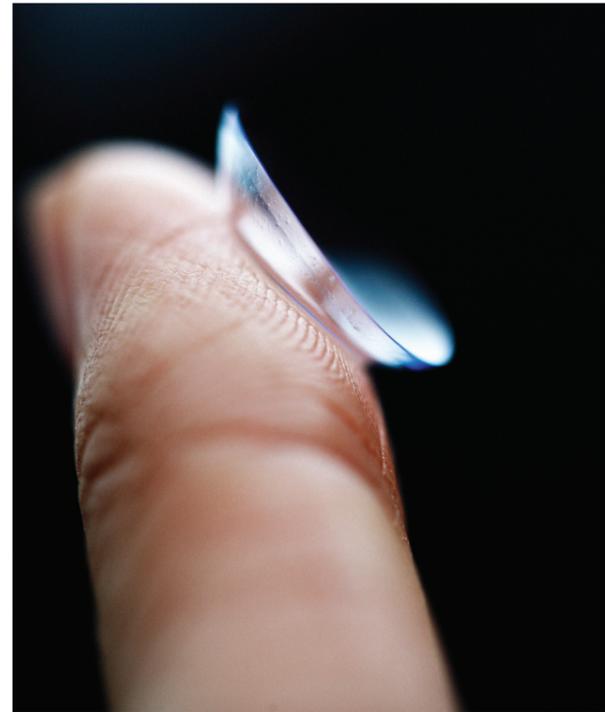
# HEALTH PRODUCTS REGULATION GROUP



We safeguard consumers by ensuring that health products in Singapore meet required standards of quality, safety and efficacy. Through a framework of pre-market, audit, licensing and post-market surveillance activities, we work tirelessly with our local, regional and global counterparts to secure public health and safety.

# Raising the Bar

We are dedicated to making continuous improvements to our regulatory work and processes through understanding the needs and concerns of our partners and stakeholders. We constantly strive towards productivity and progress by building and reviewing frameworks beneficial to the industry, without compromising public health and safety.



## Broadening of Contact Lens Grouping

A focus group discussion was held with the contact lens dealers in September 2014 to obtain feedback on the guidelines for the proposed contact lens grouping criteria during the submission of its application dossier. Following that, we expanded the list of permissible variants for contact lens grouping, so as to allow applicants to include a greater variety of contact lens specifications in their submissions. This would reduce operating costs and help them to save time. This grouping criteria came into effect on 1 December 2014.

## New Condom Import Conditions

HSA has refined the testing requirements for condoms by removing the need to test every batch of condoms at the point of import. Instead, with the product registration system in place, HSA presently requires that condoms only need to be tested as part of its periodic random sampling surveillance. This enables dealers to save on operating costs and time. These new conditions were implemented in February 2015.



## Health Supplements Guidelines Booster

In February 2015, we reviewed and published a revised version of the Health Supplements Guidelines. This provides an updated regulatory guidance to the health supplement industry to ensure that the supplements marketed are safe for consumption. The updates include examples of labelled information that would be useful for consumers, and substances that should not be included in health supplements.

## Enhanced Clinical Trials Framework

Following a series of consultation sessions in April 2014 with the respective directors and staff of institutions involved in clinical research and conducting clinical trials, a series of proposed refinements to the clinical trial regulatory framework was implemented in June 2014.

One of the refinements was to have an institution to sponsor local multi-site Investigators Initiated Trials involving a single protocol. This ensures a timely, coordinated and effective management of safety information and trial updates to all sites and a single point of contact for regulatory submissions for more effective and streamlined communication with HSA.

The provisions for the single sponsor framework and responsibilities of the lead sponsor and other participating site sponsors will be incorporated in the new Health Products (Clinical Trials) Regulation when it is ported over to the Health Products Act.

## Continuous Progress

In February 2015, we enhanced our Minor Variation Applications (MIV-1) submissions to facilitate more timely regulatory approval. The process has been enhanced so that only critical documents, such as Good Manufacturing Practice conformity assessment applications, are screened first – leaving supporting documents to be assessed during the evaluation stage. With the focus on screening only for critical documents, the aim is to reduce the screening time. This will result in a faster acceptance for evaluation and, possibly, a faster approval of the MIV-1 applications.

As part of our continual review of licensing processes, our MEDICS system has been enhanced to improve operational efficiency and reduce the administrative burden. The improved system allows all medical device dealers to update their information easily with new features like "Change of Business Information", instead of requiring multiple updates for each licence type. This enhancement also includes new fields to capture operating site addresses and scope of operations. This is to enhance transparency and to facilitate swift retrieval of essential information in the dealer's licence.



## Enhancing Efficiency with Lean Six Sigma

To work towards greater productivity, we embarked on Lean Six Sigma projects to streamline our work processes.

Some of the improvements include:

- Enhancing PRISM – our e-services licensing portal - to provide a better user experience
- Increasing the number of minor variation applications (MIV-1) that can be submitted at one time, based on feedback from the industry
- Setting up a help desk in the Audit & Licensing Division to assist applicants in submitting applications

## Faster Processing for Medical Device Notification

A Field Safety Corrective Action (FSCA) notification is required to be submitted by medical device companies when actions need to be taken to eliminate, or reduce any risks or hazards identified with their medical devices. Last year, a total of 588 Medical Device FSCA notification reports were reviewed. In order to safeguard public health and to ensure that any risks or hazards associated with existing supplies in the market are kept to the minimum, various improvements have been made to enhance the FSCA processes as part of post-market activities.

Previously, corrective actions of some FSCAs would be required to undergo a Change Notification (CN) submission. To ensure that the affected medical devices used by existing users are corrected expeditiously, the CN process for such FSCA cases was refined so that existing supplies can be corrected within 20 days. Industry input was sought through two focus group discussions and they responded positively to the change.

We also implemented triaging principles for the processing of FSCA notifications in October 2014. In doing so, notifications can be reviewed and processed more effectively, and urgent notifications can be attended to in a timely manner.

## Reducing Risks

Having an effective risk management plan (RMP) in place is important to allow us to take appropriate risk minimisation activities or monitoring to ensure that the benefit-risk profile of the product remains positive throughout its lifecycle on the market.

In an enhancement of our post-market risk management requirements, we now require RMP documents for New Drug Applications (NDA-1) and biosimilar applications for medicinal products seeking approval in Singapore. Previously, submissions were on a voluntary basis.

To take into consideration industry feedback, we organised a series of dialogue sessions in July and August 2014. Two dialogue sessions with Singapore Association of Pharmaceutical Industries (SAPI) were also conducted to address the industry's concerns and to clarify enquiries. The full implementation has been scheduled to take effect from June 2016.

## Training New Pharmacists in Inspection and Regulation

The Audit and Licensing Division and the Therapeutics Products Branch have been approved by the Singapore Pharmacy Council (SPC) as accredited training centres for non-patient care pharmacist registration training in 2013 and 2014 respectively. Together, they have trained three pharmacists from the Jurong Health Services this financial year.

# Collaborating with ASEAN and APEC Counterparts

Working together with local and international partners, we strive to build a regulatory landscape that is conducive to the advancement of public health and the development of the biopharmaceutical sector.

## Aligning Controls within ASEAN

Between August and November 2014, all the ASEAN countries signed the ASEAN Medical Device Directive (AMDD) Agreement by ad-referendum basis. This represents the commitment to having a harmonised regulatory framework for medical devices across all ASEAN member states. As the first ASEAN member state to roll out the medical device regulations, HSA maintains a framework that is closely aligned with the AMDD proposed framework.

Paving the way for an enhanced integration of the medical device sector in ASEAN, we also hosted the 18th ASEAN Consultative Committee for Standards and Quality - Medical Device Product Working Group (ACCSQ-MDPWG) Meeting – in May 2014. Delegates from all ASEAN Member States attended the event and the synergistic cooperation culminated in the adoption of the Report of the 18th MDPWG.

## APEC Harmonization Center - HSA Cell- and Tissue-based Therapeutic Products Workshop

We organised an international workshop on Cell- and Tissue-based Therapeutic (CTT) products in July 2014.

This was held in conjunction with the Regulatory Harmonization Steering Committee of the Asia Pacific Economic Cooperation Life Sciences Innovation Forum. The workshop aimed to facilitate understanding of the current regulatory landscape for CTT products; and provide a platform for regulators and product developers around the world to share on the challenges of CTT product manufacturing and manufacturing facilities.

## Working Collaboratively with Our Counterparts

An ASEAN Panel of Experts, led by HSA as Rapporteur and Team Leader, and its Malaysian and Indonesian counterparts as Co-Rapporteurs and Team Members, conducted a week-long on-site assessment of the Thai FDA in September 2014 as part of the ASEAN Sectoral Mutual Recognition Arrangement on Good Manufacturing Practice.

The recommendation to include the Thai FDA in the List of Accepted ASEAN Inspection Services was accepted at the 22nd Pharmaceutical Product Working Group Meeting held in Laos in March 2015. This will eliminate the need for additional inspections once the Thai FDA's GMP certificates, like other members in the List, are recognised by the ASEAN Member States.



# Protecting the Public

Through enforcement, we work round-the-clock to safeguard the public from products that are unsafe. Together with our counterparts in other enforcement agencies, we take a proactive approach to eradicate the illegal sales of health products.



## Seeking out Errant Suppliers

Six doctors were among 10 people who were investigated for the illegal supply of codeine cough syrup to underground drug syndicates. Of these, one general practitioner had earned large profits from illegally supplying codeine cough syrup to the black market. The doctor was found guilty and was jailed for 7.5 months, fined \$60,000, and also had his medical licence revoked subsequently by the Singapore Medical Council.

Since 2009, our tough stance against the illegal codeine trade has seen 47 people prosecuted. From 2009 to 2013, HSA has seized almost 12,000 litres of codeine cough syrup, worth an estimated street value of \$2.5 million.



## Raising Awareness of Adulterated Products

Ten press releases against adulterated products were issued to warn the public of the dangers of consuming illegal medicines in 2014. While masked as natural complementary health products, most of these illegal medicines were tested to contain dangerous prescription drugs or their analogues, such as those intended for sexual enhancement or slimming. With the help of the media, the public was alerted about the dangers of these adulterated products, such as AMACE for him, Nutri Drops Grapefruit Diet, JIN LONG Snakes' Bones Rheumatic Capsules, Golden Dragon Linzi Dong Mai Dan, VIA.X For Men and Herbal Health Jointcare.

## Cracking Down on Cybercrime

For the seventh year in a row, we took part in Operation Pangea VII, an international enforcement operation coordinated by INTERPOL in May 2014. During this week of intensified checks, online platforms were screened to identify illegal health products that were sold online in Singapore. The week of concerted action saw the largest haul of illegal sexual enhancement products amounting to an estimated street value of \$400,000. 10 individuals are under investigation for offences under the Medicines Act, Poisons Act and Health Products Act.



## Drug Dealer Apprehended

A major joint operation between HSA and the Singapore Police Force (SPF) in September 2014 saw a suspect being apprehended for illegal dealings involving large volumes of various drugs of abuse. These included 8.7 litres of codeine cough syrup, 641 tablets tested to contain nitrazepam, triprolidine and pseudoephedrine, and 1,663 diazepam tablets. The accused was sentenced to three years and seven months' imprisonment.

## Striking out Illegal Sexual Enhancement Products

In our ongoing efforts to address the recurring problem of illegal peddling involving sexual enhancement products (SED) in Geylang, HSA took part in a series of joint enforcement operations with ICA and SPF from January to December 2014. This planned multi-agency operation successfully disrupted the downstream supply of SEDs, with the arrest of 30 people. A total of 69,988 units of SEDs, worth an estimated street value of more than \$170,000, were seized.



## E-cigarette Sales Extinguished

Two illegal online operations by electronic cigarette (e-cigarette) dealers were successfully stubbed. The suspects were detected via Internet surveillance and apprehended in two raids. Records seized revealed that the suspects' past transactions totaled about \$200,000. HSA has shut down both websites.

