

creating value





A strong upward direction and movement represents a dynamic, progressive, forward-looking organisation of excellence.

The blue arch symbolises our global outlook and global renown. The two white strokes suggest progression and continuous development. The integrated blue and white segments express our strong collaborative and interactive approach. The firm but fluid "tick" communicates confidence in HSA approval and regulatory authority.

Our choice of blue colour projects our foundation of professionalism, strength and integrity. The refreshing golden yellow signifies our vibrant, innovative and people-oriented culture.

Viewed in its totality, our logo encapsulates our vision, mission and orientation towards the future.

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VISION to be world class for scientific and regulatory
expertise in health sciences

mission

to excel in applying science to:

- support healthcare services and regulation
- serve the administration of justice
- enhance safety in our community

values

- we are committed to professional excellence
- we create value for our clients
- we uphold our professional integrity
- we value and nurture our staff
- we encourage innovation and enterprise

“The main job of an organisation
is to *create value.*”

- Peter Drucker



Lim Mong King

Professor Lim Mong King

Chairman

foreword

In recent years, there is a growing trend across many parts of the world - including Singapore – of increased public expectations for accountability from the public sector agencies and the services they provide.

Many public sector agencies now also face simultaneous demands to raise revenues, reduce costs and increase the quality of their services.

Similarly, as a trusted authority in scientific and regulatory expertise, we at HSA are subject to intense public scrutiny in our mission to safeguard public health and safety.

In our quest for excellence in our regulatory, forensic, scientific and blood banking services, we need to strike a right balance between raising performance levels and reducing costs.

This means taking a value-oriented approach to identify and focus on our core capabilities so as to create and deliver value for the public we serve, our clients and stakeholders.

Having reached our fourth year of formation, we must continue to review and rethink our processes in order to improve the way by which these services are delivered and maintained in a knowledge-based and globalised economy.

Most importantly, *Creating Value* as an HSA core value must be fuelled by a bold vision and a relentless drive and passion inside each and every HSAian, who has the potential to influence the customer experience and facilitate value creation.

Going forward, we will continue to seek and create optimal value in our journey for excellent professional expertise and service quality.



A handwritten signature in black ink, consisting of the initials 'CH' followed by a stylized surname.

Dr Tan Chor Hiang
Chief Executive Officer

preface

In our fourth year since formation, we aimed to apply and achieve a value-oriented approach for HSA to stay relevant, ready and responsive to challenges, risks and opportunities in the ever-changing operating environment.

With a better informed public, we can be sure that there will be demand for a higher level of services, satisfaction and accountability.

Regulatory policies, decisions and processes are expected to be effective, transparent and made in a timely manner to not only safeguard public health and safety but to ensure accessibility to products and services that will help to improve quality of life.

Our expertise in the regulatory, scientific, forensic and blood banking services must be benchmarked with the best in the world so as to keep pace with the latest technology and the best international practices and standards.

During the year, we conducted a series of strategic review sessions to review HSA's objectives, performance measures and key initiatives for the year. A key priority identified was to sharpen our organisational efficiency and professional excellence to bring about a higher level of performance that is value-focussed, people-oriented and customer-centred.

While being committed to financial viability and stewardship, we strive to create value, improve value delivery and boost our service delivery by engaging our clients and stakeholders to understand their needs, so as to deliver outstanding and cost-effective services and solutions.

To unleash the value potential in our services, we will need to better integrate, consolidate and strengthen our diverse capabilities across our seven professional centres, as well as develop and nurture new expertise to meet the challenges of the future.

On the regulatory front, an integrated framework for regulating pharmaceuticals, medical devices, radiation-emitting apparatus and other health products will optimise the synergies between the regulatory centres to better leverage on each other's strengths and minimise duplication of work and resources.

As a provider for highly specialised forensic, scientific and blood banking services, we continuously enhance our processes and procedures by ensuring that our professionals are equipped and trained to keep up with the latest scientific and technological developments.

Strategic alliances which leverage on the strengths of our partners and counterparts must be continuously forged to allow us to upgrade our capabilities, benchmark our standards and benefit from international best practices. We will continue our quest for international recognition of our standards through formal accreditation exercises.

We also recognise that the interests of our customers, employees and stakeholders are intricately linked. Hence, we work towards translating our core values into action by encouraging a corporate culture that is innovative, creative and flexible.

Moving ahead, as we strive to create and deliver better value in our service delivery, we remain committed to achieving our mission to excel in regulatory, professional and organisational excellence.

our board members



Chairman

01. **Professor Lim Mong King**
Deputy President
Nanyang Technological University

Board Members

02. **Dr Arthur Chern**
Director, Health Service Development
Ministry of Health

03. **Mr Giam Chin Toon**
Senior Counsel
Wee Swee Teow and Company

04. **Mr Khoo Chin Hean**
Chief Executive Officer
Energy Market Authority

05



05. **Associate Professor Kong Hwai Loong**
Senior Consultant Medical Oncologist and Physician
H L Kong Medical Oncology Centre
Mount Elizabeth Medical Centre

06



06. **Professor Edmund Lee**
Professor of Pharmacology
Faculty of Medicine
National University of Singapore

07



07. **Mr Lim Hock San**
President and Chief Executive Officer
United Industrial Corporate Ltd and Singapore Land Ltd

08



08. **Professor Low Teck Seng**
President and Chief Executive Officer
Republic Polytechnic

09



09. **Ms Olivia Lum**
President and Chief Executive Officer
Hyflux Ltd

10



10. **Mr Ng Wai Choong**
Deputy Secretary, Industry
Ministry of Trade and Industry

*board
committees*
1 April 2004 - 31 March 2005

Audit Committee

Mr Lim Hock San	Chairman
Associate Professor Kong Hwai Loong	Member
Ms Olivia Lum	Member
Mr Ng Wai Choong	Member

Staff Establishment Committee

Mr Giam Chin Toon	Chairman
Dr Arthur Chern	Member
Professor Edmund Lee	Member
Professor Low Teck Seng	Member

Cost and Price Review Task Force

Mr Khoo Chin Hean	Chairman
Dr Arthur Chern	Member
Ms Olivia Lum	Member

Regulatory Oversight Committee

(covering the Centre for Drug Administration, Centre for Medical Device Regulation and Centre for Radiation Protection)

Professor Edmund Lee	Chairman
Dr Arthur Chern	Member
Mr Giam Chin Toon	Member
Associate Professor Kong Hwai Loong	Member
Mr Lim Hock San	Member

Service Provision Oversight Committee

(covering the Centre for Analytical Science, Centre for Forensic Medicine, Centre for Forensic Science and Centre for Transfusion Medicine)

Professor Low Teck Seng	Chairman
Mr Khoo Chin Hean	Member
Ms Olivia Lum	Member
Mr Ng Wai Choong	Member

corporate governance statement

The Board and Management are committed to maintaining a high standard of corporate governance and endorse the recommendations of the Code of Corporate Governance. The Board believes that good governance is essential to 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, industry, clients, 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 9 members who are appointed by the Minister for Health for a 3-year term. The Board meets every quarter to set strategic directions and to formulate policies, as well as to assume the role of monitoring and reviewing of policies leading to improved management and outcomes.

