the next decade:

our future forward

HSA Annual Report 2011/12

contents

the next decade:

our future forward

At the Health Sciences Authority, we have a history quite unlike any other organisation.

As we look back on the progress we have made with 10 good years behind us, we are inspired when we think about what more we can accomplish in our next 10 – and beyond.

The road ahead will undoubtedly have its fair share of challenges and also many opportunities.

For brighter ideas to come to life.
For smarter solutions to be delivered.
For stronger partnerships to be forged.
For bigger strides to be taken.
For safer, healthier lives to be led.

United by a powerful sense of purpose defined by our Mission and focused around our Core Values, we are more ready than ever to embrace this exciting future with the same passion, ingenuity and tenacity that brought us this far.

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.

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

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

Live Innovation
We seek constantly to improve and transform.

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

A Statutory Board of the Ministry of Health
The Singapore Public Service: Integrity, Service, Excellence

our accolades

organisational excellence

The Public Service Milestone Award
2010

Singapore Quality Class
since 2009

People Developer Certification
since 2002

Singapore Innovation Class
first public healthcare agency to be endorsed
2003

Singapore H.E.A.L.T.H. Gold Award
since 2005

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 9001:2000
Information Management Department,
Corporate Headquarters
2007

our accolades

professional excellence

Health Products Regulation Group

ISO 9001:2008
Tobacco Regulation Branch
February 2011

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

Blood Services Group

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, Illicit Drugs & Toxicology Division and Biology Division
Excellence for Singapore Award
1999

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

Pharmaceutical Division & Food Safety Division
Public Service Award for Organisational Excellence
July 2003

Singapore Quality Class
since August 2002

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

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

EC-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
EC-ASEAN Reference Laboratory for Mycotoxins Analysis
since June 2004

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

let's talk about

HSA plays a vital role in ensuring that Singaporeans have access to as wide a range of safe and effective products as possible to address issues such as access, affordability and quality.

What are your initial impressions of HSA as its new Chairman?

A: HSA has one of the most challenging tasks of any public agency, being essentially three agencies under one umbrella. I am very impressed with the enormous dedication and hard work that the staff put in to live up to their vision and mission.

What are some of the longer term challenges that HSA will have to overcome in its next decade and how best can the organisation address them?

A: It is critical for HSA to keep up with the increasingly rapid pace of science and technology, with change occurring at a rate faster than we have ever known. We must have the ability to evaluate how to utilise these advances to the benefit of Singapore.

We need to ensure a constant pipeline of top scientists, healthcare professionals, and administrators with the right skill set, excellence, and values of public service. Singapore has a small talent base, and the demands from other parts of the biomedical sciences and healthcare sector will mean that we have to create the right environment and culture to compete for these young women and men.

To compensate for our small talent base, we need to continue developing meaningful and effective partnerships with similar leading agencies internationally. We should learn from them and develop means of leveraging their skills.

There are multiple threats faced by a global city with a rapidly ageing population. These include the use of illegal substances, from narcotics to illegal health products; terrorism; chronic non-communicable diseases, and emerging and re-emerging infectious diseases. We will face a unique challenge if Singapore's median age continues to rise, with fewer potential donors coupled with a greater demand for blood products from elderly patients with multiple medical conditions.

Singapore has not been spared the global phenomenon of rising healthcare costs. HSA plays a vital role in ensuring that Singaporeans have access to as wide a range of safe and effective products as possible to address issues such as access, affordability and quality.

HSA must be able to communicate effectively across all media to healthcare professionals, industry, other public sector agencies and the public.

HSA can never be complacent and must always remain vigilant.

Professor John Wong • *Chairman*

What are your key priorities during your term at HSA?

A: HSA has come a long way and has excellent staff, but we cannot take this for granted. Working with Senior Management, we need to ensure we continue to recruit the best people who share our values, resource them appropriately, and provide them with an environment that allows them to do what they do best.

We need to review the organisational structure to ensure that it continues to serve the public well, develop our physical infrastructure to achieve what is expected of us, ensure that our science and processes are internationally benchmarked, and leverage strategic partnerships.

Please sum up in three words how the past year has been for you as CEO.

A: "exciting, educational and encouraging!

How well do you think HSA has delivered on its mission as a protector and champion for public health and safety in the past year?

A: We saw strong synergy at work across our Health Products Regulation Group and Applied Sciences Group that helped us to identify and mitigate risks associated with several poor quality and illegal health products. Having the right expertise all housed under one roof allows us to proactively and promptly deal effectively with issues such as counterfeit contact lenses and adulterated medicine, before they cause harm to consumers. This synergy is one of our distinctive features compared to overseas counterparts and has helped us to become a more responsive and reliable agency.

We are also serious about building a culture of excellence and continuous innovation. New testing processes and systems were introduced to boost blood safety at our Blood Services Group. Our Applied Sciences Group laboratories also developed new and more rigorous testing techniques to offer clients a broader range of services. New insights gained from our research in pharmacogenomics and pharmacoeconomics will help us make better health product regulatory decisions to protect public health and safety.

The HSA brand was also strengthened at home and abroad. During our tenth anniversary year, we had the opportunity to organise and host major regional and international symposiums and meetings which showcased our unique blend of expertise. Our staff also contributed to various influential regional and global networks, platforms and initiatives. Established international accreditation bodies have endorsed our competencies. All these have helped affirm our reputation as a trusted scientific authority.

What were some of HSA's efforts to better connect with its stakeholders during the year?

Assoc Professor John Lim • *CEO*

A: We expanded our network of alliances through formal collaborative agreements with several of our regional and global counterparts. We are always grateful for such opportunities to collaborate with agencies whose strengths complement and augment our own. They also allow us to share our knowledge and perspectives as we pursue shared objectives.

Closer to home, we continued to engage with industry partners and the healthcare community. Their inputs are invaluable in helping us enhance our regulatory frameworks. To ensure patients receive the best possible care, we continued to offer specialist and consultative services in transfusion medicine and cell therapy to hospitals. We also have a service level agreement to expand our capacity to provide forensic science services to support Home Team Departments.

We also stepped up our outreach initiatives to the community. The response to our first large-scale integrated consumer education programme on the dangers of purchasing health products from dubious sources was very encouraging. We also enjoyed the support from a record number of donors to meet our national blood needs through our close partnership with the Singapore Red Cross.

HSAians also did their bit for the less fortunate by generously supporting our Corporate Social Responsibility projects.

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

What were some of the challenges that HSA faced in the past year?

A: Several challenges came our way in the past year.

We discovered that a wrong concentration of reagent had been prepared and used in the testing process at our DNA Profiling Laboratory. The scientific impact of this error was assessed to be minimal. But it had a considerable downstream impact on our stakeholders' investigative and legal work. In navigating this stretch, we relied heavily on the resolve and professionalism of our laboratory colleagues to put things right again. We took responsibility and were open with sharing the issue with the public. We addressed issues thoroughly and have introduced new procedures following the recommendations of the HSA Board Review Committee. Our response and critical actions taken to prevent similar incidents are fundamentally linked to our conviction that we must always act with credibility, integrity and professionalism to instil public trust and confidence.

We also faced teething issues in the full roll-out of our medical device framework. Medical devices cover a wide range of products, and their classification and regulation can be complex. So we kept in close touch with the medical devices community to gather feedback for improvement. We fine-tuned the framework as we moved along to address our stakeholders' concerns. But we were mindful that the revisions would not compromise patient safety. We will now place a stronger emphasis on post-market vigilance, enforcement, and consumer education as part of the enhanced framework. This ensures that patients can enjoy timely access to safe, effective and good quality devices, even as we seek to be responsive to business needs.

HSAians must always remain inspired and united by a common purpose: that we are not just a part of an outstanding scientific organisation, but of a mission that truly protects and saves lives.

The title of HSA's annual report for this year is "The Next Decade: Our Future Forward". Can you share with us your priorities for the years ahead?

A: We had a very productive past decade serving the nation. I would like to especially thank our former Board Chairman, Professor Edison Liu for his visionary leadership and mentorship of HSA since 2006. Ed Liu's chairmanship has been a fundamental factor in the strides HSA has made to becoming a leading international scientific and regulatory authority, and we owe him a tremendous debt of gratitude.

I also warmly welcome Professor John Wong to the HSA family as our new chairman. Professor Wong is a highly respected haemato-oncologist with an illustrious career in academia and research, and we are indeed fortunate to have another visionary leader for our Board. We look forward to his guidance and counsel in setting the directions for HSA to soar even higher in the years ahead.

Our environment today is far more complex than it was when we first started out. New scientific and technological innovations are continually re-shaping our paradigms. Novel health products and treatments enter the market faster than ever before. Consumers' healthcare preferences are also evolving. But these changes bring into sharper focus the importance of the work we do. They remind us about why excelling in our role is so rewarding.

I am optimistic and excited about the future of HSA. Our accomplishments in the past decade were possible because of the passion and professional pride of our people. So as CEO, it is my responsibility to work with my team to build an even stronger culture galvanised around our Core Values. HSAians must always remain inspired and united by a common purpose: that we are not just a part of an outstanding scientific organisation, but of a mission that truly protects and saves lives. Enhancing our ongoing capability building efforts will also be important. This will help us to keep abreast of public health and scientific developments as we progress together. The HSA Academy will also be developed as a critical enabler to grow our professional expertise and thought leadership. We must also continue leveraging our collective strengths as one, while cultivating stronger partnerships as we scale new heights as a confident, trusted and transforming authority.

HSA Board

as at August 2012

Chairman

Professor John Wong
Isabel Chan Professor
in Medical Sciences
National University Health System
National University of Singapore

Board Members

(From Left to Right)

Ms Serene Wee
Chief Executive • Singapore Academy of Law

Dr Jennifer Lee
Senior Consultant • Primary & Community Care Division • Ministry of Health

Dr Chong Yoke Sin
Chief Executive Officer • Integrated Health Information Systems Pte Ltd

Professor Alastair Campbell
Director • Centre for Biomedical Ethics • Yong Loo Lin School of Medicine • National University of Singapore

Professor K. Ranga Krishnan
Dean • Duke-NUS Graduate Medical School

Adj Assoc Professor Lee Chien Earn
Chief Executive Officer • Changi General Hospital

Mdm Liew Wei Li
Director • Student Development Curriculum Division • Ministry of Education

Assoc Professor John Lim
Chief Executive Officer • Health Sciences Authority

Mr Clifton Tan
Director • Pembrooke Investments Pte Ltd

Professor Walter Tan
Medical Director • Raffles Hospital

HSA board committees
as at August 2012

Audit Committee

Ms Serene Wee	Chairman
Adj Assoc Professor Lee Chien Earn	Member
Professor Walter Tan	Member
Mr Clifton Tan	Member

Staff Establishment Committee

Dr Jennifer Lee	Chairman
Professor Alastair Campbell	Member
Mdm Liew Wei Li	Member

Finance Committee

Dr Chong Yoke Sin	Chairman
Dr Jennifer Lee	Member
Adj Assoc Professor Lee Chien Earn	Member

board updates

We would like to express our sincere appreciation to Professor Edison Liu for his invaluable contributions and mentorship over the past five years as the Chairman of the HSA Board. Professor Liu joined the HSA Board in 2006 as Deputy Chairman and was appointed Chairman in 2007. Under his visionary chairmanship, HSA has been inspired to make significant strides in becoming an internationally renowned scientific and regulatory authority. Professor Liu worked closely with HSA's leadership to strengthen the organisation's scientific rigour and capacity as a trusted and responsible regulator, while transforming and integrating its structures and processes to become more efficient and enterprise-oriented. Professor Liu's term as Board Chairman ended on 31 December 2011. We extend to him our very best wishes in his new role in the USA as President and Chief Executive Officer of the Jackson Laboratory.

We also congratulate Professor John Wong on his appointment as our new Chairman with effect from 1 January 2012. Professor Wong, Isabel Chan Professor in Medical Sciences, is the Vice Provost (Academic Medicine) of the National University of Singapore (NUS). He is also the Deputy Chief Executive of the National University Health System (NUHS), and Director of the National University Cancer Institute, Singapore (NCIS). We warmly welcome Professor Wong to the HSA family, and look forward to his guidance and counsel in setting the policies and directions for HSA in the years ahead, as HSA continues to serve the nation in ensuring safer and healthier lives and develops into a leading organisation for scientific and regulatory expertise in health sciences.

HSA executive committee (EXCO)

as at August 2012

Assoc Professor John Lim
Chief Executive Officer

Dr Diana Teo
Group Director
Blood Services Group
Chairman
Professional Board

Dr Lam Kian Ming
Group Director
Applied Sciences Group
Director
HSA Academy

Dr Raymond Chua
Group Director
Health Products
Regulation Group

Dr Mok Ying Jang
Acting Group Director
Corporate Services

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

Dr Christina Lim
Senior Director
International Relations
Health Products
Regulation Group

Ms Doreen Loh
Division Director
Human Capital and Legal
Corporate Services

corporate governance statement

The HSA Board and Senior Management Team are committed to maintaining a high standard of corporate governance and advocating 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 3-year term. It aims to meet every two months to set strategic directions and formulate policies, assuming 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 be interested in any such transactions made during the meetings are reminded and required to declare their interest; they are to refrain from any deliberation 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 sub-committees:

(a) The Audit Committee
This Committee assists the Board to review and assess the adequacy of internal accounting controls and financial reporting controls. It meets at least twice a year with the Management and auditors to determine the scope of the external and internal audit and to review the findings of its appointed auditors.

(b) The Staff Establishment Committee
The Staff Establishment Committee assists the Board in reviewing the adequacy of manpower numbers and budgets to meet operational needs and major Human Resource Policies regarding compensation. It oversees some staff matters such as the appointment of senior management positions.

(c) The Finance Committee
This Committee assists the Board in ensuring that financial resources are managed and utilised prudently and in the most effective and efficient manner, contributing towards the organisation's overall mission.

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 to provide information to our stakeholders.