## Efforts to Deter Tobacco Sales to Minors

Sellers from six tobacco retail outlets were caught for selling tobacco products to minors under 18 years of age. These sellers were subsequently convicted in Court and the respective tobacco retail licensees were also suspended for a period of six months.

## Shisha Ban

HSA, in collaboration with the Ministry of Health and Health Promotion Board, imposed the ban on shisha in November 2014 via the publication of the Prohibited Tobacco Products Regulations made under Section 15 of the Tobacco (Control of Advertisements and Sale) Act. As a transitional measure, existing licensed tobacco importers and retailers will be allowed to continue importing and retailing shisha tobacco until July 2016. This is to provide them with ample time to deplete their stock and adapt their businesses.

# Always On Guard

To protect patients and consumers from unsafe health products, we keep a keen eye on post-market activities. Through surveillance and vigilance work, we work hand in hand with healthcare professionals in risk mitigation.

## Staying on Top

Since 2011, Singapore has maintained its top position in the World Health Organization (WHO) Global Individual Case Safety Report (ICSR) database ranking, for the number of active individual case reports submitted per million inhabitants. According to the report published in October 2014, we submitted close to 3,200 adverse drug reports per million inhabitants per year.



## Adverse Events Reporting

Over the year, we received 28,184 local reports of adverse events (AE) that were suspected to be associated with health products. Of these, 20,404 were captured into the national database as valid reports.

Most of these reports were associated with pharmaceuticals, followed by vaccines, biologics, and complementary health products (CHPs), including Chinese proprietary medicines, traditional medicines and health supplements. The main contributors of these reports are public hospitals and polyclinics, followed by drug companies, private clinics and hospitals.

Our proactive monitoring and reviews of local AE reports also enabled us to identify the following significant drug safety signals over the course of the year. These included:

- Risk of Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis with Omeprazole
- Risk of central nervous system AEs (including seizures) with Ertapenem
- Thromboembolic events and increased risk of bleeding with Dabigatran

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

## Vaccine Vigilance

HSA continues to work in close partnership with KK Women's and Children's Hospital (KKH) in the active surveillance of suspected AEs after vaccination. From April 2014 to March 2015, 27,222 children were screened for AEs following recent vaccination. 261 cases of suspected AEs were further evaluated. Of these, 195 cases were considered as possibly associated with vaccines. An assessment of potential safety signals was done to ensure that the reports were within the expected incidences. Expert opinions were also sought to ensure that the benefit-risk profile of the vaccines remains favourable.

## Complementary Health Products

From April 2014 to March 2015, we received 147 AE reports associated with CHPs. Of these, seven reports were linked to adulterated products. A total of five press releases were issued to alert the public against taking such harmful products.



## Product Risk Management

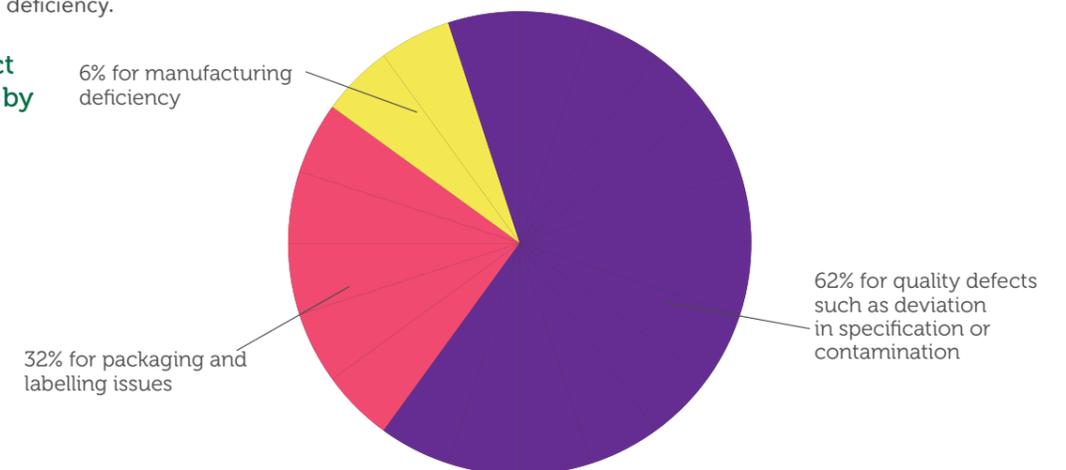
A total of 12 local risk management plans were implemented for medicinal products in response to safety concerns observed either at the point of market approval or during post-market surveillance. The products included Zaltrap, Abraxane, Folutyn, Pomalyst, Yervoy, Jetrea, Zarzio, Xeljanz, Jardiance, Erivedge, Sylvant and Eligard. Local risk management plans include activities on pharmacovigilance and risk mitigation, such as issuing educational materials for physicians and patients, to highlight safety concerns, submitting periodic benefit-risk evaluation reports, as well as strengthening safety warnings in package inserts.

During the year, we conducted 21 risk assessments arising from health products found to contain adulterants or exceeding toxic heavy metal limits. These were part of product quality surveillance and post-market surveillance activities. Regulatory actions saw press releases issued for products such as Mr Zack Powerbro, Zhenzhu Shedan Chuanbeimo, and product recalls for products such as Xi Xin.

## Surveillance of Local Product Defects

Local product registrants submitted 47 product defect reports. Of all, 42 were related to chemical pharmaceutical products, three were related to radiopharmaceutical products and two were related to biological products. 62% of submissions were attributed to quality defects such as a deviation in specification or contamination, 32% for packaging and labelling issues, and 6% for manufacturing deficiency.

### Nature of product defects reported by local product registrants



Regulatory action has been taken for 27 cases, including three retail product recalls and the issuance of two Dear Healthcare Professional Letters. These letters were sent to inform healthcare professionals about the product defects and regulatory decisions imposed on the health products.

## Enhancing Patient Safety

As part of our efforts to continuously enhance patient safety, HSA keeps public healthcare institutions updated through monthly summaries of reported Field Safety Corrective Actions (FSCA). These FSCA alerts will empower healthcare institutions to identify any affected devices within their facilities. In addition, they are able to monitor the FSCAs of the medical devices in use and take appropriate actions to ensure that corrective actions and preventive actions are in place.

Field Safety Notices (FSN), which provide further information on the FSCAs, are also available via the Ministry of Health portal. From April 2014 to March 2015, a total of 595 FSNs were uploaded onto the portal.



# Local Stakeholder Engagement

We take a risk-based approach in regulating health products. We are in constant talks with our local stakeholders to ensure that our policies and regulatory framework are relevant and effective.



## Learning from the Industry

HSA is monitoring the implementation and use of Unique Device Identifiers (UDI) globally to facilitate the track and traceability of high-risk medical devices in healthcare institutions. In February 2015, a focus group with representatives from companies marketing high-risk devices, was conducted to gather feedback on their experiences with the implementation of UDI in the United States, as well the challenges they faced.

MOH Holdings and the healthcare institutions will be looking into the implementation of the UDI further within the local context together with the support of relevant stakeholders, including HSA, due to the technical and collaborative nature required to create this infrastructure to strengthen the post-market framework of medical devices.

## Dialogue Session with Biomedical Engineering Representatives from Healthcare Institutions

HSA met with Biomedical Engineering representatives from nine healthcare institutions in July 2014 to hear their concerns in relation to defective medical devices in their premises. Medical device post-marketing surveillance activities such as the reporting of Adverse Events (AEs), Field Safety Corrective Actions (FSCAs) were shared. Case studies of reported AEs, FSCAs and medical device non-compliances were also discussed.

## Engagement in the Policy Cycle

To keep our regulatory regimes relevant to the rapidly evolving complementary health products (CHP) industry, we conducted four focus group discussions between May and July 2014 with 54 local CHP companies. Manufacturers, importers, retailers and industry associations gave valuable feedback based on the current CHP controls, as well as suggestions to further enhance the regulatory regime.

To better understand the perspective of the end-user, we also met CHP consumers in two focus group discussions on the use and regulations of CHP.

A public consultation was also conducted from December 2014 to January 2015 for the ASEAN Agreement on Traditional Medicines and the ASEAN Agreement on Health Supplements (AATMHS). The essential components of the AATMHS include the harmonised definition and scope for traditional medicines and health supplements, as well as standards for the assurance of product safety, quality and its intended benefits.

## Stakeholders Play a Part in Policy-making

To tackle issues faced by both HSA and its partners, we held a series of high-level industry dialogue sessions to share ideas, discuss issues, address challenges and explore possible collaborations. The dialogue sessions resulted in the formation of working groups with organisations such as the Singapore Association of Pharmaceutical Industries, the Singapore Pharmaceutical Manufacturer's Council, the Singapore Pharmaceutical Trade Organisation, Association of Medical Device Industry and the Singapore Manufacturing Federation - Medical Technology Industry Group.

Some of the issues discussed included the proposed changes and timelines of the Health Products Act Portover for Therapeutic Products, turnaround time for Change Notification and Field Safety Corrective Actions, and capability building for the industry.



## Keeping Tobacco Out of Sight

With plans to ban Point-of-Sale displays for tobacco products, HSA, together with the Ministry of Health and Health Promotion Board, organised four trade engagement sessions with tobacco retailers in November 2014. The sessions served as a platform to communicate the policy intent and details of its implementation. Participants also clarified concerns and provided feedback.

## More Clarity on Medical Devices

HSA took part in the Singapore Manufacturing Federation's 4th Awareness Seminar on Medical Devices, where the workflow and scientific rationale of medical device evaluation in managing public health risks were shared and discussed. Held in September 2014, the session enabled industry professionals and stakeholders to gain a better appreciation of the current regulatory framework.

We also collaborated with the Association of Medical Device Industry (AMDI) and SPRING Singapore on the Medical Technology Industry Resource Centre to launch the Regulatory Support Services Programme in October 2014. It aims to elevate quality standards and enhance regulatory professional capabilities of the medical device industry through providing consultancy and training support. In recognition of this collaboration, AMDI awarded HSA with the "Special Partnership Recognition Award" at its Annual Dinner held in October 2014.

In November 2014, HSA met the research and development and start-up community at the A\*STAR-DxD Hub-HSA Regulatory Symposium. At the dialogue session, we touched on the regulatory framework, approach and scientific rationale in the evaluation of devices to better manage public health risks.

# Reaching Out

With education being key to safeguarding public health, we continue to engage our partners and stakeholders through outreach programmes to create awareness on the importance of pharmacovigilance.

## University Students

At the National University of Singapore, we spoke on risk communications to undergraduates taking the Public Health Communications course. We shared case studies to facilitate discussions on the dangers of purchasing health products through the Internet or from dubious sources.

## Healthcare Professionals

Continuing education sessions for healthcare professionals were held at three hospitals, namely Singapore General Hospital (SGH), Alexandra Hospital and the National University Hospital. In these sessions, we shared the pharmacovigilance framework and the management of adverse drug reaction reports. The active participation of the healthcare professionals in the adverse events (AE) monitoring programme has resulted in the detection of potential safety signals related to health products.



## Up-to-Date All Year Round

We believe in keeping our stakeholders constantly informed on safety issues and regulatory decisions related to health products. Two Dear Healthcare Professional Letters (DHCPL) and 56 company DHCPLs were issued to our healthcare professionals. To the public, 11 press releases and one HSA Update were issued to convey important safety issues.

## Striving for Total AE Prevention

A joint DHCPL initiative by the Ministry of Health and HSA in April 2013 saw tremendous success in preventing Carbamazepine (CBZ)-induced Stevens-Johnson Syndrome/Toxic Epidermal Necrolysis (SJS/TEN).

The DHCPL highly recommended the genotyping of the HLA-B\*1502 allele prior to the initiation of CBZ therapy in new patients of Asian ancestry. By March 2015, a total of 1,499 blood samples had been genotyped for HLA-B\*1502, and 162 (10.8%) of these samples were tested positive for the presence of the at-risk allele.

Prior to the DHCPL, HSA received an average of 15 reports of CBZ-induced SJS/TEN annually over the last 10 years. Since its implementation, there have been no reported incidences of SJS/TEN associated with the use of CBZ in patients screened for the HLA-B\*1502 allele.



