TRANSFORMATION THROUGH SYNERGY

Health Sciences Authority Annual Report 2010/11

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TRANSFORMATION THROUGH SYNERGY

The Health Sciences Authority has witnessed a productive decade under unprecedented pressures and change since its formation.

In a short span of 10 years, our reputation has grown both at home and abroad as a protector of public health and safety. This has been made possible because of our ability to fundamentally transform ourselves by harnessing the distinctive scientific and regulatory synergies within the organisation and with our partners.

Transformation through collaboration has always been acknowledged, valued, and fostered at HSA. It has been a key enabler helping us to improve the way we operate, engage with our stakeholders and deliver on our key responsibilities.

By evolving synergistically, we have been able to rise to new challenges, identify and act on new opportunities, and grow in our scope and capabilities. We have come to enjoy increased flexibility and creativity in our processes and systems, while maintaining the scientific rigour and decisiveness expected of a responsible, trusted regulator. This has empowered us to tackle some of the most pressing issues in the health sciences, while contributing as a thought leader in our scientific and regulatory arenas.

As we step into the dawn of a new decade, we will continue to give expression to and bring to life the ideas and ideals of our vision – to the benefit of Singapore and the world.

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 Standard 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 Award
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

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

World Health Organization Prequalified Quality Control Laboratory
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

CHAIRMAN'S FOREWORD

With yet another fulfilling year behind us, and within the context of our 10th anniversary, we are reminded more than ever of our purpose as guardian and champion of national health and safety.

HSA was established as an agency tasked with this bold mission on 1 April 2001. Since then, we have sought to achieve this mission by thinking strategically, by executing with efficiency, by speaking with clarity, and by being innovative and flexible. We are continually transforming ourselves to build an organisation that will inspire trust and confidence.

Today, our system of multiple pre-market authorisation routes for evaluating new drug applications has been cited as an innovative model for expediting patient access to treatments without compromising scientific robustness. It has also enabled us to optimise resources to carry out a similar spectrum of responsibilities to that typically managed by larger overseas counterparts. As medical products are becoming increasingly complex and consumers are tending to use multiple products simultaneously, we have focussed on enhancing the robustness of our regulatory system in tandem with these changes. Our post-marketing surveillance programme has also adopted a more proactive strategy, in which adverse event and risk-benefit information is promptly provided to consumers.

Our continuing work in blood services is also making excellent progress. The opening of our first satellite site is the first step towards developing a more decentralised system of blood donation centres, while ongoing research in transfusion medicine and cell therapy holds tremendous potential for new treatment options. Beyond our shores, we have been privileged to be helping other international blood bank networks in setting up or enhancing their infrastructures and systems.

Our analytical science and forensic testing expertise provide critical support and reliable solutions to government agencies both at home and abroad in regulatory and judicial functions. Notable recent examples include the local testing of food products in the aftermath of the Japanese tsunami and nuclear crisis, and forensic expertise rendered overseas after the Christchurch earthquake.

"The accelerating advances in the scientific and biomedical scene mean that we must possess the resolve and resilience to meet these increasing demands. This will mean redoubling our efforts in strengthening the scientific foundation of our mission; ensuring integrity, transparency and accountability in our decision making; engaging our multi-stakeholder community; and investing in innovation."

Advancing our aim to be a thought leader, our research is deepening as our scientific and regulatory capabilities have matured. We have developed novel techniques and tools in the forensic and analytical sciences, grown our cell therapy facilities and their accompanying research scope, and strengthened work in pharmacogenomics, pharmacoeconomics and the regulatory sciences. The greater insights gained will help us define policies and shape frameworks to ensure safer and healthier lives in the years ahead.

The past years have also seen the significant strengthening of our collaborations with many partners – those who share our immediate interests as well as others who contribute from a different perspective. The Memoranda of Understanding and work sharing arrangements with many of our local and international counterparts, as well as new industry-oriented initiatives, are good evidence of these deepening relationships.

HSA has clearly grown in stature as a science-based and science-led agency. Our scientific and biomedical expertise has achieved regional and global repute and recognition and we appreciate the opportunity to initiate and participate in many influential networks and platforms. The HSA Academy was established to facilitate our staff in activities that enhance our thought leadership and research capabilities as we continue to push the boundaries of scientific and professional excellence and chart new territory in our unique areas of expertise.

We trust that these contributions will add to the richness of the discussions, inject more creative thought, and translate more ideas into innovations.

We will continue to face challenges in the future. The accelerating advances in the scientific and biomedical scene mean that we must possess the resolve and resilience to meet these increasing demands. This will mean redoubling our efforts in strengthening the scientific foundation of our mission; ensuring integrity, transparency and accountability in our decision making; engaging our multi-stakeholder community; and investing in innovation.

I have always been impressed by the shared conviction of the HSA leadership and team that their work is meaningful and contributes to the well-being of our community. With such dedicated individuals making up the organisation, and a strong foundation built on the outstanding achievements today, I know that HSA is ready for an even more promising tomorrow.

Professor Edison Liu
Chairman

CEO'S MESSAGE

HSA crosses a significant milestone in 2011 as we celebrate our first decade of contributions to public health and safety. We have indeed much to be proud of and thankful for.

The period since our formation has witnessed seismic shifts in our operating environment and holds many valuable lessons. The theme of this year's Annual Report aptly captures the essence of the most powerful one – the importance of being willing and able to continually transform ourselves by identifying and harnessing the synergies within and beyond the organisation.

To fulfil our mission more effectively, we have over our first decade conducted rigorous reviews of our systems and processes, simplifying and streamlining them to become more mission- and customer-focussed. We have marshalled resources and capabilities across our Professional Groups to increasingly broaden our portfolio of services. Cutting-edge technologies and synergised skills from all expertise areas across the organisation have been combined to unlock new solutions that were once beyond our reach. What these thoughtful and progressive efforts have resulted in over the years are transformational improvements in not just the quality of our decisions and services, but the manner in which we deliver them.

We are heartened to have received strong endorsements for our growing competencies and standing as a leading, innovative authority in the form of our international accreditations from and affiliations with many established agencies.

Over the past year, our international linkages were strengthened with agencies such as the Korea Food and Drug Administration and Germany's Paul-Ehrlich Institute joining our network of MOU partners. We were honoured to have had a part to play in organising major forums such as the 14th WHO International Conference of Drug Regulatory Authorities. The insights surfaced at such platforms are invaluable in deepening our collective understanding of the most urgent issues impacting world health and safety, and transforming the way we confront them. The recently established HSA Academy will continue to create opportunities for more of such engagements and promote HSA as a thought leader in our scientific and regulatory arenas.

We remain steadfastly focussed on staying at the forefront of drug and device development by challenging assumptions and developing new regulatory frameworks through research collaborations. We are partnering healthcare institutions on studies in pharmacogenomics and working with the Massachusetts Institute of Technology's Centre for Biomedical Innovation to explore a new paradigm for drug development. This will potentially increase our capacity to provide patients with faster drug access and tailored treatments through the use of niche drugs. Our diverse and distinct regulatory and scientific capabilities have been combined to deal with new realities we face as a regulator. By capturing synergies across our regulatory and enforcement arms and analytical laboratories, we were able to develop a novel device to detect counterfeit drugs. Officers from both teams also lent their joint expertise in Operation Storm, a regional initiative with INTERPOL to combat fake drugs.

"The challenges we face ahead of us will bring into sharper focus the importance of our mission. But by remaining true to our core values and our legacy of excellence, I am confident that we will see our organisation stronger and our impact greater."

Greater transformation in the way we operate our world-class blood bank is in the making with the introduction of more sophisticated technologies. These will ensure that we increase our efficiency and maintain the highest possible safety standards. New partnerships were forged with hospitals during the year through initiatives such as the Clinical Practice Improvement Programme and a pilot Massive Transfusion Protocol. These aim to reduce the waiting time for patients receiving blood transfusions and will go a long way in improving treatment outcomes. As an active member of the international community, we continued to make contributions in blood banking and transfusion medicine through our participation in global forums and collaborative initiatives both in the region and beyond.

With the increasing importance of the role of forensic science in Singapore's system in the administration of justice, HSA signed a Service Level Agreement with the Ministry of Home Affairs to strengthen and expand our capacity for forensic science services to support the Home Team Departments' operational requirements. By capitalising on our in-house, coordinated expertise across our laboratories, we further sharpened our capabilities through state-of-the-art technology to add value to our services through improved applied science testing and investigative capabilities. Through close collaborations with key local and international partners, we also enjoy a strong regional and global profile in the analytical sciences and forensics, being involved in several influential networks and important initiatives.

We truly appreciate the steady guidance of our parent Ministry and the HSA Board, without which our success over the past 10 years would not have been possible. I would also like to thank our regulatory and industry partners for their support during this journey.

The achievements we share with you in this Annual Report have been made possible because of a team of individuals who are proud to be called HSAians. I have been very encouraged to have witnessed first hand the dedication and willingness of HSAians to pull together, lending their multiple efforts and talents to make a difference. This strong spirit of purpose, enthusiasm and unity is evident beyond just work. It also came shining through at our corporate celebrations and our various activities to give back to the community.

As we embark on our next decade, three key priorities top our agenda. We will build upon our strong foundations to expand our scientific capabilities by deepening synergies within the organisation and with our partners. We will strive to identify and develop better ways we can serve our customers through innovation. Finally, we must continue to be prepared to always transform for the better, while remaining true to our fundamental purpose and what we were first set up for. The challenges we face ahead of us will bring into sharper focus the importance of our mission. But by remaining true to our core values and our legacy of excellence, I am confident that we will see our organisation stronger and our impact greater.

Dr John Lim
CEO

HSA BOARD

AS AT AUGUST 2011

01

02

05

06

07

CHAIRMAN

01
Professor Edison Liu
Executive Director
Genome Institute of Singapore

BOARD MEMBERS

02
Ms Serene Wee
Chief Executive
Singapore Academy of Law

03
Dr Jennifer Lee
Senior Consultant
Primary & Community Care Division
Ministry of Health

04
Dr Chong Yoke Sin
Chief Executive Officer
Integrated Health Information
Systems Pte Ltd

05
Professor Alastair Campbell
Director
Centre for Biomedical Ethics
Yong Loo Lin School of Medicine
National University of Singapore

06
Professor K. Ranga Krishnan
Dean
Duke-NUS Graduate Medical School

07
Adj Assoc Professor Lee Chien Earn
Deputy Director of Medical Services
(Health Services &
Healthcare Performance)
Ministry of Health

03

04

08

09

10

11

08
Mdm Liew Wei Li
Deputy Director
Curriculum Policy and Pedagogy and
Project Director (Special Projects)
Curriculum Planning &
Development Division
Ministry of Education

09
Dr John Lim
Chief Executive Officer
Health Sciences Authority

10
Mr Clifton Tan
Director of Finance & Administration
Estée Lauder Cosmetics Pte Ltd

11
Professor Walter Tan
Medical Director
Raffles Hospital

HSA BOARD COMMITTEES

AS AT AUGUST 2011

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

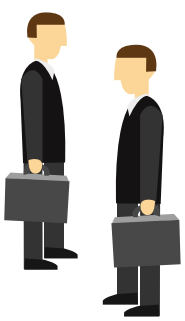
Finance Committee

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

BOARD UPDATES

We extend a warm welcome to our new Board Member, Professor K. Ranga Krishnan. Professor Ranga is currently the Dean of Duke-NUS Graduate Medical School.

We look forward to the continued guidance and support of our Board, as we continue to grow as an organisation in our pursuit to be the leading innovative authority protecting and advancing national health and safety.