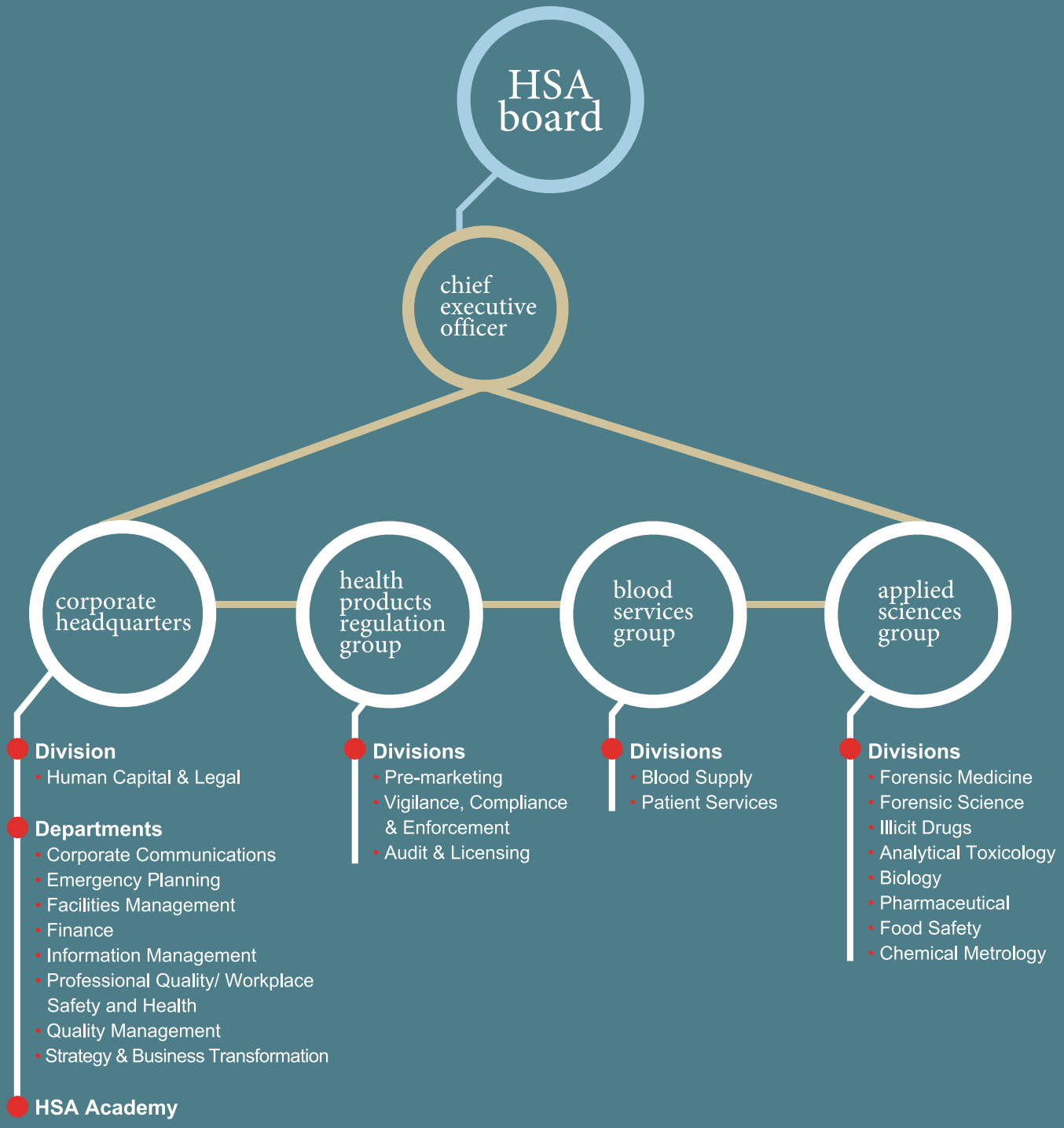
In addition, regular updates on matters of interest to our stakeholders are posted on our internet website. Our Quality Service Manager promptly handles all feedback and queries received from interested parties.

Code of Business Conduct
The Board, officers and employees are required to observe and maintain high standards of integrity, and are in compliance with the law and government regulations, and organisation policies.

Risk Management
The Management is continually reviewing and improving the business and operational activities to identify areas of significant business risks as well as appropriate measures to control and mitigate these risks. The Management also reviews all significant control policies and procedures and highlights all significant matters to the Board and the Audit Committee.

organisation chart

as at August 2012



principal officers
as at august 2012

CORPORATE HEADQUARTERS

Chief Executive Officer
Assoc Professor John Lim

CORPORATE SERVICES
Acting Group Director
Dr Mok Ying Jang

Strategy & Business Transformation
Director
Mr Prashant Dhami

Corporate Communications
Director
Mr Adrian Chia

Finance
Director
Ms Grace Chan

Facilities Management
Deputy Director
Ms Lynette Goh

Information Management
Director
Mr Santhanam Srinivasan

Emergency Planning
Senior Manager
Mr Wong Soon Lee

Quality Management
Senior Manager
Mr Toi Shean Hoon

HUMAN CAPITAL & LEGAL DIVISION
Division Director
Ms Doreen Loh

Legal & Prosecution
General Counsel
Ms Linda Chen

Human Capital Management
Director
Ms Lily Goh

Organisational Excellence
Senior Manager
Ms Joyce Nang

PROFESSIONAL QUALITY/WORKPLACE SAFETY & HEALTH DEPARTMENT
Director
Professor Bosco Chen Bloodworth

HSA ACADEMY
Director
Dr Lam Kian Ming

HEALTH PRODUCTS REGULATION GROUP

Group Director
Dr Raymond Chua

Deputy Group Director
Assoc Professor Chan Cheng Leng

Senior Director
International Relations
Dr Christina Lim

Senior Advisor
Health Products Regulation Group
Mr Yee Shen Kuan

Advisor
International Collaboration
Mrs Marie Tham

Advisor
Administration and Pharmacoeconomics & Drugs Utilisation Unit
Mdm Suwarin Chaturapit

GROUP DIRECTOR'S OFFICE
Acting Director
Ms Lee Hui Keng

PRE-MARKETING DIVISION
Division Director
Dr Lou Huei-Xin

Senior Group Regulatory Consultant
Dr Tam Kai Tong

Group Regulatory Consultant
Ms Agnes Chan

Pharmaceuticals & Biologics Branch
Deputy Director
Ms Jalene Poh Wang Woon

Generics & Biosimilars Branch
Director
Dr Sannie Chong

Medical Device Branch
Director (covering)
Dr Lou Huei-Xin

Clinical Trials Branch
Director
Mr Foo Yang Tong

Complementary Health Products Branch
Director (covering)
Ms Lee Hui Keng

AUDIT & LICENSING DIVISION
Division Director (covering)
Mr Sia Chong Hock

Deputy Division Director
Ms Jessica Teo

Audit Branch
Director
Ms Jessica Teo

Licensing & Certification Branch
Acting Director
Dr Lai Weng Fai

VIGILANCE, COMPLIANCE & ENFORCEMENT DIVISION
Division Director
Assoc Professor Chan Cheng Leng

Vigilance Branch
Director
Ms Dorothy Toh

Compliance Branch
Director
Mrs Joanna Koh

Enforcement Branch
Director
Ms Ruth Lee

Tobacco Regulation Branch
Deputy Director
Mr Norman Chong

BLOOD SERVICES GROUP

Group Director
Dr Diana Teo

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

Assistant Group Director (Professional)
Dr Ang Ai Leen

Division Director
Dr Tan Hwee Huang

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

Senior Manager
People Development & International Collaboration
Ms Leou Kwee Kim

Senior Manager
Quality & Accreditation
Ms J Thilakavathi

BLOOD SUPPLY DIVISION
Branch Director
Blood Resource
Mr William Sim

Laboratory Director
Blood Supply Management
Ms Sally Lam

Deputy Senior Laboratory Manager
Blood Supply Management
Ms Shu Pei Huey

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

Senior Laboratory Manager
Immunohaematology & Cell Therapy Support
Ms Phang Chew Yen

APPLIED SCIENCES GROUP

Group Director
Dr Lam Kian Ming

GROUP DIRECTOR'S OFFICE
Senior Consultant &
Forensic Scientist, ATD/IDD
Dr Lui Chi Pang

Senior Scientific Advisor
Professor Bosco Chen Bloodworth

Director
Accreditation, Professional & Technical Education
Dr Michael Tay

FORENSIC MEDICINE DIVISION
Division Director
Dr Paul Chui

Professional Practice Branch
Branch Director
Assoc Professor Gilbert Lau

Forensic Medicine Operations Branch
1 Branch Director
Assoc Professor Cuthbert Teo

2 Branch Director
Dr George Paul

FORENSIC SCIENCE DIVISION
Division Director & Laboratory Director
Forensic Chemistry & Physics Laboratory
Ms Lim Chin Chin

BIOLOGY DIVISION
Division Director
Mrs Tan Wai Fun

Laboratory Director
DNA Database Laboratory
Mrs Tan Wai Fun

Laboratory Director
DNA Profiling Laboratory
Assoc Professor Christopher Syn

ILLICIT DRUGS DIVISION
Division Director & Laboratory Director
Illicit Drug Laboratory
Dr Angeline Yap

ANALYTICAL TOXICOLOGY DIVISION
Division Director
Dr Yao Yi Ju

Analytical Toxicology Laboratory
Drug Abuse Testing
Laboratory Director
Dr Yao Yi Ju

Analytical Toxicology Laboratory
Clinical and Forensic Toxicology
Laboratory Director
Dr Yao Yi Ju

PHARMACEUTICAL DIVISION
Division Director
Ms Low Min Yong

Laboratory Director
Pharmaceutical Laboratory
Ms Low Min Yong

Laboratory Director
Cosmetics Laboratory
Ms Cheah Nuan Ping

Laboratory Director
Cigarette Testing Laboratory
Ms Cheah Nuan Ping

FOOD SAFETY DIVISION
Division Director & Laboratory Director
Food Safety Laboratory
Ms Joanne Chan

CHEMICAL METROLOGY DIVISION
Division Director & Laboratory Director
Chemical Metrology Laboratory
Dr Lee Tong Kooi

Robustness and Responsiveness

Health Products Regulation Group

HPRG

The Health Products Regulation Group (HPRG) continually strives to maintain the trust of those we serve by ensuring that all health products in Singapore meet the highest standards of safety, quality and efficacy.

We advocate a robust yet flexible and risk-based regulatory system that places an utmost priority on patient safety, while enabling timely access to potentially life-saving medicines and devices. We are also consistently enhancing the rigour of both our pre- and post-market regulatory processes.

By collaborating closely with our counterparts both at home and abroad, we seek to broaden our knowledge and strengthen our capabilities as we aim to be at the forefront of global advances in the regulatory sciences. This ensures readiness to accept new innovative technology and scientific advances so that we can facilitate the entry of new medical treatments to promote public health.

Novel and increasingly complex health products will continue to pose challenges to us as a regulator. In response to this, we aim to always stay ahead of the curve so that we are equipped with the latest knowledge, tools and methodologies to assess the safety, efficacy and quality of these health products.

We are also constantly supporting the development of the biomedical industry through our pro-enterprise orientation, whilst ensuring that national public health is safeguarded.

wise regulation

To wisely regulate health products, we have established robust regulatory systems for various groups of health products. These are supported by efficient and responsive processes and programmes for product evaluation and registration, dealer audits and licensing, compliance monitoring, safety vigilance, and enforcement.

The past year saw the controls for various health product groups being brought under the Health Products Act (HPA)'s regulatory umbrella. To facilitate a smooth transition for industry and ourselves, we have adopted a phased approach to fully implementing the HPA.

The following legislation under HPA was published in the past year:

- Health Products (Composition of Offences) Regulations 2011
- Health Products (Good Manufacturing Practice Certificate – Cosmetic Products) Regulations 2011

In FY2011, we held several communication sessions with industry stakeholders to ensure the smooth transition of regulations for therapeutic products to the HPA.

Significant progress was also made in the revision of the existing regulatory framework for clinical trials, which will be introduced as the Health Products (Clinical Trials) Regulations in 2012. The key changes will aim to reduce the regulatory burden for companies, increase time savings and enable greater operational efficiency without compromising safety standards. The scope of the new regulations will also include clinical trials for medical devices.

building *bridges*

At HSA, we are committed to creating a conducive environment for businesses, by being more transparent on regulatory decisions and more responsive to concerns and feedback.

Staying in Touch

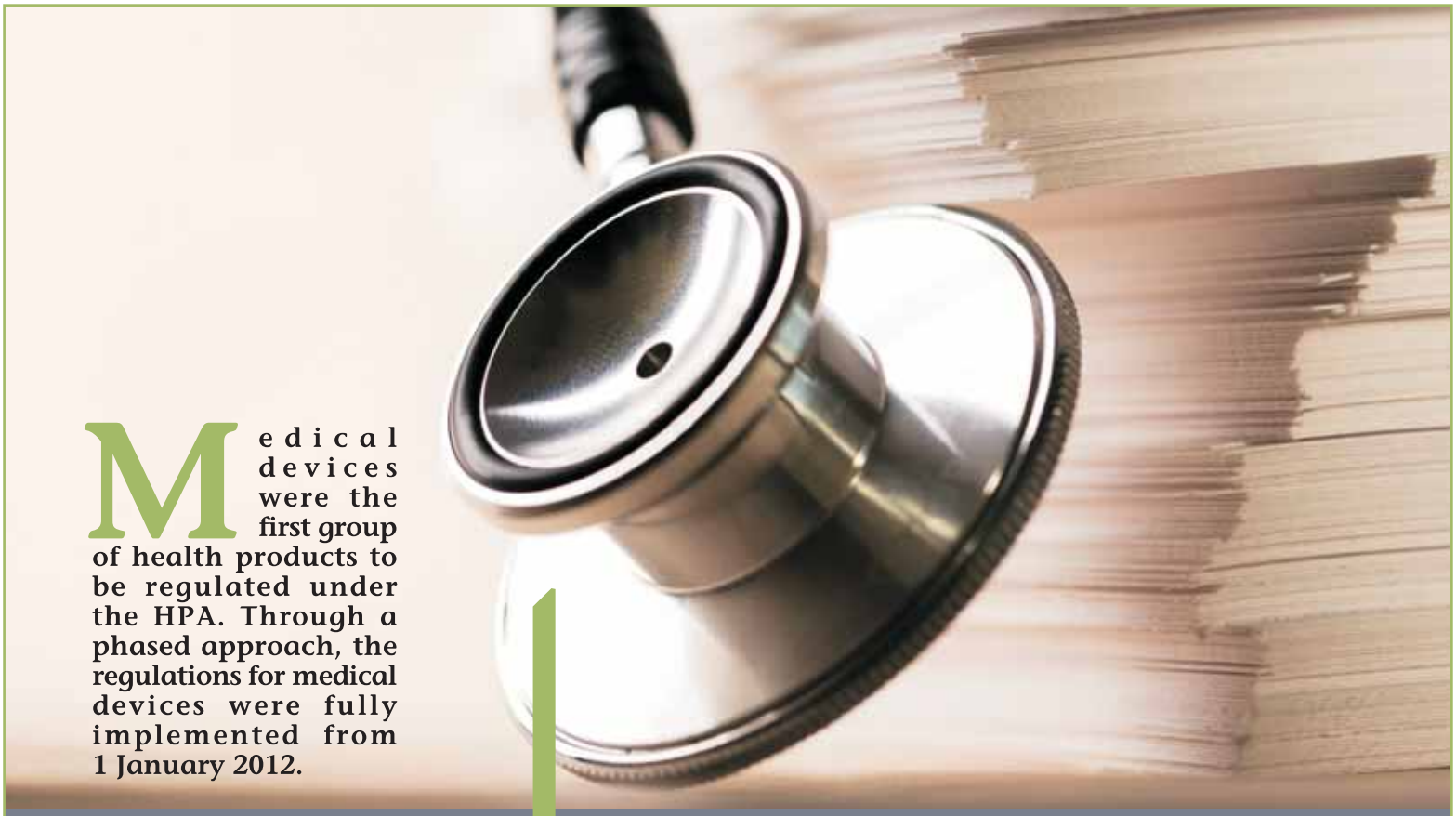
We held a series of sessions with our partners that served as useful platforms for explaining our new policies and processes, and seeking feedback on our upcoming plans. These included:

- A dialogue session in August 2011 with pharmacy managers regarding the mandatory recording requirement for Pharmacy-Only medicine.
- A Joint Regulatory Workshop in February 2012 attended by more than 500 industry stakeholders who were keen to further their understanding of our regulatory requirements.
- A briefing and workshop in March 2012 on the clinical development of medical devices.

Regular Reviews

We also worked on improving the efficiency, clarity and transparency of our work procedures for the benefit of companies. Some key improvements made during the year included:

- Acceptance notifications were issued to companies with regard to their minor variation (MIV-1) applications for post-approval changes.
- The product registration requirement for a Good Manufacturing Practice (GMP) certificate has been removed for manufacturers that do not need to undergo GMP conformity assessment.
- The online screening checklists were enhanced for New Drug Applications and Generic Drug Applications.
- Regulatory guidelines and documents for complementary health products were developed and updated to provide additional assistance to companies in their applications and submissions.
- Distinct dental grouping terms were created to facilitate the pre-market submissions of dental medical devices.
- The validity of Medical Device Special Authorisation Routes were extended from six months to one year.
- A focus group discussion with healthcare practitioners was conducted on the proposed terms and conditions for cell- and tissue-based therapeutic (CTT) products licensing.