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 are deemed to be interested in any transactions which may be made by and between such corporations.

Accountability and Audit

The Senior Management Team is accountable to the Board and the Board is accountable to the Minister for Health. The Board is furnished with complete and adequate information in a timely manner to allow the Board to discharge its duties properly. Senior management staff are invited to give briefings and to 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 in reviewing and assuring itself of 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 the auditors.

(i) Internal Audit

HSA has engaged an external party to provide the internal audit function on an annual basis. To date, internal audit has covered areas such as the Inventory and Procurement processes, Billings and Collections, Human Resource and Payroll, Accounts Payable, and Fixed Assets.

(ii) External Audit

The external statutory audit of the financial statements has been conducted by Deloitte & Touche for the past four financial years since the formation of HSA. The Ministry of Finance allows the same Public Accounting firm to perform the external statutory audit of a Statutory Board for a maximum of five consecutive years. The compulsory rotation of the external auditors after five years is to ensure independence and objectivity of the statutory audit function.

(b) The Staff Establishment Committee

The Staff Establishment Committee assists the Board in reviewing the adequacy of staffing numbers and budgets to meet operational needs and of Human Resource Policies for compensation and benefits. It oversees some staff matters such as the appointment of senior management positions.

(c) The Cost & Price Review Task Force

This Task Force assists the Board and Management in reviewing the existing fee structures in the Professional Centres and making recommendations for changes where necessary. This is to ensure compliance with local and international policies and practices, acceptance by the local community and industry and, at the same time, ability to meet the organisation's objectives and mission.

(d) The Regulatory Oversight Committee

This Committee assists the Board in providing an independent oversight of issues related to the regulatory functions of the Centre for Drug Administration, Centre for Medical Device Regulation and Centre for Radiation Protection.

(e) The Service Provision Oversight Committee

This Committee assists the Board in providing an independent oversight of issues related to the provision of services by the Centre for Analytical Science, Centre for Forensic Science, Centre for Forensic Medicine and Centre for Transfusion Medicine.

Communication with Stakeholders

The Professional Centres 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.

senior management

- 01. **Dr Tan Chor Hiang**
Chief Executive Officer
- 02. **Dr John Lim**
Director, Centre for Drug Administration



- 03. **Mr Wong Yew Sin**
Director, Centre for Medical Device Regulation
- 04. **Mr Stephen Chong**
Director, Centre for Radiation Protection

05



06



07



08



09



05. **Dr Paul Chui**
Director, Centre for Forensic Medicine

06. **Dr Chow Shui Tse**
Director, Centre for Forensic Science

07. **Dr Diana Teo**
Director, Centre for Transfusion Medicine

08. **Associate Professor Bosco Chen Bloodworth**
Director, Centre for Analytical Science
Quality Service Manager

09. **Mr Vincent Fong**
Director, Corporate Management Group

principal officers

■ CENTRE FOR DRUG ADMINISTRATION

Director
Dr John C W Lim

Senior Clinical Pharmacology Advisor
Prof Vernon Oh

Product Evaluation & Registration Division
Deputy Director & Head, New Chemical Entities, Innovative Therapeutics Group
Dr Gerard Wong

Senior Assistant Director & Covering Head, Drug Registration Branch
Dr Kerwin Low

Head, Biologics, Innovative Therapeutics Group
Dr Philip Ngai

Head, Policy & Regulatory Affairs
Ms Lee Hui Keng

Acting Head, Clinical Trials Branch
Foo Yang Tong

Compliance & Complementary Medicines Division
Senior Deputy Director
Yee Shen Kuan

*Complementary Medicines Branch
Deputy Director, Complementary Medicines Branch & Head, Cosmetics Control Unit*
Mrs Marie Tham

Head, Chinese Proprietary Medicines Unit
Ms Chu Swee Seng

Head, Health Supplements Unit
Chao Ye Peng

*Compliance Branch
Acting Head, Prosecution Unit*
Kelvin Tan

Head, Investigation & Surveillance Unit
R. Sivalingam

Head, Tobacco Regulation Unit
Tham Lup Hong

Manufacturing & Quality Audit Division
Deputy Director & Head, Good Manufacturing Practice Unit
Sia Chong Hock

Head, Good Distribution Practice Unit
Ms Hui Foong Mei

Head, Certification Unit
Dr Lai Weng Fai

Head, International Operations Unit
Boon Meow Hoe

Pharmacovigilance, Communications & Research Division
Deputy Director
Mdm Suwarin Chaturapit

Head, Pharmacovigilance Unit & Head, Information & Research Unit
Ms Chan Cheng Leng

International & External Programmes
Deputy Director
Mrs Marie Tham

Head, Regulatory Support Unit
Ho Yu Nam

CENTRE FOR MEDICAL DEVICE REGULATION

*Director &
Registrar, Contact Lens Practitioners Board*
Wong Yew Sin

CENTRE FOR RADIATION PROTECTION

*Director &
Head, Environment Radiation & Waste
Management Unit &
Head, Nuclear Safety & Emergency
Planning Unit*
Stephen Chong

*Head, Ionising Radiation Control Unit &
Head, Ionising Radiation Dosimetry Laboratory*
Ms Annie Tan

*Head, Non-Ionising Radiation Control Unit &
Head, Non-Ionising Radiation Dosimetry Laboratory*
Dr Phua Tan Tee

Chief Radiographer
Tan Joo Thai

CENTRE FOR FORENSIC MEDICINE

Director
Dr Paul Chui

*Deputy Director &
Head, Professional Standards & Research*
Associate Professor Gilbert Lau

Principal Consultant Forensic Pathologists
Dr Clarence Tan
Dr Wee Keng Poh

*Consultant Forensic Pathologist &
Head, Professional Training & Education*
Dr George Paul

Consultant Forensic Pathologist
Dr Teo Eng Swee

Associate Consultant Forensic Pathologist
Dr Lai Siang Hui

CENTRE FOR FORENSIC SCIENCE

Director
Dr Chow Shui Tse

Physical Evidence Division
*Deputy Director &
Head, Criminalistics Laboratory*
Dr Tay Ming Kiong Michael

*Head, DNA Profiling Laboratory &
Head, DNA Database Laboratory*
Mrs Tan Wai Fun

Head, Document Examination Laboratory
Ms Lee Gek Kwee

Drugs & Toxicology Division
*Deputy Director &
Head, Narcotics I Laboratory*
Dr Lee Tong Kooi

Head, Narcotics II Laboratory
Dr Lui Chi Pang

Head, Toxicology Laboratory
Dr Danny Lo

CENTRE FOR TRANSFUSION MEDICINE

Director
Dr Diana Teo

Deputy Director, Blood Resources
Dr Tan Hwee Huang

Deputy Director, Clinical Service
Dr Mickey Koh

Head, Blood Processing & Inventory
Ng Kok Quan

Head, Quality Control
Ms Sally Lam

Head, Hospital Services
Dr Marieta Chan

Head, Blood Collection
Ms Ong Chye Leng

Head, Blood Programme Support
Ms Koh Geok Tin

Quality Manager
Ms Tan Meng Kee

CENTRE FOR ANALYTICAL SCIENCE

Director
Associate Professor Bosco Chen Bloodworth

*Head, Planning, Research & Development Unit &
Quality Manager*
Ms Cheah Nuan Ping