HSA EXECUTIVE COMMITTEE (EXCO)

AS AT AUGUST 2011

01
Dr John Lim — Chief Executive Officer

02
Dr Diana Teo — Group Director, Blood Services Group; Chairman, Professional Board

03
Dr Lam Kian Ming — Group Director, Applied Sciences Group; Director, HSA Academy, Corporate Headquarters

04
Dr Christina Lim — Acting Group Director, Health Products Regulation Group

05
Dr Raymond Chua — Deputy Group Director, Health Products Regulation Group

06
Ms Doreen Loh — Division Director, Human Capital & Legal Division, Corporate Headquarters

07
Dr Mok Ying Jang — Division Director, Corporate Development & Operations Division, Corporate Headquarters

01 02 03 04

05 06 07

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

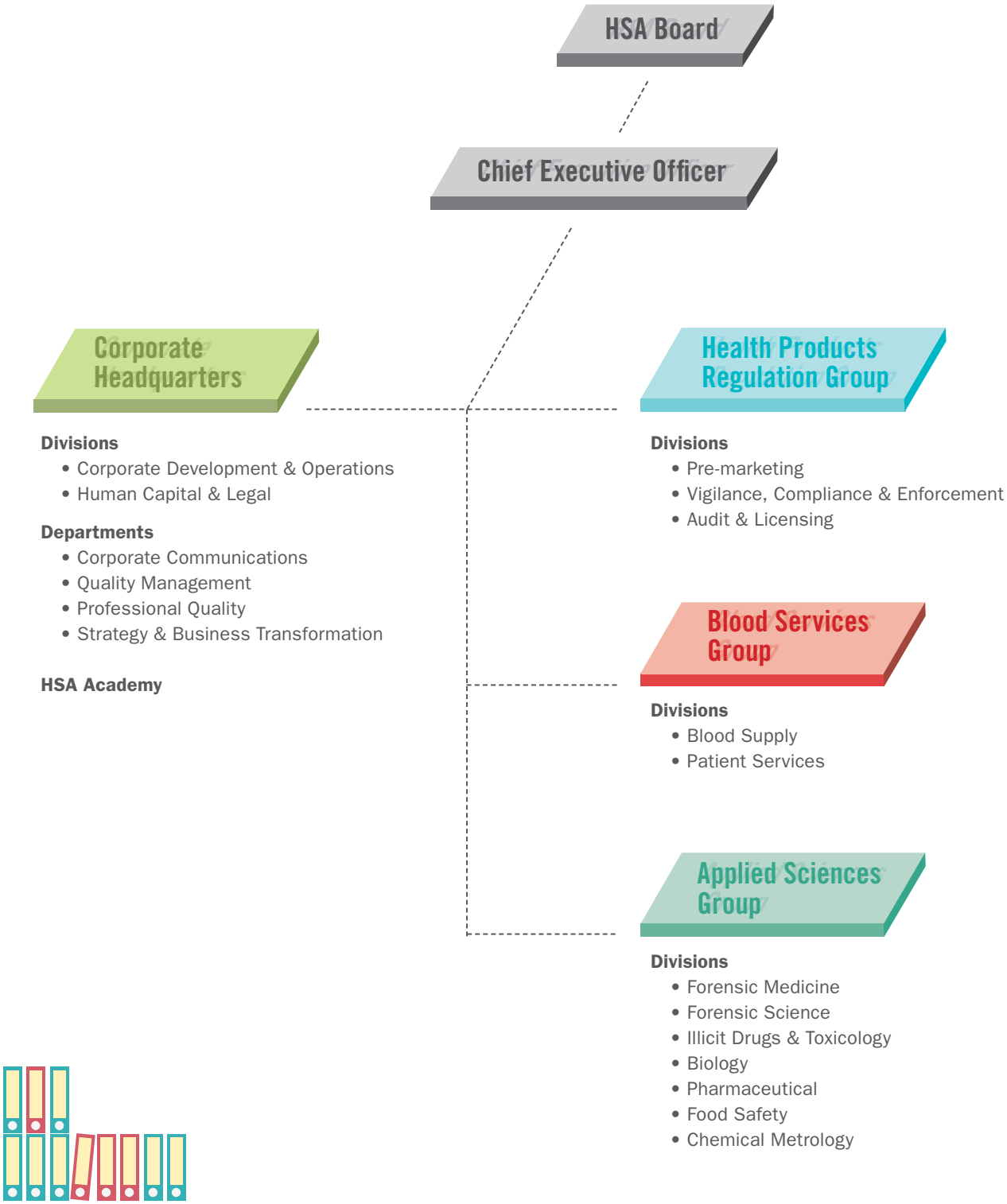
The Board, officers and employees are required to observe and maintain high standards of integrity, and are in compliance with the law and government regulations, and organisation policies.

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 2011



PRINCIPAL OFFICERS

AS AT AUGUST 2011

CORPORATE HEADQUARTERS

Chief Executive Officer
Dr John Lim

CORPORATE DEVELOPMENT & OPERATIONS DIVISION

Division Director
Dr Mok Ying Jang

FINANCE
Director
Ms Grace Chan

INFORMATION MANAGEMENT
Director
Santhanam Srinivasan

FACILITIES MANAGEMENT
Deputy Director
Ms Lynette Goh

HUMAN CAPITAL & LEGAL DIVISION

Division Director
Ms Doreen Loh

LEGAL
General Counsel
Ms Linda Chen

HSA ACADEMY

Director
Dr Lam Kian Ming

STRATEGY & BUSINESS TRANSFORMATION DEPARTMENT

Director
Prashant Dhami

CORPORATE COMMUNICATIONS DEPARTMENT

Director
Adrian Chia

QUALITY MANAGEMENT DEPARTMENT

Quality Service Manager
Professor Bosco Chen Bloodworth

PROFESSIONAL QUALITY/ WORKPLACE SAFETY AND HEALTH DEPARTMENT

Director
Professor Bosco Chen Bloodworth

HEALTH PRODUCTS REGULATION GROUP

Acting Group Director
Dr Christina Lim

Deputy Group Director
Dr Raymond Chua

Assistant Group Director
Ms Chan Cheng Leng

Senior Advisor
Health Products Regulation Group
Yee Shen Kuan

Advisor
International Collaboration
Mrs Marie Tham

Advisor
Administration and Pharmacoeconomics & Drugs Utilisation Unit
Mdm Suwarin Chaturapit

Advisor
Complementary Health Products
Ms Chu Swee Seng

GROUP DIRECTOR'S OFFICE

Director
Policy, Legislation & Operations
Dr Daniel Tan

Deputy Director
Policy, Legislation & Operations & Project Management
Ms Lee Hui Keng

PRE-MARKETING DIVISION

Acting Division Director
Dr Lou Huei-Xin

PHARMACEUTICALS & BIOLOGICS BRANCH
Director
Dr Lou Huei-Xin

GENERICS & BIOSIMILARS BRANCH
Director
Dr Sannie Chong

Senior Group Regulatory Consultant
Dr Tam Kai Tong

MEDICAL DEVICE BRANCH
Director
Mrs Joanna Koh

CLINICAL TRIALS BRANCH
Director
Foo Yang Tong

COMPLEMENTARY HEALTH PRODUCTS BRANCH
Director
Ms Lee Puey Ngee

AUDIT & LICENSING DIVISION

Division Director & Director,
Quality Assurance Office
Sia Chong Hock

AUDIT BRANCH
Director
Ms Jessica Teo

VIGILANCE, COMPLIANCE & ENFORCEMENT DIVISION

Division Director
Ms 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
Norman Chong

BLOOD SERVICES GROUP

Group Director
Dr Diana Teo

GROUP DIRECTOR'S OFFICE

Director
Blood Service Operations
Ms Koh Geok Tin

Senior Manager
People Development &
International Collaboration
Ms Leou Kwee Kim

Senior Transfusion Medicine Scientist
Research & Knowledge Management
Dr Garnet Suck

Senior Manager
Quality & Accreditation
Ms J Thilakavathi

BLOOD SUPPLY DIVISION

Division Director
Dr Tan Hwee Huang

Acting Branch Director
Blood Resource
Ms Toh Ching Lian

Laboratory Director
Blood Supply Management
Ms Sally Lam

Senior Laboratory Manager
Blood Supply Management
Ng Kok Quan

PATIENT SERVICES DIVISION

Division Director
Dr Mickey Koh

Consultant
Clinical Transfusion Medicine
Dr Ang Ai Leen

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 Advisor
Dr Paul Chui

Senior Scientific Advisor
Professor Bosco Chen Bloodworth

Accreditation, Professional & Technical Education Director
Dr Michael Tay

FORENSIC MEDICINE DIVISION

Division Director
Dr Paul Chui

PROFESSIONAL PRACTICE BRANCH

Branch Director
A/Professor Gilbert Lau

FORENSIC MEDICINE OPERATIONS BRANCH

1 Branch Director
Dr Cuthbert Teo

2 Branch Director
Dr George Paul

FORENSIC SCIENCE DIVISION

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
Dr Christopher Syn

ILLICIT DRUGS & TOXICOLOGY DIVISION

Division Director
Dr Lui Chi Pang

Laboratory Director
Illicit Drugs Laboratory
Dr Angeline Yap

Analytical Toxicology Laboratory
Drug Abuse Testing
1 Director
Dr Lui Chi Pang

Analytical Toxicology Laboratory
Clinical and Forensic Toxicology
2 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
Ms Joanne Chan

Laboratory Director
Food Safety Laboratory
Ms Joanne Chan

CHEMICAL METROLOGY DIVISION

Division Director
Dr Lee Tong Kooi

Laboratory Director
Chemical Metrology Laboratory
Dr Lee Tong Kooi

CORPORATE HEADQUARTERS

Working hand in hand with our three Professional Groups, HSA's Corporate Headquarters provides the leadership, support and governance to enable our organisation to succeed as a thought leader in public health and safety.

We are constantly pursuing new ways to achieve our strategic objectives by translating the diversity of capabilities and expertise within HSA into new projects and programmes. We strive to create a dynamic environment where our systems are highly efficient and integrated, and where all staff members can contribute meaningfully to the best of their abilities. Through collaboration and cross-pollination of ideas across HSA, we achieve synergies that will promote innovation and thought leadership across our areas of scientific expertise.

GOING BEYOND OURSELVES

Having already been certified as a Singapore Quality Class, People Developer and Singapore Innovation Class organisation, we were heartened to be conferred the Public Service Milestone Award in May 2010. This affirmation of business excellence spurs us on to translate our vision and mission into effective plans and outcomes that will gear us towards becoming an even more exceptional agency.

We made good progress in the implementation plans following a business process re-engineering exercise that was completed in 2010. The exercise, which involved re-examining and re-designing work processes and identifying opportunities to optimise our resources, was conducted as part of our efforts to foster greater organisational excellence and better position HSA to respond effectively to business challenges. The strategic plans which have been put in place will enable us to further improve collaboration across our Professional Groups, boost our overall efficiency and serve our customers better. We also conducted reviews of our key performance indicators and performance tracking system, to enhance our effectiveness and governance systems.

WHERE BRIGHT IDEAS COME TO LIFE

At HSA, we recognise that much of what we have achieved today comes from cultivating a stimulating work environment that acknowledges our people, and promotes creativity and innovation.

In May 2011, we launched a new web-based portal to enable staff to easily contribute ideas and make suggestions. However, more than just a forum for collecting ideas, the portal also integrates tools for reviewing ideas and tracking their implementation. A review of the philosophy and guidelines for work innovation projects within workgroups was also conducted, with new procedures formalised and rolled out in mid-June 2010.

The HSA Organisational Excellence Forum was held on 22 July 2010 for all HSA staff. The forum serves as a key platform for promoting a learning culture within HSA and spreading knowledge, ideas and organisational best practices in areas that drive corporate development, improvement and excellence. As part of the forum, Maestro Tsung Yeh, Music Director of the Singapore Chinese Orchestra (SCO), was invited to share with HSA staff about SCO's journey of transformation through innovation. In addition to sharing insights, Maestro Tsung and four SCO musicians also treated the forum attendees to a wonderful musical performance.

TAKING CUSTOMER SATISFACTION TO A WHOLE NEW LEVEL

Building and maintaining a customer service culture is an ongoing task that we embrace with passion. To better meet the needs of our customers, we launched a satisfaction survey in early 2011 to understand how we can better respond to our customers and improve our service delivery. The survey results will help to set benchmarks for service standards and identify key areas for improvement.

We also carried out a review of our Customer Service Training Framework with a focus on the skills and competencies required by different groups of staff within HSA. As a result of this review, we made enhancements to the training curriculum to better equip staff with the means to manage customer interactions and deliver good customer service.

Applauding Our Service Ambassadors

Our second HSA Customer Service Day was celebrated in February 2011. Keynote speaker Mr Seah Seng Choon, Executive Director of the Consumers Association of Singapore, shared insights into the importance of good customer service management and related his own efforts to champion a consumer-friendly society.

To motivate our staff to maintain consistently high service standards and recognise role models within HSA, we expanded our annual Outstanding Service to Customers Awards (OSCA) to include a new Team Award category. This year, 25 service stars were presented with OSCA Individual Awards, while six groups of staff received the inaugural OSCA Team Awards for their commitment to delivering excellent customer service.

In addition to internal recognition, our efforts in pursuing service excellence were also recognised at the national level. Mr Tan Eng Kiat from the Health Products Regulation Group was awarded the PS21 Star Service Award, while 17 other HSAians received Excellence Service Awards – comprising one Star Award, 11 Gold Awards and five Silver Awards – for their contribution and commitment to exceptional service.

Moving forward, we will focus on a holistic approach to customer service and relationship management, ensuring that consistently high service standards are maintained at all customer touchpoints. One way in which we will do this is through the enhancement of our feedback management system, which will enable us to address feedback in a timely and comprehensive manner.

INVESTMENTS IN IT

The past year saw the implementation of key initiatives under HSA's IT Masterplan and the optimisation of IT resources to improve our service to customers and accelerate our response to new opportunities. By expanding and refining various applications and systems, we have enabled greater operating efficiency and achieved better customer service delivery standards.