Medical devices were the first group of health products to be regulated under the HPA. Through a phased approach, the regulations for medical devices were fully implemented from 1 January 2012.

greater responsiveness

Following extensive consultation with industry stakeholders, HSA rolled out enhancements to the regulatory framework for Class A and B medical devices in April 2012 to facilitate expedited access and lower registration fees for these products. The changes were targeted at addressing companies' concerns while ensuring patient safety. HSA will continue to risk stratify the regulation of medical devices based on international best practice, while allowing greater customisation and flexibility in each class through judicious referencing of key overseas agencies and history of safety.

To ensure that medical devices remain safe for use in Singapore, and that any significant adverse events are dealt with swiftly, we will also be stepping up medical device post-marketing compliance and vigilance activities, as well as the auditing activities of dealers and manufacturers.

To help minimise delays due to incomplete submissions and documentation, HSA is in discussion with the Singapore Manufacturers' Federation (SMa) to pilot a project to provide training to companies on dossier submission, as well as a "concierge service" to help screen the completeness and appropriate risk classification of dossier applications to HSA. We have also launched the HSA-SMaRT Dossier Submission E-Guide on our website to provide companies with step-by-step advice on submission procedures.

Electronic Enhancements

Further improvements were made to our online licensing system, PRISM, providing our stakeholders with greater convenience.

- The system's auto-renewal feature for product licenses now offers businesses a choice to opt in or out.
- We launched clearance@prism, an e-service that makes the reporting of import and export consignments of controlled drugs and psychotropic substances more convenient and easier to track for companies.

a progressive facilitator

HSA, through the HPRG, is the national agency that regulates the conduct of clinical drug trials in Singapore, ensuring that these are carried out in accordance with international ethical and scientific standards.

Improving Awareness

A public Clinical Trials Register will be implemented in 2012 to enhance the transparency of the number and types of clinical trials being conducted in Singapore. This will allow industry stakeholders to make informed strategic decisions and keep the public informed of ongoing local clinical trials and their status.

Towards Greater Transparency

Several initiatives and activities over the past year have helped to make our operations more transparent to industry. Materials for GCP site inspections – including inspection metrics and findings – were made available on the HSA website and via communication sessions to facilitate the preparation of trial sites for inspection. Specific guidance and templates for investigational product management in clinical trials were also added to the HSA website to raise awareness and to aid in consistent interpretation of regulations and guidelines.

safe and sure

We implemented record keeping for medicines purchased from pharmacists in phases with effect from 1 April 2011. It is mandatory for members of the public who purchase these medicines to have their personal particulars recorded by pharmacists. This is to ensure safe and appropriate use of medicines, as well as to allow pharmacists to follow up with the public when there are any concerns.

We initiated a project to publish the approved package inserts (PI) and patient information leaflets (PIL) of registered medicinal products (innovator products) on the HSA website. The PIs, which contain the approved indications, dosing regimen and information to ensure safe and effective use of the product, will serve the needs of healthcare professionals. The PILs, featuring simplified information that is easily understood, are designed for patients and consumers.

At the same time, together with the pharmacist professional body, we have developed PILs for prescription medicines with exemptions for supply without a prescription. In addition, for pharmacists distributing these leaflets when supplying these medicines, the PILs are also available for download from the HSA Reclassified Medicines webpage.

The first generic products for the following off-patent drugs were approved for marketing in Singapore: imipenem and cilastin powder, meropenem, montelukast sodium, olanzapine, levofloxacin, anastrazole, raloxoifene and mometasone. These first generics were approved within the published timeline, ensuring accessibility of affordable medications to Singaporeans.

pro-enterprise *initiatives*

During the year, we put in place a wide range of activities and initiatives to create a positive experience for all businesses interacting with us. These are based on five key components: Review of Rules, Transparency, Customer Responsiveness, Compliance Cost and Pro-enterprise Orientation.

Review of Rules & Regulations

The criteria and requirements for the verification route for new drug application and major variation application were revised from 1 April 2011. The revision was done in response to feedback from industry and allows greater flexibility in using this route, enabling more companies to benefit from faster approval timelines (cut from 180 working days to 60 working days).

Transparency

Our application guidelines are easily accessible on our website. To improve the application experience, attachments sent during applications have been made viewable by applicants. This initiative was effected from 1 April 2011.

A template of the Good Clinical Practice (GCP) Site Inspection Dossier as well as a GCP Site Inspection Preparation Checklist are provided on our website. GCP inspection metrics and findings are also shared with industry. These initiatives provide greater transparency and facilitate the preparation of clinical trial sites for GCP inspections.

Customer Responsiveness

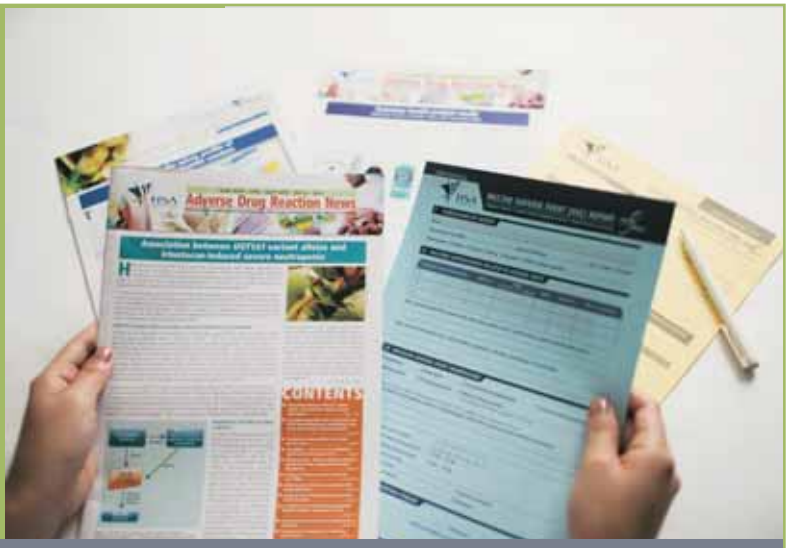
In an effort to streamline the enquiry process for applicants who are unsure of the classification of their products, we launched a consolidated Product Classification Enquiry Form & Workflow from mid-May 2011. This initiative allows all product classification enquiries to be received through a single channel.

Pro-enterprise Orientation

With effect from July 2011, a step-by-step guideline for Client Registration and Identification Service (CRIS) application and product notification was made available on our website. This provides clearer guidance on submission of CRIS applications and product notifications, especially for new companies dealing with cosmetic products.

We are grateful that the concerted efforts of our regulatory staff have been positively received by our stakeholders. In 2011, HSA rose to 13th place in an annual survey on the pro-enterprise orientation of regulatory agencies commissioned by the Action Community for Entrepreneurship in 2011.

always on the lookout



We recognise that no product is completely free of risk. This is why we have continued to strengthen our post-market vigilance systems to ensure swift corrective responses when safety concerns are detected.

Our Adverse Event (AE) Monitoring Programme, drawing on a network of local healthcare professionals who proactively support this programme, by reporting unwanted and unexpected reactions suspected to be related with health products, remained effective in tracking and identifying safety trends.

Similarly, our Product Quality Surveillance (PQS) Programme continued its integrated approach involving pre- and post-market groups to holistically recommend the health products for sampling, conduct risk assessments, determine the class and levels of recalls, and recommend regulatory actions to be taken.

We worked closely with our Applied Sciences laboratories to test potentially harmful products and took quick steps to alert the public not to consume them.

Our achievements during the year include:

- Ranked first internationally in terms of the number of active individual case reports per million inhabitants submitted to the WHO global database.
- 30,175 local reports of AE suspected to be related to health products were received. 23,724 of these were captured in our national database as valid reports.
- 228 benefit-risk assessments of health products were performed.
- 14 products' International Risk Management Plans were reviewed in response to safety issues. Risk mitigation activities were conducted for seven of them at the point of product registration.
- 14 Periodic Safety Update Reports for targeted products with safety concerns at the point of product registration were reviewed.
- 112 suspected AE reports were received for complementary health products. Of these, 22 adulterated products were detected as a result of our investigations. Six press releases were issued to alert the public against taking these harmful products. The detection of adulteration also led to convictions of the accused in court, including the cases involving unlabelled black pills and the recalls/ cancellation of product registration in overseas market of Pao Ni Kang [保腆康] and Huo Li Bao [活力宝].
- 2,067 products were sampled and tested under the PQS programme. eight products were found to be non-compliant and were recalled from the market. The non-conformities included the presence of toxic heavy metals above permissible limits, microbial contamination or undeclared western medicines in these products. Enforcement action was taken against all the companies involved.

Vaccine Vigilance

- 22,893 children were screened for vaccine adverse events (VAE).
- 1,061 cases of suspected VAE were further evaluated.
- 116 cases were considered to be serious.

KK Women's and Children's Hospital (KKH) contributed 68% of the VAE reports received. Safety signals identified include lymphadenitis with BCG vaccination and hepatitis B infection in infants born to hepatitis B carrier mothers. Risk assessments were conducted and an article in the HSA Adverse Drug Reaction news bulletin was published to create awareness of these safety signals and to encourage healthcare professionals to report VAE in order to better estimate the incidence rate at the national level and gain a better understanding of the safety signals.

An in-depth benefit-risk study was conducted for Prevenar 13, a pneumococcal vaccine, in collaboration with Ministry of Health (MOH). This review led to the adoption and dissemination of new clinical guidelines for the use of Prevenar 13 in children with co-morbidities.

a closer watch

The Common Vigilance Unit (CVU) was further strengthened in 2011 to ensure a coordinated approach on safety and quality issues with an immediate impact on patient safety. Information from local and overseas sources such as product defect reporting by companies, feedback from healthcare professionals and information sharing by other regulatory authorities were streamlined through a common vigilance process. This has resulted in a holistic and coordinated approach from pre-licensing to post-licensing with respect to risk management and provides consistency in the vigilance process to the industry and public.

We established the SingVigiSystem (SVS), a central database for storing knowledge on safety, efficacy and quality issues associated with health products. The SVS also serves as a case management tool to aid in the event of escalation.

Some of the notable cases managed by the common vigilance team during the year included:

Precautionary Steps

In response to concerns over the potential radiation contamination of health products imported from Japan following the Fukushima nuclear incident, we took steps to work with our stakeholders to safeguard the integrity of future supplies of such products from Japan as a precautionary measure. Based on our consultations with experts, overseas regulatory agencies and internal assessments, it was assessed that the possibility of radioactive contaminants in health products was remote. To date, there have been no known reports of radioactive contaminants in health products.

Quick Action

In June 2011, HSA took a risk-based approach to sample and test health products manufactured in Taiwan for Di(2-ethylhexyl)phthalate (DEHP), following reports of varying levels of DEHP in Taiwan-manufactured health foods and products.

Closer to Home

We suspended the sales and distribution of Zerin® (Paracetamol) 500mg tablets in August 2011, following investigations revealing that tablets from some batches were found to contain small foreign particles. Although the health risk to consumers was assessed to be low, we wanted to prevent the exposure of members of the public to a product that is not compliant with quality standards. We also worked with the relevant drug companies and healthcare providers to ensure that there are sufficient supplies of other brands of paracetamol to meet national needs.

swift and stern action

During the year, we continued to gather intelligence, carry out investigations and take firm enforcement action against activities relating to unregistered, counterfeit and adulterated health products.

A Closer Watch

In mid-June 2011, HSA was notified by CIBA VISION of the presence of counterfeit coloured contact lenses in local optical shops. Following an investigation, we seized 122 boxes of counterfeit goods and laid charges under the HPA against seven parties, including owners of optical shops and their suppliers. This was the first case of counterfeit contact lenses being sold in optical shops in Singapore, and seven accused persons have been charged under the HPA. Together with Optometrists and Opticians Board, we sent circulars to professional associations and hospitals. These were accompanied by advisories for the public. We also visited major chains of optical shops to highlight the issue and to educate practitioners on the safety concerns. A "Regulatory Control of Contact Lenses in Singapore" seminar was also conducted for all optometrists to share our regulatory controls and safety issues linked to counterfeit lenses. Additionally, we continued to actively monitor the situation through a surveillance programme so as to detect and remove counterfeit contact lenses in the regulated supply chain.

A First for Ads

We responded to feedback regarding advertisements for products marketed by a company. It was found guilty of advertising medical claims for its products through flyers, brochures, newspapers and radio, and was fined $5,000. These non-compliant claims include medicinal claims relating to medical conditions such as eczema, rhinitis, low libido and joint pain, as well as prohibited claims such as diabetes. This was the first case related to non-compliant medical advertisements that we have prosecuted.

Cough Mixtures Uncovered

In two separate operations, we uncovered cases of the illegal sale of codeine cough mixtures for the black market. Our officers discovered that forged documents were used to purchase large quantities of cough mixtures and tablets containing codeine from pharmacies. We also found cough mixture canisters at the homes of the accused. Both cases were also referred to the Singapore Police Force (SPF) in relation to the forgery activity. Three individuals were prosecuted for the illegal sale of codeine cough mixtures. The accused were sentenced to imprisonment ranging from 18 weeks to 52 weeks.

Sleeping Pills Seized

On 26 July 2011, our officers, working together with the Immigration and Checkpoints Authority (ICA), seized approximately 10,000 midazolam sleeping tablets being smuggled into Singapore. They were mislabelled, hidden in steel flasks and falsely declared. The suspect was apprehended in connection with the case.

A Whirlwind of Raids

In our ongoing battle against the illegal sale of sexual enhancement products, we carried out a number of raids under Operation Whirlwind, targeting peddlers of these products. Further efforts have included collaboration with the SPF to conduct raids and working with the ICA and Singapore Post to intercept falsely declared parcels containing sexual enhancement products.

Online Operations

From 20 to 27 September 2011, we participated in Operation Pangea IV, a global action targeting the online sale of unregistered, counterfeit and illegal medicines to the public. Coordinated by INTERPOL and several international agencies, the operation saw participation from 81 countries as it targeted suspected websites around the world. In Singapore, 14 online platforms were screened and two sites were found to be selling illegal health products, resulting in the seizure of $13,560 worth of products and the investigation of seven individuals.

many hands at work

Partnerships with external agencies and between internal HSA groups are an important part of our efforts to broaden our reach and strengthen our capabilities. In 2011, HPRG strengthened its internal partnership with ASG's forensic and analytical testing laboratories to better investigate adverse reactions arising from the consumption of drugs from dubious sources and quality-related defects. We also participated in a multi-agency networking meeting with the environmental scanning teams from the MOH, Agri-Food & Veterinary Authority, Health Promotion Board and National Environment Agency to develop closer ties and exchange information.

The healthcare community plays an indispensable role as our partner in protecting public health. We continued to keep in close touch with healthcare professionals through a variety of channels during the year.

HSA issued nine Dear Healthcare Professional Letters (DHCPL) and vetted 20 company DHCPL informing healthcare professionals of safety issues and regulatory decisions for health products and medical devices. In addition, two Traditional Chinese Medicine Practitioners (TCMP) letters were issued, alerting the physicians to serious adverse events reported with illegal health products and complementary medicines. To enhance our communication efforts, we conducted a survey to obtain feedback from local doctors, dentists and pharmacists on our risk communication tools and channels.

In 2011, we reached out and established networks with TCMP, herbalists and interns to introduce the concept and importance of adverse event reporting in the practice. The team also engaged several Traditional Chinese Medicine (TCM) associations and related academic institutes to conduct interactive sessions on the AE reporting programme. Our first TCM educational material was featured in TCM organisations' bulletins and posters to assist TCMP in their reporting activities. Roadshows were also organised for community pharmacists at retail outlets. This was intended to heighten their awareness of adverse events and possible herb-drug interactions, as well as to encourage adverse drug reaction reporting.

We believe in empowering consumers with information on the responsible use of health products so that they can take the necessary steps to protect themselves and their loved ones. During the year, we regularly reached out to the public through press releases and HSA Updates. This allowed us to provide important information on product safety and vigilance activities, including the results of product tests, warnings about counterfeit products in the local market, and product recalls.