Head, Quality Support Unit
Ng Soon

Food Division
*Deputy Director &
Head, Food Laboratory*
Ms Chan Sheot Harn Joanne

Head, Water Testing Laboratory
Dr Chow Yue Thong

Pharmaceutical Division
*Deputy Director &
Head, Pharmaceutical Laboratory*
Ms Low Min Yong

*Head, Cosmetics Laboratory &
Head, Cigarette Testing Laboratory*
Mrs Wong Geok Eng

CORPORATE MANAGEMENT GROUP

Director, Corporate Management
Vincent Fong

Deputy Director, Corporate Services
Chua Hong Tong

Deputy Director, Finance
Philip Ngiam

Deputy Director, Human Resource
Mrs Sarojini Padmanathan

Deputy Director, Information Management
Andrew Chong

CEO'S OFFICE

Quality Service Manager
Associate Professor Bosco Chen Bloodworth

Deputy Director, Corporate Communications
Ms Jeannie Thng

Deputy Director, Office for Corporate Planning
Ms Lim Peck Seah

about HSA

At the **Health Sciences Authority (HSA)**, we apply medical, pharmaceutical and specialised scientific expertise to safeguard public health and safety in Singapore. As one multidisciplinary agency, we serve as the national regulator of all therapeutic products by providing a seamless yet rigorous regulatory process to the healthcare and biomedical sciences industries. We also operate the national blood bank, Bloodbank@HSA, protecting the integrity of the nation's blood supply. As the national reference agency, we exploit specialised scientific, forensic, investigative and analytical capabilities in order to serve the administration of justice and enhance safety in our community.

Our seven professional centres in HSA seek to excel in applying science to support healthcare services and regulation, serve the administration of justice and enhance safety in our community.

Our **Centre for Drug Administration** safeguards public health and contributes to the development of the biomedical sciences by administering a robust, scientific and responsive regulatory framework, which ensures that medicines, innovative therapeutics and health-related products in Singapore meet appropriate standards of safety, quality and efficacy.

Our **Centre for Medical Device Regulation** ensures that medical devices meet the requirements of safety, efficacy and quality so as to protect public health and safeguard the interests of the patients and users.

Our **Centre for Radiation Protection** excels in radiation science so as to enforce and promote the radiation safety of workers, the public and the environment; and ensure that irradiating apparatus and nuclear materials meet the statutory requirements of quality, safety and efficacy.

Our **Centre for Forensic Medicine** excels in applying forensic medicine and related sciences to serve law enforcement and the administration of justice; support healthcare services, medical audit, medical education and health regulation; and enhance safety in the community.

Our **Centre for Forensic Science** excels in forensic science for the purpose of law enforcement, medico-legal investigations and administration of justice.

Our **Centre for Transfusion Medicine** excels in transfusion medicine to ensure a safe and adequate national supply of blood and blood products, the appropriate use of blood and blood products, and to provide high quality blood banking services.

Our **Centre for Analytical Science** excels in applying analytical science to safeguard public health by providing high quality, cost-effective and timely service to our clients.

For more details on the Health Sciences Authority, [visit www.hsa.gov.sg](http://www.hsa.gov.sg).

highlights of the year

April 2004

The Authority hosted the HSA-State Food and Drug Administration (China) Memorandum of Understanding's 1st Plan of Co-operation Meeting of the Singapore-China Working Group on Traditional Chinese Medicines Co-operation from 20 to 24 April.

CDA

- Launched its Overseas Audit Programme for all overseas manufacturers intending to market their western medicinal products in Singapore.
- Implemented Phase I of the Quality Medicines Harmonisation Programme which involved the introduction of requirements for new products.
- Conducted a joint operation with the Singapore Police Force and Immigration Checkpoints Authority to uncover illegal sale of cough mixture containing codeine.

CRP

- Hosted the International Atomic Energy Agency (IAEA) regional training course on IAEA's regulations for the safe transport of radioactive materials from 5 to 16 April. It was attended by 30 participants from 15 countries. Its Centre Director was also nominated to be the Training Course Director.

CFM

- Began its review of its professional and biosafety work processes, as part of the preparations to seek accreditation with the National Association of Medical Examiners.

May 2004

The Authority celebrated its 3rd Anniversary on 8 May with a retro-themed Dinner & Dance.

The Authority collaborated with the National University of Singapore [NUS] to host the 2nd HSA-NUS Scientific Seminar on 19 May. A total of 22 papers and 17 posters was presented based on the theme "Health Through Scientific Research."

CDA

- Issued a public advisory to increase awareness and advise consumers to be cautious about misleading or exaggerated claims in health supplement advertisements.

CMDR

- Developed and soft launched the online Singapore Medical Device Register (SMDR) to capture database information of legally available devices and establishments dealing with devices. It will be ready for public access when the medical device regulation is enacted.
- Conducted industry briefings in May and June on the Medical Device Information and Communication System (MEDICS@hsa), registration of medical devices and listing in SMDR.

CFS

- Its Toxicology Laboratory started a new service to provide screening and confirmation of buprenorphine and its metabolite norbuprenorphine.

CTM

- Reduced the interval for Apheresis donations from six to four weeks to meet increased need in blood and blood products, and to make platelet donations more convenient for our donors.

CAS

- Its Centre Director was invited to participate in the International Laboratory on Counterfeit Medicines (ILFCM). ILFCM aims to share information on scientific techniques used to detect counterfeit drugs and harmful substances in dietary supplements.
- Its Cigarette Testing Laboratory participated in the 12th Asia Collaborative Study on ISO Tar and Nicotine in Cigarettes together with 55 laboratories from 20 countries in the Asia-Pacific region and Europe.

June 2004

CDA

- Amended the Medicines Act to allow HSA to take into consideration the status of the original patent when granting marketing approval to another product and to extend the data exclusivity period to five years from the date of marketing approval.

CTM

- Celebrated the inaugural World Blood Donor Day on 14 June with Singapore Red Cross to thank blood donors and to promote the importance of voluntary, non-remunerated blood donations.

CFS

- Its Narcotics II Laboratory started testing for the presence of benzodiazepines in urine for the various enforcement agencies.

CAS

- Under the European Union-ASEAN Co-operation Programme on Standard, Quality and Conformity Assessment, its Food and Cosmetic Laboratories were designated as ASEAN reference laboratories, with two of its scientists being appointed as Senior Experts in this programme.

July 2004

The Authority received the Singapore Family Friendly Award 2004 on 21 July for its efforts in promoting the benefits of balancing work with a healthy family life, while introducing innovative pro-family work practices and policies.

CDA

- Reviewed the potential risk of Rosuvastatin (Crestor®, AstraZeneca) in Asian population following the completion of a local pharmacokinetic study which showed that Asian patients react to the drug differently. The package insert of the product was subsequently amended to recommend use of a lower dose for the Asian population.