## Traditional Chinese Medicine Practitioners/Students

Roadshows promoting AE reporting for Traditional Chinese Medicine (TCM) were held at the Singapore College of Traditional Chinese Medicine, Nanyang Technological University and TCM College (S). In addition, a separate roadshow was held for doctors, pharmacists and nurses in SGH. A brochure encouraging AE reporting of suspected cases of liver injury from complementary health products was also sent to all 1,504 members of the Singapore Chinese Physicians' Association.

## Scientists

The importance of identifying pharmacogenetic associations behind serious skin rashes has always been a focus. We conducted an educational session at NUH's Molecular Diagnosis Centre to share about the "Association of HLA-B\*1502 and Carbamazepine-induced Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis".

# The World at HSA

We were also pleased to have welcomed the following guests to HSA.

Sept 2014	Oct 2014
<ul style="list-style-type: none"><li>Swissmedic, Switzerland</li><li>Hokkaido Bureau of Economy, Trade and Industry, Japan</li></ul>	<ul style="list-style-type: none"><li>Department of Health, Hong Kong SAR, China</li></ul>
Nov 2014	Dec 2014
<ul style="list-style-type: none"><li>State Administration of Traditional Chinese Medicine, China</li></ul>	<ul style="list-style-type: none"><li>Shanghai Food &amp; Drug Administration, China</li></ul>

# Gaining Insights from International Experts

Over the year, we welcomed a number of esteemed experts to Singapore. Their generous insights have been extremely beneficial to policy makers and stakeholders in the field of regulatory controls.



## Learning from China's Best

In a review of our controls for Chinese Proprietary Medicines (CPMs) and Traditional Medicines (TMs), we hosted two experts from the China Food and Drug Administration (CFDA), National Institutes for Food and Drug Control, in March 2014. They were: Ms Lu Jing, Chief Pharmacist and Mr Jin Hongyu, Acting Head of the National Medicines Office, who was also HSA's Health Manpower Development Plan Visiting Expert for Traditional Chinese Medicine (TCM). They shared valuable insights into the regulation of TCM, natural medicines, raw herbs, and the developments in the analysis of these products. These were useful in our ongoing reviews for the regulatory controls of CPMs and TMs.

## Gathering the World's Experts in Herbal Medicines

We welcomed international experts in herbal medicines as we hosted the 12th Standing Committee Meeting of the Western Pacific Regional Forum for the Harmonisation of Herbal Medicines (FHH) and the 5th FHH International Symposium in November 2014.

During the Standing Committee Meeting on 25 – 26 November 2014, participants shared updates on the regulation of herbal medicines in their respective countries, as well as research related to the standardisation of herbal materials. These included FHH member states, special member Canada and observers from the United States Pharmacopoeial Convention (USP) - China and Switzerland's CAMAG Laboratory. The 5th FHH International Symposium on 27 November 2014 served as a platform for experts to exchange views and share developments in their research. Besides the FHH member states and overseas observers, participants also included representatives from the Singapore Traditional Chinese Medicine Organisations Committee and Singapore's tertiary institutions.



## Eliminating Work Duplication between Regulatory Agencies

The 7th Australia-Canada-Singapore-Switzerland (ACSS) Consortium Generic Working Group Meeting held in October 2014 saw the initial development of a work-sharing model to prevent work duplication and to facilitate market entry. This model is designed for registration of the same generic product in multiple jurisdictions within the ACSS Consortium at the same time.

To date, several pharmaceutical companies have shown interest and the model is expected to be piloted in the near future. The meeting, which was hosted by HSA in partnership with Australia's Therapeutic Goods Administration, Health Canada and Switzerland's Swissmedic, sought to develop collaborative strategies for generic drug applications.

## Knowledge Sharing

Paving the way for future collaborations on cyber investigations between Singapore and China, we were invited to train delegates from the Chinese Customs and Police in Guangzhou. During the intensive three-day training course, delegates learnt about various software, cyber investigation techniques and case studies.

In March 2015, HSA received delegates from the Vietnam Ministry of Health who studied our best practices on the enforcement of tobacco use by minors under the age of 18, errant tobacco retailers who sold tobacco to minors, as well as the administration of our national tobacco retail, import and wholesale licensing system.

We also had the honour of delivering a presentation on GMP inspection of human cell and tissue-based therapeutic products at the 19th Annual Meeting of International Society for Cellular Therapy. Held in Paris, this meeting was attended by researchers, industries and regulators from around the world.

## Towards Productivity in Generic Drug Regulations

The 7th International Generic Drug Regulators Pilot (IGDRP) Meeting in November 2014 was hosted by HSA. The IGDRP addressed the challenges posed by increasing workloads, globalisation and complexity of scientific issues. Common forms and report templates have been developed for use by IGDRP members. IGDRP has also been collaborating with the European Union (EU) in an information-sharing pilot involving product applications submitted under the EU Decentralised Procedure. Launched in July 2014, the pilot has received positive feedback by the industry in Europe. Information sharing is expected to begin as soon as the dossiers undergo evaluation.

## Pharma Crime Training

Officers from the Korea Ministry of Food and Drug Safety attended a pharmaceutical investigation and enforcement training programme in November 2014 that was hosted by HSA. Apart from the in-house enforcement training, the four officers also had the opportunity to visit the Enforcement Branch's collaborating partners in the Applied Sciences Group, Agri-Food & Veterinary Authority of Singapore, National Environment Agency and the Immigration & Checkpoints Authority.



# BLOOD SERVICES GROUP



# Enhancing Donors' Experience

Our donors are the lifeline for patients. With their altruistic contributions, we can help ensure that there is a regular blood supply for those in need. That is why we are committed to making the blood donation process seamless and a positive experience for our donors.



## Donor-friendly Operating Hours

We have revised the operating hours for Bloodbank@Dhoby Ghaut to better cater to our donors' preferences. From August 2014, donors are now able to donate blood on Saturdays and Sundays between 10am and 5pm. This change was based on visiting patterns of weekend donor traffic. This donor-friendly initiative has enabled more people to come forward to donate during weekends.



## Leading Donors to Bloodbank@Woodlands

To enable donors to locate Bloodbank@Woodlands easily and to attract potential donors, several onsite publicity efforts were put in place. In November 2014, escalator stickers were put up and in January 2015, a façade signage was set up to indicate the location of the blood bank at Woodlands Civic Centre.



## Going Electronic for Shorter Waiting Times

The apheresis suite at the Bloodbank@HSA has moved from a manual to an electronic system of documentation using handheld personal digital assistant devices (PDA) in September 2014. This has resulted in faster retrieval and tracking of past donation records, and hence, a shorter waiting time for donors. Greater operational efficiency and reduction of paperwork mean that our nurses can spend more time interacting with our donors.

## Treasuring Our Donors

Our blood donors and their families had a splash of a time at the 11th World Blood Donor Day on 7 June 2014. Celebrating "Blood: The Greatest Treasure of Life", 12,000 donors gathered at the Port of Lost Wonder in Sentosa for a carnival of fun, food and performances. Graced by Guest of Honour, Mr Gan Kim Yong, Minister for Health, the event recognised 1,610 awardees for their selfless contributions, with 584 of them receiving the Champion Donor Award.



# Enhancing Blood Safety

We strive to enhance blood safety by regularly reviewing our blood testing processes and implementing new workflows, tests and technologies.



## Double Checking on Compatibility

Before any blood transfusion is carried out, it is crucial that blood group testing is performed accurately to prevent adverse transfusion reactions. We have introduced a new process to run a second blood verification for new patients who have no historical blood group records, which is aligned to international accreditation recommendations. This serves to enhance transfusion safety and will enable future implementation of electronic cross-matching, if required.



## Giving Blood to the Right Patients

Handwritten recipient labels for blood and blood components assigned for transfusion have now been replaced by system-generated labels. This recipient label contains the patient's particulars and details of the blood unit, which help ensure the correct identification of patients and the overall safety of transfusion.



## Reducing the Risk of Transfusion Related Acute Lung Injury (TRALI)

As a risk reduction measure, all female apheresis donors who have been pregnant before are screened for antibodies against Human Leukocyte Antigen (HLA). This has resulted in better patient care and reduced incidence of TRALI. In April 2014, HSA began offering the service of screening at-risk female donors to the National University Hospital.

Moving forward, we plan to use new HLA antibody screening kits that will include screening of antibodies to Human Neutrophil Antigen, which is also implicated in TRALI.

## Introducing HLA-DP Typing to Reduce Transplant Rejection

HLA-DP typing has been introduced as recent reports have suggested that anti-DP antibodies can be associated with allograft rejection and graft loss in kidney transplant. This enables doctors to know whether anti-DP antibodies, if detected in a potential recipient, will react with the HLA-DP antigens or alleles of the donor. It may lead to rejection if the transplant is carried out.

# Maximising Our Precious Resources

Being an effective blood service means constantly making improvements in our processes to increase our efficiency and maximise the use of our resources. At the same time, we need to be prepared for emergencies and ensure workplace safety.



## Identifying Problems, Seeking Solutions

Three Lean Six Sigma projects were submitted for poster presentations at the 25th Regional Congress of the ISBT (International Society of Blood Transfusion) in London. These projects, which were completed in 2014, target to gain more yield in platelet collection, reduce excess usage of commercial Antisera in phenotyping, and streamline the work process for retrieval of Fresh Frozen Plasma.

Project team members also shared their projects at their quarterly staff meetings. In preparation for their projects, they underwent coaching sessions where they were guided through the application of Lean Six Sigma tools. This has helped accelerate the progress of the project.

## Ready for Contingencies

As the national blood service, it is important that we are always ready and prepared for any emergencies. 88 participants from HSA, the restructured hospitals' blood bank laboratories (BBL) and the MOH Emergency Preparedness and Response Division took part in a tabletop exercise (TTX) in April 2014. The objectives of the TTX were to familiarise the hospitals' BBL on Singapore's current blood supply and distribution plans during a mass-casualty emergency. The exercise also facilitated thinking and clarification on tactical issues under various scenarios, which included an industrial accident and a terrorist attack in a crowded MRT station.

## Enhanced Workplace and Staff Safety

The safety of our staff is paramount. With this in mind, we have replaced gamma irradiators with X-ray irradiators for the preparation of irradiated blood products. Our staff will be less exposed to radiation risks since no radiating source material is used in X-ray irradiators.



# Vital Progress in Research

Our specialised testing laboratories provide high quality and well-managed research services to research institutions and hospitals, to elevate patient care and safety.



## Clinical Trial Shows Promise

With its potential benefits demonstrated in several small-scale clinical trials, we have embarked on a large-scale expansion of mesenchymal stromal cells (MSC). This is done by our GMP laboratory for the treatment of patients with graft versus host disease (GvHD). The disease is manifested in some patients after an allogeneic transplant, and MSC infusion is used as an alternative treatment for patients who have exhausted standard GvHD treatment options. The ex vivo expansion of MSC from a bone marrow cell source were carried out in the Cell Therapy Facility, in accordance with GMP standards. To date, these in vitro cultured MSC have been given to two patients successfully.

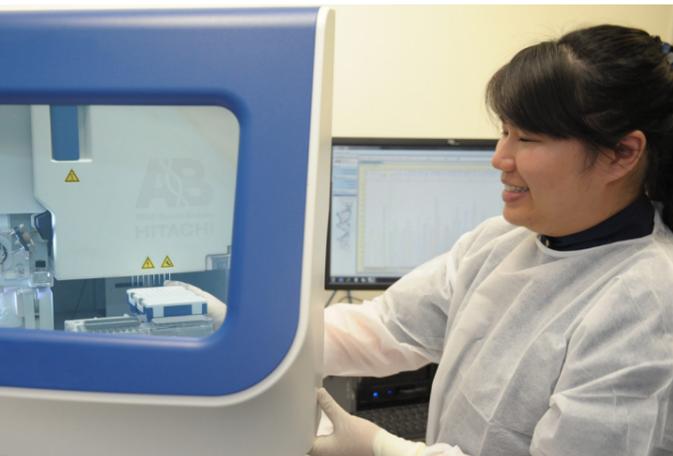
## Taking Steps Towards Another Cure

We have successfully completed a pre-clinical study to isolate human regulatory T cells (Tregs) from apheresed peripheral mononuclear cells (PBMCs) obtained from nine healthy donors. Tregs constitute a rare population of immune suppressor cells which are of clinical interest for the treatment or prevention of inflammatory diseases and syndromes, including autoimmune diseases, graft rejections and GvHD.