We also launched our first integrated public education campaign in September 2011 to emphasise the dangers of purchasing contact lenses, slimming medicines and sexual enhancement products from dubious sources. The campaign featured a series of three advertisements that appeared in mainstream media, public transport and outdoor spaces, as well as a specially designed consumer advisory micro-site. Response to the campaign was very encouraging, with both the website and mobile site receiving more than 130,000 visits as at end March 2012.

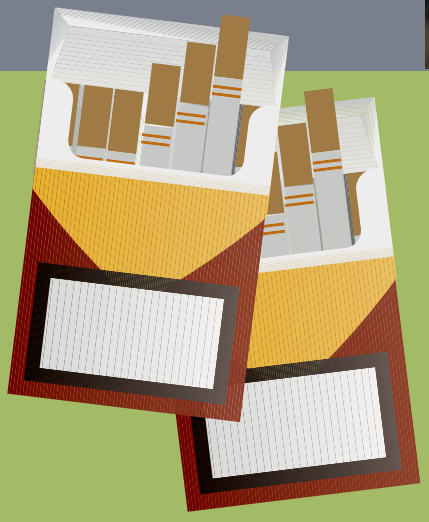
From Information *to Insight*

We continued to expand our pharmacogenomics research capabilities and efforts in 2011 through a range of partnerships and projects. Through our findings, we hope to tap the power of scientific discovery and innovation to advance public health and safety.

Project	Partners	Objectives
Cost Effectiveness of Genotyping – HLA-B*1502 and Anti-epileptic Drug Selection	Health Services and Systems Research Programme at Duke-National University of Singapore (NUS) Graduate Medical School	This joint study was conducted in response to feedback gathered from the Pharmacogenetics Expert Panel. The results of this study revealed that, due to the different population allele frequencies of HLA-B*1502 in Singapore's ethnic groups, genotyping for HLA-B*1502 prior to initiation of antiepileptic therapy with carbamazepine and prescribing alternative antiepileptic drugs to patients who test positive for HLA-B*1502 is cost effective for Singaporean Chinese and Malays, but not for Singaporean Indians. These findings support pharmacogenetic testing prior to administering carbamazepine to treat newly diagnosed epilepsy patients. HSA has initiated consultations with neurologists to evaluate the practicalities of genotyping before making a recommendation.
Regulatory Frontiers: Initiate and Advance New Frontiers in Pharmacogenomics-Based Pharmacovigilance	Changi General Hospital, National University Hospital (NUH), Singapore General Hospital, NUH-NUS Tissue Repository and Singapore Immunology Network	Collaborating with several of Singapore's public hospitals, we aim to pilot programmes for serious skin rash and drug-induced liver injury. These ongoing projects, which were initiated since 2009, will allow us to build an understanding of adverse drug reactions, with the ultimate goal of identifying patients who are more susceptible to serious adverse drug reactions before dosing, so that treatment plans can be modified.
Singapore Genome Variation Project	University of British Columbia and the Department of Statistics and Applied Probability, Saw Swee Hock School of Public Health, NUS	This project, initiated in 2011, aims to create a resource of genetic variability in Singapore's ethnic groups and a toolbox of bioinformatic applications that will help regulators to assess the importance of genetic variation when evaluating new drug applications and revising prescribing information. It will also assist in developing regulatory guidelines on a standardised approach to the use of bioinformatic tools. The development of a web resource to facilitate access to this information is ongoing.
Development of new capabilities in assessing hepatotoxic potential of complementary and alternative medicine implicated in drug-induced liver injury (DILI)	Pharmacy Department, NUH	This project aims to enhance the capabilities of HSA's Pharmaceutical Laboratory by developing a practical in vitro method to assess the inherent hepatotoxicity potential of complementary and alternative medicines implicated in adverse drug reaction cases. This work has identified some chemicals that may be in part responsible for the hepatotoxicity seen with some of the products implicated in DILI. Further work may be carried out to determine other potentially hepatotoxic components and to assess the causality. A publication on the research findings is being prepared.

tough against tobacco

Following the National Tobacco Control Programme's tightening of the tobacco retail licensing criteria in April 2011, tobacco sales are disallowed in outlets dealing in health-related products or youth-centric products. To ensure a fair and consistent mechanism for reviewing new tobacco retail licence applications, as well as existing licences, a nine-member Tobacco Licensing Consultative Panel was formed in April 2011, with HSA acting as its secretariat.



We are collaborating with the Health Promotion Board and industry players to implement the following new measures, to be effective from 1 March 2013, to curb smoking in Singapore:

- New graphic health warnings and labels on tobacco products
- Removal of misleading descriptors on cigarette packs such as "light", "mild" and "low-tar"
- New tar and nicotine limits
- Requirement to sell cigarillos in packs of at least 20 sticks

We attended the first WHO International Tobacco Regulators (ITR) Conference – hosted by the US Food and Drug Administration in November 2011 – where we shared our experiences in regulating the advertising and promotion of tobacco-related products in Singapore's context. The second WHO ITR Conference was held in Singapore in March 2012 in conjunction with the World Conference on Tobacco or Health. During this meeting, we shared on the ongoing efforts to enhance tobacco control legislative measures in Singapore.

stronger through partnerships

The signing of agreements enables us to consolidate already firm friendships and facilitate frequent and prompt information exchanges. We are privileged to be part of platforms that have not only opened up exciting areas for cooperation in regulatory science and systems, but also deepened our good relations with many key partners.

In 2011, we conducted a number of bilateral meetings with our partners on a regular basis for continual engagement and to explore possible collaboration. Key highlights from the outcomes of the bilateral meetings included training attachments for our officers with selected Memorandum of Understanding (MOU) countries, confidence building exercises in the area of generic drug evaluation to prepare for worksharing initiatives and increased sharing and exchange of information relating to GMP and pharmacovigilance.

A New Chapter

We signed an MOU with INTERPOL in June 2011 to strengthen the training in the investigation and testing of counterfeit medical products for law enforcement. This training agreement is unique because it is the first of its kind between INTERPOL and a national health agency. Through this MOU, both HSA and INTERPOL will work closely to build up greater anti-counterfeit awareness, knowledge, capabilities and skill sets for the Asia Pacific region.

Closer Ties with our Neighbours

In 28 March 2012, HSA became the first national drug regulatory agency with which Malaysia's Ministy of Health has signed an MOU with. This collaborative arrangement seeks to strengthen, promote and develop pharmaceutical regulatory affairs cooperation in areas that include regulatory science, enforcement activities, post-market surveillance and product investigations, Good Manufacturing Practice and Good Clinical Practice for Clinical Trials.

A Collaborative Consortium

Progress was made in work-sharing efforts with our Consortium partners – Health Canada, Australia's Therapeutic Goods Administration, and Swissmedic. Collaborative activities undertaken by the consortium aim to lead to greater regulatory convergence of requirements and approaches, which should eventually result in more efficient use of resources and improved application approval times. We also took over the chairmanship of the International Pharmacovigilance Worksharing Group (IPWG), a collaboration initiated among the Consortium partners.

Developments in NEWDIGS

During the year, we worked with MIT's Center for Biomedical Innovation in its NEW Drug Development ParadiGmS (NEWDIGS) Programme. This initiative provides a platform for industry, government, non-government organisations and academia to seek and develop a more flexible and adaptive regulatory and development framework for the approval of novel drugs, including those to address major unmet medical needs or rare diseases in Asia (e.g. diabetes and cancers atypical in the West).

global gatherings

We hosted and participated in a wide range of workshops, meetings and conferences throughout the year, which provided opportunities for open sharing and staying up to date regarding each other's concerns and challenges. These gatherings allowed us to work together closely and become even more responsive and ready to effectively promote public health and safety, both regionally and globally.

18th ACCSQ (ASEAN Consultative Committee on Standards & Quality) Pharmaceutical Products Working Group (PPWG) Meeting

On 7 to 10 June 2011, we hosted the meeting for the Group, which is responsible for harmonising the technical registration requirements for pharmaceuticals in ASEAN. At the session, it was also agreed that HSA will chair the Joint Sectoral Committee overseeing the implementation of the ASEAN Sectoral MRA on GMP Inspection.

Riding the New Wave of the Medical Device Industry Seminar

Organised by HSA from 28 to 29 June 2011, this event was an opportunity for local and international industry leaders to share their insights on the global medical device market and emerging technologies.

4th PIC/S Expert Circle Meeting on Active Pharmaceutical Ingredients

Together with the Australian Therapeutic Goods Administration, we co-hosted this event in Singapore from 12 to 14 October 2011. HSA was also invited to be a member of the Steering Committee for the Expert Circle on Active Pharmaceutical Ingredients during the session.

INTERPOL Operation Storm Workshop

Held from 14 to 15 November 2011, this initiative was jointly organised by HSA, INTERPOL and the World Health Organization's Regional Office for the Western Pacific. Representatives from 11 countries took part in the workshop to explore opportunities for cooperation and training in combating pharmaceutical crime.

Human Genome Meeting 2012: Genomics and Regulatory Affairs Working Summit

Held in Sydney, Australia, and targeting industry and academia, this event articulated a regulatory perspective for using pharmacogenomic knowledge optimally to protect public health. Working with the Human Genome Organization (HUGO), we took a leadership role in translating pharmacogenetic advances into improving public health by organising the Pharmacogenetics in Regulatory Affairs workshop at the event.

1st International Workshop on Cell and Tissue Therapy: Converging Sciences & Regulations

Hosted by HSA from 22 to 24 March 2012, the workshop focused on current trends and challenges, for both translational science and regulation, in the diverse areas of cell and tissue therapies. It brought together clinicians, manufacturers and regulators to help build better connections between these communities.

HSA's 10th Anniversary Roundtable Event: "The Future of Global Health Regulations – A US FDA Perspective"

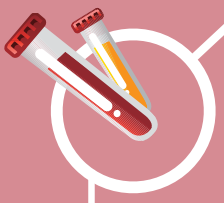
This event held on 31 October 2011 was organised under the HSA Academy. Its key speaker was Dr Murray Lumpkin, Commissioner's Senior Advisor and Representative for Global Issues at the US FDA. Senior people from industry and academia were invited for the roundtable discussions. Dr Lumpkin's insightful observations on the need for more regulatory collaboration with industry and academia to encourage the development of regulatory science, as well as more proactive public engagement and education to manage risks and address concerns, resonated amongst participants.

Annual Basic Training in Health Products Regulation

This was organised in September 2011 and was attended by 16 officers from four overseas regulatory agencies. The key objective of the programme was to provide a platform for our overseas regulatory counterparts to gain more in-depth knowledge of Singapore's health products regulatory approaches and systems. The participants provided positive feedback on the 5-day programme, which covered the entire spectrum of pre-market and post-market regulatory activities carried out by HSA to ensure that health products – in particular medicinal products and medical devices – available in the Singapore market meet appropriate standards of safety, efficacy and quality.

Apart from the above initiatives, our officers play active roles in many other WHO-related scientific committees and networks, as well as regional associations and bodies.

strategy and service



Blood Services Group
BSG

The Blood Services Group is the national blood service of Singapore and is committed to ensuring the sustainability and safety of the nation's blood supply. We play an integral part in Singapore's healthcare system by providing blood and blood components of the highest possible standards of safety and quality to all hospitals. This is achieved through the application of stringent safety protocols aligned with international best practices.

As the reference centre for immunohaematology, tissue typing and transfusion medicine in Singapore, we provide laboratory and consultative services to local and regional healthcare institutions. With the expanding boundaries of knowledge in the field of transfusion medicine, we have also embarked on building our expertise in the exciting arena of cell therapy.

Working closely with our clinical colleagues, we strive to transform the promise of science and medicine into treatment options that have the power to save lives. Close partnerships with local and international organisations also allow us to further develop our knowledge base and capabilities so that we remain at the forefront of our field and deliver the best possible services to our stakeholders.

generous giving by donors

Our strategic partnership with the Singapore Red Cross (SRC), now into its eleventh year, has seen significant success in encouraging more to become blood donors. In 2011, we received the overwhelming support of 67,310 blood donors, who made 104,895 whole blood and 10,299 apheresis donations.

Saluting Life Savers

Together with the SRC, we celebrated World Blood Donor Day at the Singapore Science Centre on 11 June 2011. More than 1,600 individuals and groups who made significant contributions to the National Blood Programme were honoured at this event. It was heartening to know this represented an 11% increase in the number of awardees from the year before. Guest of Honour Mr Gan Kim Yong, Minister for Health, also launched the global theme for the event, "More blood. More life.", which reinforced the urgent need for individuals to donate blood regularly.

Enhancing Donors' Experiences

During the year, we undertook several projects and developed new avenues for engaging donors to improve their experience with us. These included:

- Introducing a self-service kiosk for the Donor Health Assessment Questionnaire. This eases congestion at the registration counter and enables staff to provide a better service experience for donors.
- Implementing a new queue management system that lets donors know the estimated total processing time and donation status upon collecting their queue ticket. The system also allows our staff to issue, prioritise and route the queue number to different processing locations within the bloodbank to optimise workflow.

Bringing Bloodbanks Closer to Donors

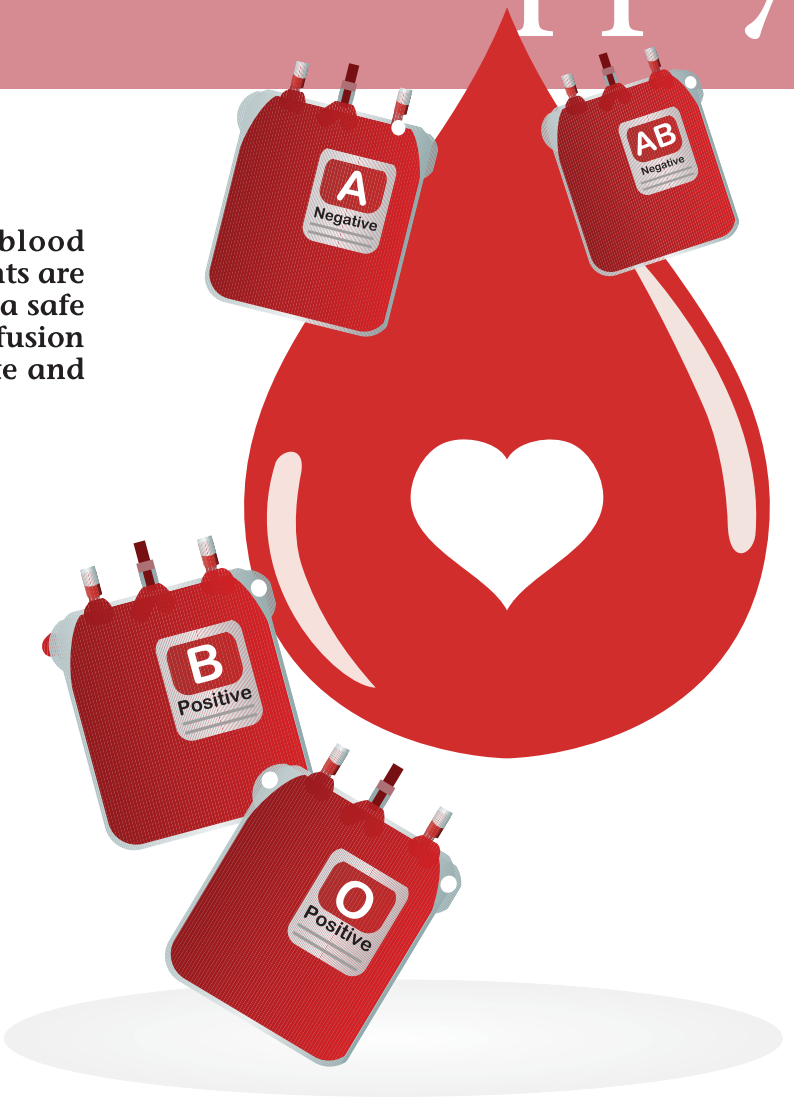
The launch of our second satellite site, Bloodbank@DhobyGhaut, is slated for September 2012. It is part of our strategy to bring our bloodbanks closer to our donors and encourage blood donation as part of an active lifestyle. It will allow us to more closely engage with the many employees and students who work and study around that area.