CAS

- Its Cosmetic Laboratory added two new tests to identify oestrogens and tretinoin in skin care cosmetic in the scope of its accredited tests.

August 2004

The Authority celebrated National Day with a National Day Observance Ceremony and started a 4-Colour House Teams to encourage camaraderie and esprit de corps among HSAians. All HSAians were grouped into four different colour houses and dressed up in different cultural costumes for the National Day Songs Singing Competition.

The Authority organised a series of strategic review sessions to review its objectives, performance measures and key initiatives for the year.

CDA and CMDR relocated to their new premises at Biopolis, the newly completed biomedical sciences hub in Asia.

CDA

- Implemented the revised Smoking (Control of Advertisements and Sale of Tobacco) (Labelling) Regulations 2003, which introduced the new requirement of graphic health warning labels.

- Established a Joint Confidentiality Commitment Agreement with the US Food and Drug Administration (FDA) to facilitate better exchanges of information.



September 2004

To promote awareness of each of HSA's five core values, the Authority introduced a series of *Living Core Values, the HSA Way* posters and launched the *Core Values Recognition Programme* to recognise HSA officers who are living examples of "the HSA Way" and role models for a particular HSA core value.

CDA

- Was appointed by the ASEAN Consultative Committee for Standards and Quality Pharmaceutical Product Working Group as the focal point for the EC-ASEAN Pharmaceutical GMP Harmonisation Programme.

- Issued public and professional advisories on the worldwide voluntary recall of Vioxx following concerns of cardiovascular risks. Enquiry lines were set up for consumers and healthcare professionals.

- Was appointed by World Health Organisation (WHO) as a consultant for several projects, including a workshop for China's State Food and Drug Administration held in Shenyang, China on Post-marketing Regulation of Medicines and a Good Clinical Practice Inspection of an Indian Clinical Research Organisation under the WHO Prequalification Project in November 2004.

CRP

- Its Centre Director led the Singapore delegation team comprising officers from various ministries and agencies for the IAEA 48th General Conference in Austria and delivered the Singapore Statement during the plenary session.

CTM

- Hosted the first Asia-Pacific Joint Symposium on Transfusion Medicine and Alternatives on 18 and 19 September with the Network for the Advancement of Transfusion Alternatives.

CAS

- Its Pharmaceutical Laboratory was invited by the British Pharmacopoeia Commission Secretariat to contribute towards the development of the British Pharmacopoeia monographs for Traditional Chinese Medicines and Ayurvedic Medicines.

October 2004

To sustain an innovative culture, the Authority introduced to HSAians Part II of the FISH! Philosophy – FISH! Sticks, which emphasised the importance of commitment to the HSA corporate vision.

CMDR

- Launched COLLINS, an integrated electronic system for licensing and registration of contact lens practitioners on 12 October.

CTM

- Hosted the 3rd WHO Quality Management Training (Advanced course) on Blood Transfusion Services in the Western Pacific Region from 4 to 16 October.

- Launched its newly renovated Donors' Refreshment Lounge, specially dedicated to all blood donors, in recognition of their selfless contribution of the gift of life.

CAS

- Two of its scientific officers were invited as ASEAN Experts for the Regional Workshop on Access to Reference Substances held in Bangkok from 21 to 22 October.

November 2004

The Authority held the Annual IDEAS Forum on 17 November to encourage and inspire HSAians to be creative in their work and to showcase their innovative award winning creations and projects.

CDA

- Implemented the Disease Awareness Campaigns (DAC) Guidelines developed jointly with the Singapore Association of Pharmaceutical Industries to guide the pharmaceutical industry on DAC advertisement.
- Three GMP Auditors were appointed as technical experts under the EC-ASEAN Pharmaceutical GMP Harmonisation Programme to assist in the review of GMP implementation in some ASEAN countries.

CFS

- Its Narcotics II Laboratory started a new testing service for lysergide (LSD) and its metabolite.
- Partnered Nanyang Technological University's (NTU) School of Biological Sciences to organise the NTU-JC-HSA Challenge held from November 2004 to February 2005.

CTM

- Implemented the Hepatitis B Virus and Nucleic Acid Test screening for all donated blood and Malaria Polymerase Chain Reaction test to screen blood donated by donors with Malaria risk.

December 2004

The HSA Family came together for some healthy sporting action, fun and games between the four houses on 30 December at the annual HSA Games Day.

The Authority participated in the Asian Tsunami Relief Efforts as follows:

- CFM sent two forensic medicine teams to Phuket to assist in the Disaster Victims Identification (DVI) efforts and donated body bags for Mercy Relief's disaster relief operations in Aceh, Indonesia.
- CFS sent two DNA profiling experts to Phuket to assist in identifying Singaporean victims and in the international DVI efforts. Its DNA Laboratories were also involved in the profiling work of the personal effects collected from the Singaporean victims and helped to expedite the processing of blood samples collected from the next-of-kin.
- A medical officer from CTM joined the Singapore Red Cross' medical relief team in Meulaboh, Indonesia.
- CDA issued guidelines to facilitate the supply of medicinal products donated by Singapore-based companies and individuals to Tsunami hit countries.



- A fund-raising drive for the tsunami victims led by the HSA Staff Well-being Committee was organised for the Singapore Red Cross. HSAians also donated clothings, blankets, medical and food supplies for the victims.
- For their active participation in the international DVI efforts, members of our forensic teams were awarded commendation medals and certificates by Mr Khaw Boon Wan, Minister for Health, in recognition of their contribution to the relief efforts.

CDA

- Launched the new *Guidelines for Submission of Non-prescription Medicines* which provided a simpler evaluation process for low risk non-prescription medicines.
- Legislated the exemption from product licensing requirement of medicinal products manufactured solely for export out of Singapore.
- Implemented the Demerit Points System to curb the illegal sales of tobacco products to underaged youths.
- Reviewed the risk profile of Selective Serotonin Reuptake Inhibitors (SSRIs), in particular the risk of suicidality in children and adolescents. Healthcare professionals were alerted to the risk. The package inserts of SSRIs and related antidepressants were also amended to reflect this safety concern.

January 2005 CDA

- Launched a voluntary Good Distribution Practice (GDP) certification scheme for companies to obtain an official GDP certification from HSA to facilitate the sales, supply and export of their medicinal products.
- Developed guidelines for manufacturers of complementary medicines to minimise the transmission risk of Transmissible Spongiform Encephalopathy in complementary medicines.

CAS

- Its Food Laboratory launched a new analytical service to screen irradiated food by photostimulated luminescence.
- Its Pharmaceutical Laboratory expanded its existing accredited adulterants' list for Chinese Proprietary Medicines screening by another 52 adulterants.

February 2005

CDA

- Introduced a simplified pharmacy registration scheme to facilitate registration of new pharmacy outlets of existing licensed pharmacies.
- Conducted a Traditional Medicine (TM) survey to gain insights on local TM products, dealers and users for the formulation of a control framework for TM in Singapore.
- Issued a new guidance document outlining the important drug safety information to be submitted by pharmaceutical companies in Singapore.