The following are some of the key highlights of our recent IT projects:

- We commissioned a new data centre under the Server room COnsolidation and Technology Transformation (SCOTT) project. Apart from having an increased capacity to host additional systems and applications in-house, the centre also boasts advanced environmental monitoring and protection features.
- Business-friendly improvements were made to our online licensing systems. We upgraded the database server hardware of our Pharmaceutical Regulatory Information System (PRISM) and made enhancements to the Medical Device Information and Communication System (MEDICS) for the implementation of medical device legislation.
- A new queue management system was implemented at the Bloodbank@HSA to improve the queuing process and thereby enhance the overall experience for our blood donors.
- New modules and enhancements were rolled out under CREST (Common REsource SysTem), including new modules for performance management, travel management and inventory management.
- Changes were implemented to automate the approval process for customs declarations for imported medical devices via Singapore Customs' TradeNet system. This has improved our customers' experience by eliminating the previous 4 to 8 hour waiting time for approval, while allowing staff to focus on other value-added activities.
- A series of IT security awareness briefings and a security review of HSA's application systems were conducted as part of our IT Security Programme.

Other IT improvements are either underway or in the planning stages. We are working on a new Online Safety, Compliance Application and Registration (OSCAR) system, which will sharpen product vigilance and facilitate the monitoring of health product imports entering Singapore. Our planned Customer Relationship Management (CRM) System will also see new features that will contribute towards providing improved service to our customers.

We continue to progress with our rollout of the Standard ICT Operating Environment (SOE) initiative – a government-wide programme to standardise all desktops, messaging and online collaborative tools and network environments across public agencies – throughout our organisation. Our immediate focus going forward is to synchronise the IT systems in our applied sciences laboratories, blood bank and mortuary with the new environment.

More Winning Ways

The Laboratory Integrated Scientific Administration (LISA) system used by our applied sciences laboratories received the MIS Asia IT Excellence Award 2010 in the Best Business Enabler (Public Sector) category. The award recognises the use of diverse technologies (e.g. barcode scanning, biometrics and enterprise content management) in LISA to enhance operations relating to service quality and agility. As part of our continuous efforts to boost efficiency, further improvements are being made to the LISA system to enhance our capabilities in tracking turnaround times and monitoring cases.

HSA is one of the key agencies participating in the planning and development of the FRONTIER (Facilitating Reforms for Innovation and Enterprise) project, a whole-of-government initiative aimed at reinventing the Government's approach to business licensing. Once developed and implemented, this new system will standardise business licence application processes across agencies, which will provide cost savings to both businesses and Government while facilitating better customer service.

PUTTING PEOPLE FIRST

HSA's sustained success is possible because of its dedicated team of passionate professionals. Developing our people therefore takes priority alongside our other business goals because we recognise that in order to thrive as an organisation of excellence, HSAians must be given every opportunity to make the most of their personal and professional potential. This is why we have consistently placed great emphasis on creating an empowering work environment that energises our people to give their best.

As a People Developer organisation, we believe that it is important for HSAians to have a thirst for knowledge and a desire for continuous learning. We instil this mindset by being firmly committed to investing in our people through a comprehensive range of training programmes. During the year, HSAians were offered a wide variety of programmes that included classroom sessions, on-the-job training, conferences and seminars, as well as international study trips. These aimed to sharpen technical, leadership and soft-skill competencies, as well as deepen their scientific and regulatory knowledge. To address the risks and challenges facing HSA due to an ever-changing external environment, training programmes to enhance knowledge and understanding of operating processes and increase awareness of the need for good corporate governance and internal controls were also organised.

Several electronic processes were introduced to improve workflows in key human resource functions such as performance management as well as the recruitment and induction of new employees. Officers can now submit updates on their personal information electronically, instead of doing so manually. With these online systems up and running, the HSA Human Capital Management team is now able to achieve greater productivity and efficiency, while offering HSAians greater convenience.

Nurturing our human capital in tandem with HSA's progress will always remain a key focus. This means exploring creative ways to attract the best minds, innovative methods to hone their capabilities, and progressive frameworks to reward their performance. To ensure that HSA is sufficiently prepared to take on new challenges well into the future, we will continue to review our leadership development framework to ensure that we have a sustainable pipeline of talented, visionary and motivated leaders.

Working and Playing Hard

At HSA, we believe that we can have fun too, while working hard to deliver on our mission. To this end, a host of exciting and memorable activities were organised to allow ourselves some time to relax and recharge. From baking workshops and kite-making classes to personal grooming courses, HSAians enjoyed rejuvenating breaks that also enabled them to pick up informative tips and new skills.

During the year, HSAians were encouraged to get on their feet and participate in activities under our well-being programme. These included weight management talks, walks in the heart of the city to the newly constructed Helix Bridge, as well as an Active Day event which was organised as a mass aerobics workout. Our efforts to promote a healthy work environment and improve awareness of long-term health issues paid off when we were honoured at the biennial Singapore Health Awards with a Gold Award.

With a growing number of staff joining us, an HSA-wide teambuilding programme will be introduced to allow colleagues from different parts of the organisation to interact with each other in an enjoyable and engaging setting. The programme also hopes to foster a greater appreciation of our core values and strengthen synergies across the organisation.

ENSURING ALL'S WELL AT WORK

Working closely with other government bodies and industry groups, HSA plays its part to ensure that our employees work in a safe and healthy environment. We develop systems, publish guidelines and promote processes and practices that pave the way for even more conducive work environments.

We completed a key project to standardise all laboratory safety manuals in the Applied Sciences Group and align them to the Workplace Safety and Health (WSH) management system. Our next priority is to align the Blood Services Group's safety manual with the WSH management system. We will also be completing a WSH risk assessment in the Health Products Regulation Group in preparation for the expansion of the WSH Act to include general offices as workplaces. This allows us to benchmark HSA against industry best practices and more effectively manage WSH measures throughout the organisation.

At the national level, we continued to contribute as a member of the Workplace Safety and Health Council's Healthcare (Practices) Committee and the national Globally Harmonised System (GHS) Taskforce for the labelling of chemicals and other hazardous products. Our involvement in the latter is supporting the move towards the successful implementation of GHS in Singapore.

Strengthening Public Confidence

Public communications remained an important area of focus during the year. Our timely and transparent approach in connecting with stakeholders and the community assures them of our commitment to HSA's mission.

Through media briefings and advisories, we advocated support for our various causes and were able to secure editorials on a broad range of topics. These included consumer safety pieces which provided clear and prompt risk-benefit information on health products, as well as profile stories on our new blood bank and expertise in analytical sciences and forensics. We also enjoyed positive media coverage on our new partnerships with other global regulators, and how these will enhance our efforts as a responsible regulator.

To better explain HSA's role and strategies, we also produced a new corporate video to showcase our people and programmes.

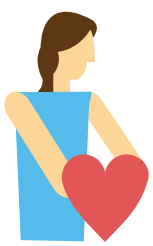
HSA GIVES BACK

The philosophy behind our Corporate Social Responsibility (CSR) initiatives is simple: every effort, big or small, can result in a positive outcome to our community and the environment. Our CSR framework builds upon this philosophy through staff volunteerism, environmental preservation and caring for our community.

During the past year, we partnered with APSN Katong School for a clay art co-creation project called *Harmony In Diversity,* which provided valuable opportunities for HSA volunteers to learn and build bonds with our young friends from this special needs school. This CSR effort culminated after eight months with a delightful art piece that now takes pride of place at the school's main entrance.

HSAians also came together to support other meaningful causes. We organised a charity bazaar in aid of Lions Befrienders and supported the Singapore Red Cross in their blood donation drives throughout the year. To lend emphasis on the need for HSAians to preserve our environment, an educational tour to Marina Barrage was organised which highlighted Singapore's limited fresh water supply and how we all must make efforts to conserve this precious resource. HSA continues to support the Green movement in our daily operations to reduce, reuse and recycle.

HSA is proud to be awarded the Total Defence and Home Team Partner Awards once again. This recognises HSA as a committed organisation that supports our officers in the defence of our nation.



BEING AT THE FOREFRONT

The HSA Academy was set up to spur the agency's next phase of growth and be a key enabler in transforming the organisation as it continues to push the boundaries of scientific and professional excellence.

A key priority of the Academy is to spearhead the development of the agency's thought leadership in its various professional areas, thus creating avenues to engage internal and external experts through think tank meetings and forums. It will also help consolidate, support and develop HSA's research capabilities. These efforts are part of a wider vision of enabling Singapore to set the direction and pace for new approaches and frameworks in health products regulatory science, transfusion medicine and the applied sciences.

Expertise Exchanges

We were proud to partner the World Health Organization (WHO) and the Uppsala Monitoring Centre (UMC) to jointly organise the first tailored training on pharmacovigilance developed for ASEAN health products regulators. The programme was held from 31 May to 4 June 2010. Participants had the opportunity to build up their capabilities and knowledge while learning from the experiences of internationally-renowned and local clinical experts, as well as HSA's pharmacovigilance trainers.

We also supported a panel of experts from the Asian region at a discussion on "A Regional Framework for Ethics of Research in Traditional Medicine" at the 10th World Congress of Bioethics. The insights gained from the session will go towards generating a WHO position paper outlining the guidelines on developing an ethical framework for research on Asian systems of medicine, as well as making regional recommendations for ethics in the design and conduct of traditional medicine research.

Steps were taken to start shaping the thinking and approach to the regulation of genetic kits through a Philosophy to Practice Workshop which brought together the collective wisdom of experts from diverse fields. The roundtable dialogue explored ethical considerations and current technology available in this previously uncharted area. Ideas flowed freely on how and whether genetic test kits should be regulated, as participants reviewed the concerns faced by regulators.

We continued our fruitful engagements with the Massachusetts Institute of Technology's New Drug Development Paradigms (NEWDIGS) consortium comprising academia, industry and regulatory bodies. This project explores progressive authorisation and the progressive market entry of a product as outcomes evidence is generated under real-world use to better define the benefit risk profile at the time of full market authorisation. The objective is to improve the therapeutic product innovation in healthcare and make safer drugs available to patients.

Photo Courtesy of MICA

Creating Connections

Our operating environment is undergoing intense changes. Only by teaming up and aligning our strengths and actions with others who share our mission can we overcome and thrive amidst some of the most complex challenges. HSA is therefore always on the lookout for opportunities in which we can support our partners' strategic goals while achieving our own.

During the year, we inked several Memoranda of Understanding with our overseas regulatory counterparts, including the Irish Medicines Board, New Zealand Medicines and Medical Devices Safety Authority, Korea Food and Drug Administration and Germany's Paul-Ehrlich Institute. We also tied up with INTERPOL through an agreement to allow HSA to design and tailor training programmes to build up the capabilities of overseas law enforcement officers in identifying and testing for counterfeit medical products. Such mutually beneficial alliances will remain a key element in the way we run our business as they keep us on track in performing our role as a reliable and responsive regulator. They also reflect the maturity of our organisation and our growing impact on world health and safety.

Where the Best Minds Meet

We provided several prominent platforms for international and local experts to discuss and brainstorm on a broad range of issues concerning regulatory agencies. Our hope is that the compelling ideas and insights shared at these sessions will inspire and catalyse the development of tomorrow's most revolutionary solutions to the real-world issues we face today.

We welcomed fellow national medicines regulators to the 14th International Conference of Drug Regulatory Authorities (ICDRA) from 30 November to 3 December 2010. The event, which was held in Singapore for the first time, was organised in collaboration with the WHO. It saw its highest rate of participation to date, with close to 400 members from over 90 countries attending. The event provided opportunities for regulators to share and discuss current and topical issues of global concern.

The Academy hosted two key events in celebration of HSA's 10th anniversary. The first was a scientific symposium themed "Science Saves Lives". The event was held on 30 June 2011 and showcased how HSA's unique blend of diverse scientific expertise housed under one roof contributed to advancing public health and safety. Guest-of-Honour, Mr Teo Chee Hean, Deputy Prime Minister, Coordinating Minister for National Security and Minister for Home Affairs, delivered the keynote address at the event, which also saw experts from around the world sharing their thoughts and valuable experiences in the challenging fields of transfusion medicine, forensic science and regulation.

Another symposium took place on 14 July 2011. Titled "Scientific Advances and Regulation in Blood and Cellular Therapy", it sought to explore new developments in blood and cellular therapy and the impact and challenges this provides for stakeholders. Participants at the event enjoyed a thought-provoking session which featured leading experts in the areas of health products regulation and blood services. The HSA Academy also rendered support at the 7th IABS Symposium on Advances in Transfusion Safety from 15 to 17 July 2011.

Strengthening Research

Research and innovation is an important part of HSA's culture, and integrity and transparency are cornerstones of our research philosophy. To this end, a Research Integrity Framework was developed to outline a clear policy on governance in the conduct of research activities done under the auspices of HSA. To complement this, a Research Governance Framework, was also implemented to provide a structured framework for research conducted at HSA and the decision making process, monitoring responsibilities, ethical standards and collaboration guidelines.