Better Service Ahead

On our radar for the coming year is an improvement to our apheresis documentation and record keeping by introducing an electronic system to replace current manual procedures. In addition, a self-service kiosk will be set up at Bloodbank@HSA to allow donors to access their donation history electronically. We have implemented in phases the replacement of paper-based donation record cards with electronic cards. The new cards can be used to book an appointment and locate the nearest bloodbank by scanning the card's QR code. Donors can also use the cards in place of their identify cards when they register to give blood.

keeping Vigilance on our blood supply

The quality and safety of the blood products we provide to our patients are of utmost importance. To ensure a safe blood supply and minimise transfusion risks to patients, we continuously evaluate and harness new technologies and processes.



Sharper Screening

We commenced automated atypical red cell antibody screening for blood donations using the indirect antiglobulin test in December 2011. This method improves the sensitivity and specificity of detecting clinically significant antibodies. At the same time, we changed the testing method for syphilis to an automated Treponema Pallidum Particle Agglutination (TPPA) testing, which is performed concurrently with the ABO and Rhesus blood grouping for a more efficient workflow. As a precautionary measure, malaria antibody testing is also carried out on the donated blood of donors who have travelled to malaria endemic areas. In addition, we are conducting a feasibility study on the use of the pathogen-reduction technology on our platelets and plasma products to further reduce the risks of transfusion-transmitted infections.

driving performance

To ensure the highest quality standards and timely availability of our blood supply, we regularly review and enhance our blood management and processing capabilities. This includes adopting new technologies and looking for ways to raise efficiency.

Workplace Improvements

2011 saw major renovations take place at our blood processing laboratories. By creating a more organised work environment, we were able to improve our workflows and productivity to handle the growing number of blood units.

Novel Methods in Place

We introduced new component preparation methods that enable us to provide patients with better products such leuco-reduced pooled platelets and pre-pooled cryoprecipitate.

Innovation in Inventory Management

In April 2012, we started using the new Frozen Blood Inventory Management System (FRIES) to enhance our frozen blood storage management. FRIES provides real-time information on frozen blood units, allowing us to track storage locations, improve storage space planning and raise the overall efficiency of our processes.

Future Plans

New technologies will also be introduced to further streamline our processes and improve product quality. Projects in the pipeline include:

Use of Apheresis Plasma for Cryoprecipitate

To be produced in smaller units, this product will supplement the pre-pooled cryoprecipitate used in adults to cater to paediatric use. The use of such apheresis products not only enhances patient safety because donor exposure is minimised, but also increases productivity of an apheresis plasma donation from one to two usable components.

Implementation of ISBT 128 Labelling for Parabombay and Bombay Blood Group

Streamlining the labelling process of these rare blood types using the ISBT 128 standard will allow more timely and efficient identification of rare blood to support patients' need for such blood.

New Packing Material for Transportation of Platelets and Frozen Plasma

Inflatable insulating airliners and phase change material packs will soon replace rigid foam packaging boxes and conventional ice packs to improve the cold chain management of transporting platelets and frozen products.

putting first patients

Patient safety is always top of mind in everything we do, from record-handling to meeting the needs of patients with rare blood types. This year was no exception, as we undertook a number of projects aimed at improving our service delivery to patients.

Tracking Donors with Rare Blood Types

In 2011, we started a database to track donors with rare blood types, including rhesus negative blood and special red cell antigen phenotypes. We are now able to reach out directly to these individuals to donate when the need for their blood arises. This initiative is a positive step forward in tackling the challenge faced by many blood services in supporting patients with rare blood types.

Going Digital

We completed a project to digitise all our patient records. Existing physical copies have now been converted electronically and stored in our computer system. Information pertaining to a patient's history – such as blood type, antibody screen and identification results – can now be easily retrieved from the system.

Platelet Matchmaker

To better support patients with platelet refractoriness, the Tissue Typing Laboratory embarked on a project to classify all apheresis platelet donors for Human Leucocyte Class I Antigens (HLA). This allows for better matching and improves the effectiveness of platelet transfusions. To further enhance our matching capabilities, we developed and implemented an algorithm for evaluating and selecting HLA-matched units in patients who are platelet refractory. We are also exploring increasing the pool of HLA-typed donors to boost the chances of finding fully compatible units for patients.

delivering treatments together

We work very closely with our hospitals to ensure safety and quality blood supply for our patients.

Ready for Emergencies

A massive transfusion protocol (MTP) was formulated in collaboration with emergency medical and trauma specialists in our public hospitals. Developed by surgeons, anaesthetists, haematologists and BSG doctors, the MTP improves the speed and effectiveness of blood transfusion support during severe trauma and obstetric emergencies. It was implemented in the first quarter of 2012 and will be reviewed and refined regularly to ensure optimal treatment for patients.

RFID Tracking Takes Off

We conducted a pilot project with Tan Tock Seng Hospital to test RFID (radio frequency identification) technology for the tracking of blood units from collection to transfusion. The system was found to enhance process efficiency. With the success of this pilot, there are plans to roll out this initiative with other hospitals.

benchmarked against the best

With our firm focus on scientific excellence, it was gratifying to see our capabilities and processes receiving endorsements from leading accreditation bodies during the year.

We retained our AABB accreditation for two more years following a successful re-assessment in March 2012. As the first bloodbank in our region to be accredited by the AABB in 2006, this is testament of our strong commitment to quality and safety in the field of transfusion medicine.

Our Tissue Typing Laboratory, which offers critical support to hospitals in providing transplant patients with new life-saving treatments, completed and passed the American Society for Histocompatibility (ASHI) 2011 Self-Inspection. It has received re-accreditation valid till August 2012.

We also underwent regular quality inspections and risk assessment audits by local and overseas authorities to ensure that our blood products comply with Good Manufacturing Practices (GMP) standards.

always exCELLing

With our well established clinical connections, HSA's Cell Therapy Facility has been expanding its scientific capacity in this field that is increasingly recognised as one of the most exciting new modalities in the treatment of cancers and immunity disorders.

Teaming Up for Research

Working closely with several partners, we are engaged in a number of cell therapy research initiatives, including:

- Culturing cytokine-induced killer (CIK) cells for patients with haematological malignancies, in collaboration with the Haematology Department at Singapore General Hospital
- A cord blood expansion project with Duke-NUS Graduate Medical School
- A cardiomycyte expansion project with the Singapore National Heart Centre
- A T-regulatory cell isolation project with the Singapore Immunology Network

These new capacities and capabilities will continue to strengthen HSA's valued partnerships with hospitals and biomedical research institutions in clinical translational trials. This work will also promote the facility as a regional reference centre for new advances in cellular therapy.

The Next Steps Forward

To develop our cell processing and therapy programme further, we are benchmarking our research processes against international standards. The implementation of a quality management system will be a key component of this effort, allowing us to improve our laboratory performance and the level of patient care provided. In addition to expanding our collaboration with national and international hospitals and research institutes on translational clinical projects, we are targeting to obtain international accreditation in the near future.

fostering stronger ties

During the year, we continued to strengthen our global and regional strategic alliances, as well as our networking and cooperation efforts. By participating in and conducting workshops, meetings and exchange attachments, we have been able to learn from other agencies around the world and also share our knowledge and experience. These opportunities have enabled us to deepen our collective understanding of the most pressing issues impacting blood and transfusion safety, and provided insights to transform the way we manage them.

Our Regional and Global Contributions

We are honoured to be re-designated as a WHO Collaborating Centre for Transfusion Medicine for another four years from April 2012. In this capacity, we will continue to assist in the development of sustainable blood programmes, conduct research in blood supply safety, and assist WHO member states in implementing systems for safe clinical transfusion and rational use of blood.

As a founding member of the Asia Pacific Blood Network (APBN), we sought to strengthen our cooperation efforts through various collaborative activities in the past year. We signed Memoranda of Understanding (MOU) with the European Blood Alliance and America's Blood Centers to form a wider alliance that covers Europe and the Americas. Through this alliance, we are able to share experience and knowledge with key blood services to ensure patient safety, as well as to undertake joint collaborative projects to improve operational effectiveness and efficiency.

Expanding our Network

We signed an MOU with the Beijing Red Cross Blood Centre in June 2011, providing a framework for staff from both agencies to undergo training exchange attachments. The interactions between our agencies will lead to a strengthening of capabilities and provide opportunities to network and share best practices in blood banking.

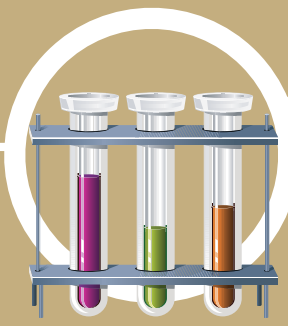
Fruitful Meetings

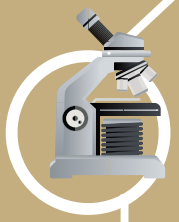
We hosted a symposium titled 'Scientific Advances and Regulation in Blood and Cellular Therapy' on 14 July 2011. The event, which was part of a series of activities planned in conjunction with HSA's 10th anniversary, saw four leading experts in the areas of blood services and health products regulation sharing their insights and perspectives. The topics covered included new developments in blood and cellular therapies, as well as the impact and challenges that these development pose for regulators.

In partnership with the International Alliance for Biological Standardization (IABS), the APBN and Singapore's Agency for Science, Technology and Research (A*STAR), we also hosted the 7th IABS Symposium on Advances in Transfusion Safety from 15 to 17 July 2011. More than 300 participants from 34 countries participated in the event, which focused on current issues in blood supply and transfusion safety, as well as regulation and cell therapy.

Going forward, we will continue to value every opportunity that allows us to collaborate with and learn from our partners, as we recognise that the challenges we face today are best addressed through joint efforts. Through these partnerships, we hope to make meaningful contributions and translate more ideas that will help shape and spearhead global developments in blood banking and transfusion medicine.

rigour and reliability





Applied Sciences Group

ASG

Our Applied Sciences Group is the national authority in forensic medicine and science, analytical testing, and chemical metrology. We aim to provide the highest quality forensic response and scientific analysis to support the administration of justice and the safeguarding of public health in Singapore.

We serve a broad stakeholder base – from regulatory and law enforcement agencies to the judiciary. Our approach is always guided by the need to promptly meet the unique and critical needs of our clients by adhering to international standards and through continuous innovation.

We also actively seek to be a thought leader in our scientific arenas. We are privileged to be an active facilitator and contributor on many established platforms and forums – both at home and on the global stage – that enable us to push new frontiers in forensics and analytical sciences.

making the mark

Our commitment to scientific excellence is demonstrated by our achieving and maintaining international accreditation standards and following international best practices.

A NAME for Ourselves

Our Forensic Medicine Division was re-accredited by the US-based National Association of Medical Examiners (NAME) for the period of March 2011 to March 2016. We are the only NAME-accredited forensic pathology entity in Asia, a testament to our dedication to the highest international standards of mortuary operations.

Another Accomplishment

All our forensic laboratories – the DNA Profiling, DNA Database, Forensic Chemistry & Physics, Illicit Drugs and Analytical Toxicology laboratories – completed the assessment for accreditation under the American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB) International Programme in February 2012. This is our first accreditation under the International Programme since coming under the ASCLD/LAB Legacy Programme in 1996.

Sustained Success

Our Pharmaceutical, Cosmetic and Cigarette Testing Laboratories successfully underwent renewal assessments for the ISO 17025 accreditation, under the Singapore Accreditation Council – Singapore Laboratory Accreditation Scheme (SAC-SINGLAS).

During the year, all our laboratories also embarked on the Lean Six Sigma process improvement initiative, with the objective of making work processes more efficient.

food safety *first*

Our Food Safety Laboratory plays a key role in promoting food safety in Singapore by supporting emergency, surveillance and enforcement activities.

With 12 new tests accredited by SAC-SINGLAS in 2011, we are now able to offer our clients a wider range of reliable services regarding the safety of food products.

During the Fukushima nuclear incident in Japan, we expanded our radioactivity testing regime from Cesium 134 and 137 to include Iodine 131 to assist the Agri-Food & Veterinary Authority in its testing of food imports from Japan.

We also stepped up our activities in June 2011 when a wide variety of food products from Taiwan were reported to be contaminated with plasticisers. Using advanced High Performance Liquid Chromatograph Tandem Mass Spectrometry (HPLC-MS-MS) and Gas Chromatograph Mass Spectrometry (GC-MS), we were able to quickly and efficiently set up a robust testing service for potentially contaminated imports.

no place for phony pharmaceuticals...

Our Pharmaceutical Laboratory gained accreditation for two new tests: the analysis of mercury and lovastatin in herbal medicines by Inductively Coupled Plasma Mass Spectrometry, and High Performance Liquid Chromatography Diode Array Detection (LC-DAD).

We worked with colleagues from the Health Products Regulation Group (HPRG) to safeguard public health through the swift detection of adulterants in health products sent to our laboratories for testing. Our confirmatory testing and efficient internal processes enabled HSA to promptly alert the public not to consume these products, thus preventing them from causing further harm.

In June 2011, we acted quickly to analyse a total of 170 cases of medicinal and health products when concerns arose about health products from Taiwan contaminated with plasticisers. We also jointly initiated a project with the HPRG to develop testing methodologies for a priority list of natural toxic alkaloids, which will enhance HSA's ability to assess the safety of herbal health products.

... or harmful cosmetics

Two new tests developed by our Cosmetics Laboratory were accredited during the year: the assays of p-phenylenediamine in hair care products and of formaldehyde in cosmetic products by the LC-DAD technique.

In the past year, we conducted heavy metals analysis on various brands of talcum powder in response to an alert from a hospital. To enhance our support to our regulatory colleagues and other agencies, we developed new testing capabilities in the determination of azelaic acid and tetrahydrocannabinols in cosmetic products and m-aminophenol in hair care products.

Our Chemical Metrology Laboratory completed three regional and international comparisons in the past year, involving the determination of creatinine in human serum, trace and essential elements in herb, and toxic elements in cosmetic creams.

advances in chemical metrology

We organised an External Quality Assessment Programme in Clinical Chemistry for local clinical laboratories and two proficiency testing schemes for local testing laboratories.

We also started the production of certified reference materials (CRM), the first of which was on benzoic acid in orange juice. A CRM on trace elements in water is nearing completion.

As part of a Memorandum of Understanding signed in 2010, we concluded a project with the National Institute of Metrology, Standardization and Industrial Quality (INMETRO), Brazil, on the determination of benzoic acid in orange juice. We also worked with the National Institute of Metrology, China, on the determination of ethanol in bioethanol fuel using gas chromatography-isotope dilution mass spectrometry.

doing more with DNA

Our DNA Profiling and DNA Database Laboratories continue to provide critical expertise in support of investigations by law enforcement agencies in Singapore. We provided critical breakthrough leads over the past year in the identification of perpetrators, and victims, in several prominent cases. To cater to our growing workload, our DNA Profiling Laboratory (DNAPL) has established a second laboratory at Biopolis to complement the first one. The facility is specially designed to handle low-level DNA samples.

Enhanced Extraction

In 2011, we enhanced our capabilities through the implementation of a semi-automated paramagnetic silica bead solid phase DNA extraction methodology for enhanced DNA extraction from crime samples. The new method allows for faster processing of DNA samples to help solve cases quickly and efficiently.

Uncovering Ties that Bind

We also established the allelic frequencies of the Singapore Chinese, Malay and Indian populations for six additional DNA markers. These highly polymorphic and robust markers greatly improve our ability to resolve complex kinship analysis cases.