CAS

- Its Pharmaceutical Laboratory re-examined three chemical reference substances namely Indomethacin, Fluorouracil and Methorexate, for the WHO Collaborating Centre for Chemical Reference Substances in Sweden.

March 2005

PASSION - Pass Innovation On, was the fiery theme for the Authority's Innovation Month. A series of creative and fun-filled activities over a 1-month period was held to stimulate the heart and mind of every HSAian to embrace innovation with passion.

CMDR

- A pilot implementation of additional e-services in MEDICS@hsa was introduced on 1 March.

CFS

- Its DNA Database Laboratory underwent an audit by American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB) from 7 to 10 March and was subsequently accredited on 8 April.
- All its other forensic laboratories also passed the annual ASCLD/LAB audit and its DNA Profiling Laboratory also passed the external ASCLD/LAB audit in March.

CAS

- Was invited to participate in the Asia Pacific Laboratory Accreditation Co-operation proficiency testing programme organised by Hong Kong Laboratory Accreditation Services on the Analysis of Lead in Herbal Medicine.

international visitors at HSA

Date	Visits By:
5 April 2004	Dr Han Tieru, WHO Representative for Brunei, Malaysia and Singapore
5 - 6 April 2004	Professor Helen Whitwell, Professor of Forensic Pathology, University of Sheffield, United Kingdom
12 April 2004	Delegation from Shandong Province of People's Procurator Police Department led by Mr Zhang Qibo, Head, Shandong Province Police Department
21 April 2004	Delegation from State Food and Drug Administration, China
3 May 2004	Dr Albert Farrugia, Senior Principal Research Scientist & Head, Blood and Tissues Unit, Office of Devices, Blood and Tissues, Therapeutic Goods Administration, Australia
3 - 5 May 2004	Mr Keith M. Smith, Manager, Medical Device Assessment Section, Therapeutic Goods Administration, Australia
12 - 13 May 2004	Delegation from Hong Kong Special Administrative Region's Department of Health led by its Director, Dr T H Leung
21 May 2004	Dr Vivienne Christ, Chief Microbiologist, Therapeutic Goods Administration, Australia
28 May 2004	Associate Professor David Wells, Head, Clinical Forensic Medicine, Victorian Institute of Forensic Medicine, Australia
31 May 2004	Delegation from the Royal Government of Bhutan, Ministry of Health led Dr Dorji Wangchuk, Director, Department of Public Health
3 June 2004	Ms Shelley Tang, Head, Medical Device Assessment Section, Office of Devices, Blood and Tissues, Therapeutic Goods Administration, Australia
15 June 2004	Delegation from China's Jinan Board of Health led by its Deputy Director, Mr Ma Jiren
24 July 2004	Delegation from Thailand led by His Excellency Phongthep Thepkanjana, Justice Minister
27 July - 6 August 2004	Professor D J Anstee, Director, Bristol Institute for Transfusion Science and International Blood Group Reference Laboratory, Bristol, United Kingdom

Date	Visits By:
27 August 2004	Dr John McEwen, Medical Advisor, Therapeutic Goods Administration, Australia
13 - 22 September 2004	Dr David Ranson, Deputy Director, Victorian Institute of Forensic Medicine, Australia
15 September 2004	Mr Mike Ward, Assistant Manager, Therapeutic Products Directorate, Health Canada
20 September 2004	Delegation from Fiji led by Mr Solomon Naivali, Minister of Health
11 - 12 October 2004	Delegation from Malaysia's Ministry of Health led by Mr Zamane Bin Abdul Rahman, Deputy Director, Engineering Services Division
11 - 13 October 2004	Delegates from Vietnam's Ministry of Health National Institute of Drug Quality Control
18 - 19 October 2004	Dr Martin Devitt, Medical Advisor, Clinical Section, Office of Devices, Blood and Tissues, Therapeutic Goods Administration, Australia
21 October 2004	Delegation from Thailand led by Mr Manit Sutaporn, Deputy Permanent Secretary of Justice
8 November 2004	Dr Lee Seung Hwan, DNA specialist, Supreme Public Prosecutor's Office, Korea
6 - 7 December 2004	WHO Fellows from China's Academy of Traditional Chinese Medicine and State Administration of Traditional Chinese Medicine
24 January - 1 February 2005	Professor Beatriz Silva Lima, Health Manpower Development Programme Expert, Portugal
17 February 2005	Dr Han Tieru, WHO Representative for Brunei, Malaysia and Singapore
17 March 2005	Dr Niyada Kiatying-Angsulee, Lecturer, Faculty of Pharmaceutical Sciences, Chulalongkorn University, Thailand



creating value

As we strive towards our strategic destination in being world class for scientific and regulatory expertise in health sciences, we must focus on our core competencies to create value for the public we serve, our clients, stakeholders and employees.

Our Centre for Drug Administration (CDA) safeguards public health and contributes to the development of the biomedical sciences by administering a robust, scientific and responsive regulatory framework, which ensures that medicines, innovative therapeutics and health-related products in Singapore meet appropriate standards of safety, quality and efficacy.





REGULATING PHARMACEUTICALS AND HEALTH-RELATED PRODUCTS

Our **Centre for Drug Administration (CDA)** administers the Medicines Act, the Poisons Act and the Smoking (Control of Advertisements and Sale of Tobacco) Act, amongst others, to safeguard public health.

We implement a wide range of regulatory measures to help protect consumers from the potential risks of medicines, complementary health products, cosmetics and tobacco products. These measures include:

- Pre-market evaluation and approval of medicinal products to ensure their safety, efficacy and quality;
- Certification and monitoring of clinical drug trials conducted in Singapore;
- Pre-market assessment and listing of Chinese proprietary medicines based on set criteria for safety and quality;
- Good Manufacturing Practice inspection/audit and licensing of manufacturers/assemblers of products regulated;
- Good Distribution Practice inspection/audit and licensing of wholesale dealers, importers of products regulated and registration of retail pharmacies;
- Post-market surveillance and monitoring of products sold in Singapore to ensure regulatory compliance;
- Monitoring of adverse drug reactions and risk assessment of medicinal products after they have been marketed;
- Provision of up-to-date and unbiased drug information to healthcare professionals and consumers;
- Regulating advertisements and sales promotions of medicinal and complementary health products sold over the counter;

- Regulating tar and nicotine content in tobacco products, licensing of tobacco importers and dealers, and enforcement of prohibition of tobacco advertisements and prohibition of smoking by youths under 18;
- Enforcement of legal requirements and investigation of activities that might contravene legislation administered by CDA.

In spite of this spectrum of regulatory measures, consumption of medicinal and complementary health products is always associated with varying degrees of risk that cannot be totally removed by regulatory activities alone. Consumers are advised to obtain as much information as they can about what they are using from reputable sources like their healthcare professionals, so that they can make informed decisions and choices on suitability of such products for their particular needs.

To facilitate the timely approval of new and innovative medicines in Singapore and the region, we also aim to provide the expertise to evaluate new drugs which have not been evaluated and approved by any other regulatory agencies. This includes medicines targeted for diseases prevalent in the region. CDA has now begun to evaluate new vaccines not registered elsewhere at time of submission. A new Biologics Unit has also been set up within our Innovative Therapeutics Group (ITG) to manage the increasingly important portfolio of biologic and biotech products. From the wider national perspective, ITG is part of the infrastructure to develop Singapore into a regional medical hub for life sciences research and development.