Together with A\*STAR's Singapore Immunology Network (SIgN), we developed a protocol for the isolation of these cells, which uses an automated immune-magnetic cell isolation system, as well as customised kits for large-scale production. The first phase of a clinical trial project, in collaboration with the Singapore General Hospital's Haematology Department and SIgN, will be carried out to determine the feasibility and safety of using Tregs to treat acute GvHD.

# Achieving International Accreditation

Aligned with our dedication to providing quality blood products, we undergo regular audits and inspections by international bodies to ensure compliance with global standards.



## Gold Standard in HLA Genotyping

HSA's new Sequence Based Typing (SBT) for HLA genotyping as a routine test implemented in September 2014 has provided a higher level of sensitivity and accuracy in its results to improve the transplant outcome for patients. Validated and accredited by the American Society for Histocompatibility (ASHI), SBT is the gold standard for haematopoietic stem cell transplants which delivers complete sequence information, helping to resolve ambiguities. In addition, our Tissue Typing & Platelet Reference Laboratory (TTPR) has once again passed the ASHI 2014 inspection and remains accredited by ASHI. In the future, we are looking to also offer HLA-DQ and HLA-DP testing for an optimal haematopoietic stem cell match between patient and donor.

## GMP Certification for CTT Products

We are proud to have achieved the Good Manufacturing Practices (GMP) certificate for our human cell and tissue-based therapeutic (CTT) products. This certifies that our Cell Therapy Facility has maintained an overall acceptable level of compliance with the Pharmaceutical Inspection Convention/Co-operation Scheme (PIC/S) Guide to GMP for Medicinal Products (Part I) and the relevant annexes.

This also means that we can look forward to potential new projects in cellular skin therapy treatment, adipose tissues, biophysically derived mesenchymal stromal cells for human haematologic applications, and producing GMP or Guanosine-5'-triphosphate (GTP) stem cells.



# Acquiring and Imparting Knowledge

We are on a constant lookout for best blood banking practices to help us do our work better. And while we gain knowledge from others, we also actively share our know-how with our local and regional counterparts.

## Sengkang Hospital Training, from April 2014

HSA conducted three successive training programmes to train a total of six blood bank technologists from Sengkang Hospital to enable them to perform pre-transfusion testing for patients in the hospital.

## SGH Attachment, July 2014

Five HSAians attended a two-day attachment programme at the Singapore General Hospital Haematology Centre to gain insight into the current transfusion practices and other related services.



## Immunohaematology Workshop, October 2014

Staff reported enhanced knowledge on red cell serology after attending a workshop which included a knowledge assessment on immunohaematology.

## Jurong Health (Ng Teng Fong General Hospital) Training, February 2015

HSA conducted refresher training for four Jurong Health (Ng Teng Fong General Hospital) staff from the Blood Transfusion Services section.



### Study Visit to Hong Kong Red Cross, July 2014

We learned about the various layouts and designs of blood donation centres on a study visit to the Hong Kong Red Cross Blood Transfusion Service Blood Donation Centres. The information gained will aid in the planning of our future satellite blood banks.

### Australia Study Trip on Inventory Management System, March 2015

Staff from HSA and the Singapore Red Cross visited the manufacturing facility and National Contact Centre to learn more about the Australian Red Cross Blood Service inventory management and donor management system.

### Myanmar "Train the Trainer in Red Cell Serology", November 2014

In collaboration with the Singapore International Foundation and the Myanmar Ministry of Health, HSA led a series of four "Train the Trainer in Red Cell Serology" workshops which provided skills upgrading for Myanmar's transfusion physicians and medical technologists in blood serology testing. This was followed by a post-training evaluation upon project completion.

# Transfusion Medicine Training

We had the opportunity to share our skills with blood banks from other countries.



### May 2014

We welcomed 15 delegates from the Macau Blood Centre.

### July 2014

We hosted medical professionals from the Thailand Red Cross.

### August 2014

We hosted two medical professionals from the Zambia National Blood Transfusion Service.

### November 2014

We welcomed one professional staff from Hong Kong Red Cross Blood Transfusion Service who was attached to our Cell Processing Laboratory.



### April 2014

Two delegates from the Clinical Laboratory of Karachi's Aga Khan University in Pakistan visited HSA to learn about flow cytometry histocompatibility in renal transplant.

### May 2014

One doctor from the Bangladesh Haematology Department joined us for an attachment at the Human Leukocyte Antigen Laboratory.



### September 2014

We received five medical professionals from the Indonesia Red Cross, Jakarta.

### January 2015 – January 2016

A doctor from Sri Lanka is currently undergoing a year-long clinical attachment with HSA for her post-medical doctorate training.

# APPLIED SCIENCES GROUP



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**BOOSTING  
SCIENTIFIC  
EXPERTISE**



As the national authority in forensic science, forensic medicine, analytical science, and chemical metrology, we strive to provide critical expertise to law enforcement agencies, regulators and the judiciary. In supporting the administration of justice and safeguarding public health, we carry out our mission to use science positively and effectively to ensure that stakeholders' rapidly changing needs are met.

# Broadening Our Expertise

We are always acquiring new analytical science expertise and strengthening our work processes to better serve the needs of our nation.



## Serving up More in Food Product Testing

Twelve new analytical services such as detecting illegal dyes, mycotoxins in food products and fluorescent whitening agents in food contact materials were developed to support the Agri-Food and Veterinary Authority. This boost in services was pushed forward with innovative and advanced analytical techniques such as high-resolution mass spectrometry (TOF-MS) to achieve greater testing accuracy.

In our focus to develop new and reliable testing services in the areas of food contaminants, additives and food contact materials, we participated in the proficiency test organised by the European Commission. We attained good performance in the proficiency test on mycotoxin and zearalenone in maize oil which was organised by the European Commission, Joint Research Centre, Institute for Reference Materials and Measurements. We also organised the 2014 ASEAN proficiency test on aflatoxins B & G, in peanut powder to increase the competency of national laboratories in ASEAN. The event saw a total of 21 participating laboratories from nine ASEAN countries.

## Faster Analysis for Complementary Health Products

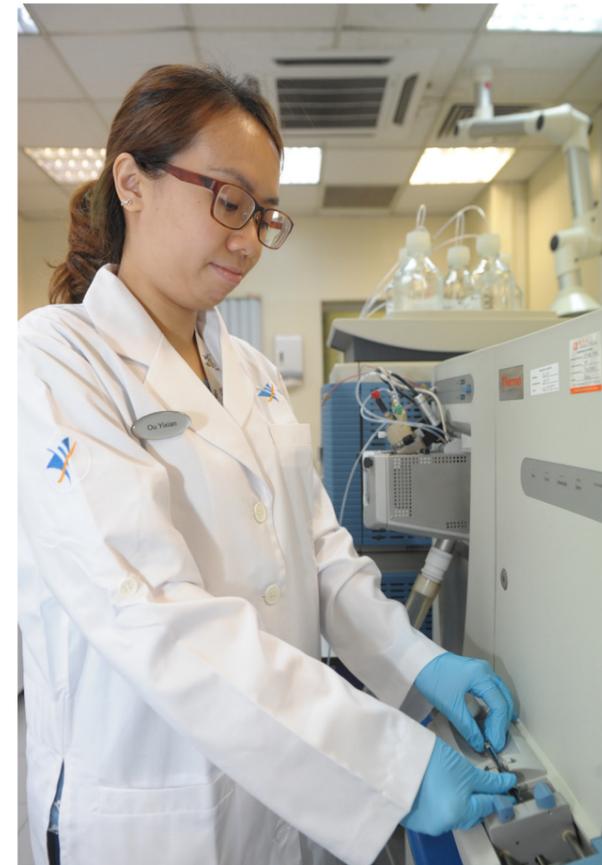
With the growth in variety and consumption of health products, a new pharmaceutical testing method that simultaneously detects 32 toxic alkaloids in complementary health products has been successfully implemented. This high-resolution, enhanced mass spectrometry system combined with quadrupole linear ion trap was developed to help support the adverse drug investigation efforts by the Health Products Regulation Group (HPRG).

This high throughput system was also shared in the Forum for the Harmonization of Herbal Medicine, an international forum comprising herbal medicine experts from Japan, China, Korea and Singapore. The event was held in Singapore and hosted by HSA in November 2014. Additionally, a paper on the application of this methodology has been submitted to an international scientific journal for publication.



## Eliminating Health Risks

Routine pre-market surveillance checks have enabled us to successfully assist HPRG in preventing the sale of a health product containing N-cyclopentyl tadalafil. This is the first time that the novel PDE-5 inhibitor analogue has been found in health supplements and this significant finding resulted in HPRG initiating a product recall.



## A Boost in Testing Body Building Supplements

Yohimbine is commonly used in body building supplements to give a fat loss effect by boosting lipolysis. There has been an increased interest in the use of alpha-yohimbine, a stereoisomer of yohimbine, in health supplements as it offers similar fat loss results as yohimbine, but with fewer side effects. A new testing methodology was developed to analyse structurally-similar stereoisomers to effectively support HPRG in analysing health products containing these two substances.



## Getting into the Root of Things

Our database on hair dyes has expanded to include two commonly used oxidative hair dye formulations. With the inclusion of aminophenol and resorcinol, our Cosmetics Laboratory can now screen up to 17 different oxidative dyes.



## Safe Use of Preservatives in Cosmetics

The use of isothiazolinone (methylisothiazolinone and chloromethylisothiazolinone), as antimicrobial preservatives in cosmetic products has increased since it was permitted for use in 2005. It is commonly found in the formulation of shower gels, hair care products such as shampoos and conditioners. However, it has been reported to cause skin allergies. As concentrations of up to 15 ppm of this combined preservative are permitted, we have developed a new testing capability to support the needs of HPRG's Cosmetics Control Unit.

## Advancing Chemical Metrology Capability

We successfully completed two international comparisons, which included glycosylated haemoglobin (HbA1c), a biomarker for diabetes mellitus, and carbamazepine, an anticonvulsant. Our participation in these comparisons has expanded our metrological services into new areas of work.

We have also expanded the Certified Reference Materials (CRMs) production programme to include three new pure substance CRMs (L-leucine, sodium cyclamate and saccharin), as well as a matrix CRM on trace elements (arsenic, chromium, copper and molybdenum) in water.

## Strengthening Our Scope in Proficiency Testing

We continued to expand our External Quality Assessment (EQA) Programme in Clinical Chemistry for local clinical laboratories. This year, chloride was included in the list of analytes. It is one of the electrolytes commonly tested by clinical laboratories. The inclusion of chloride ensured that the common electrolytes were covered by our EQA programme.

Two proficiency testing programmes involving the determination of preservatives in soy sauce and trace elements in drinking water were also organised for local testing laboratories. These programmes allowed the participating laboratories to assess the accuracy and comparability of their test results.



# Recognitions and Accreditations

To serve our community to the fullest, we need to be at the top of our game. To do so, we seek to continually surpass our own standards. Our awards and accreditations reinforce our commitment to continue striving to achieve our goals.

## Membership to CCQM

We were granted the membership to the Consultative Committee for Amount of Substance: Metrology in Chemistry and Biology CCQM by the International Committee for Weights and Measures in November 2014.

## Re-accreditation

In April 2014, our Food Safety, Pharmaceutical, Cosmetics, and Cigarette Testing Laboratories were re-accredited for four years with the ISO 17025: Testing and Calibration of Laboratories by the Singapore Accreditation Council (SAC-SINGLAS). Ms Angela Li, Senior Analytical Scientist, was presented the SAC Assessor Award (Bronze) at the Quality and Standards Conference on 5 August 2014.