Our Uncompromising Commitment

In August 2011, HSA discovered that a reagent of higher than usual concentration had been prepared and used as part of the DNA testing process in our DNAPL from October 2010 to August 2011.

Although the scientific impact was assessed by external international experts to be minimal because there is no possibility of false positives, we initiated the re-test of the DNA samples from 87 criminal cases in January 2012 as a precautionary measure in consultation with the Singapore Police Force (SPF), the Central Narcotics Bureau (CNB) and the Attorney-General's Chambers (AGC). A HSA Board Review Committee was also set up to review the incident.

As a scientific authority, we recognise that ensuring public trust in our test results and decisions is paramount. This is why following the discovery of the incident, we investigated the issue thoroughly, proactively shared the information with our partner agencies, and communicated with the media and public in a transparent manner.

We have also taken actions to strengthen the processes in the DNAPL by introducing tighter procedural checks on the reagent preparation process. In implementing the recommendations of the Review Committee, we are enhancing our quality improvement and risk management framework to build in even more robust systems and processes in the DNAPL and other laboratories.

Our Forensic Chemistry and Physics Laboratory continued to see increasing demand for its expertise, which came to the fore in a number of high profile cases in Singapore throughout the year. Our expertise in trace evidence, damage analysis, toolmarks and reconstruction were urgently required to assist law enforcement agencies in the analysis and identification of critical evidence used to solve these cases.

a sharp eye

In-house Synergies

We worked closely with our regulatory group colleagues, providing research and analysis support for their regulatory activities for counterfeit medical devices and drugs. This included the analysis of coloured contact lenses in the first case of counterfeit medical devices sold by legitimate suppliers in Singapore. Tests by our laboratories confirmed these products to be counterfeit. We also collaborated on a study on the availability of erectile dysfunction and anti-obesity drugs available to Singaporean consumers on the Internet.

A 4-year counterfeit drugs analysis project was successfully completed during the year. The project aimed to establish HSA as a reputable reference centre for counterfeit drug investigation, render scientific support to our regulators for investigation and prosecution of offenders and provide consultancy to overseas laboratories. A database comprising more than 600 samples has been developed and a framework for authentication of suspected counterfeit drug samples was established.

Labels with a Difference

We are keen to collaborate with tertiary students on projects that enable them to apply their knowledge and creativity to complement the work that we do. Working with Nanyang Polytechnic, we revamped the packaging labels for our evidence collection kits during the year. The labels were re-designed in light of feedback from the SPF, to which we supply the kits to. Developed and produced in-house for four years now, these kits come in 10 different types and are customised to clients' needs. They are quality assured and self-contained with the necessary tools to preserve evidence collected at crime scenes.

The Road Ahead

We will continue to grow our basket of services in the year ahead. Efforts are ongoing to extend the ways in which we use physical evidence and our databases of vehicle paints, glass and packaging materials in the investigation and prosecution of criminal cases. To complement the work of our enforcement colleagues in combating counterfeit drugs, we will also explore the use of advanced instrumentation and technologies in the detection, fingerprinting and authentication of active pharmaceutical ingredients.

dealing with drug cases

Our Illicit Drugs Laboratory completed a major renovation, allowing for greatly improved workflow and space optimisation to cater for an increased workload. Upgrades included a new dedicated counter for the submission and collection of drug exhibits, leading to better customer service.

During the year, the Analytical Toxicology Laboratory worked closely with our partners to move towards implementation of truncated timelines for drug consumption cases. In order to meet the requirements of a shorter turnaround time, the laboratory is reviewing the processes to streamline the analysis of controlled drugs in urine samples.

In order to meet the challenging demand of fast-emerging new synthetic drug analogues, our testing capabilities will also be enhanced to include the analysis of these new drugs.

The Analytical Toxicology Laboratory continues to work closely with our regulatory colleagues by highlighting cases of adverse reaction arising from consumption of illegal sex drugs or drugs from illicit or unknown sources.

sharing knowledge

We recognise the need to remain relevant and keep abreast of the latest happenings and upcoming developments in our field. Our staff participated in international conferences to learn about the global trends impacting our work, and also gave presentations at these events. We interacted closely with our community and enjoyed many invaluable sessions for the sharing of work experiences.

Informative Interactions

HSA hosted the International Laboratories Forum on Counterfeit Medicines in October 2011. The forum provides an opportunity for members to share scientific findings and testing methodologies for counterfeit drugs and illegal health products.

We were also invited to speak on the detection of counterfeit medicines at several high level meetings, including:

- APEC Life Sciences Innovation Forum Drugs Safety and Detection Workshop
- Institute of Medicine of the National Academies First Public Meeting
- Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) Expert Circle on Active Pharmaceutical Ingredients (API)
- Global Forum on Pharmaceutical Anti-counterfeiting

We partnered the national forensic DNA laboratories of Indonesia, Thailand, Philippines, Vietnam and Brunei to host a 1-week regional workshop entitled "New Frontiers in Forensic DNA" in October 2011. Attended by over 50 scientists from the region, the event provided a platform to share knowledge and skills, and to discuss the application of DNA profiling in crime cases in various jurisdictions. Internationally renowned forensic scientists and a technical specialist also conducted in-depth lectures on DNA mixture interpretation, population statistics, forensic ethics, and emerging technologies.

Learning Together

We were privileged to have had many opportunities to share our knowledge with Home Team officers on a broad range of topics – from the value of trace evidence, and exhibit handling to the collection of biological samples.

We also continued to offer scientific capabilities in the examination of cases submitted by the Royal Brunei Police Force, and conducted overseas training for its officers on the collection of biological samples.

During the year, we played host to many of our overseas counterparts. Through these technical exchanges, we have gained a deeper understanding of each other's work and strengthened ties for future collaborations.

Reaching Out

Together with the Singapore Accreditation Council, our officers conducted a training course on the measurement of uncertainty for civil engineering and mechanical testing laboratories. A workshop on the estimation of measurement uncertainty for medical testing was also held.

We also worked with a number of commercial organisations – for example, giving lectures to commercial banks on the forensic examination of handwriting and signatures.

Grooming the Next Generation

Our laboratories opened their doors to host local and overseas internship students. We also continued to give lectures to university students in their forensic modules and courses. As part of their career development programmes, some secondary school students were also offered a sneak peek at the work of our forensic scientists.

collaborative contributions

The past year saw several new partnerships forged as we continued to expand our collaborations and activities locally, regionally and globally.

Partnerships Forged and Renewed

HSA signed a service level agreement (SLA) with the Ministry of Home Affairs on 1 April 2011. This aims to strengthen our capability to enhance the scientific scope and timeliness of our forensic laboratories' services to support the operational requirements of the Home Team Departments. During the year, our forensic laboratories were expanded to add value to our services under the SLA.

A letter of collaboration was signed between the Republic of Korea's National Forensic Service and HSA in May 2011. This aims to promote closer ties between both agencies through information exchanges, study visits, joint seminars, research collaborations, and staff attachments and exchanges.

HSA's synergy in regulatory enforcement and laboratory testing of health products puts us in a good position to make significant contribution to anti-counterfeit efforts, both regionally and globally. Singapore was accepted as a member of the Forensic Expert Group led by INTERPOL and HSA was assigned as a designated testing laboratory for INTERPOL's Storm Network. In June 2011, our ties with INTERPOL were furthered strengthened through the signing of a cooperation agreement to provide training to law enforcement officers in the region on the testing of counterfeit drugs. The first training was conducted in November 2011 for the 12 Asian countries under INTERPOL's Storm Network.

HSA currently represents the Asian Forensic Sciences Network (AFSN) in the International Forensic Strategic Alliance (IFSA) meetings as the International Liaison Officer and assists to bringing forensic science laboratories in the region together in international cooperation and coordination.

More Milestones Reached

As WHO Collaborating Centre for Drug Quality Assurance, our Pharmaceutical Laboratory continued to support WHO in the draft monographs development for International Pharmacopeia on anti-infective and anti-retroviral medicines.

We were granted observer status to the European Pharmacopeia Commission in February 2012, enabling us to participate in the scientific work of the Commission and its expert meetings. In this capacity, we will also be involved in other activities of the European Directorate for the Quality of Medicines and Healthcare (EDQM). This will further enable HSA to stay informed of public health matters and also share expertise on issues pertinent to the pharmaceutical sector.

Regional Partnership Sees a First

We partnered the national laboratories of Thailand and Vietnam to collaborate with the United States Pharmacopeia (USP) in the establishment of an ASEAN CRM for diphenhydramine hydrochloride. This was the first ASEAN CRM developed under the ASEAN-USP collaboration.

We continued our active involvement in the ASEAN Reference Substance Project, which establishes secondary drug reference standards for use in member countries. Singapore has completed the inter-laboratory collaborative studies for diphenhydramine hydrochloride, atenolol and ceftazidime. The project is useful in providing economical ASEAN secondary drug reference standards to be used in drug analysis.

Taking the Lead

In our capacity as a WHO Collaborating Centre for Tobacco Testing and Research, our Cigarette Testing Laboratory actively supported WHO activities. This included method validation work, as well as chairing a series of technical meetings in September 2011 and March 2012. We were also appointed as the co-chair to the WHO Tobacco Laboratory Network in May 2011.

Working with our Neighbours

As a lead member of the ASEAN Cosmetics Committee since 2003, we were involved in several ASEAN Cosmetic Directive scientific meetings, including the 16th ASEAN Cosmetic Committee Meeting and 16th ASEAN Cosmetic Scientific Body in Brunei in May 2011. Singapore was also the Chair of the 2nd Special Experts' Meeting of the ASEAN Cosmetic Testing Laboratories Network, held in Brunei in June 2011.

Forensic Forums

During the year, a senior forensic scientist was invited to be a member of the International Association of Bloodstain Pattern Analysts' Scientific Working Group on Bloodstain Pattern Analysis (SWGSTAIN) Document Review Committee. One of our senior scientists was also voted in as a corresponding member of the American Society of Questioned Document Examiners in August 2011. Being the Chair of the AFSN's Trace Evidence Workgroup, we were invited to participate in the Scientific Working Group for Materials (SWGMAT) meeting and the European Textile and Hair Expert Working Group (ETHG) meeting.

We worked very closely with the United Nations Office on Drugs and Crime (UNODC), having a senior HSA staff serving as one of their appointed International Forensic Experts. Being the Chair of the AFSN's Illicit Drugs Workgroup, we participated twice at the Scientific Working Group for the Analysis of Seized Drugs (SWGDRUG) meetings. One of our toxicologists also served as the regional representative in The International Association of Forensic Toxicologists (TIAFT).

Our participation in these platforms signifies the maturity of our organisation and our growing impact on health and safety issues around the world and at home. Cultivating these partnerships will remain an indispensable part of our strategy.

As our new decade beckons, we remain committed to building on our legacy of scientific and professional excellence. We can and must continue to transform ourselves, and strive to deliver smarter, value-generating solutions as we chart new courses in our fields of expertise.

Insight and foresight

Corporate HQ

HSA's Corporate Headquarters provides strategic leadership for the organisation, ensuring the highest quality support and effective engagement with internal and external stakeholders.

Working closely with the three Professional Groups, we are committed to bringing our Core Values to life through our people and practices. We do this by nurturing an innovative spirit and developing a workplace where ideas flourish, and by embracing partnerships that will enable us to effectively deliver our promise to all we serve.

By creating an organisation where excellence and integrity are celebrated, fostered, and proven, we seek to place HSA in a stronger position than ever to overcome challenges and seize opportunities for a brighter future ahead.

passion driven

In 2011, HSA continued to make good progress in fostering organisational excellence as a Singapore Quality Class, People Developer and Singapore Innovation Class certified agency. We seek to raise the bar for ourselves through continuous improvements in the quality of our professional standards and processes, and to always be a valued partner of choice to our stakeholders and the best workplace for our employees.

Significant Steps Forward

HSA made a notable and commendable improvement in the eighth annual survey on the pro-enterprise orientation of regulatory agencies commissioned by the Action Community for Entrepreneurship (ACE) in 2011. Our stakeholders have appreciated the concerted efforts of our staff to improve the ways we engage and communicate with them over the last few years. Connecting and engaging with our stakeholders will continue to be a top priority for us.

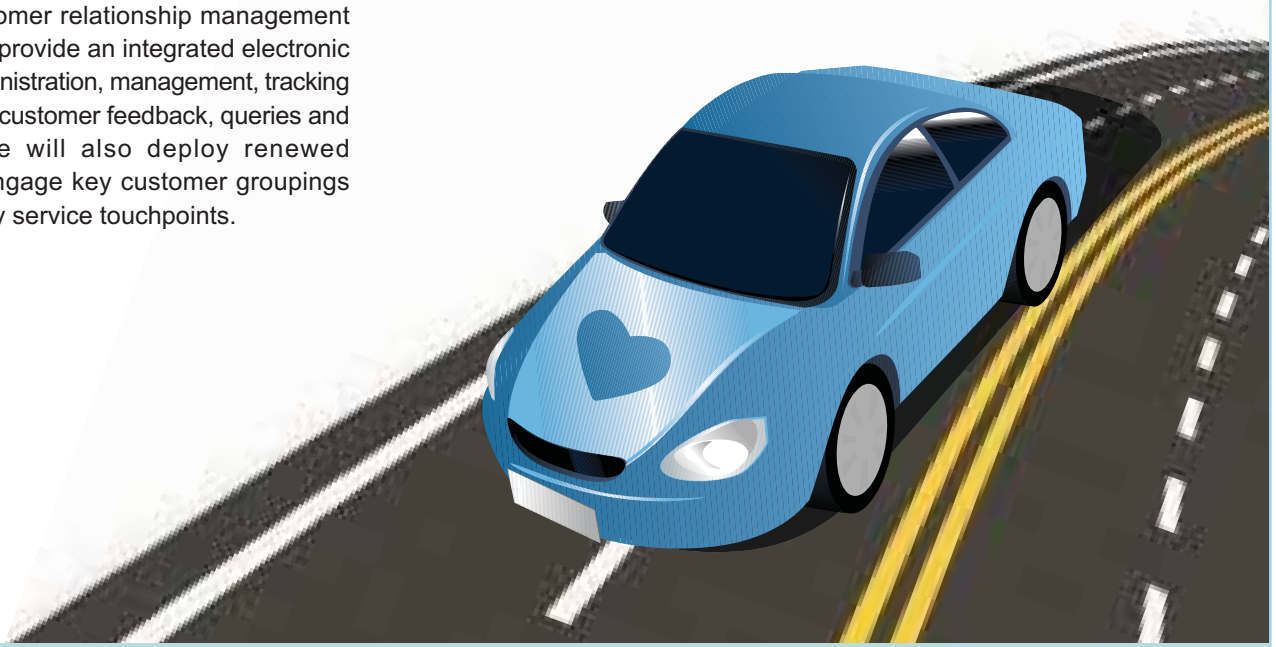
Service with a Sparkle

A customer satisfaction survey conducted in 2011 showed we fared well across HSA in delighting our customers with our service. Our customers gave us the thumbs up for anticipating market needs and keeping up to date with new technologies and solutions. They also responded positively to statements on our ability to safeguard public health, inspire trust and project professional integrity.

We saw a total of 44 HSAians clinching the national-level 2011 Excellent Service Award (EXSA). Apart from recognising individuals who have delivered outstanding service, this award also seeks to develop service role models and create service champions.

HSA held its 3rd HSA Customer Service Day with the theme 'Hear Me Out, Make My Day' on 21 February 2012. Mr Ron Kaufman, author and founder of *UP! Your Service*, was invited as our guest speaker. We also held our own Outstanding Service to Customers Awards (OSCA) ceremony during the event, honouring 36 officers and 4 teams with the Service Champion, Service Leader and Service Advocate Awards, as well as the OSCA Team Awards.