A 2-year agreement was signed with the National Healthcare Group Domain Specific Review Board (DSRB) to provide ethics oversight for human biomedical research conducted at HSA. This will provide further assurance that our research activities are ethically sound and are reviewed by an external body.

For a full listing of the research initiatives that we have embarked on in FY10/11, please visit: www.hsa.gov.sg/publications.

HEALTH PRODUCTS REGULATION GROUP

The Health Products Regulation Group ensures that health products in Singapore meet internationally benchmarked standards of safety, efficacy and quality. We have implemented a robust and risk-based framework that enables safe and timely access to health products, while taking into account industry needs for greater transparency and flexibility.

Faced with the ongoing evolution of the regulatory landscape, we strive to remain at the forefront of global trends and technological advances with regard to drugs and devices. We are constantly looking to redefine our processes and helping to define new regulatory frameworks, as well as pursuing new areas of research. In this way, our growing capabilities enable us to face the challenges of health product regulations.

Through our strong partnerships with local and overseas agencies, we strive to develop sound regulatory policies that could make a positive impact on public health and safety both in Singapore and beyond our borders. By leveraging our strengths to deepen integration across different disciplines, we will continue to sharpen our operating synergies to translate our strategic vision into tangible outcomes for our stakeholders.

TOWARDS SMARTER REGULATION

The past year saw new requirements under the Health Products Act (HPA) coming into effect for medical devices as part of the phased regulatory roll-out. The HPA, which was passed in 2007, serves to amalgamate existing controls under the Medicines Act and Poisons Act, as well as regulates new product groups not covered under the earlier legislation.

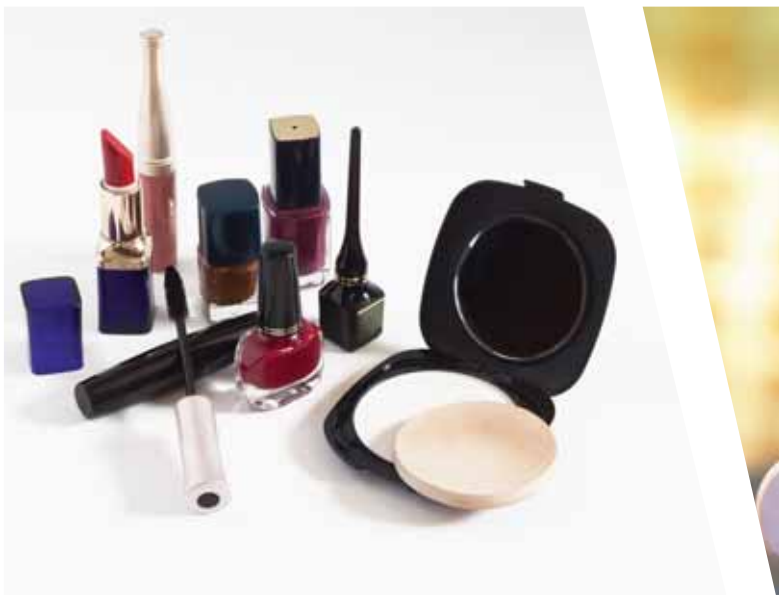
Medical devices were the first group of health products to be regulated under the HPA, followed by cosmetic products, with the implementation of the ASEAN Cosmetic Directive in 2008.

Product registration for Class C and Class D medical devices and dealer licensing for all medical devices were implemented in August 2010. Medical device dealers will be required to comply with the Quality Management System criteria for manufacturing and importing or supplying products. A transition list for Class C and Class D medical devices was published to allow the continued supply of products that met prescribed criteria in order to avoid disrupting patient needs. We further implemented six authorisation routes to allow novel and unregistered high-risk medical devices to be imported and supplied locally.

We are currently preparing for the product registration of Class A and Class B medical devices, which we are aiming to roll out in January 2012. The full legislative controls for medical devices will be in place with the completion of this final phase, with a total of over 15,000 products expected to be registered in Singapore. On-site regulatory audits of medical device dealers will also be carried out under the Good Distribution Practice for Medical Devices inspection scheme.

In the year ahead, we will be working to transfer the regulatory controls for the various product groups related to manufacturers, importers and dealers from the Medicines Act to the Health Products Act.

To help ensure a smooth transition for industry stakeholders in light of recent and upcoming developments, we organised briefings, focus group sessions and workshops to keep them well informed and engaged regarding the various regulatory changes taking place. A revised Guidance on Medicinal Product Registration was implemented on 1 April 2011 to reflect HSA's current regulatory processes following industry consultations on the drafted guidance in October 2010. In August 2010, we also revised the HSA Guidance Notes on Good Distribution Practice in response to industry feedback seeking greater clarity regarding the guidelines for the management and control of cold chain products.



Elevating Safety Standards

A new verification evaluation route was introduced on 1 January 2011 for the registration of Generic Drug Applications (GDAs) to facilitate market entry of generic products that have been evaluated and approved by at least one of HSA's reference agencies. This new route offers a shorter processing time and facilitates public access to generic medicines.

As a measure of enhancing public safety and meeting the growing needs of the public for wanting to know more about medicinal products, package inserts for new medicinal products will now require listing of the product's non-active ingredients and/or materials with allergenic potential.

Looking ahead, other key priorities include the implementing of a risk-based approach to regulate new therapeutic products. We also aim to strengthen the enforcement action taken against errant dealers while continuing to engage our stakeholders with regard to the development of our regulatory framework.

Work is also currently underway to consolidate existing regulations for Chinese Proprietary Medicines (CPMs), traditional medicines and health supplements under the Complementary Health Products regulatory framework. We have implemented new initiatives related to CPMs and health supplements, such as allowing the use of vitamin K in health supplements under stipulated conditions and offering exemptions from CPM product listing requirements for locally manufactured CPMs produced solely for export.

We are also in consultation with the Ministry of Health (MOH) to develop a regulatory framework for the regulation of Cell and Tissue Therapies (CTTs) for both high-risk and lower-risk CTT products.

The existing regulatory framework for clinical trials is being revised and will be introduced in 2012 as the Health Products (Clinical Trials) Regulations. We conducted focus group consultation sessions with industry players and other stakeholders as part of the review process. Several new initiatives will be introduced to reduce the burden of regulatory processes without compromising the safety standards for conducting clinical trials.

QUICK DETECTION, PROMPT PREVENTION

Post-marketing surveillance remains a significant part of our ongoing efforts to ensure that the safety and efficacy of health products are optimised for patients and the general public. Singapore was ranked 2nd, up six spots from the 8th position in 2009, in a ranking of Adverse Drug Reaction (ADR) report submissions by the World Health Organization (WHO) Collaborating Centre for International Drug Monitoring at the Uppsala Monitoring Centre (UMC) in Sweden. In addition to the active contributions by our healthcare professionals to ADR reporting, the Critical Medical Information Store (CMIS) system, an electronic repository of patients' medical records and drug allergies, has also significantly contributed to the high reporting rate.

In April 2010, we significantly enhanced our Product Quality Surveillance (PQS) initiatives to include involvement from pre-market and post-market groups in planning the selection of products for sampling, determining the class and level of recalls, and deciding upon the regulatory actions to be taken.

We developed a local risk management programme with the product license holder for restricted use of products containing rosiglitazone (Avandia®, Avandamet®). This step was taken in light of international concerns regarding cardiovascular safety issues associated with the use of these products.

Public Safety: Our Top Priority

In consultation with the MOH and its Expert Committee on Immunisation, we conducted an in-depth benefit-risk assessment on rotavirus vaccines in light of the discovery of DNA fragments of porcine circovirus 1 (PCV1) in Rotarix® and PCV1 and porcine circovirus 2 (PCV2) DNA fragments in Rotateq®. This assessment resulted in the issuance of a Dear Healthcare Professional Letter regarding recommendations on the use of rotavirus vaccines, as well as two product safety updates to provide information on the findings and outcome of our review.

We also conducted risk assessments for nine unregistered products arising from PQS and recommended regulatory actions that included retail level recalls and the issuance of press releases.

Several precautionary steps were taken over the course of the year to minimise consumers' access to potentially harmful products. A total of 214 risk assessments on health products were carried out during the year, which led to regulatory changes such as the strengthening of package inserts; the issuance of Dear Healthcare Professional Letters and press releases; and the publication of ADR News Bulletin articles. The sales and product licences of sibutramine products (e.g. Ectiva®, Reductil®, Reduxade® and Slenfig®) were suspended due to an unfavourable benefit-to-risk ratio.

CONSTANT VIGILANCE

During the year, we took steps to strengthen our risk communication for medical devices through various communication channels. This included the issuance of a press release for the recall of Johnson & Johnson Acuvue contact lenses; a Dear Healthcare Professional Letter regarding Baxter Colleague Infusion Pumps; and an article in the ADR News Bulletin announcing the recall of the DePuy ASR™ Hip Resurfacing System and DePuy ASR™ XL Acetabular.

Several illegal traditional medicines found to be adulterated by Western medicinal ingredients were detected and withdrawn from the market. These included “Te Xiao Huo Luo Jing” [特效活络金], “Jianbu HuQian Wan” [健步虎潛丸] and “HorKut Chooi Foong Hor Lok Tan” [虎骨追风活络丹].

Other recalled items included Beijing 101 hair growth products detected to contain minoxidil, and non-compliant nail polish products that contained benzene, dibutyl phthalate or diethylhexyl phthalate, which are prohibited ingredients under the ASEAN Cosmetic Directive. Following the detection of B Cepacia contamination in Oral Guard Antiseptic-Antiplaque Mouthwash and Care Wipes, two other mouthwash products found to be similarly contaminated were also taken off the market.

Due to the increased popularity of Traditional Chinese Medicine (TCM), it is important to enhance our vigilance over traditional medicines in Singapore. As part of our ongoing efforts, we will continue to work with TCM practitioners to review the Adverse Event (AE) reports that we receive and to increase awareness of AE reporting. We are working in collaboration with our healthcare colleagues in the hospitals to enhance the safety monitoring of AEs related to TCM.

Maximising the quality, safety and efficacy of vaccines is recognised as an essential component of a successful immunisation programme. HSA is collaborating with KK Women’s and Children’s Hospital (KKH) on a project known as HK-InSpire (HSA-KKH Inpatient Surveillance of Post-Immunisation Reactions). It was developed to monitor pandemic influenza vaccines, with KKH serving as a sentinel site for intensive inpatient surveillance for Vaccine Adverse Events (VAEs).

The project was expanded in March 2010 to study VAEs following childhood immunisations. From the period November 2009 to December 2010, KKH has screened 15,458 children for VAEs and 636 cases with suspected VAEs were further evaluated. Of these, 93 were deemed to be serious cases.

As medical AE reporting has the potential to improve patient safety, we have also conducted outreach programmes to encourage healthcare professionals to submit AE reports for health products. As part of these efforts, we are also developing plans to establish a common vigilance function to strengthen post-marketing surveillance of health products in Singapore. We aim to coordinate follow-up actions to address identified risks to the public by enabling vigilance information to be shared across departments and allowing coordinated operations related to post-market surveillance activities to be carried out.

Venturing into New Ground

We further expanded our capabilities in pharmacogenomics through training workshops for staff as well as research collaborations with hospitals and institutions in the area of serious skin reactions and drug-induced liver injuries. Review of pharmacogenomic data was incorporated as part of risk assessments for certain drugs. Important associations such as irinotecan-induced severe neutropenia in individuals carrying certain UGT1A1 polymorphisms were communicated to healthcare professionals through regulatory label changes and communication tools.

New research in the area of pharmacoeconomics was also initiated to critically evaluate the cost and benefit of various strategies for incorporating pharmacogenetic knowledge in clinical practice aimed at reducing the incidence of ADRs. Collaborations have begun with bioinformatic scientists and statisticians to develop tools to measure the extent of differentiation in genes important for the mechanism of action, metabolism and transport of drugs among the three major ethnic groups in Singapore and populations in the International HapMap project. This will assist regulators in understanding the potential for an altered benefit-risk profile when examining clinical trial data from populations that differ from those in Singapore.

Looking ahead, we will expand our pharmacogenomics research capacity through various initiatives. These include establishing the necessary infrastructure and frameworks to reduce the risk of ADRs through the identification and validation of genetic associations. Ultimately, we aim to translate research findings into clinical practice in order to benefit patients.

TAKING A FIRM STANCE

We stepped up our enforcement efforts this year against syndicates involved in the illegal sale of codeine cough mixtures. Some of these enforcement operations and raids were conducted jointly with the Singapore Police Force, Singapore Customs, and the Immigration and Checkpoints Authority of Singapore.