Additionally, the Chemical Metrology Laboratory completed an annual re-assessment by SAC as a Proficiency Testing Provider in accordance with ISO/IEC 17043:2010 in October 2014.

The forensic laboratories (Analytical Toxicology Laboratory, Illicit Drugs Laboratory, DNA Profiling Laboratory, and Forensic Chemistry and Physics Laboratory) passed the ASCLD/LAB surveillance assessment with zero non-conformities in September 2014.

## Excellent Results in Proficiency Testing

We are proud to have achieved excellent results in proficiency testing for Assay by Liquid Chromatography (metronidazole) by the European Directorate for the Quality Medicines and Healthcare, and Assay and pH by the Laboratory of Dutch Pharmacists. In particular, the Cosmetics Laboratory performed exceptionally well in three external proficiency tests organised by the Laboratory of the Government Chemist on the Assay of Fluoride by Ion Selective Electrode in Toothpaste, Dienstleistung Lebensmittel Analytik GbR on the Assay of Parabens in Cosmetic Products and Assay of Three Heavy Metals in Finger Paint.



## Partners in Keeping Drugs Out

We have supported the Central Narcotics Bureau (CNB) in drafting the legislation for the controls of New Psychoactive Substances (NPS) by providing scientific advice on the different groupings, their global and regional prevalence, as well as the naming of NPS. In view of this excellent collaboration, we were conferred the Director CNB's Commendation Award. Dr Angeline Yap and Dr Lui Chi Pang received the award from Mr Ng Ser Song, CNB Director, on 7 August 2014.

# Focused on Forensics

Our forensic scientists work round the clock to streamline processes for greater speed and efficiency and to boost our capabilities in the areas of DNA profiling, drugs testing and 3D scanning for crime scenes.

## World-class Services

We have continued to build new capabilities as well as streamline processes in order to provide top-class forensic services with technical sophistication and efficiency. These include the use of isotope ratio mass spectrometry, laser ablation inductively coupled plasma mass spectrometry, liquid chromatography high resolution mass spectrometry (Orbitrap), 3D laser scanner and computer simulation software in forensic casework.

## Victim Identification in Crucial Times

In response to the AirAsia flight QZ8501 crash on 28 December 2014, we sent forensic experts Dr Lee Chin Thye, Forensic Pathologist, and Dr Tan Peng Hui, Visiting Consultant Forensic Dentist, to participate in the Disaster Victim Identification (DVI) team led by the Singapore Police Force. On 9 February 2015, Assoc Professor Cuthbert Teo Eng Swee, Senior Consultant Forensic Pathologist, was sent as part of a second team of DVI experts.



## Speedy DNA Profiling

Our new rapid analysis system has been used to great success in resolving crimes quickly, including rape and murder cases. Introduced in 2015, the system allows DNA profiles to be generated from crime exhibits in under three hours. While rapid DNA analysis for offender reference samples has been offered in some European and US laboratories since 2014, HSA is believed to be the first to adopt this technology in the region (and possibly the world) to process crime scene samples.

## Zeroing in on the Suspect

The adoption of two new powerful tools means that male perpetrators in sexual assault cases can now be identified with greater accuracy. Previously, an overwhelming excess of female cells could result in the masking of the male DNA profile. These two tools that have proven effective are the laser microdissection in combination with fluorescent-labelled monoclonal antibodies for the targeted excision of spermatozoa, and the use of Y chromosome STR markers. The specific isolation of only spermatozoa even in the presence of a 1,000 fold excess of female cells, and use of male-specific markers, will facilitate identification of male perpetrators.

## Profiling Illicit Drugs

Drug profiling provides critical information that can enable investigators to determine the drug synthesis route, as well as provide the link to drug seizures and/or to its original source. For the profiling of Yaba tablets, the laboratory has developed several techniques such as the determination of dye colour used in tablets, identification and quantitation of impurities and determining the carbon and nitrogen isotope ratios using isotope ratio mass spectrometry. While unprecedented and previously beyond the laboratory's routine casework, we are now able to gain new expertise in the area of profiling work and establish additional services to clients.



## Improvements in Drug Testing

The abuse of new psychoactive substances (NPS) has presented challenges in both legislative controls and analyses. On the analytical front, the laboratory has expanded our capability in instrumental methodologies by adopting non-routine methods of analysis in some of the cases. An example is the use of nuclear magnetic resonance spectroscopy to determine and confirm the identity of substances which have similar chemical structures.

Underway is the process of developing and validating new methodologies on the solid phase deposition gas chromatography infrared detection (GC-IRD) to cope with the challenges of the analysis of NPS with similar structures, especially for substances which occur in complex mixtures. In line with the scheduling of the NPS into the Misuse of Drugs Act, the laboratory has also added the provision for the testing of NPS in urine using liquid chromatograph coupled with high-resolution mass spectrometry.

An automated online drug of abuse analysis on amphetamines was implemented to help meet the urgent needs of the enforcement agencies, cutting down processing time for a batch of urine samples from 2.5 days to less than a day.



## Crime Investigation Takes on a New Dimension

The accuracy and proper documentation of any crime scene and evidence is of utmost importance. To do so, we have developed 3D laser scanning capabilities for scene documentation. This allows investigators to revisit the scene virtually, take measurements, and present the virtual crime scene in court for better illustration as opposed to still photographs and crime scene sketches. On pilot since August 2014, the 3D laser scanner is currently ready for deployment in crime scene or traffic accident caseworks.

## Gathering of Forensic Experts in Seoul

As a founding member of the Asian Forensic Sciences Network (AFSN), HSA was actively involved in the World Forensic Festival 2014, which saw over 1,300 forensic experts gather in Seoul, Korea from 12 – 18 October. The event comprised meetings of the 6th AFSN, the 20th International Association of Forensic Sciences (IAFS), the 5th Asia Pacific Medico-Legal Agencies and the 10th World Police Medical Officers. HSA was also responsible for organising a number of workshops in the AFSN meeting. In sharing its expertise, HSA gave a total of 10 oral presentations and showcased three posters at the AFSN meeting, and one oral presentation and four posters at the IAFS meeting.



### In 2014, we actively contributed to the advancement of AFSN in these capacities:

- International Liaison Officer and Board Member
- Chairman, Illicit Drugs Workgroup
- Chairman, Quality Assurance and Standards Committee
- Chairman, Toxicology Workgroup
- Vice Chairman, Trace Evidence Workgroup
- Secretary, Crime Scene Investigation Workgroup

## Elevating Forensic DNA Testing

HSA takes the role and responsibility of strengthening forensic DNA testing in the region seriously. In November 2014, the first inter-laboratory collaborative exercise was initiated to evaluate DNA extraction methods. Through this exercise, laboratories would be able to assess the effectiveness and consistencies of their DNA extraction methods relative to other laboratories. A total of 11 forensic DNA laboratories from Indonesia, Malaysia, Mongolia, Philippines, South Korea, and Thailand took part. A second exercise to evaluate interpretation and reporting of mixed DNA profiles has been scheduled for August 2015.

## Partnering Reputable DNA Laboratories

We seek to achieve service continuity and minimise impact to turn-around times for normal crime casework in the event of a national crisis, such as a mass disaster requiring victim identification. To achieve this, we have been developing strategic partnerships with reputable forensic DNA laboratories worldwide. We are proud to have built strong links with organisations such as the Institute of Applied Genomics at the University of North Texas, the New York Office of the Chief Medical Examiner in the US, and Austria's Innsbruck Medical University.

## Learning from the Best

We are pleased to have welcomed the following strong line-up of visiting experts:

- 1 Dr Sandra Rodriguez-Cruz, Senior Forensic Chemist, Drug Enforcement Administration Southwest Laboratory, USA, August 2014
- 2 Mr Michael DiTallo, Consultant, (traffic accident reconstruction expert), Northwestern University Center for Public Safety, USA, January 2015
- 3 Dr Mark Reynolds, Forensic Science Consultant, (a world authority on fabric bloodstain pattern analysis), Western Australia Police, Australia and Subcommittee Chair of SWGSTAIN, January 2015
- 4 Mr Ted Sileniaks, Coordinator of Evidence Recovery, (fabric bloodstain pattern analysis expert), Forensic Science South Australia, Australia and Vice-President of the International Association of Bloodstain Pattern Analysis, January 2015



- 5 Professor Olaf Drummer, Deputy Director (Academic Programs) at the Victorian Institute of Forensic Medicine, (renowned forensic toxicologist), and head of the Department of Forensic Medicine at Monash University, Australia, February 2015



- 6 Professor Marilyn Huestis, Chief (Chemistry and Drug Metabolism) at the Intramural Research Program, National Institute on Drug Abuse, National Institutes of Health, USA, March 2015



- 7 Ms Sue Fiddian, Manager of the Botany Branch of the Victoria Police Forensic Services Department, Victoria, Australia, March 2015



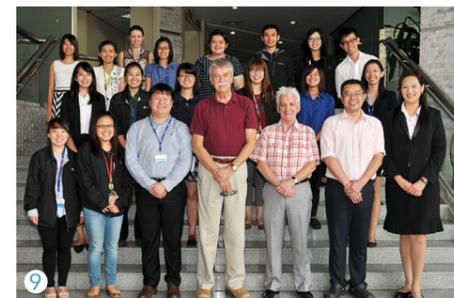
- 8 Mr Ross Gardner, Vice President, Bevel, Gardner and Associates Inc., (crime scene reconstruction and bloodstain pattern analysis expert), USA, March 2015



- 9 Mr Skip Palenik, President, Microtrace LLC, (forensic microscopist and trace evidence forensic expert), USA, March 2015



- 10 Dr Bruce Budowle, Professor and Executive Director of the Institute of Applied Genetics at the University of North Texas, USA, March 2015



- 11 Dr Angela van Daal, Forensic DNA Consultant and former Professor, Bond University, Australia, March 2015



## Sharing Our Best

The experts at HSA have enabled us to earn our reputation as a respected authority in forensic science. We are honoured to have been involved in these international groups:

- International Forensic Expert, United Nations Office on Drugs and Crime
- Core Committee Member, Scientific Working Group for the Analysis of Seized Drugs
- Steering Group Member, the Forensic Isotope Ratio Mass Spectrometry Network
- Member, European DNA Profiling Group
- Member, European Network of Forensic Science Institutes DNA Working Group Member, Asia-Pacific Economic Cooperation (APEC) Detection Technology Working Group (photo on the left)



# Exchanging Expertise

To grow, we believe in sharing and learning. We are committed to working together with our local and global partners in an exchange of expertise for the betterment of our capabilities.



## Safety in Food Staples

HSA participated in the International Atomic Energy Agency coordination project on the authentication of rice and milk products. Our scientists attended trainings on stable isotopic analysis in the Philippines in February 2014, and in Sri Lanka in October 2014.

## Audit for ASEAN

In August 2014, HSA led an ASEAN expert team comprising scientists from Vietnam and Malaysia in an audit on the Department of Science, Thailand, for its application to become an ASEAN reference laboratory on food contact material. Similarly, we were involved in the ASEAN expert team on the audit of the National Quality Control Laboratory of Drug and Food, Indonesia, which had applied to be an ASEAN reference laboratory on food additives. The ASEAN Food Testing Laboratory Committee accepted the recommendations of both expert teams.

## First Asian Member in GEON

We are proud to have been granted the Associate Membership to the General European OMCL (Official Medicines Control Laboratories) Network (GEON) of EDQM on 1 May 2014. Singapore is the only Asian country to be admitted into this renowned network, which includes our consortium partners, Therapeutic Goods Administration of Australia, US Food and Drug Administration and Health Canada. This membership is an important scientific platform for technical exchange in the fields of pharmaceutical testing and counterfeit drugs analysis, and will allow our scientists to keep abreast of emerging advancements in pharmaceutical testing.

## Keeping Cosmetics Safe

HSA continues to strengthen its capabilities and global network in cosmetics testing. In September 2014, we attended the 10th Official Cosmetics Control Laboratory Network held at the Council of Europe, Brussels. As the only Asian member to be invited, we were privileged to gain access to the cosmetics database, as well as to exchange technical knowledge within the network.