Evaluation and Licensing of Medicinal Products

• Product Licences

In FY 2004/05, 189 product licences for new and generic medicinal products were issued. We processed and approved 5,130 applications for variations in product licences for medicinal products, with 119 applications involving changes to the indications, dosing regimen and/or patient group. The remainder involved changes to the product licence holder, product owner, product manufacturer/re-packer, and/or product specifications.

• New Drug Approvals

From 1 April 2004 to 31 March 2005, we approved 20 new chemical and biological entities, which were presented in 32 new medicinal products, for marketing in Singapore. A list of new drugs approved in each calendar year from 2001 to 2004 can be viewed at our website at:

http://www.hsa.gov.sg/html/business/cda_adr_bulletins.html

• Non-Prescription Medicines Guidelines

The new *Guidelines for Submission of Non-Prescription Medicines* was launched in December 2004. These guidelines provide for a simpler evaluation process for low risk non-prescription medicines, and were implemented following an 8-month pilot phase.

• Implementation of US-Singapore Free Trade Agreements (US-S-FTA)

The Medicines Act was amended to effect implementation of the patent linkage and modified data exclusivity systems under the US-S-FTA from July 2004.

• Exemption for Export-only Medicinal Products

The exemption from product licensing requirement of medicinal products manufactured solely for export out of Singapore was endorsed by the Ministry of Health and legislated to take effect from 1 December 2004.

• Quality Medicines Harmonisation Programme (QMHP)

The QMHP was initiated to update and strengthen our regulatory framework to ensure that medicines available in Singapore meet relevant standards of quality, and that Singapore's regulatory requirements and standards are harmonised with current ASEAN and international standards. This ongoing review process comprises three key components:

- (1) Good Manufacturing Practice audit of manufacturers,
- (2) Bioequivalence study requirements, and
- (3) Enhanced pharmaceutical data review. A phased approach has been adopted to ameliorate the impact on industry.

Following dialogue sessions with the industry, Phase I of the QMHP implementation plan which involved the introduction of requirements for new products came into effect on 1 April 2004.

Improving Consumer Access to Medicines

• Reclassification of Medicinal Products

Duro-Tuss Expectorant, Duro-Tuss Mucolytic Cough Liquid 12 mg/15 ml and Xenical (Pharmacy-Only) Capsule were reclassified from Prescription-Only Medicine (POM) to Pharmacy-Only Medicine (P) during the year.



As of 31 March 2005, 7,145 medicinal products were registered in Singapore. The forensic classification of products is shown below:

Forensic Classification	No. of Registered Products	Percentage
Prescription-Only Medicines (POM)	4,909	69%
Pharmacy-Only Medicines (P)	986	14%
General Sale List Medicines (GSL)	1,250	17%
Total	7,145	100%

Approval for Importation of Unregistered Medicinal Products on a Named Patient Basis

We issued 2,138 individual approvals for import of unregistered medicinal products, not registered for various reasons, for treating specific patients. Such products are imported for use by individual patients and administered under the supervision and responsibility of their attending doctors.

Certification of Clinical Drug Trials

During the year, 200 clinical trial certificates* were granted to various institutions. The number of applications increased by 25% compared to 2003, when clinical research was significantly affected by the SARS outbreak. There was also a significant increase of 30% in phase I studies in the same period. Trials in therapeutic areas of oncology and gastroenterology, in particular Hepatitis B studies, formed the bulk of studies being conducted in Singapore.

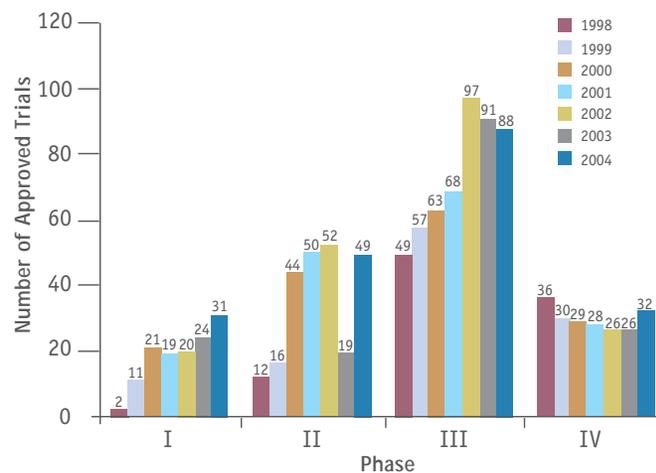
* One clinical trial certificate is issued for each participating site in a clinical trial.

Phase	1998	1999 [^]	2000 [^]	2001 [^]	2002 [^]	2003 [^]	2004 [^]
I	2	11	21	19	20	24	31
II	12	16	44	50	52	19	49
III	49	57	63	68	97	91	88
IV	36	30	29	28	26	26	32
Total	99	114	157	165	195	160	200

* Number of clinical trial certificates issued.

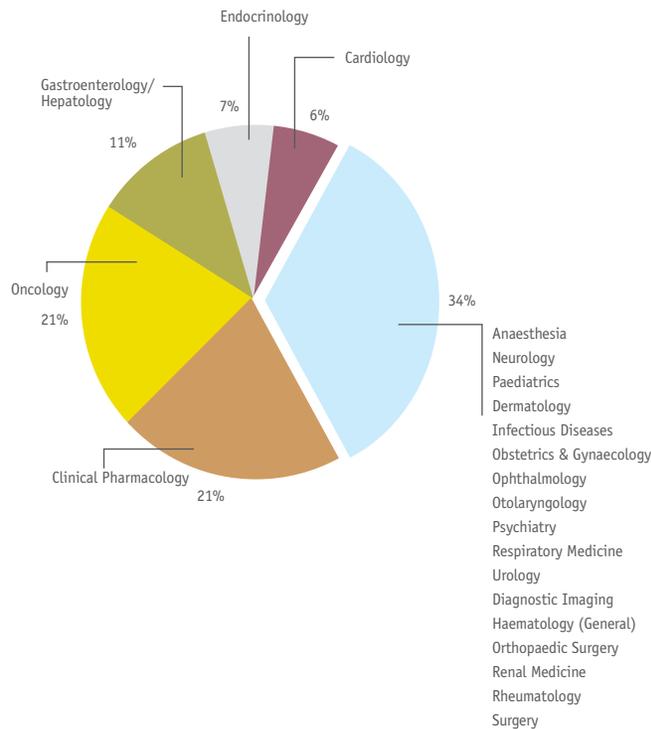
[^] 1 January to 31 December of stated year.

Approved Clinical Trials* from 1998 to 2004



* Number of clinical trial certificates issued.

Clinical Trials by Therapeutic Areas (2003-2004)



As part of our ongoing safety monitoring of clinical drug trials, all serious and unexpected adverse drug reactions related to investigational products are subject to expedited reporting to CDA. In 2004, 4,187 initial reports and 2,378 follow-up reports were received from January to December 2004.