Due to the borderless nature of the Internet and the ease of purchasing illegal health products online, we are constantly on the lookout for illegal health products in cyberspace. In October 2010, we represented Singapore in Operation Pangea III, an effort involving drug regulatory authorities from 44 countries. Besides increasing public awareness of the risks of buying health products from unregulated websites, the operation sought to close down illegal websites and take action against offenders. About 5,000 units of illegal items including hair loss products, slimming drugs and contraceptives were seized during the operation.

Our fight against illegal health products involves collaboration on a global scale with various international partners and agencies. We were appointed as one of six Vice-Chairs in the WHO Working Group of Member States on Substandard/Spurious/Falsely-Labelled/Falsified/Counterfeit Medical Products, which examined WHO's role in the prevention and control of medical products of compromised quality and safety.

Going forward, we will strengthen our proactive enforcement measures by creating a framework for processing intelligence information using different types of analysis from tactical, operational and strategic perspectives. To tackle the rise in online distribution of health products, we will also be enhancing our capacity and capabilities in carrying out cyber-surveillance and cyber-crime investigations.

Strengthening Tobacco Control

In support of the National Tobacco Control Programme to curb underage smoking, we collaborated with the Health Promotion Board (HPB) to curb the supply and demand of tobacco products among youths. This included increasing the composition fine for underage smokers and penalties on errant retailers and licensees in December 2010. In addition, together with the policy makers at the MOH and HPB, we enhanced and renamed the parent Act to the Tobacco (Control of Advertisements and Sale) Act. This revised Act took effect on 1 September 2010.

We have ongoing initiatives to leverage community involvement and trade engagement to encourage compliance with tobacco control measures. These include setting up a tobacco licensing consultative panel in April 2011 to seek advice on contentious tobacco licence applications by retailers selling health-related or youth-centric products. We will also be holding trade briefings to ensure that retailers understand the new regulatory measures that will be rolled out over the next two years.

CLOSER INDUSTRY TIES

Recognising the competitive and challenging business environment faced by industry players, we strive to provide a positive experience by refining our policies and practices to meet business needs while ensuring that no sacrifices are made regarding health and safety. With this in mind, we have established a Service Management Office staffed by a cross-functional team to drive service-related initiatives and activities aimed at enhancing communication with industry and streamlining query-handling processes.

Maintaining an open communication channel with our stakeholders and industry partners has helped to facilitate the understanding of existing and upcoming regulatory requirements. Over the course of the year, we held numerous meetings, focus group discussions and dialogues to explain new regulatory policies and seek feedback on upcoming plans.

These included the inaugural Health Products Regulation Group (HPRG) Joint Regulatory Workshop held from 17 to 20 January 2011 for 700 industry and HSA participants, covering a wide range of topics including clinical practice, drug registration updates, analysis of Good Manufacturing Practice (GMP) inspection findings and GMP documentation. In addition, dialogue sessions were held with health product dealers to discuss new pro-enterprise initiatives and enhancements.

We keep industry stakeholders updated on the regulatory and administrative changes and the availability of services through our industry newsletter, HSA Connects. To complement this, we organised training sessions during the year to familiarise businesses with regulatory requirements and implementation timelines. These sessions helped industry members to discuss and clarify their doubts regarding product registration and regulatory processes, reducing uncertainty about the steps they need to take for product submissions.

Smoother Transactions

Besides improving communication with industry, we also established an integrated product enquiry handling workflow. Enquiry forms from the various HSA branches were consolidated into one form to streamline the query handling process.

To improve our customers' experience when transacting with us electronically, we have made enhancements to our online licensing system, PRISM, by implementing new application modules for the following:

- Licence to Import Controlled Drugs
- Licence to Export Controlled Drugs
- Licence to Export Psychotropic Substances
- Authorisation to Import Psychotropic Substances
- Authorisation to Import Restricted Substances

Under the enhanced system, users can also submit up to three major variation applications at any one time. Other improvements include the ability to view contraindications of herbal ingredients used in CPMs and the updated Anatomical Therapeutic Chemical Code in registered medicinal products.

External stakeholders and the public can also stay abreast of medical developments, such as information on approved new medicinal products, through the HSA website.

SHARING THE HSA EXPERIENCE

We brought our expertise in health product regulation to a global level throughout the year by sharing our insights and lessons learnt with international colleagues and stakeholders. Our participation in various meetings, working groups and committees provided valuable opportunities for the exchange of resources and knowledge.

We not only represented Singapore in the WHO Copenhagen Assessment Meetings No. 55 and 56, and contributed in the evaluation of Chemistry, Manufacturing and Controls, as a member of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as PIC/S), we also aim to share our expertise in GMP standards by cooperating and networking with international organisations. HSA is currently an Alternate Member in the PIC/S Executive Bureau, which provides us with a platform for creating a significant impact at the global level. We will also be co-hosting the PIC/S Expert Circle on Active Pharmaceutical Ingredients in Singapore in October 2011.

Besides being involved in PIC/S meetings and expert circles, we also chaired the ASEAN Sectoral Mutual Recognition Agreement for GMP Inspection. In June 2010, we were appointed Chair of the ASEAN Cosmetic Scientific Body for a term of three years. In August 2010, we were also appointed Chair of the ASEAN Traditional Medicines Health Supplements Product Working Group for three years.

Other achievements include our participation in the 8th Standing Committee Meeting and the 4th Symposium of the Western Pacific Regional Forum for the Harmonisation of Herbal Medicines. The presentations included updates on the surveillance of herbal medicines and Complementary Health Products in Singapore.

PRODUCTIVE PARTNERSHIPS

Together with the WHO and UMC, we hosted a 5-day Basic Pharmacovigilance Training Course from 31 May to 4 June 2010. The purpose of the course was to equip participants from ASEAN countries with the necessary skills to strengthen pharmacovigilance capabilities in their respective countries. The event featured local and international pharmacovigilance experts and offered a curriculum that included the management of traditional medicines and ADR reporting.

We have also organised a 3-day training workshop on Bioequivalence (BE) Trial Inspection in May 2010, which was attended by regulators from Hong Kong, Indonesia, Malaysia and Saudi Arabia. An experienced inspector from AFSSAPS (Agence française de sécurité sanitaire des produits de santé), the French Agency for the Safety of Health Products, shared the relevant knowledge to ensure that BE studies are conducted in compliance with the International Conference on Harmonisation (ICH)'s Good Clinical Practice and Good Laboratory Practice standards.

From 27 September to 1 October 2010, we also organised the inaugural annual basic training in Health Products Regulation in Singapore for overseas regulators, which was attended by regulators from Korea, Malaysia, Macau, Qatar and Saudi Arabia. We will continue to share and learn practices with other regulators.

We also hosted study visits throughout the year for delegates from regulatory authorities in Brunei, India, Macau, Hong Kong and China, introducing them to the roles and responsibilities of HSA, as well as the regulatory controls undertaken to ensure the supply of safe health products. These initiatives promote the exchange of information and help to identify future opportunities for collaboration.

We recognise that the challenges facing regulatory authorities are best addressed through joint efforts, rather than by individual organisations working in isolation. We therefore value opportunities that allow us to learn from others and apply international best practices in our regulatory processes.

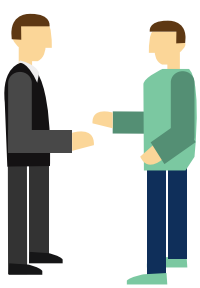
We co-hosted the 14th International Conference of Drug Regulatory Authorities (ICDRA) held from 30 November to 3 December 2010 together with the WHO. The year marked the 30th anniversary since the inauguration of this important gathering, and we were honoured to receive close to 400 members from over 90 countries, the highest rate of participation for the ICDRA to date. We were also very encouraged by the positive feedback received from the WHO and participants in the 4-day programme, which provided regulators the opportunity to share and discuss current and topical issues of global concern. These included access to quality medicines, counterfeit medicines, pharmacovigilance, clinical trials and lessons learned from the H1N1 pandemic.

Our ongoing efforts to broaden our global network and strengthen cooperation with international regulators included the signing of several Memoranda of Understanding (MOUs) during the year with the following entities:

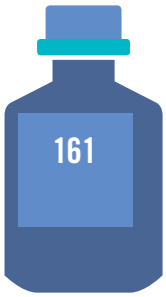
- Pharmaceutical and Food Safety Bureau of the Ministry of Health, Labour and Welfare and Pharmaceuticals and Medical Devices Agency, Japan
- Korea Food and Drug Administration, Republic of Korea
- Irish Medicines Board, Ireland
- New Zealand Medicines and Medical Devices Safety Authority
- Paul-Ehrlich Institute, Germany

These MOUs strengthen our strategic alliances and create opportunities for us to leverage the expertise of other authorities to contribute to the effectiveness of our regulatory decision-making.

Our work-sharing consortium with four agencies – Health Canada, Australia's Therapeutic Goods Administration, Swissmedic, and New Zealand's Medsafe – was strengthened as we tackled challenges in the field of GMP inspections. Through this consortium, we participated in three joint audits with our regulatory partners.



KEY STATISTICS



New Product Licences Issued

Registered Medicinal Products

Medical Device Product Registration Applications (Class A, B, C & D)

Medical Device Product Registration Applications by Product Models (Class A, B, C & D)

Medical Device Product Models Approved

Approved Products on the Singapore Medical Device Register (SMDR)

Chinese Proprietary Medicines Listed

Cosmetic Products Notified under the ASEAN Cosmetic Directive (ACD)

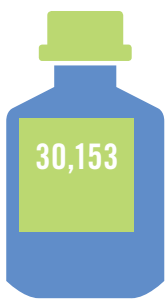
Clinical Trials Certificates Granted

Medical Advertisement Permits Issued

Site Audits Conducted for Good Manufacturing & Good Distribution Practices

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

Authorisation Letters for Travellers Bringing Personal Medication into Singapore



Spontaneous Adverse Drug Reaction Reports Received

Units (tablets/capsules/ liquids/creams) Seized

Tobacco Retail Outlets Licensed

Underage Youth Smokers Caught

BLOOD SERVICES GROUP

The Blood Services Group is dedicated to providing a sustainable and secure blood supply for Singapore. We aim to meet the clinical needs of our patients through the application of stringent standards and safety protocols aligned with international best practices.

Driven by our commitment to excellence, we are constantly adopting cutting-edge technologies that enable us to maintain high standards of safety and service delivery. Our expertise in the many fields of transfusion medicine has broadened over the years, including the fields of tissue typing and cell therapy.

By working closely with both local and international stakeholders, we achieve synergies that enable us to transform our organisation through constant self-improvement. Our collaborations with hospitals enable us to develop, improve and deliver life-saving treatments. Similarly, through our strong ties with international organisations such as the World Health Organization (WHO), and networks such as the Asia Pacific Blood Network (APBN) – of which HSA is a founding member – we enjoy opportunities to share ideas and expertise, which ultimately helps to improve our delivery of the national blood service in Singapore.

REACHING OUT TO BLOOD DONORS

2011 marks the 10th year of our strategic partnership with the Singapore Red Cross, our National Blood Donor Recruiter. Through this partnership, we have successfully increased the number of blood donations collected annually to meet the growing medical needs of our nation. A total of 63,796 donors made 99,355 whole blood and 10,685 apheresis donations in 2010.

Our blood donors were honoured for their contribution to saving lives at the World Blood Donor Day celebrations on 12 June 2010. Held at Clifford Square, the celebrations included a carnival and heritage-themed games for blood donors and their family members. More than 1,500 awards were presented to committed individuals and corporate/community groups for their support of the National Blood Programme.

The event also saw Mr Heng Chee How, Minister of State for the Prime Minister's Office, launching the "Someone in My Family is a Blood Donor" campaign, which aimed to identify Singapore's largest family tree of blood donors.

To make blood donation more convenient and to reduce waiting time at peak hours, an 'Express Q' system was introduced to enable donors with an appointment to donate at their scheduled times. In addition, enhancements were made to the Donorweb – a website that provides up-to-date information on mobile blood donation drives and the latest activities of the Blood Donor Recruitment Programme – to better indicate the supply status and to serve as a communication channel for issuing a call for donors of specific blood groups in the event of a blood shortage.

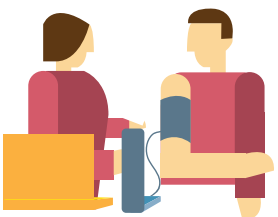
The opening of Bloodbank@Woodlands – Singapore's first fixed satellite blood collection centre, located in the Woodlands Civic Centre – marks a significant milestone in the national blood programme. Part of HSA's broader strategy to provide more fixed blood collection centres beyond the Bloodbank@HSA at Outram Road, it aims to bring blood donation to the community and to provide donors with greater convenience. Launched in January 2011 by Mr Khaw Boon Wan, Minister for Health, Bloodbank@Woodlands was developed with the support of the DesignSingapore Council to encourage regular blood donation within the community. As of end-March 2011, about 2,080 donors donated there, of which 381 were first time donors.