Service quality training continues to be a key emphasis to inspire and equip staff with the relevant skills required to manage our customer interfaces and deliver good customer service. The new year will see the rollout of a newly developed customer relationship management system that will provide an integrated electronic platform for administration, management, tracking and reporting of customer feedback, queries and responses. We will also deploy renewed processes to engage key customer groupings and improve key service touchpoints.



An Eye for Innovation

Our quest for excellence is reflected in our continuous search for new ways to discover, develop and deliver smarter solutions. We foster and harness innovation as we believe that some of the very best ideas will come from our diverse and talented employees.

Held annually since our inception, the HSA Innovation Day remains a key platform to promote a learning culture as we come together to share new knowledge and skills on innovation tools and practices. It is a day for HSAians to be inspired to think innovatively. Mr Fredrik Härén, the author of *The Developing World* and *The Idea Book* and a known expert in the field of creativity and idea generation, was invited to share with staff on the topic of business creativity.

Following the successful Phase 1 rollout of the electronic portal for staff to contribute ideas and suggestions, work is underway for a second phase to be launched. This new module will include workflows for work innovation project sharing, features to track idea implementation statuses, and options for statistical collation and report generation. New discussion platforms, including a project collaboration space, will be built in as part of the revamped HSA intranet platform.

people power

Our ability to develop, challenge, motivate and reward our workforce is the cornerstone for our sustained growth as a trusted authority.

Progressive Processes

We implemented a variety of programmes throughout the year to enhance technical, leadership and soft-skill competencies of our staff. These encompassed classroom sessions, on-the-job training, conferences and seminars, as well as international exposure opportunities to hold in-depth discussions on scientific and regulatory subjects.

We also made improvements to several key processes and workflows. These included:

- the introduction of e-Recruitment and an Employee Referral Scheme to facilitate the recruitment process;
- the enhancement of our online Performance Management System to make it more user-friendly; and
- the pilot launch of a career development module to align competencies to the performance management system and long-term development of staff. This has been rolled out initially to the corporate functions, and will subsequently be extended across HSA.

Going forward, we will continue to develop every HSAian, ensuring that they have the skills to carry on HSA's mission and values of scientific and professional excellence. Immediate challenges include recruitment of the right talent, as well as implementing innovative and active efforts to retain the best employees. We will also constantly review the leadership development framework to achieve a sustainable pipeline of future leaders.

A Stronger Sense of Purpose

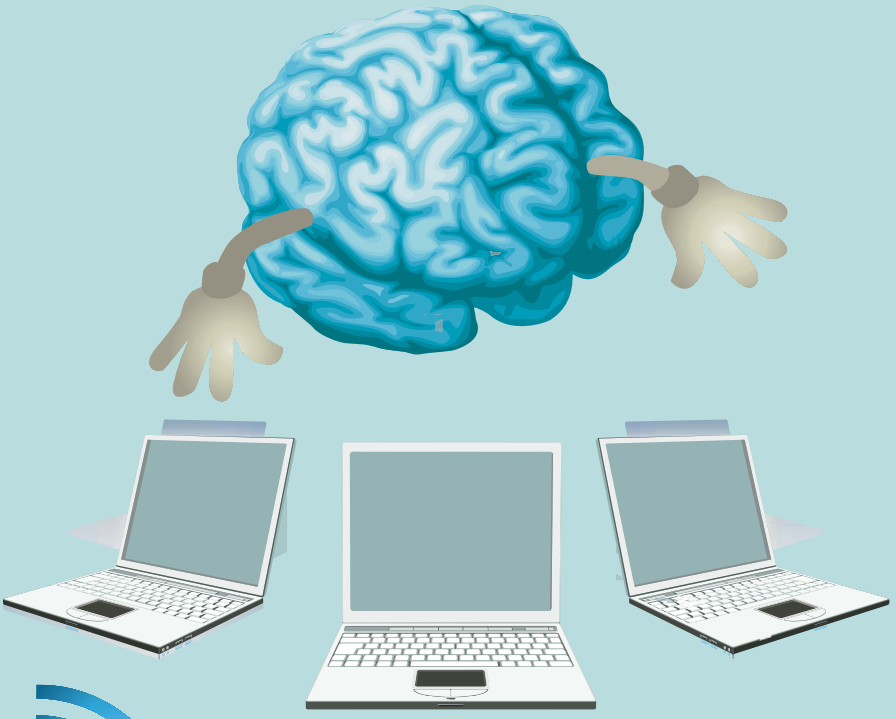
We conducted an Organisation Capability Survey as part of our ongoing staff engagement initiatives in 2011. The first-ever online survey saw an 83% response rate, with some 670 HSAians sharing their views and providing feedback for HSA's continued capability improvements. Over four out of five HSAians strongly believe in our goals and are proud to be a part of the organisation. Moving forward, we will be working on areas highlighted for improvements to build a more future-ready HSA that is better able to meet the expectations of both our external and internal customers.

To address the risks and challenges facing HSA in our ever-changing operating environment, efforts were made to increase organisation-wide awareness of the need for good corporate governance and internal controls at all times. We implemented the Ethos of Professional Conduct to set out ethical guidelines of professional conduct, and also updated our Whistle Blowing Policy to expand its scope, facilitate better reporting, and align it more closely with the Public Service Division guidelines. In addition, we started training programmes and initiatives to enhance operating processes, and we will continue to focus on this in the year ahead.

Happy HSAians

In spite of all our work deadlines and demands, there was no lack of programmes for us to relax, learn and celebrate together as HSAians. Events included parties to herald the New Year and our 10th Anniversary, as well as Learning Day held in conjunction with Public Service Week. We also gamely donned our sporting gear to pit our prowess against each other at a bowling competition, and enjoyed a lively Active Day programme at Fort Canning Park. A tea appreciation session, and workshops covering an exciting array of topics – from health management, and skincare to colour coordination and chocolate designing – were among the many other activities that HSAians signed up for to recharge and interact with each other.

To enhance synergies across the organisation and promote an even deeper appreciation of Core Values as a compass guiding our actions and decisions, we introduced the HSA-wide Core Values-based teambuilding programme.



think tech

At HSA, optimising and investing in our IT resources have empowered us to respond more nimbly to new business challenges. By developing new applications, aligning our systems and integrating new processes into our existing IT environment, we have been able to significantly raise staff effectiveness and improve our operating efficiencies.

Connections Completed

We fully migrated to the Standard ICT Operating Environment, also known as the SOE initiative, in 2011. This was accomplished after the IT systems of our Applied Sciences laboratories, mortuary and bloodbank were upgraded successfully to function in the new environment. HSA is a part of this government-wide initiative that empowers public officers to operate in a uniform and secure IT environment.

We also enhanced our Laboratory Integrated Scientific Administration System (LISA) to support a new business model arising from a service level agreement (SLA) that we signed with the Ministry of Home Affairs. This SLA aims to strengthen and expand our capacity for forensic science services to support the Home Team Departments' operational requirements.

Right on Track

The Frozen Blood Inventory System was successfully implemented at our Blood Services Group in March 2012, enhancing the efficiency of the blood dispatch process to hospitals.

With a similar aim to improve our workflows and boost patient safety is another ongoing pilot project with Tan Tock Seng Hospital. This initiative tracks blood bags supplied to the hospital through the use of RFID technology.

We are also developing a new system to manage the records of apheresis blood donors electronically. This will improve donor information management and retrieval processes.

With Stakeholders in Mind

Work is ongoing to commission a customer relationship management (CRM) System that will assist us in our service and feedback management functions. Continual enhancements to our Pharmaceutical Regulatory Information System (PRISM) are also being made in line with new legislative requirements that are being progressively implemented.

We are also one of the key agencies participating in the FRONTIER (Facilitating Reforms for Innovation and Enterprise) project. This is a whole-of-government initiative aimed at re-inventing the government's approach to business licensing.

A Smarter Workplace

With the completion of the Shared Portal for Information, Collaboration & Engagement (SPICE), HSAians can now enjoy greater accessibility and flexibility, as well as improved navigation and search capabilities through this new intranet portal. Enhancements to wireless access facilities also enable staff and visitors to access a wireless connection in meeting rooms within our premises.

In the pipeline is a business intelligence (BI) system to be piloted in our regulatory group. Through automation of management reporting and the generation of reports in the form of dashboards, the system allows management and staff to better monitor the business information collected for trend analysis and decision-making purposes.

In time to come, all HSAians will be able to conveniently file, search for and retrieve emails from a centralised electronic repository. An email management system (EMS) capturing a valuable pool of institutional knowledge retained in email exchanges will be rolled out in phases across the agency.

A key ongoing priority is to upgrade and update our IT infrastructure to comply with IPv6 requirements. We will also continue to put in place protective measures in line with global standards to mitigate against zero day vulnerabilities, emerging attack patterns and known threats.

working *well*

As a champion for public health and safety, HSA has formed close public and private partnerships to encourage best processes and practices at workplaces.

One of our key contributions in promoting Workplace Safety and Health (WSH) at the national level is our participation in the National Globally Harmonised System of Classification and Labelling of Chemicals (GHS) Taskforce. We provided inputs to develop guidelines for chemical manufacturers and suppliers on how they can be GHS compliant for the benefit of their staff and customers.

We also put in place measures targeting our employees' well-being and safety within our own organisation. With the new cycle of WSH Risk Assessment (RA) taking place in 2011, we reviewed and updated our RA forms for the whole of HSA, using the latest matrix recommended by the Ministry of Manpower. During the year, the WSH policies across the corporate and laboratory work environments within HSA were aligned to achieve better safety performance standards organisation-wide, and to improve our risk management capacities.

Regular safety audits were extended beyond higher-risk work areas to all facilities across HSA, including the offices of administrative staff and stores. This is to ensure that all workplaces and spaces within HSA meet the highest possible safety benchmarks.

Our in-house WSH Training Programme was modularised to meet the unique needs of the different laboratory environments at HSA, and all professional and technical staff have since been trained. This programme will soon be rolled out to the administrative staff working in the laboratories as well, to increase their awareness of safety issues.

helping *hands@HSA*

HSA's Corporate Social Responsibility (CSR) framework, called CARE (Community Action, Responsible for our Environment), encourages efforts and participation in three main areas: staff volunteerism, preservation of our environment and cultivating a community-caring culture.

Through a series of fund-raising projects during the year, we raised some $18,000 for our two beneficiaries – the APSN Katong School and Lions Befrienders Service Association (Singapore). The most notable event was a Charity Walk-A-Jog that was organised to commemorate Singapore's 46th National Day and our 10th Anniversary. HSAians gave generously towards this cause, raising $15,530 for needy senior citizens from Lions Befrienders. These funds brought us closer to the target of equipping 1,000 seniors' homes with motion-sensing devices that will enable them to live more confidently.

Through tranquil nature education tours of Sungei Buloh Wetland Reserve and Chek Jawa Wetlands, as well as a terrarium-making workshop, HSAians also had the opportunity to hone our knowledge and understanding of how we can monitor our environmental footprint.

educating, engaging and empowering consumers

The past year saw the launch of our first-ever large-scale integrated public education campaign with a firm message to consumers not to buy contact lenses, weight loss pills and erectile dysfunction drugs from unknown and dubious sources. The campaign featured attention-grabbing ads in newspapers, and on buses, bus shelters and SMRT trains. A micro-site (www.healthdangersonline.sg) providing more information, advice and safety tips was also developed. Both the website and mobile site received more than 130,000 visits as at end March 2012.

The positive response to the ads has helped us achieve two key objectives: firstly, the campaign encouraged the public to take positive steps towards protecting themselves and their loved ones from the possible risks associated with products from dubious sources; and secondly the initiative has equipped us with another communication channel to effectively reach out to consumers on key public health and safety issues.

We were also able to reach out to the public through the prominent media coverage garnered by various aspects of our work. Notable mentions in the key local dailies included those on our vigilance and enforcement efforts in halting the entry of potentially harmful heath products into the market, as well as consumer-oriented articles carrying useful safety advice. There were also news stories on our life-saving research initiatives in cell therapy, as well as features on the intriguing and challenging work of our forensic professionals. Collectively, these profile pieces presented a positive and compelling impression of how HSA makes tangible contributions to protecting and safeguarding public health and safety.

our impact and influence

Established in 2010, the HSA Academy aims to be the enabler for our professional groups to achieve thought leadership as we continue to pursue scientific and professional excellence. This is part of a wider strategy to enable HSA – and Singapore – to play a more compelling role in shaping progressive approaches in health products regulation, transfusion medicine, forensics and the analytical sciences in the global arena.

Convening for a Cause

One of the key activities of the HSA Academy is to create avenues for experts to come together to prioritise and be prepared for our most pressing challenges.

To this end, the HSA Academy facilitated and supported our professional groups in hosting many international and national events and engagements during the year, actively drawing together stakeholders and counterparts from the region and around the world. It is our hope that the insights and understanding from these discussions and debates will influence and inspire new creative thought.

June 2011

10th Anniversary Symposium "Science Saves Lives"

The key highlight of the year was a symposium organised to celebrate a decade of HSA's contributions as a champion of public health and safety, as well as to showcase our agency's unique blend of diverse scientific expertise. Mr Teo Chee Hean, Deputy Prime Minister, Coordinating Minister for National Security and Minister for Home Affairs, graced the event attended by more than 200 participants. Four international experts shared their perspectives and experiences in the challenging fields of transfusion medicine, forensic science, and health product regulation. Dr Tachi Yamada, former President of the Global Health Program at the Bill and Melinda Gates Foundation, delivered the keynote lecture at the event.

We also created other platforms that brought together regulators, industry players, professionals and experts from both the scientific community and academia, including the following:

July 2011

Scientific Advances and Regulation in Blood and Cellular Therapy

7th IABS Symposium on Advances in Transfusion Safety

October 2011

HSA 10th Anniversary Roundtable: The Future of Global Health Regulations – A U.S. FDA Perspective

"New Frontiers in Forensic DNA" Training Symposium

March 2012

International Workshop on Cell and Tissue Therapy: Converging Science and Regulations

Human Genome Meeting 2012: Genomics and Regulatory Affairs Working Summit

A Wellspring of New Possibilities

The innovative spirit that energises HSA today stems from our goal to transform the promise of science into systems, solutions and therapies with the power to protect and save lives. One key objective of the HSA Academy is to consolidate, support and develop our research capabilities, so that we can retain the agility and decisiveness to continually push the frontiers of scientific inquiry in our diversified specialty areas.

Investing in research and harnessing the new expertise has put us in a stronger position to move forward more confidently as a trusted authority. During the past year, we were privileged to have had the opportunity to share, both at home abroad, new knowledge gleaned from research across our various fields of expertise.

For a full listing of the research initiatives that we embarked on in FY11/12, please visit: www.hsa.gov.sg/publications.

globally networked

HSA places a very high value on cultivating meaningful partnerships with local and global counterparts whose strengths complement and augment our own. By teaming up with others, we have created immense opportunities to optimise resources and leverage each other's expertise while pursuing a shared mission.

Our MOU partners include:

- Health Canada, Canada
- United States Food and Drug Administration, United States
- United States Pharmacopeia, United States
- Irish Medicines Board, Ireland
- Medicines and Healthcare Products Regulatory Agency, United Kingdom
- Paul-Ehrlich-Institut, Germany
- Swissmedic, Switzerland
- The National Institute of Metrology, Standardization and Industrial Quality, Brazil

We recently saw further expansion of our growing international network through the signing of Memoranda of Understanding (MOU) with three agencies:

01. Ministry of Health, Malaysia
02. Beijing Red Cross Blood Centre, China
03. International Criminal Police Organization - INTERPOL

We also conducted many fruitful work-sharing arrangements and collaborative initiatives with other regulatory counterparts, with whom we have also established strong and strategic alliances through earlier MOUs.