As the Vice-Chair in the ASEAN Cosmetics Testing Laboratory Committee (ACTLC), HSA participated in the 21st ASEAN Cosmetics Committee and 4th ACTLC meeting held in Manila, the Philippines in November 2014. During this meeting, efforts were focused on strengthening the analytical capabilities among the ASEAN network with possible support from Germany's Physikalische-Technische Bundesanstalt.



## Collaborating with the USP

For over five years, HSA has actively collaborated with the United States Pharmacopeia (USP) on the establishment of the acceptance ranges for their Dissolution Performance Verification test. In 2014, we completed a collaborative study on the acceptance range on USP Prednisone Tablets (Lot R001B). This established range will be used as a reference for the Dissolution Apparatus Suitability Test.

## Supporting Food Safety

In a significant milestone to support the national food safety programme, HSA and the Agri-Food and Veterinary Authority of Singapore signed a three-year service level agreement (SLA) in August 2014. The SLA will see the Food Safety Laboratory provide regulatory and crisis food safety testing services on processed food and food contact materials.

## Sharing Our Know-how

In partnership with the Singapore Accreditation Council, we organised two training courses in December 2014. These were the Method Validation for Chemical Testing and Measurement Uncertainty Made Easy. A re-run of the courses is in the pipeline as a result of the overwhelming positive response.



## Keeping Tobacco in Check

HSA showcased its scientific role in the National Tobacco Control Programme when the Cigarette Testing Laboratory took part in the annual National Tobacco Control Campaign in May 2014. Held in conjunction with the World No Tobacco Day, and led by the Health Promotion Board, the media was given a tour on how Singapore adopts a whole-of-government approach in tobacco control. This multi-agency effort also involved the National Environment Agency and the Singapore Customs.

# Maintaining Close Ties with WHO

We continue to actively contribute to and support the World Health Organization (WHO) in its activities.

## Sharing Our Expertise

HSA was invited to participate in various meetings to share our experiences and provide expert opinions. These included an invitation by the Government of Nepal, on the recommendation of WHO, to provide technical assistance in the development of Nepal's National Drug Quality Control Laboratory in May 2014. We were also invited to the 2nd WHO Consultation meeting on Quality Control of Herbal Medicines at Hong Kong in November 2014, to finalise the draft guidelines for the selection of herbal origin substances for quality control of herbal medicines. In April 2014, we also contributed as Temporary Adviser at the WHO Consultation on New Medicines, Quality Control and Laboratory Standards, and at the WHO Expert Committee meeting on Specifications for Pharmaceutical Preparations in October 2014. Both events were held in Geneva, Switzerland.

## Our Role in Food Contamination Monitoring

At the First Regional Forum of WHO Collaborating Centres held in the Philippines in November 2014, we presented a poster on our role as a WHO Collaborating Centre for Food Contamination Monitoring.

## Developing Monographs

HSA is supporting the WHO International Pharmacopoeia in the review of magnesium sulfate and magnesium sulfate injection monographs, as well as the development of new draft monographs for "Ceftriaxone Sodium" and "Ceftriaxone Sodium Powder for Injection".

## Tobacco Testing

As a WHO Collaborating Centre on Tobacco Testing and Research, HSA took part in a WHO meeting at Fiji in September 2014 where we provided analytical support and expertise on tobacco testing to countries from the Pacific Islands. These countries included Micronesia, Samoa, Fiji, Vanuatu and Solomon Islands.

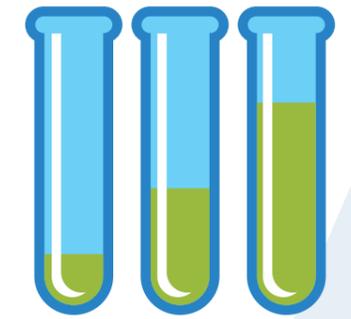
HSA was also invited as Vice-Chair of the WHO Tobacco Laboratory Network (WHO TobLabNet) to speak at the 16th World Conference on Tobacco or Health, held at Abu Dhabi in March 2015, and as a member of the WHO Secretariat to the 6th Session of the conference of the Parties of the WHO Framework Convention for Tobacco Control in Moscow, Russia in October 2014.

We are supporting WHO TobLabNet in the global validation of two methods: determination of aldehydes in mainstream cigarette smoke under ISO and intense smoking conditions, as well as to determine volatile organic compounds in mainstream cigarette smoke under ISO and intense smoking conditions.



## Establishment of International Chemical Reference Standards

Together with WHO, the European Directorate of Quality of Medicines and Healthcare (EDQM) has invited us to participate in the inter-laboratory collaborative study to establish the International Chemical Reference Standards for "Rifampicin".



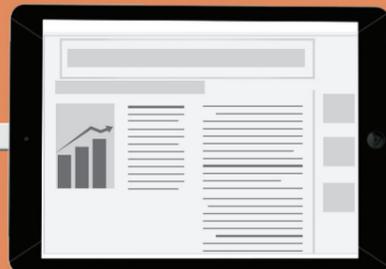
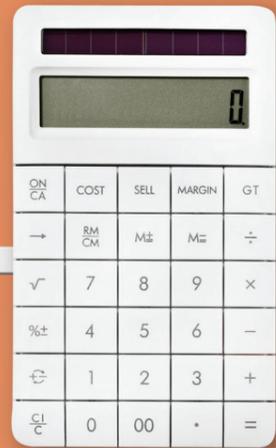
## Global Sharing

Maintaining our global presence has been mutually beneficial and has also enabled us to learn and share skills and knowledge with our counterparts. These are some of the key international events which we have participated in:

- Presentation on "Singapore's Perspective on European Directorate of Quality of Medicines and Healthcare's Global Role" at the EDQM Conference: 50 years of Leadership in the Quality of Medicines – Paving the Way for the Future, in Strasbourg, France, October 2014
- Presentation on "Monograph Structure and Function" at Day Briefing on International Pharmacopoeia at the WHO Consultation on New Medicines, Quality Control and Laboratory Standards Meeting, in Geneva, Switzerland, April 2014
- Presentation on "Singapore's Approach to the Testing of Medicines in Disguise" at the Official Medicines Control Laboratories' Symposium on Combating Counterfeit and other Illegal Medicines, in Strasbourg, France, September 2014
- Poster presentations on "WHO Collaborating Centre for Drug Quality Assurance" and "WHO Collaborating Centre for Tobacco Testing and Research" at the First Regional Forum of WHO Collaborating Centres in the Western Pacific, in Manila, the Philippines, November 2014
- Presentations on "Screening of Toxic Natural Substances in Herbal Medicines by Liquid Chromatography - Coupled Quadrupole Tandem Mass Spectrometry" and "Adulteration and Authentication of Herbal Medicines" at the Western Pacific Regional Forum for the Harmonisation of Herbal Medicines (FHH) & FHH International Symposium, in Singapore, November 2014



# CORPORATE HEADQUARTERS



To support our Professional Groups, we build a strong and strategic corporate team that is innovative, resourceful and competent. Through continual review of our processes and the adoption of best practices, we enhance synergies within corporate departments for better collaborations with our professional groups. We value learning and training to make our people the best they can be.

# Uplifting Our People

A strong and cohesive team has enabled HSA to be where we are today. To continue fostering this spirit of growth, we seek to understand what resonates with our people, and develop policies and programmes that can enrich and inspire them to perform at their best.



## Getting Down to the Core

At HSA, we place great emphasis on continually enhancing synergies across departments and groups while promoting a better understanding of our Core Values. Hence, in the first quarter of 2014, we reviewed and realigned the objectives and curriculum of the HSA-wide Team Building Workshop which is part of the HSA Orientation Programme. We successfully facilitated two workshops in July and October 2014 where our new staff learned the Core Values while being inducted into the HSA family by fellow HSAians.

## Trusted to Safeguard Public Health

As the authority protecting and advancing national health and safety, HSA plays an active role in informing and educating the public through advisories and media stories. 2014 saw significant and sustained media coverage on the dangers of illegal health products, online purchases of health products, and the crackdown on illegal codeine cough syrup.

These media stories heightened public awareness about risks, and reinforced our efforts in protecting public health. Other media coverage put the spotlight on blood donation, forensic expertise, and enforcement actions carried out on the sale and supply of illegal products and tobacco regulatory infringements.

In the lead-up to SG50, we worked closely with the Public Service Division to feature HSA staff working in the Cross-Match Laboratory, as well as the Vigilance and Compliance Branch in videos posted on social media platforms. There were also TV interviews featuring staff from the Analytical Toxicology Laboratory and Pharmaceutical Laboratory. We also facilitated an interview with our forensic medicine staff for a Singapore Public Service 50 publication.



## Bolstering Cohesion and Learning

Cohesiveness amongst HSAians is a vital component in working effectively. To promote learning and staff interaction, and in line with our values as a learning organisation, we continued our annual efforts to organise corporate-wide events such as the Staff Forum, New Year's Gathering, Learning Day in conjunction with Public Service Week and the National Day Observance and Celebration.

To help staff achieve excellence both at home and at work, we organised a series of work-life balance lunchtime talks for staff every quarter. These talks included topics on relationship management, emotional management, and parenting styles.

In addition to building up our domain expertise, we organised programmes to improve better coordination and enhance efficiencies across groups. One such programme to boost cross-functional competencies was procurement training, which helped non-procurement specialists within HSA to better understand procurement processes to smoothen their workflow.



## Fishing for an Innovative Culture

Mr Kenny Yap, Executive Chairman & Group CEO of Qian Hu Corporation Limited, graced our HSA Innovation Day by delivering a special keynote on driving innovation. To further encourage this culture of innovation, we organised a series of learning journeys to FusionWorld@A\*STAR and the Qian Hu Fish Farm to provide staff with a first-hand glimpse into their best practices and culture for innovation.

## Into the Heart of the Blood Bank

Public officers from across the ministries and statutory boards received insights into what keeps the heart of Bloodbank@HSA pumping. In conjunction with the PS21 ExCEL (Public Service 21 Excellence through Continuous Enterprise and Learning) Convention 2014, this informative tour hosted by HSA showed public officers how blood is collected, and how the different components of blood are processed in the laboratory to meet patient needs.

# Making IT Better

Information technology is a crucial tool for HSA. We seek to continually improve in our Information and Communications Technology processes for a more connected and efficient organisation.



## Ready, Set, Standardised

HSA has completed the transition from the Standard Operating Environment to the Whole-Of-Government Information and Communications Technology (WOG ICT) Infrastructure. This government-wide initiative standardises all desktops, messaging and online collaborative tools and network environments across public agencies.

In the face of more sophisticated cyber security threats, HSA's focus in 2015 will be to continually enhance our WOG ICT services to support further strengthening of the Government ICT infrastructure.

## Excelling in Security Awareness

HSAians scored well in the Public Sector Infocomm Security Awareness Survey 2014 by the Infocomm Development Authority of Singapore (IDA). Of the 293 respondents in HSA, 92.15% were fully aware of the essential security practices among public sector end-users.

# Centred on Excellence

Going back to the basics, we looked at fine-tuning processes to help HSA work even more effectively.



## Service Improvement with ISO

In our efforts to boost the service commitment that we offer to the three Professional Groups, we embarked on the ISO 9001:2008 Certification preparatory journey in September 2014. To ensure effective implementation of the procedures, we conducted discussions and sharing sessions to bring across improved systems and outcomes that would advance HSA towards improvements in organisational excellence. HSA was successfully awarded the ISO certification in June 2015 following the successful completion of the external audits.

## Understanding to Improve

The biennial Organisational Capability Survey was conducted for three weeks in March 2014 to assess our staff engagement level, and to understand how we stand relative to other organisations. This survey, which gathered an overall response rate of 83%, also aims to identify and prioritise the focus areas in driving engagement and improvements. Following the results, we held many townhalls and conversation sessions to share the detailed survey findings, examine our key strengths and areas for improvement, and solicit ideas and co-create solutions with our staff.