The clinical trial safety reporting and management system was explained in an article, "How Singapore Regulates Safety Reporting from Clinical Trials", published in the October 2004 issue of the international Regulatory Affairs Journal. In addition, a guidance document on the safety reporting requirement for drug trials for the industry was also published and is available on our website.

Licensing of Manufacturers, Assemblers, Importers, Wholesale Dealers and Pharmacies

During the year, 119 applications* for licences were processed and approved for manufacturers/assemblers of medicinal products, Chinese Proprietary Medicine (CPM) and Cosmetic Products. In the same period, applications* for 434 Wholesale Dealer's Licences, 704 Import Licences and 287 Pharmacy Certificates were processed and approved. These licences and certificates were granted to manufacturers and dealers found to be in compliance with relevant Good Manufacturing Practice (GMP), Good Distribution Practice (GDP) and other quality system standards and regulatory requirements.

In addition, we also processed and approved applications* for 100 Export Licences, 435 Form A**, 668 Form C***, 555 Certificates of Pharmaceutical Products, 45 GMP Certificates and 53 Free Sale Certificates for CPM, as well as 18 statements of licensing status.

* Includes new, renewal and amendment applications (where applicable).

** Form A is a licence to import, store and sell poisons (items as listed in the Poisons Act) by way of wholesale.

*** Form C is a licence to import and deal generally in poisons (items as listed in the Poisons Act) by wholesale and retail.



- **Good Distribution Practice (GDP) Certification Scheme**

A voluntary GDP certification scheme took effect from 15 January 2005. With this new scheme, pharmaceutical distributors, warehousing and logistic companies can obtain an official GDP certification to facilitate the sales, supply and exportation of their medicinal products.

- **Simplified Pharmacy Registration Scheme**

On 14 February 2005, a simplified pharmacy registration scheme was introduced to facilitate registration of new pharmacy outlets of existing licensed pharmacy chains. Any new pharmacy eligible for this scheme can be registered without a pre-approval audit, resulting in significant reduction in processing time.

Good Manufacturing Practice (GMP)

On 1 April 2004, we launched the first phase of the Overseas GMP Audit Programme. This is applicable to all new overseas manufacturers intending to market their western medicinal products in Singapore. New manufacturers are subject to GMP conformity assessment either via verification of GMP documentary evidence or on-site audit by CDA. Ten applications were received in FY 2004/05, including eight which were evaluated based on verification of documentary evidence, and one was evaluated based on an on-site audit.

Regulation of Chinese Proprietary Medicines (CPM)

- **Listing of CPM**

During the year, we received 788 CPM product listing applications and approved 615 products for listing, based on assessment of safety and certain aspects of quality requirements. As of 31 March 2005, 10,914 CPM products were listed. We rejected 475 CPM products due to harmful content, objectionable names or inability to fulfil

documentation requirements. Four of these CPM products were detected to contain poisons like steroids and tadalafil, and were rejected for listing.

- **Issue of CPM Licences**

As of 31 March 2005, the number of licensed CPM importers, manufacturers, re-packers and wholesale dealers stood at 219, 39, 23 and 331 respectively.

- **Traditional Medicine (TM) Survey**

A TM survey was conducted by an external consultant in February 2005 to gain insights on local TM products and dealers in the local market, as well as to understand the usage pattern among local TM users. The results will be useful in formulating the approach for a proposed control framework for TM in Singapore.

Regulation of Health Supplements

Although health supplements are currently not subject to licensing requirements, we provide assistance and advice to the trade on product-related enquiries. During the year, we handled 5,387 enquiries mainly on product classification, import and sale requirements. The large number of enquiries received indicates a growing interest in the industry.

- **Public Forum**

We were invited by the National Cancer Centre to make a bilingual presentation on "The Role of Health Supplements in Cancer Care; Know the Good, The Bad & The Ugly" in 2004. This was a repeat of the well-received presentation made in the first forum held in November 2003.

- **Caution on Misleading or Exaggerated Claims in Health Supplement Advertisements**

As health supplement advertisements are currently not subject to medical advertisement regulation, we posted an advisory on the HSA website in May 2004, to promote public awareness on exaggerated claims in health supplement advertisements.

- **Development of Transmissible Spongiform Encephalopathy (TSE) Guidelines**

During the year, we developed the TSE guidelines for Complementary Medicines and posted them on our website in January 2005. These guidelines highlight the various measures that manufacturers of complementary medicines should take to minimise the risk of TSE transmission in Complementary Medicines.

- **Regulation of Cosmetics**

We issued 17,086 cosmetic product licences for the year. These included 6,704 new, 10,161 renewed and 221 amended cosmetic product licences. Four applications were rejected; two applications were turned down owing to the presence of banned ingredients in the products and another two applications were rejected based on the inability of the importers to provide pertinent product information. A total of 429 import licences was issued: 65 for new, 330 for renewed and 34 for amended import licences.

- **Adverse Drug Reaction (ADR) Monitoring**

The spontaneous reporting of ADR is an important programme to safeguard public health and to quickly deal with unexpected reactions from medicinal products after they have been approved for marketing in Singapore. The success of the programme is highly dependent on the reporting rate from our healthcare professionals.

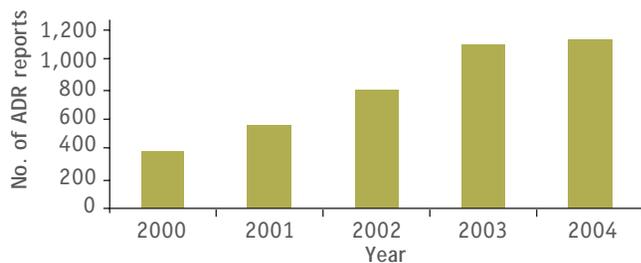
As a result of continuous efforts to promote ADR reporting through various activities, including lectures and talks to doctors and pharmacists and publication of ADR News bulletins, the number of ADR reports submitted reached 300 reports per 1 million inhabitants, a figure that is accepted internationally as a reasonable effective level of reporting. For the period January to December 2004, 1,139 ADR reports were submitted by healthcare professionals and pharmaceutical companies. Serious reports, accounting for 25% of the total reports received, were promptly investigated.

Healthcare professionals from the public hospitals submitted 60% of the ADR reports received in 2004. The remaining reports were from national specialty centres and other public health institutions (17.8%), private medical clinics (8.9%), private hospitals (7.2%), pharmaceutical companies (5.2%) and community pharmacies (1.2%).



ADR reports received from 2000 to 2004					
Year	2000	2001	2002	2003	2004
No. of ADR reports received	375	561	801	1,100	1,139
% change over previous year	- 14%	+ 50%	+ 43%	+ 37%	+3.5%

No. of local ADR reports received from year 2000 to 2004



• **Establishment of Guidance on Safety Reporting for Marketed Drugs**

To safeguard public health, pharmaceutical companies that market their products in Singapore are legally required to submit important drug safety information to CDA. We conducted a review of the local drug safety reporting requirements in 2004 taking into consideration the requirements of other major regulatory authorities and international guidelines. Feedback and inputs were also sought from the industry on the local reporting requirements before the new guidance was finalised and issued to the industry in February 2005.