ENHANCING BLOOD SAFETY

We continuously evaluate and harness new technologies that will enable quality and safety improvements in the blood products provided to our patients. These include technologies that help to minimise the risk of infectious disease threats to the national blood supply. A new process currently under evaluation is pathogen reduction technology, which enables blood components such as platelets and plasma to be treated to reduce the levels of viruses, bacteria and parasites that may be present in the blood.

New testing technologies that have been adopted to improve infectious disease screening of blood donations include an enhanced Nucleic Acid Amplification Test (NAT) with even greater sensitivity in detecting the AIDS virus (HIV), Hepatitis B virus (HBV) and Hepatitis C virus (HCV). Additionally, we regularly evaluate new and emerging pathogens that may pose a potential threat to blood supply safety. This includes the West Nile Virus (WNV), which was studied and found to be not prevalent in the blood donor population in 2010.

In addition to the assessment of new tests and process technologies, we scan the environment continuously through its many networks and information channels to identify potential threats early. This includes the National Haemovigilance Programme, which has been in place in all hospitals since 2005. This enables us to put the necessary precautionary measures in place early, which may include the identification of risk factors and appropriate deferral measures.



HIGH EFFICIENCY AND QUALITY IN BLOOD PROCESSING

We recognise the need to regularly review our processes and implement technologies and programmes that will help us maintain high standards of quality and timely availability in the blood products provided to patients. Automated blood processing is one way in which we enhance the efficiency of our systems and ensure consistent high quality in the blood products processed.

To improve the production of platelets from whole blood donations, we have evaluated and validated a change in the process of platelet preparation from the platelet-rich plasma (PRP) method to the buffy-coat method. The new platelet preparation method allows white cell filtration and pre-storage pooling of platelets to be performed prior to issue, which will enable a better product that can be administered more easily. Using this method, platelets can be prepared up to 24 hours after the blood is collected compared to the current limit of six hours, which will also help to improve scheduling efficiency. The new buffy-coat method will be implemented into routine processes in 2011.

HIGH STANDARDS OF SERVICE AND QUALITY IN PATIENT TESTING

We place a high priority on the standards of quality and excellent customer service in our specialised testing laboratories. In order to provide highly specialised testing services that are accurate and timely, we have applied automation and new technologies to maintain our cutting edge.

The implementation of automated DNA extraction in October 2010 allowed us to handle higher sample volumes with greater efficiency in the Tissue Typing Laboratory. In addition, the laboratory introduced the use of a digital gel imaging system. Compared to traditional gel imaging using Polaroid films, the gel from polymerase chain reactions can be captured electronically and archived for a longer period.

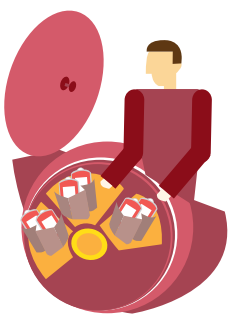
One of the challenges for a blood service is to provide blood support for patients with rare blood types. We are expanding and strengthening the rare blood donor database of special red cell antigen phenotypes. This database will enable us to call upon blood donors to donate when the need for rare blood types arises. We are also developing our expertise in molecular testing techniques for red cell antigen analysis, which will improve the ability to screen our donor panels for rare antigen genotypes, as well as the potential to identify new antigen genotypes in our population.

STRONG PARTNERSHIPS WITH HOSPITALS

We maintain strong partnerships with healthcare providers in public and private hospitals, with the aim of providing our patients with the best possible care.

During the past year, our medical staff collaborated with emergency medicine and trauma specialists from our public hospitals to review the effectiveness of a Massive Transfusion Protocol (MTP) in managing blood support in cases of severe trauma. We also worked with clinical staff at KK Women's and Children's Hospital in developing a pilot MTP for obstetric bleeding emergencies. Based on this, we, in collaboration with a workgroup comprising trauma specialists, are developing a national MTP that can be used in all hospitals in Singapore, and which will improve the speed and effectiveness of blood transfusion support during severe trauma situations and obstetric bleeding emergencies.

To ensure that blood and blood products are used with appropriate clinical indications, the HSA-Ministry of Health Clinical Practice Guidelines (CPG) for Clinical Blood Transfusion were developed and published in 2011. The CPG are distributed to all medical practitioners to guide them in good clinical practice.



ACHIEVING INTERNATIONAL EXCELLENCE AND ACCREDITATION

Accredited by AABB (formerly known as the American Association of Blood Banks) since 2006, we continued to attain our successful 2-yearly re-assessment in March 2010. AABB accreditation is a testament of our strong commitment to quality and continuous improvement in the field of transfusion medicine.

Our Tissue Typing Laboratory achieved additional accreditation by the American Society for Histocompatibility and Immunogenetics (ASHI) for the use of Flow Cytometry and Solid Phase Technology for HLA Antibody Screening & Identification and Crossmatching. These tests are used to support renal transplant programmes at local hospitals.

In line with our dedication to providing quality blood products, we undergo regular audits and inspections by regulatory agencies to ensure compliance with Good Manufacturing Practices (GMP) standards for blood products. This includes risk assessment audits by the Ministry of Health as well as inspections by overseas agencies.

We also conduct audits on hospitals and clinics where blood transfusion is performed to ensure that the blood and blood products provided are properly and safely transported, stored and issued.

PLAYING OUR PART IN THE GLOBAL BLOOD COMMUNITY

As the national blood service and a WHO Collaborating Centre in Transfusion Medicine, we have played an active role in global blood and transfusion safety and availability initiatives. In addition to conducting training programmes through workshops and attachments for staff from other countries, our senior medical and scientific staff participate in global technical consultations and international forums involving important issues affecting transfusion medicine and cell therapy.

We produced a compilation of the proceedings at the three WHO workshops on Management of National Blood Programmes which were held in Singapore from 2007 to 2009. This document, published by WHO, will provide countries, donor agencies, international organisations and others with the information they need to strengthen their capacity in education and training in all aspects of blood transfusion. We also provided inputs for another WHO publication, a manual titled “Design Guidelines for Blood Centres”. The guidelines are intended to be a useful reference for authorities responsible for developing and designing facilities to house blood transfusion services.

We also recognise the need to remain relevant and keep abreast of the latest technologies and developments around us. Our staff participated in international conferences to learn about international trends and best practices in this field. We also gave poster and oral presentations at these events, which provide invaluable opportunities for the sharing of work experiences and the exchange of information.

We interact closely with leading scientists in the field to remain informed about ongoing research work and to maintain our position as a leading voice in transfusion medicine in the region. As part of the HSA Academy Series, we hosted a symposium titled "Scientific Advances and Regulation in Blood and Cell Therapy" on 14 July 2011. The symposium served as a platform for regulators and blood services to explore new developments in blood and cellular therapy, including the relevant impacts and challenges for stakeholders.

We also collaborated with the International Alliance for Biological Standardization (IABS) to organise the 7th IABS Symposium on Advances in Transfusion Safety from 15 to 17 July 2011, in partnership with the APBN and the Agency for Science, Technology and Research (A*STAR). This international symposium focussed on current issues in the areas of blood supply and transfusion safety, as well as regulation and cell therapy.

One way in which we seek to strengthen our networking and regional cooperation efforts is through staff exchange programmes. Through a Memorandum of Understanding between the Beijing Red Cross Blood Centre and ourselves to promote training exchange programmes, staff are given the opportunity to gain working experience in a different work environment, broaden their skill sets and exchange knowledge at an international level.

During the past year, we also participated actively in key APBN initiatives, including the online publication of a White Paper on Dengue and the Blood Supply. We continue to work with other APBN members in various collaborative activities including the comparison of practices, clinical red cell utilisation studies, anaemia in blood donor studies, blood inventory management, and pandemic planning programmes. In 2011, the APBN will link up with other blood alliances in Europe and the Americas to form a larger international network.

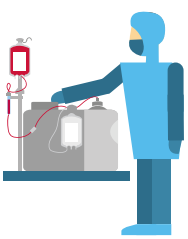
LOOKING TO THE FUTURE

Going forward, we will continue to strengthen our resources and boost our capabilities to meet the future.

We believe in continuous improvement. Over the years, we have made significant strides in building up our professional capabilities and improving operational efficiency and quality. In 2010, we adopted a Lean Management Initiative to embed lean management and continuous improvement principles into our daily work practices. Our staff underwent intensive training in Lean Six Sigma and formed project teams to study specific processes and develop initiatives for development using DMAIC (Define, Measure, Analyse, Improve and Control) and Lean methodologies. These projects aim to reduce wasted time and shift the focus of work from running processes to managing change, with the ultimate goal of improving service to our patients and blood donors.

The project teams studied ways to improve the turnaround time for blood donation and urgent blood requests from private hospitals, as well to reduce platelet discard during component preparation. Following the success of the Lean Management Initiative in the pilot year, the programme is being expanded to involve more project teams.

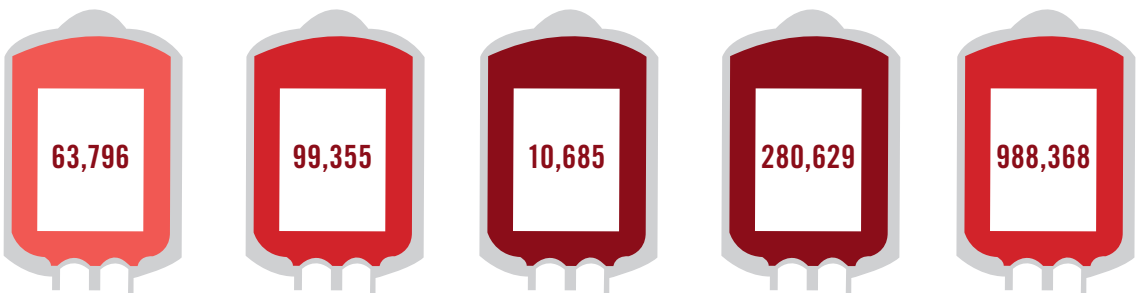
In addition, we will continue to champion good research governance built on internationally recognised standards of good practice. A comprehensive framework for research was developed and implemented in 2010, to enable stronger coordination and management of research conducted within the group. We also work closely with the HSA Academy to ensure that all research projects involving human subjects – such as those involving blood or cell samples obtained from blood donors – are approved by an institutional review board in compliance with national ethical guidelines.



We continue to grow our research capabilities to ensure that we continue to produce and collect scientific data and developments that contribute to medical science and practice. For example, projects being carried out in our Cell Therapy Facility have moved forward to publication and for prospective clinical translation. This includes the establishment of a successful protocol for the generation of a greater number of potent Lymphokine Activated Killer (LAK) cells/Natural Killer (NK) cells.

The Cell Therapy Facility continues to work on optimising and streamlining protocols and parameters, such as the scale-up and testing of haematological patient samples, by taking into account the stringent requirements of future production in a GMP environment. It is also preparing for international accreditation to ensure that quality systems and practices are benchmarked to international standards.

KEY STATISTICS



Blood Donors

Whole Blood Donations

Apheresis Donations

Processed Blood Components

Laboratory Tests

APPLIED SCIENCES GROUP

HSA's Applied Sciences Group serves the administration of justice with its expertise in forensic medicine and science, analytical testing and chemical metrology.

From crime scenes to courtrooms and pharmacies to grocery stores, our diverse capabilities span many scientific fields and strengthen our position as a key resource in serving the administration of justice and the safeguarding of public health. The combination of expertise within our laboratories allows us to explore scientific synergies across our professional groups and pursue exciting opportunities for innovation.

We will continue to leverage these synergies in our pursuit of excellence in all facets of our organisation by growing our capabilities, pushing the frontiers of scientific enquiry and translating knowledge into tangible benefits for our many clients and stakeholders.

OUR QUEST FOR EXCELLENCE

In March 2011, our Forensic Medicine Division (FMD) was successfully re-accredited by the US-based National Association of Medical Examiners (NAME). This accreditation provides recognition that FMD meets the highest and most comprehensive international standards of mortuary operations, thereby strengthening the trust that stakeholders have in our capabilities in this field. FMD is the only forensic pathology entity in Asia accredited by NAME.

Our analytical testing laboratories are committed to providing prompt, reliable and value-adding solutions to a broad client base. With our Food Safety and Pharmaceutical Divisions achieving SAC-SINGLAS (Singapore Accreditation Council-Singapore Laboratory Accreditation Scheme) accreditation in May 2011, we remain focussed on maintaining our standing as a service provider of choice.

As part of our ongoing efforts to ensure operational readiness, we participated in Operation Andromeda II in March 2011, which incorporated a joint exercise involving the Singapore Civil Defence Force's (SCDF) Emergency Response Procedures. This exercise tested our ability to respond to a critical event through the deployment of our Bio-Safety Level 4 portable dual-containerised mortuary, known as Blue Box II. We mobilised Blue Box II using flatbed trucks, set up operations at a different site and worked through various mock emergency scenarios. The success of this exercise reinforced that we have the capabilities to respond efficiently and effectively to situations requiring mobile mortuary support.