## Service Made Simple

22 Excellent Service Awards and 45 Outstanding Service to Customers Awards were presented to HSAians at the 6th HSA Customer Service Day. This select group of staff was recognised for having delivered excellent quality service. To help inspire better service delivery, Mr Tan Teck Beng, a professional coach and trainer gave a presentation on customer-centric thinking. He demonstrated how organisations can build their processes towards addressing the needs of the customers, while aligning the goals and objectives of the organisation.



# Giving with All Our Heart

HSA is committed to giving more to society through our Corporate Social Responsibility Framework, CARE (Community Action, Responsible for our Environment).



## Mentoring the Young

For four years, HSA has had a great partnership with APSN Katong School for their English and Science Learning Journey. In 2014, HSA volunteers took the students on a study visit to the River Safari. During the HSA Public Service Observance and Learning Day, students were invited to set up a booth to sell their handmade items. This offered them an opportunity to showcase their talents while encouraging their entrepreneurial spirit. In October, HSA volunteers spent Children's Day putting together a series of fun booth games and 'telematch' activities to brighten up their young faces.

## Giving Hope

Fifteen staff volunteers, including one female staff, stepped up to have their hair shaved for a good cause – to raise funds for the Children's Cancer Foundation (CCF). The satellite event, held at the HSA Outram Office, was jointly organised by HSA and CCF. Families and friends of staff members came together to support the volunteers, who raised a total of \$20,642 from the event.



## Spending Time with the Elderly

HSAians spent a day out with the seniors of Mei Ling Street, delighting in fun and interactive activities. As part of the "HSA CARE-in-action through Sponsoring, Packing and Distributing" initiative, 170 bags of household items were also presented to the seniors through the Lions Befrienders Centre.

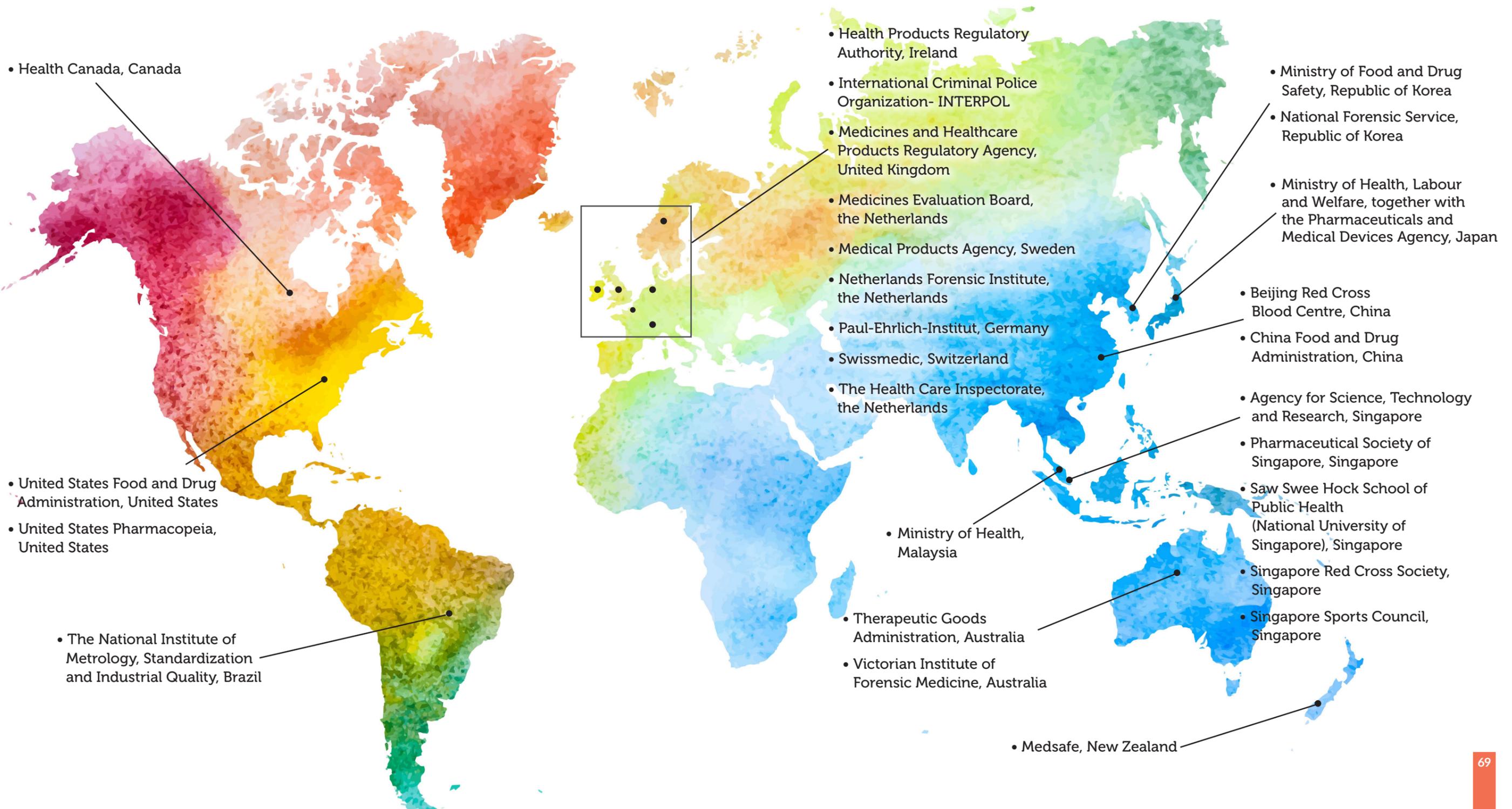


## Getting in Touch with Nature

HSAians got in touch with nature by spending an afternoon at the Sungei Buloh Wetland Reserve. There, they learned how to protect our natural environment and gained a better appreciation of environmental conservation, especially in land-scarce Singapore.

# Opening Doors to Knowledge Exchange

Through the signing of Memoranda of Understanding, we strengthened our partnerships with these dynamic organisations:



## Providing Support for Closer Ties

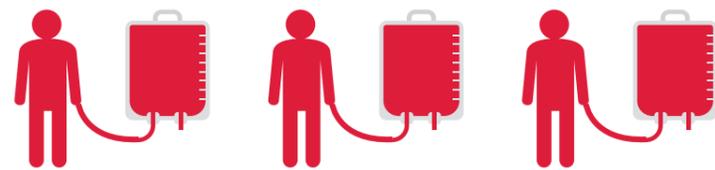
The HSA Academy supports our Professional Groups by advancing HSA's scientific and research expertise, establishing a stronger identity and enhancing relations with key partner agencies worldwide.

We work closely with our Professional Groups to support their active participation in international training programmes, which help develop our internal capabilities and foster strong professional relationships with our global partners. The events we supported in 2014 included a training programme by Traditional Chinese Medicine experts from the National Institute for Food & Drug Control of the China Food & Drug Administration, and the 2014 APEC Harmonization Centre - HSA Cell and Tissue-based Therapeutic Products Workshop in July.

# Our Achievements in Figures

## Blood Services Group

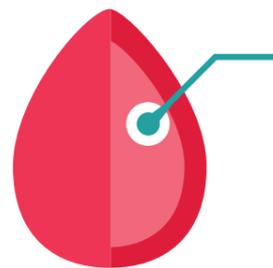
Key Statistics as at end December 2014



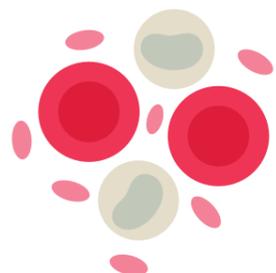
Blood Donors  
**68,868**



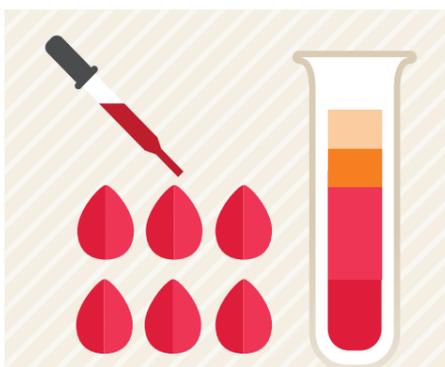
Whole Blood Donations  
**108,058**



Apheresis Donations  
**9,337**



Blood Components Processed  
**355,956**



Laboratory Tests Conducted  
**1,187,533**

## Applied Sciences Group

Key Statistics as at end March 2015

### Food Safety Division



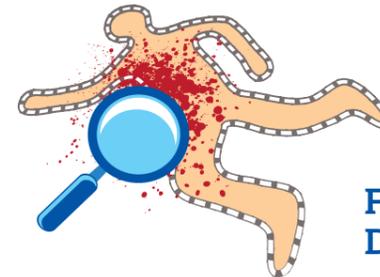
Analytical Cases  
**3,341**  
Analytical Tests for Laboratory Samples  
**23,815**

### Pharmaceutical Division



Analytical Cases  
**2,809**  
Analytical Tests for Laboratory Samples  
**13,238**

### Forensic Medicine Division



Coroner's Cases  
**4,041**  
Coroner's Autopsies  
**1,594**

### Forensic Science Division

Forensic Cases  
**264**  
Forensic Exhibits  
**1,078**

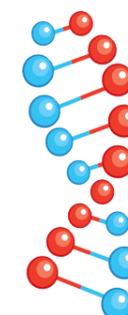


### Illicit Drugs Division

Forensic Cases  
**2,338**  
Forensic Exhibits  
**5,755**

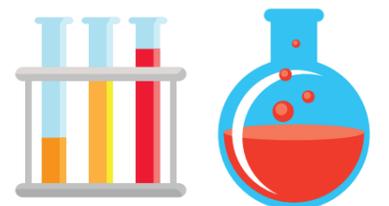
### Biology Division

Forensic Cases  
**25,398**  
Forensic Exhibits  
**31,632**



### Analytical Toxicology Division

Forensic Cases  
**21,043**  
Forensic Exhibits  
**36,916**



# Health Products Regulation Group

Key Statistics as at end March 2015



Western Pharmaceutical Product Licences Approved **233**

Western Pharmaceutical Product Licences (New Innovator Drug) Approved **115**

Western Pharmaceutical Product Licences (Generics) Approved **118**

Medical Device Product Listing Approved (Class A, B, C & D) **1,913**



Registered Western Pharmaceutical Products **5,493**

Approved Products on the Singapore Medical Device Register **15,377**

Total Number of Cosmetic Products Notified **147,300**



Total Number of Chinese Proprietary Medicines Listed **10,312**

New Chinese Proprietary Medicines Listed **504**



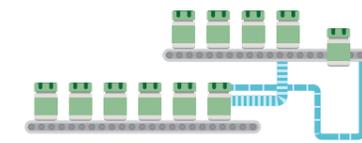
New Cosmetic Products Notified **41,763**



Clinical Trials Certificates Granted **322**



Medical Advertisement Permits Approved **3,184**



Site Audits Conducted for Good Manufacturing & Good Distribution Practices and Pharmacies **432**

Applications for Import of Medicinal Products for Personal Use Processed **2,148**



Applications for Licences/Certificates of Premises, Dealers and Importers & Exporters of Health Products Approved **5,858**

Applications for Licences/Certificates for **Manufacturers of Health Products Approved** 393

Applications for Licences/Certificates for **Importers of Health Products Approved** 3,217

Applications for Licences/Certificates for **Wholesalers of Health Products Approved** 1,361

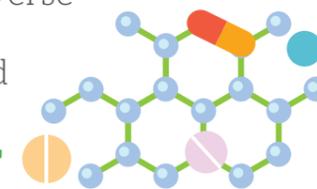
Applications for Registration of **Retail Pharmacies Approved** 371

Applications for Licences/Certificates for **Exporters of Health Products Approved** 516

**5,858**



Spontaneous Adverse Drug Reaction Reports Captured **20,404**



Post-Market Feedback Received (Relating to Potential Contravention of Health Product Legislation) **3,368**

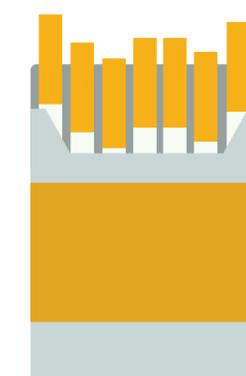


Number of Field Safety Corrective Action Reporting for Medical Devices Received **588**