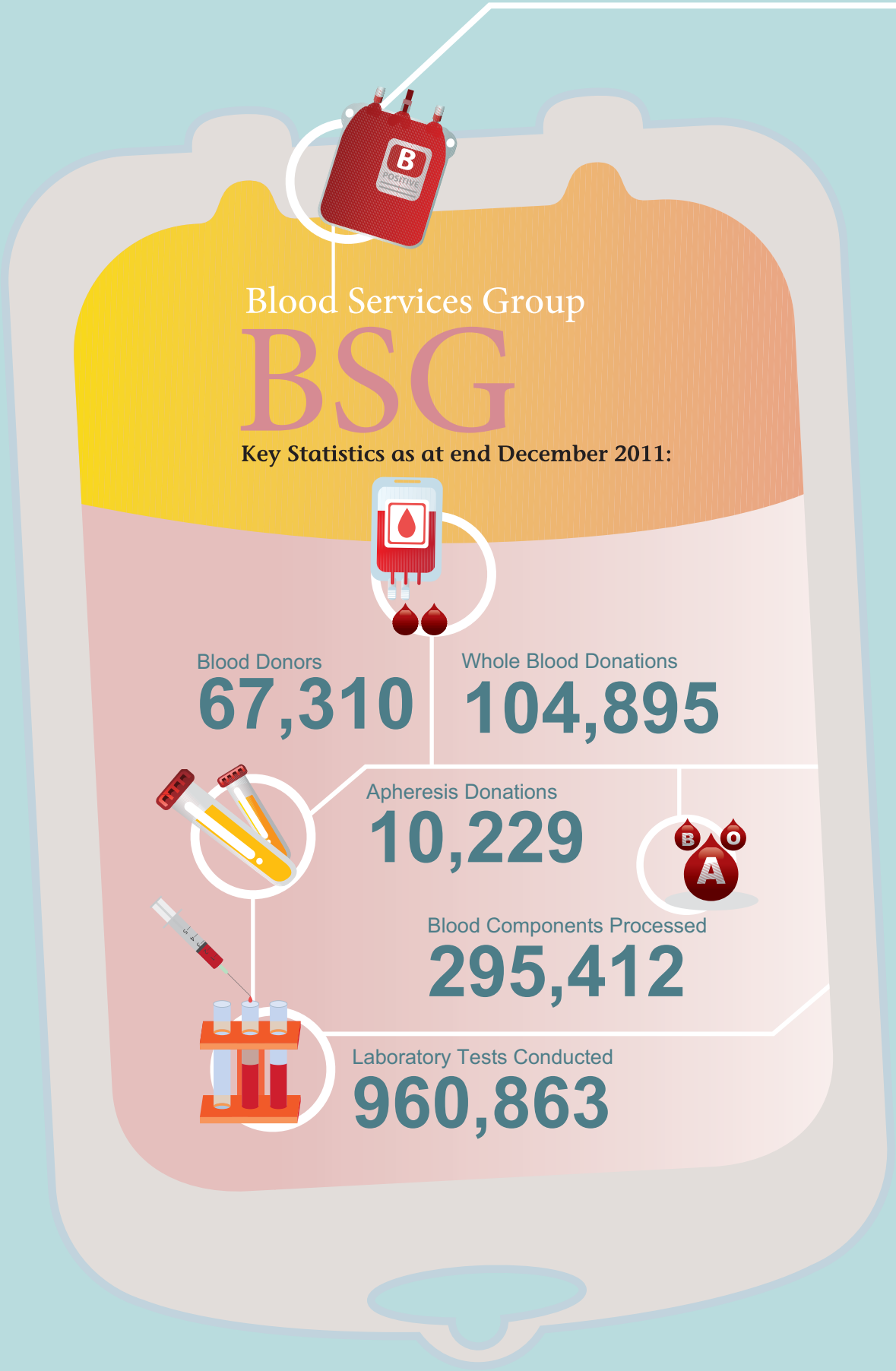
- Medical Products Agency, Sweden

- Korea Food and Drug Administration, Korea
- Ministry of Health, Labour and Welfare, together with the Pharmaceuticals and Medical Devices Agency, Japan
- National Forensic Service, Korea
- State Food and Drug Administration, China

- Therapeutic Goods Administration, Australia
- Victorian Institute of Forensic Medicine, Australia

- Medsafe, New Zealand

our achievements in figures


Blood Services Group
BSG
Key Statistics as at end December 2011:
Blood Donors
67,310
Whole Blood Donations
104,895
Apheresis Donations
10,229
Blood Components Processed
295,412
Laboratory Tests Conducted
960,863

Health Products Regulation Group

HPRG

Key Statistics as at end March 2012:

188 New Product Licences Issued

Listed Chinese Proprietary Medicines

9,218

New Chinese Proprietary Medicines Listed

358

Registered Medicinal Products

5,302

New Medical Device Product Listings Approved

3,077

Approved Products on the Singapore Medical Device Register (SMDR)

9,230

Cosmetic Products Notified

134,665

New Cosmetic Products Notified

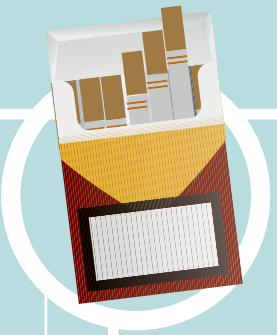
38,878

Clinical Trial Certificates Granted

238

Medical Advertisement Permits Approved

2,842



Tobacco Retail Outlets Licensed **5,539**

Tobacco Retail Licences Approved **325**

Underage Youth Smokers Caught

5,801

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

481

Premises, Dealers, Importers and Exporters of Health Products Licensed/Certified/Approved

3,964

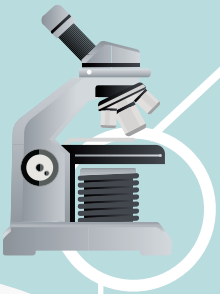
Applications Processed for Travellers Bringing Personal Medication into Singapore

1,787

Spontaneous Adverse Drug Reaction Reports Received **30,318**

Spontaneous Adverse Drug Reaction Reports Captured **23,881**

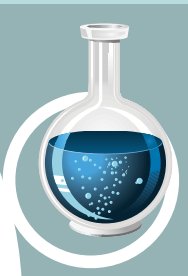
Number of Post-Market Feedback Received **2,694**



Applied Sciences Group

ASG

Key Statistics as at end March 2012:



Pharmaceutical Division

Analytical Tests for Laboratory Samples

14,852

Analytical Cases

3,917

Food Safety Division

Analytical Tests for Laboratory Samples

31,874

Analytical Cases

4,748

Forensic Medicine Division

Coroner's Cases | Coroner's Autopsies

4,005 | **2,104**

Forensic Science Division

Forensic Cases | Forensic Exhibits

323 | **983**

Biology Division

Forensic Cases

17,077

Forensic Exhibits

21,584

Illicit Drugs Division

Forensic Cases | Forensic Exhibits

2,853 | **8,690**

Analytical Toxicology Division

Forensic Cases | Forensic Exhibits

28,176 | **46,842**

financial *highlights*

Balance Sheet

	FY11/12 $'000	FY10/11 (Restated) $'000	Increase / (Decrease) $'000	%
Property, Plant & Equipment	101,967	102,103	(136)	(0)
Intangibles	5,782	7,680	(1,898)	(25)
Current Assets	91,901	58,220	33,681	58
Total Assets	**199,650**	**168,003**	**31,647**	**19**
Equity	103,601	91,576	12,025	13
Long-term Loans	24,932	27,843	(2,911)	(10)
Other Non-Current Liabilities	12,748	14,002	(1,254)	(9)
Current Liabilities	58,369	34,582	23,787	69
Total Equity and Liabilities	**199,650**	**168,003**	**31,647**	**19**

Income & Expenditure Statement

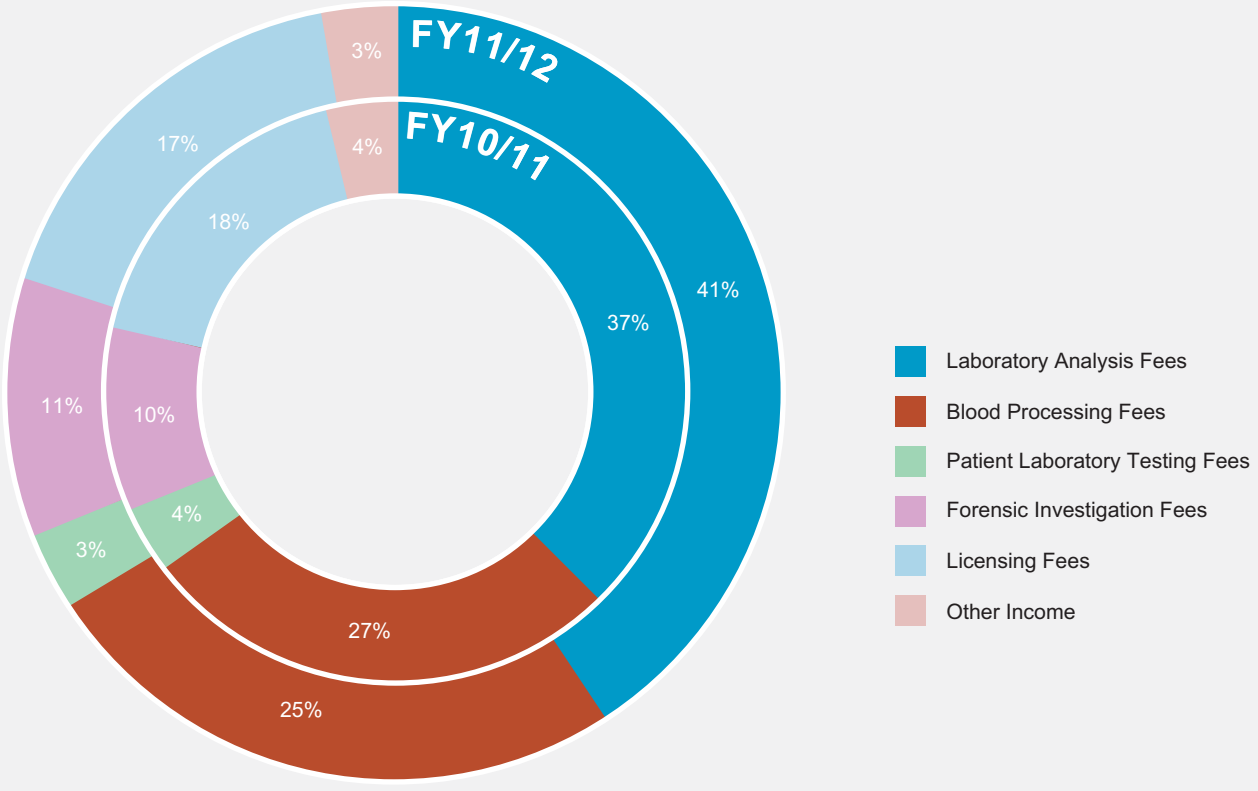
The Authority has achieved an overall net surplus of $6.1m for FY11/12.

	FY11/12 $'000	FY10/11 $'000	Increase / (Decrease) $'000	%
Operating Income	95,067	83,926	11,141	13
Operating Expenditure	(165,688)	(154,820)	10,868	7
Deficit before Government Grants	**(70,621)**	**(70,894)**	**(273)**	**(0)**
Government Grants	78,023	75,114	2,909	4
Surplus before Contribution to Consolidated Fund	**7,402**	**4,220**	**3,182**	**75**
Contribution to Consolidated Fund	(1,258)	(717)	541	75
Net Surplus	**6,144**	**3,503**	**2,641**	**75**

Operating Income

The Authority earned a total operating income of $95.1m in FY11/12, an increase of $11.1m (13%) over FY10/11's revenue of $83.9m.

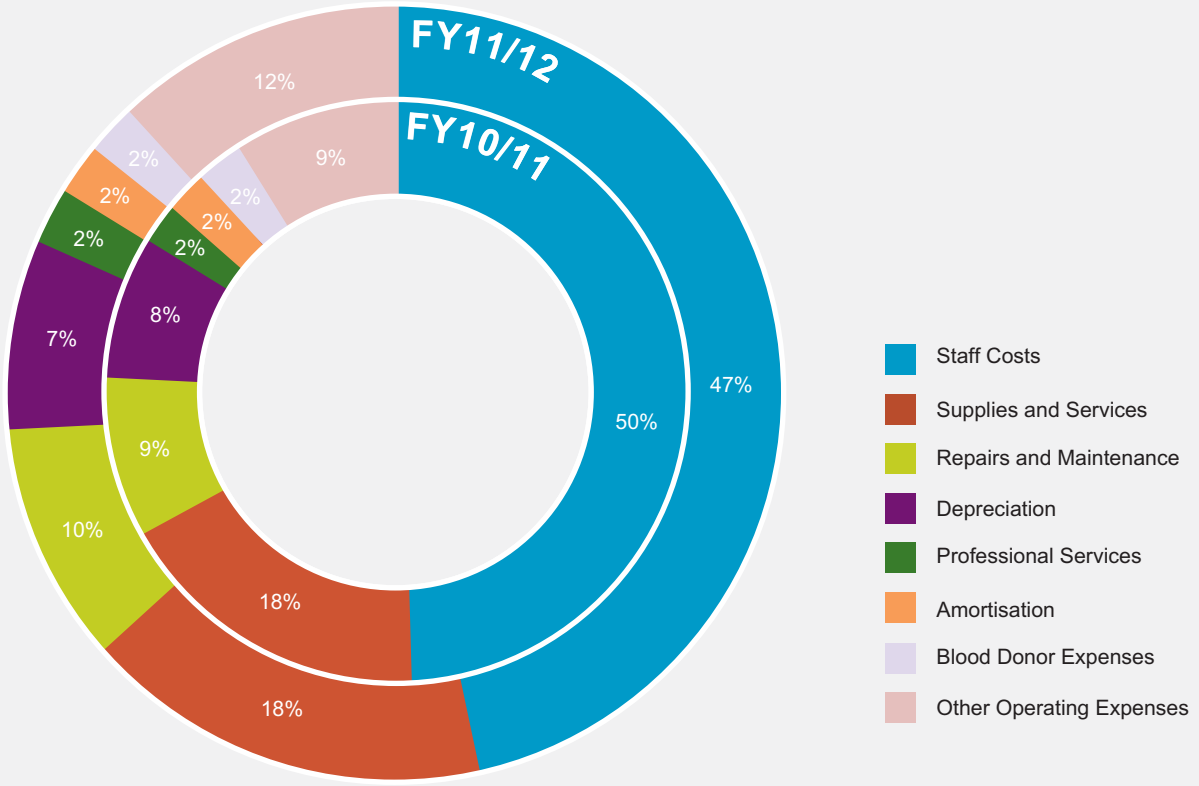
	FY11/12 $'000	FY10/11 $'000	Increase / (Decrease) $'000	%
Laboratory Analysis Fees	38,793	31,478	7,315	23
Blood Processing Fees	23,792	22,829	963	4
Patient Laboratory Testing Fees	3,128	2,939	189	6
Forensic Investigation Fees	9,985	8,793	1,192	14
Licensing Fees	16,424	14,691	1,733	12
Other Income	2,945	3,196	(251)	(8)
Total Operating Income	**95,067**	**83,926**	**11,141**	**13**



Operating Expenditure

The Authority incurred a total operating expenditure of $165.7m in FY11/12, an increase of $10.9m (7%) over FY10/11's expenditure of $154.8m.

	FY11/12 $'000	FY10/11 $'000	Increase / (Decrease) $'000	%
Staff Costs	76,669	75,896	773	1
Supplies and Services	28,519	27,877	642	2
Repairs and Maintenance	17,157	14,212	2,945	21
Depreciation	12,388	11,703	685	6
Professional Services	3,753	3,759	(6)	(0)
Amortisation	3,654	3,474	180	5
Blood Donor Expenses	3,380	3,599	(219)	(6)
Other Operating Expenses	20,168	14,300	5,868	41
Total Operating Expenses	**165,688**	**154,820**	**10,868**	**7**



the next decade:

our future forward

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