Implementing Innovation

We continually explore new ways to refine internal processes and methods to improve the outcomes of our work. Innovation is a key priority and we regularly invest in advanced technology to keep pace with emerging techniques and industry developments.

Together with HSA's Health Products Regulation Group, we acquired two portable devices during the past year: an AHURA (now known as Thermo Scientific) FirstDefender (a portable Raman system) and an AHURA TruDefender (a portable Fourier Transform Infrared system). Used in screening health products for the rapid identification of unsafe or counterfeit health products, these devices enhance our work processes in various regulatory enforcement scenarios, such as conducting market surveillance and gathering operational and strategic intelligence.

FMD acquired a new 64-slice MSCT scanner as part of our commitment to transforming and improving work processes through the adoption of cutting-edge technology. The commissioning of the scanner in August 2010 involved extensive staff training, including building up expertise in operating the scanner and reading and interpreting CT images. The scanner is now used on a daily basis to assist in autopsy work. We will continue to actively develop our capabilities in post-mortem radiological imaging, particularly through the use of CT scans as a non-invasive tool for the examination of findings and the validation of diagnoses.

Greater Foresight in Forensics

We strengthened our forensic investigation capabilities during the past year by developing three new trace evidence databases.

One of these is a glass database, which was created to capture important physical and chemical properties of commonly used glass types in Singapore. To date, we have collected and analysed 75 glass samples from different sources, including the Traffic Police, automotive workshops and glass manufacturers. This database will serve as a valuable resource for the interpretation of glass evidence in criminal and traffic investigations.

Clothing samples have also been collected and analysed to compile chemical profiles for a clothing and upholstery database, which will provide useful background data on matrix interferences in the analysis of fire debris. In addition, a local petroleum-based ignitable liquids database was created to assist in fire investigations, with 24 samples analysed to date. These three databases provide forensic scientists with useful reference data to interpret laboratory findings holistically within the physical context of the crime, and help solve cases quickly and efficiently.

NEW POSSIBILITIES

Drawing on our extensive expertise and scientific capabilities, we provided critical investigative and analytical support to law enforcement agencies throughout the year. We successfully assisted the Singapore Police Force (SPF) in the investigation of several major cases, including a hit-and-run traffic accident that required paint and glass analyses, and a murder case that required bloodstain pattern analysis for the reconstruction of events. The DNA Database Laboratory scored a first in the use of a new genetic algorithm, familial searching, in the tracing of a murder suspect through his relatives in the criminal database.

Our collaboration with SPF in developing a vehicular paint database has won several Ministry of Home Affairs (MHA) and HSA awards. This initiative was also presented at the International Exposition on Team Excellence in June 2010.

More capabilities are being built to enable us to stay ahead. We are actively developing our expertise in forensic anthropology – a specialised field that has evolved in recent years beyond simply the identification of skeletal remains to include the determination of special characteristics and the nature of death based on the analysis of skeletal remains. We have set up a forensic anthropology laboratory and are currently developing methods for processing, measuring and reproducing skeletal remains to generate information and materials that could be used by pathologists and would be admissible in court.

During the past year, we achieved synergies by capitalising on the in-house expertise and capabilities across our laboratories to deliver innovative solutions to customers and bring science to a higher level of excellence. We steadily expanded and extended our testing proficiencies for a wide range of products, from pharmaceuticals to food to cosmetics.

Expanding Tests for Pharmaceuticals

Our Pharmaceutical Laboratory took steps to enhance its procedures for screening pharmaceuticals and medicines. We added 35 new drugs to the accredited screening list for Western drug adulterants in herbal medicines, bringing the total to 413 Western drugs.

In addition, we achieved ISO 17025 accreditation for our testing methods for identifying organophosphorus pesticides and lobeline in herbal medicines using Gas Chromatography with Tandem Mass Spectrometry (GC/MS/MS) and Liquid Chromatography with Tandem Mass Spectrometry (LC/MS/MS), respectively.

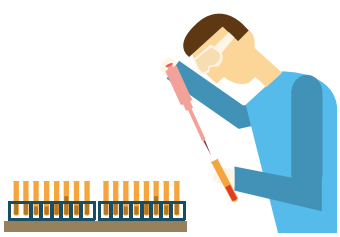
Stepping Up Food Safety

Our laboratories play a key role in maintaining food safety in Singapore by supporting surveillance and enforcement activities in this field. With successful accreditation under the SAC-SINGLAS for 19 new tests in 2010, our Food Safety Division is now offering our clients a wider range of reliable services and providing greater assurance regarding the safety of food products.

Due to the global trend of increasing food fraud, we implemented a new testing service using advanced Isotopic Ratio Mass Spectrometry (IRMS) instrumentation to detect adulteration in food products such as honey and alcoholic beverages. Water safety has also been further enhanced, with the scope of testing services carried out for the Public Utilities Board extended to include the analysis of cylindrospermopsin, microsystines and anatoxin A in water.

Our Chemical Metrology Laboratory completed seven regional and international comparative studies during the past year. Some touched on the issue of food safety such as melamine in milk powder and benzoic acid in curry paste. Others included the assessment of the purity of organic compounds and trace elements in drinking water. We also organised two proficiency-testing surveys for local food testing laboratories with the Singapore Accreditation Council.

Moving ahead, we will focus our food safety research and development resources in four key areas, namely food additives, food contact materials, environmental contaminants and mycotoxins. Collaborating closely with the Agri-Food and Veterinary Authority – one of our key stakeholders in this field – we will provide customised solutions to address emerging food safety issues.



Enhanced Testing for Cosmetics

Our Cosmetics Laboratory successfully accredited two new tests under the ISO 17025 scheme during the past year – the assay of mercury by Inductively Coupled Plasma Mass Spectrometry (ICPMS) and the screening of corticosteroids by High Performance Liquid Chromatography (HPLC) and Gas Chromatography Mass Spectrometry (GCMS).

We have also developed four new testing methods to support the Health Products Regulation Group, including:

- Determination of 1,4 dioxane in hair care products
- Determination of formaldehyde in hair care products
- Determination of volatile organics (methanol and toluene) in nail polish
- Determination of phthalates (dibutyl phthalates and bis[2-ethylhexyl] phthalates) in nail polish

COMBATING COUNTERFEITS

Together with HSA's Health Products Regulation Group, we continue to support INTERPOL in the analysis of counterfeit drugs in Operation Storm, a joint effort to combat fake drugs in the region. To date, the physical and chemical characteristics of more than 570 drug samples and their packaging materials have been entered in a counterfeit drugs database.

We collaborated with other countries in the region and the World Health Organization (WHO)'s Western Pacific Regional Office, to set up the Storm Network, to coordinate, improve and shape anti-counterfeit drug efforts in the region.

An agreement with DIR Technologies from Israel resulted in the installation at HSA of a novel counterfeit detection device code-named "Black Eye" – a prototype based on thermal infrared imaging technology and a sensitive mid-wave IR detector to analyse drugs. Using the device, we carried out testing on erectile dysfunction drugs Cialis and Viagra, establishing protocols for the identification of counterfeit tablets. The project revealed that more than 90% of each type of counterfeit tablet could be successfully distinguished from authentic tablets.

INCREASED CAPABILITIES AND CAPACITIES

We have also made advances in developing new methods using IRMS to trace the source of counterfeit drugs. We have completed carbon isotope ratio studies on authentic Cialis samples to establish variances in isotope ratios for different product batches from different manufacturing sites, and compared them with IRMS data from 50 counterfeit Cialis samples. We are continuing to analyse these samples to identify their hydrogen and oxygen isotope ratios.

The isotope characterisation of counterfeit drug samples will be integrated into a master database of counterfeit drugs encountered in the region. This database will include investigation, chemical and physical information regarding the samples and will be shared with other countries in the region.

With a broad range of customers who rely upon our expertise in various fields, we are constantly seeking ways to enhance and extend our services in order to remain a valued partner. Throughout the past year, we focussed on strengthening these relationships while helping our clients achieve their strategic goals.

Our collaboration with the MHA's Home Team Departments in providing forensic science analytical expertise was given an added boost with the signing of a Service Level Agreement. In recognition of the increasingly important role forensic science will play in Singapore's system in the administration of justice, the agreement aims to establish a comprehensive framework that will strengthen HSA's capability to further improve the scientific scope and timeliness in delivery of our services.

We also created a new customised evidence collection kit to help police officers collect and preserve unknown solids found at crime scenes, resulting in more efficient lab processing and analysis. Blood-screening kits were also purchased by the National University of Singapore for educational purposes.

Extending Our Outreach

During the course of the year, we were honoured to have had the opportunity to share knowledge and skills in our various fields of expertise with a wide range of stakeholders. These included officers from the Central Narcotics Bureau, SCDF and SPF, as well as magistrates and law clerks. We also conducted lectures for undergraduate and postgraduate students.

In response to the growing interest in the intriguing fields of forensics, our laboratories participated in the Singapore Science Centre's Crime Scene Investigation exhibition. The event, which was tied to the hit television series, was held from October 2010 to February 2011. Through displays showcasing our forensic equipment and tools, contests, talks, and information panels profiling our expertise and capabilities, visitors were given insights into the scientific principles and techniques used in crime-solving.

TAKING PRIDE IN OUR PARTNERSHIPS

We place a high priority on strengthening our partnerships with both local and overseas collaborators, and we take pride in contributing positively to the global scientific community through these relationships.

In March 2011, two HSA staff members were part of a 5-member Disaster Victim Identification team sent to New Zealand by the Singapore Armed Forces in response to the devastating earthquake that hit Christchurch on 22 February 2011. There, the team assisted in victim identification efforts, which involved conducting autopsies; processing antemortem dental, fingerprint and DNA data; and reconciling antemortem data with the postmortem data of unidentified remains. Specifically, HSA contributed in the areas of autopsies and DNA analysis.

Scientists from our various divisions and laboratories participated in overseas exchange and training programmes throughout the year in several different countries, including Australia, Austria, Malaysia, South Korea and Thailand. At the same time, we also hosted our counterparts from various countries, including Abu Dhabi, Japan and Taiwan. Such interaction with overseas colleagues provides opportunities for us to share our expertise and build up HSA's international reputation, while at the same time helping us to improve our own capabilities by learning from others. We also provided consultancy on quality systems and American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ACSLD/LAB) international accreditation in the discipline of toxicology to Thailand's Central Institute of Forensic Science.

Putting Singapore on the World Map

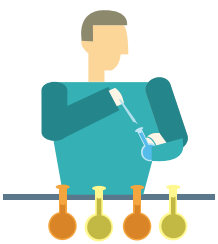
We are actively involved as members of numerous international forums and workgroups, through which HSA has taken on a variety of leadership roles. We served as the President of the Asian Forensic Sciences Network (AFSN) Board from 2009 to 2011. Apart from chairing the AFSN's Trace Evidence Workgroup and DNA Workgroup, we currently hold the vice-chairmanship of AFSN's Quality Assurance and Standards Committee. We also sit in the steering committee for the Illicit Drugs Workgroup, and represent the group at meetings held by the Scientific Working Group for the Analysis of Seized Drugs (SWGDRUG).

In April 2010, we attended the United Nations Office on Drugs and Crime (UNODC) International Quality Assurance Programme Standing Panel Meeting and were invited to serve in the UNODC International Panel of Forensic Experts for a 2-year term.

We also serve as the Vice-Chair in the WHO's Tobacco Laboratory Network. This appointment represents recognition for our ongoing contributions to international tobacco control initiatives and provides opportunities for us to continue playing a leading role in tobacco testing and research at a global level. In July 2010, we successfully co-hosted a 2-day TobLabNet Working Group Meeting with WHO Tobacco Free Initiatives for delegates from 13 countries.

In November 2010, we successfully co-hosted the 2nd Consultative Committee for Amount of Substance – Metrology in Chemistry (CCQM) Working Groups Meeting (Bioanalysis, Gas Analysis and Organic Analysis) with the Agency of Science, Technology and Research (A*STAR)'s National Metrology Centre. Overseas delegates from 35 agencies in 27 countries attended the meeting.

Our Pharmaceutical Laboratory was invited to collaborate with the WHO in the characterisation of international chemical reference substances (ICRSs), which are used by quality control laboratories to test pharmaceuticals according to physical and chemical tests and assays described in *The International Pharmacopeia.* We will be participating in two ICRS trials in 2011.



We will also continue to support the WHO in the development of draft monographs for *The International Pharmacopeia* on anti-infective and antiretroviral medicines. These activities play an important role in ensuring unified standards of quality, safety and efficacy in pharmaceutical products worldwide.