Total Number of Licensed Tobacco Retail Outlets **4,932**

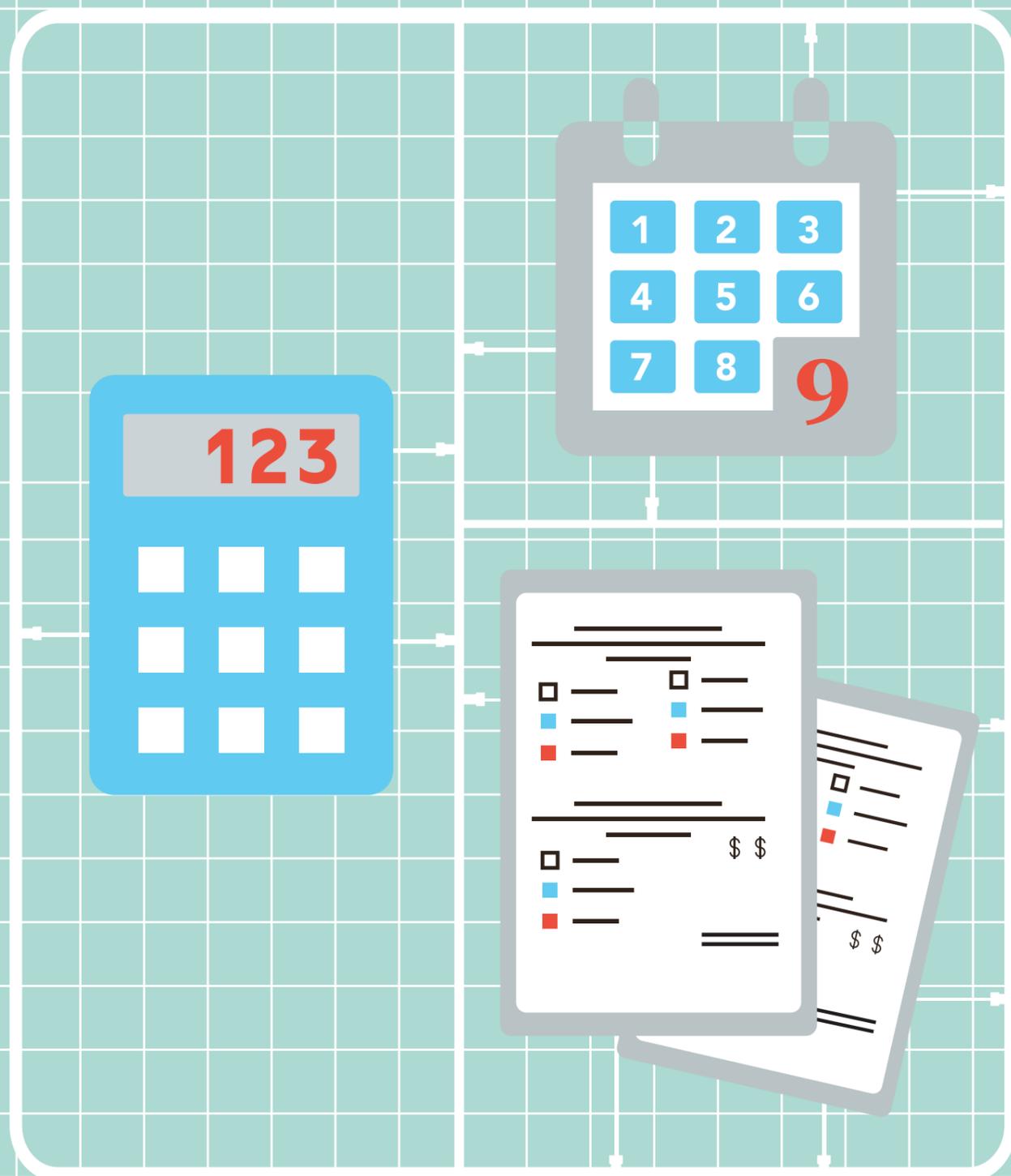
Under-18 Smokers Caught **5,753**



Tobacco Retail Licences Approved **580**

Number of Electronic Cigarettes Cases Referred to HSA **4,187**

# FINANCIAL HIGHLIGHTS



## Balance Sheet

	FY14/15 \$'000	FY13/14 \$'000	Increase / (Decrease)	
			\$'000	%
Property, Plant & Equipment	86,023	91,816	(5,793)	(6)
Intangibles	2,310	2,512	(202)	(8)
Current Assets	137,306	121,280	16,026	13
<b>Total Assets</b>	<b>225,639</b>	<b>215,608</b>	10,031	5
<b>Equity</b>	<b>127,428</b>	<b>121,587</b>	5,841	5
Long-Term Loans	18,200	19,110	(910)	(5)
Other Non-Current Liabilities	9,376	10,061	(685)	(7)
Current Liabilities	70,635	64,850	5,785	9
<b>Total Equity and Liabilities</b>	<b>225,639</b>	<b>215,608</b>	10,031	5

## Income & Expenditure Statement

The Authority has achieved an overall net surplus of \$5.2m for FY14/15.

	FY14/15 \$'000	FY13/14 \$'000	Increase / (Decrease)	
			\$'000	%
Operating Income	121,899	121,810	89	0
Operating Expenditure	(195,441)	(192,192)	3,249	2
<b>Deficit before Government Grants</b>	<b>(73,542)</b>	<b>(70,382)</b>	3,160	4
Government Grants	80,490	78,776	1,714	2
<b>Surplus before Contribution to Consolidated Fund</b>	<b>6,948</b>	<b>8,394</b>	(1,446)	(17)
Contribution to Consolidated Fund	(1,181)	(1,427)	(246)	(17)
<b>Net Surplus</b>	<b>5,767</b>	<b>6,967</b>	(1,200)	(17)
Other Comprehensive Income	(537)	(141)	396	281
Contribution to Consolidated Fund	(24)	24	48	200
<b>Net Comprehensive Income</b>	<b>(561)</b>	<b>(117)</b>	444	379
<b>Net Surplus and Comprehensive Income for the Year</b>	<b>5,206</b>	<b>6,850</b>	(1,644)	(24)

### Operating Income

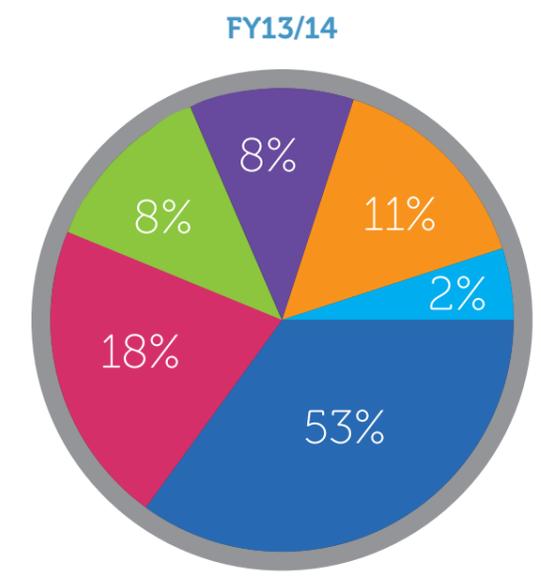
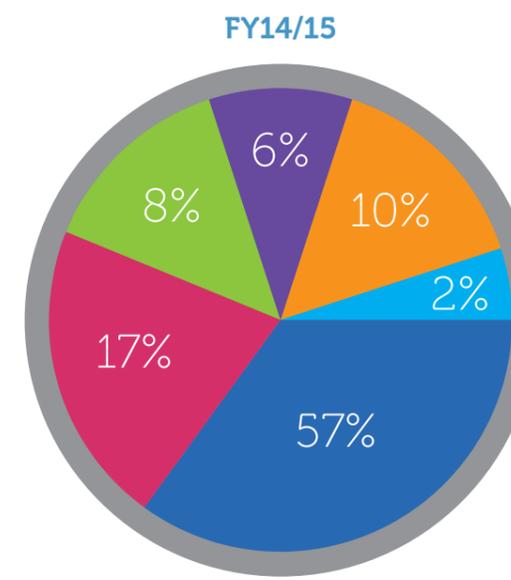
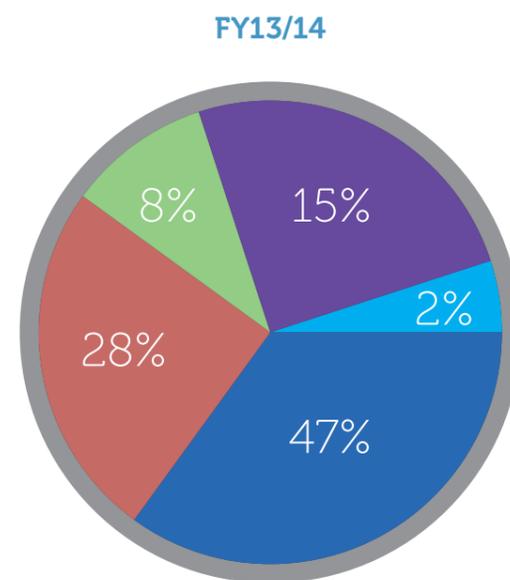
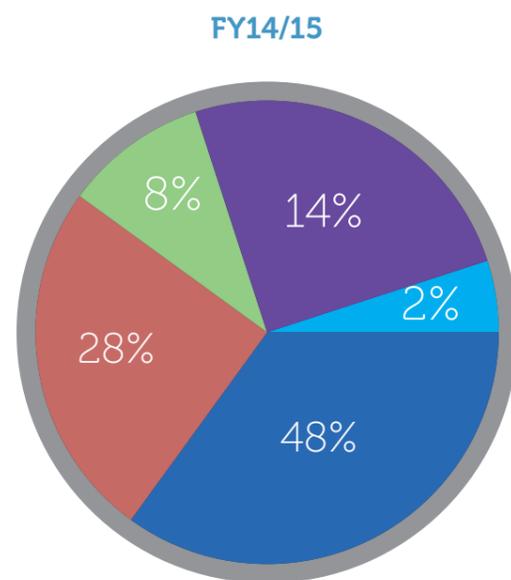
The Authority earned a total operating income of \$121.9m in FY14/15, an increase of \$0.1m (0.1%) over FY13/14's revenue of \$121.8m.

	FY14/15	FY13/14	Increase / (Decrease)	
	\$'000	\$'000	\$'000	%
Laboratory Analysis Fees	57,945	57,738	207	0
Blood Processing and Patient Laboratory Fees	34,556	34,651	(95)	(0)
Forensic Investigation Fees	9,547	9,081	466	5
Licensing Fees	17,024	17,709	(685)	(4)
Other Income	2,827	2,631	196	7
<b>Total Operating Income</b>	<b>121,899</b>	<b>121,810</b>	<b>89</b>	<b>0</b>

### Operating Expenditure

The Authority incurred a total operating expenditure of \$195.4m in FY14/15, an increase of \$3.2m (2%) over FY13/14's expenditure of \$192.2m.

	FY14/15	FY13/14	Increase / (Decrease)	
	\$'000	\$'000	\$'000	%
Staff Costs	112,079	102,578	9,501	9
Supplies and Services	33,716	34,844	(1,128)	(3)
Repairs and Maintenance	16,169	15,471	698	5
Depreciation and Amortisation	11,469	15,414	(3,945)	(26)
Blood Donor Expenses	3,536	3,490	46	1
Other Operating Expenses	18,472	20,395	(1,923)	(9)
<b>Total Operating Expenditure</b>	<b>195,441</b>	<b>192,192</b>	<b>3,249</b>	<b>2</b>



- Laboratory Analysis Fees
- Blood Processing and Patient Laboratory Fees
- Forensic Investigation Fees
- Licensing Fees
- Other Income

- Staff Costs
- Supplies and Services
- Repairs and Maintenance
- Depreciation and Amortisation
- Blood Donor Expenses
- Other Operating Expenses



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