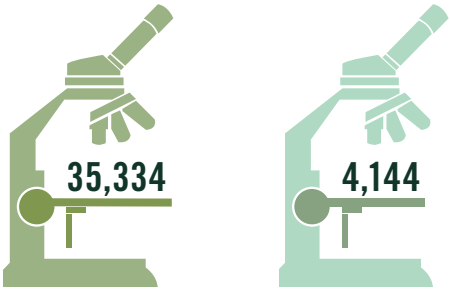
As the WHO Collaborating Centre for Food Contamination Monitoring since 2008, we continue to play an active role in updating stakeholders regarding the levels and trends of contaminants in food via our annual food contamination database. This information is critical for understanding the contribution of food contaminants to total human exposure, and for assessing the significance of food contamination with regard to public health and trade.

We recognise the importance of staying up-to-date with the latest developments and emerging issues in the area of food safety. In addition to participating in food contact materials training at the European Reference Laboratory for Food Contact Materials in Italy, we also connected with the scientific community through various oral and poster presentations locally and internationally during the past year. These events included the International Mycotoxin Conference; ASEAN Food Safety Standards Harmonization Workshop; and the Food Standards Committee Meeting hosted by SPRING Singapore.

In the year ahead, we will devote more efforts to consolidate our multiple capabilities into an even better coordinated strategy to deliver more cutting-edge solutions. We also look forward to working collaboratively with our partners to tap scientific and systemic synergies that will offer deeper and more progressive insights in the arenas of analytical testing and forensics.

KEY STATISTICS

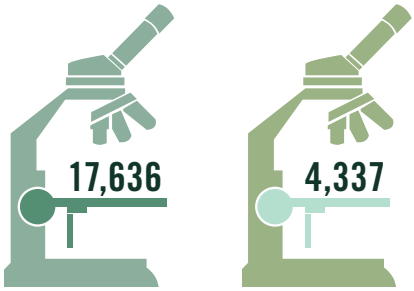
FOOD SAFETY DIVISION



Analytical Tests for Laboratory Samples

Analytical Cases

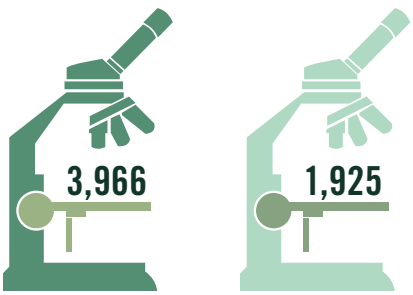
PHARMACEUTICAL DIVISION



Analytical Tests for Laboratory Samples

Analytical Cases

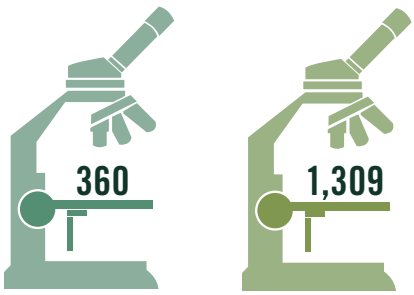
FORENSIC MEDICINE DIVISION



Coroner's Cases

Coroner's Autopsies

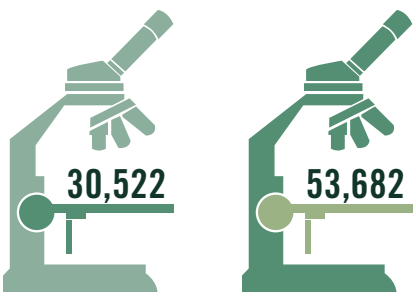
FORENSIC SCIENCE DIVISION



Forensic Cases

Forensic Exhibits

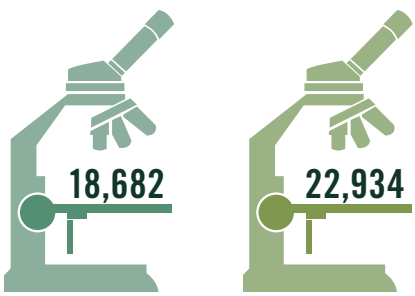
ILLICIT DRUGS & TOXICOLOGY DIVISION



Forensic Cases

Forensic Exhibits

BIOLOGY DIVISION



Forensic Cases

Forensic Exhibits

FINANCIAL HIGHLIGHTS

BALANCE SHEET

	FY10/11 $'000	FY09/10 $'000	Increase/ (Decrease) $'000	%
Property, Plant & Equipment	102,103	104,110	(2,007)	(2)
Intangibles	7,680	10,323	(2,643)	(26)
Current Assets	58,220	44,508	13,712	31
Total Assets	**168,003**	**158,941**	**9,062**	**6**
Equity	91,576	81,809	9,767	12
Long-term Loans	24,932	21,840	3,092	14
Other Non-Current Liabilities	12,207	13,688	(1,481)	(11)
Current Liabilities	39,288	41,604	(2,316)	(6)
Total Equity and Liabilities	**168,003**	**158,941**	**9,062**	**6**

INCOME & EXPENDITURE STATEMENT

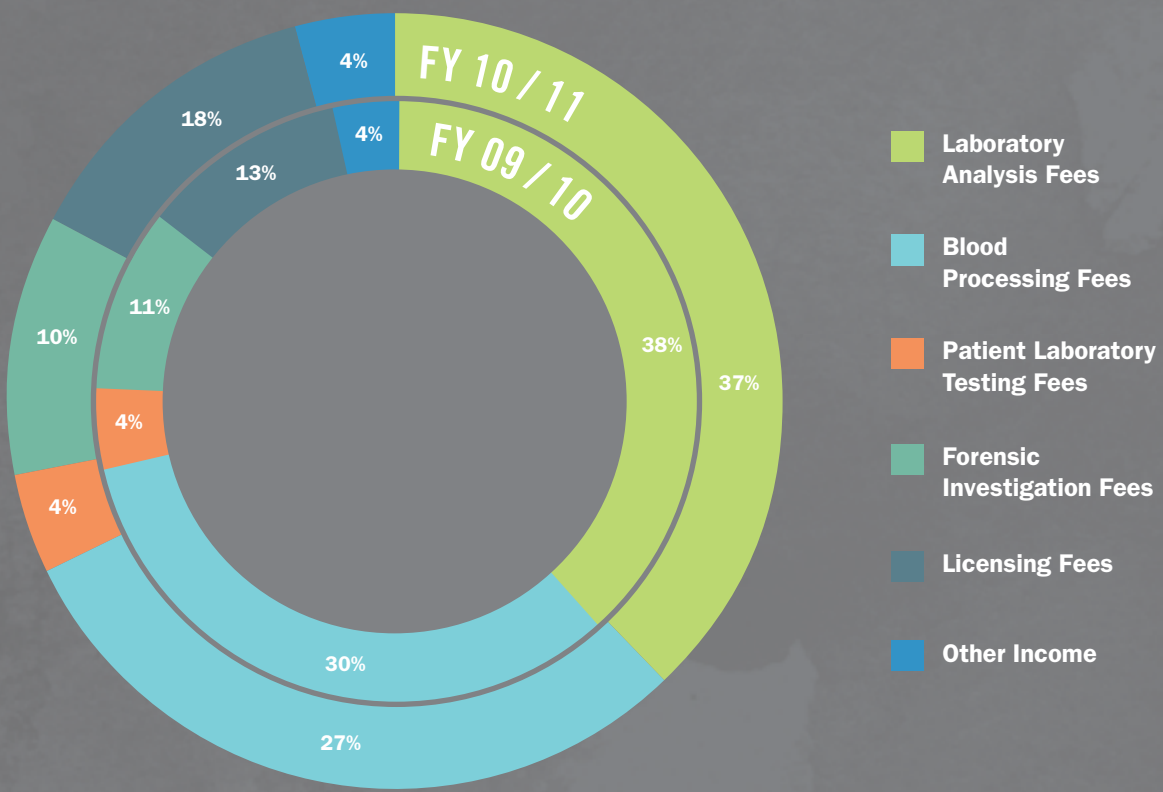
The Authority has achieved an overall net surplus of $3.5m for FY10/11.

	FY10/11 $'000	FY09/10 $'000	Increase/ (Decrease) $'000	%
Operating Income	83,926	71,180	12,746	18
Operating Expenditure	(154,820)	(135,856)	18,964	14
Deficit before Government Grants	**(70,894)**	**(64,676)**	**6,218**	**10**
Government Grants	75,114	68,300	6,814	10
Surplus before Contribution to Consolidated Fund	**4,220**	**3,624**	**596**	**16**
Contribution to Consolidated Fund	(717)	(616)	101	16
Net Surplus	**3,503**	**3,008**	**495**	**16**

OPERATING INCOME

The Authority earned a total operating income of $83.9m in FY10/11, an increase of $12.7m (18%) over FY09/10's revenue of $71.2m.

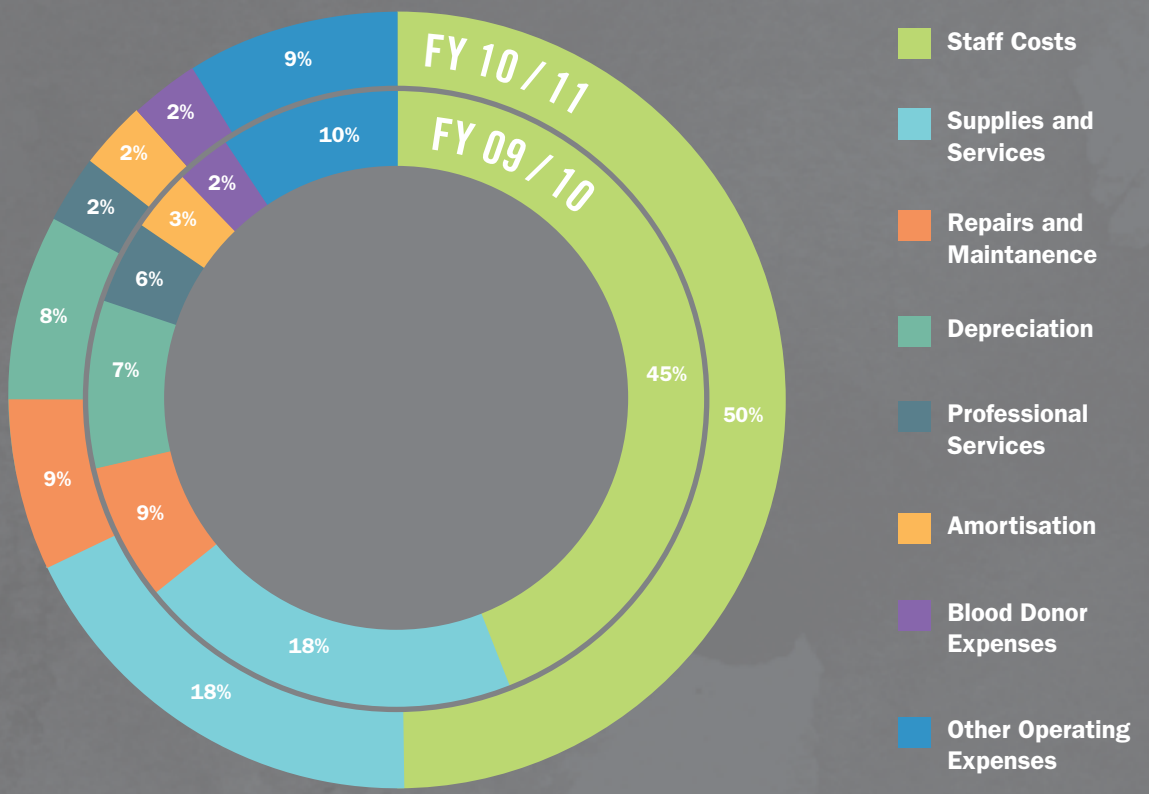
	FY10/11 $'000	FY09/10 $'000	Increase/ (Decrease) $'000	%
Laboratory Analysis Fees	31,478	26,691	4,787	18
Blood Processing Fees	22,829	21,695	1,134	5
Patient Laboratory Testing Fees	2,939	2,823	116	4
Forensic Investigation Fees	8,793	7,985	808	10
Licensing Fees	14,691	9,430	5,261	56
Other Income	3,196	2,556	640	25
Total Operating Income	**83,926**	**71,180**	**12,746**	**18**



OPERATING EXPENDITURE

The Authority incurred a total operating expenditure of $154.8m in FY10/11, an increase of $19.0m (14%) over FY09/10's expenditure of $135.9m.

	FY10/11 $'000	FY09/10 $'000	Increase/ (Decrease) $'000	%
Staff Costs	75,896	60,389	15,507	26
Supplies and Services	27,877	24,037	3,840	16
Repairs and Maintenance	14,212	12,772	1,440	11
Depreciation	11,703	10,050	1,653	16
Professional Services	3,759	8,031	(4,272)	(53)
Amortisation	3,474	3,722	(248)	(7)
Blood Donor Expenses	3,599	3,382	217	6
Other Operating Expenses	14,300	13,473	827	6
Total Operating Expenses	**154,820**	**135,856**	**18,964**	**14**



TRANSFORMATION THROUGH SYNERGY

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