• **Provision of Unbiased Drug Information to Consumers and Healthcare Professionals**

Of the 671 enquiries handled, the bulk of the enquiries were from members of the public, followed by healthcare professionals (18%) and others such as media representatives (16%). The queries were largely related to questions on medicinal product safety such as adverse reactions of a drug, drug withdrawals and recalls (56%). Queries on the availability and forensic classification of medicinal products (13%) were the next most commonly asked questions, followed by those related to clinical usage and pharmacological effects of medicinal products. The most commonly used medium for inquiring of queries was via telephone (59%), followed by e-mails (40%) and then letters and faxes (1%).

• Assessment of Major Drug Safety Issues in 2004

Several major drug safety issues which have a high impact on clinical practice were reviewed and appropriate regulatory actions were undertaken to safeguard public health. The table below lists the summary of safety issues reviewed by CDA.

S/N	Safety Issue	Assessment	Regulatory Actions
1	Vioxx® (rofecoxib) and risk of cardiovascular (CV) toxicity	Unfavourable risk benefit profile	<ul style="list-style-type: none"> i) Voluntary withdrawal of Vioxx by Merck Sharpe & Dohme ii) Issued press release and Dear Healthcare Professional Letter (DHCPL) to alert of the increased risk of CV toxicity iii) Enquiry lines set up to deal with calls from consumers and healthcare professionals
2	Selective Serotonin Reuptake Inhibitors (SSRIs) and risk of suicidality in children and adolescents	Unfavourable risk benefit profile when SSRIs and related antidepressants are used in children with major depressive disorders	<ul style="list-style-type: none"> i) Issued advisory to healthcare professionals ii) Labelling changes in package inserts of affected products to reflect this risk
3	Crestor® (rosuvastatin) and increased serum concentration in Asian patients	<ul style="list-style-type: none"> • Pharmacokinetic handling differences observed among different ethnic groups • Lower dose advised for Asians 	<ul style="list-style-type: none"> i) Issued DHCPL to alert healthcare professionals of this finding ii) Package insert of Crestor revised to reflect this new information
4	Erythropoietins (EPOs) and increased risk of thromboembolic events and fatalities	Unfavourable risk benefit profile when EPOs are used for the prevention of anaemia in cancer patients	<ul style="list-style-type: none"> i) Issued DHCPL to targeted group of healthcare professionals ii) Removal of licensed indication for the use of EPO in the prevention of anemia in cancer patients in the package insert of all EPO products
5	Thioridazine and cardiovascular toxicity	Unfavourable risk benefit profile	<ul style="list-style-type: none"> i) Issued DHCPL to warn of risk ii) Deregistration of thioridazine by 31 March 2006



• **Publication of ADR News Bulletin**

In 2004, three issues of the HSA ADR News bulletins were published and disseminated to more than 7,000 medical doctors and pharmacists by mail. Some of the key safety issues reported in the ADR News bulletins are listed below:

- (1) Safety update on tumour necrosis factor (TNF) inhibitors,
- (2) Conclusion of the Women's Health Initiative (WHI) trials,
- (3) Bisphosphonates and osteonecrosis of the jaw,
- (4) Pergolide associated with cardiac valvulopathy and local case reports,
- (5) Termination of galantamine (Reminyl®) trials on mild cognitive impairment,
- (6) Information on the contraindication for the use of promethazine (Phenergan®) in children under two years old in the US.

Regulation of Medical Advertisements and Sales Promotions

During the year, 1,198 applications were received and 1,128 permits issued for advertisements and sales promotion of medicinal products.

As a council member of the Advertising Standards Authority of Singapore (ASAS), we play an active role in providing advice and professional input to ASAS in the assessment of advertisements relating to medicinal and health-related products.

• **Disease Awareness Campaign (DAC)**

The DAC guidelines jointly developed by HSA and the Singapore Association of Pharmaceutical Industries (SAPI) were implemented on 1 November 2004. These guidelines serve to guide the pharmaceutical industry on the appropriate content of a DAC. In addition, an HSA-SAPI working arrangement has also been established to deal with enquiries and feedback on DAC. This initiative is a milestone achievement as we move towards fulfilling HSA's long-term objective of engaging the industry in self-regulation of medical advertisements.

Investigation, Surveillance and Prosecution

As part of our ongoing post-market surveillance programme, we rely on various sources of information, including information obtained from field and media surveillance, to detect defective health products and health fraud. We received a total of 542 complaints in the year. 62 product defect reports were received and 94 products assessed. We conducted 31 product recalls for western medicinal products and CPM due to concerns over their safety and quality requirements, such as contents of active ingredients not within specification limits, toxic heavy metals above permissible limits and the presence of adulterants.

Legal actions were taken against errant and non-compliant dealers. During the year, we completed 37 prosecution cases in court, resulting in \$302,000 worth of fines being imposed by the courts and five cases with imprisonment terms. In addition, we also issued 37 composition notices amounting to a total of \$30,800 in fines for the year.

- **Illegal Sale of Medicinal Products**

We also conduct surveillance of the Singapore market to curb the illegal import and sale of medicinal products. The surveillance activity covers the media and Internet, including auction sites, for any advertisement on the sale of medicinal products.

Acting on information received, we conducted several raids on illegal drug peddlers at various locations in Singapore, including MRT stations and HDB townships. Several illegal peddlers were rounded up and the illegal medicines seized were mainly anti-fungal creams and sexual enhancement products.

- **Counterfeit Medicines**

We continued with our surveillance and enforcement activities to detect counterfeits sold by illegal peddlers in the black market. Joint operations were conducted with other enforcement agencies including Singapore Customs, Immigration & Checkpoints Authority and the Police. Several offenders were caught and charged in court. A press statement to alert the public on counterfeit medicines was released in January 2004.

Tobacco Regulation

During the year, 1,347 tobacco retailer licences were issued. We continued our enforcement efforts to curb smoking by youths under the age of 18 years. 6,107 youths were caught smoking or in possession of cigarettes. Some 5,800 young offenders were compounded and 307 prosecuted in court.

- **Implementation of the Pictorial Health Warnings and Labelling (HWL)**

The revised Smoking (Control of Advertisements and Sale of Tobacco) (Labelling) Regulations 2003 to include the new health warning labels were successfully implemented on 1 August 2004. Enforcement checks after the implementation date revealed that the compliance rate was high.

Prior to the implementation of this new requirement, we presented the guidelines for the HWL and held extensive consultations with traders from the tobacco industry on the implementation plans. Upon the implementation of the HWL in Singapore, the Tobacco Control Office from the Department of Health, Hong Kong consulted us on enforcing the pictorial HWL in its territory.

- **Stepping Up Enforcement on Retailers and the Demerit Points System (DPS)**

As part of our enforcement strategies to curb the illegal sales of tobacco products to the underaged, we stepped up enforcement actions on errant retailers to curb access by the underaged to tobacco products in 2004. In addition, we implemented the DPS on 1 December 2004. Under the DPS, points are pegged to the retail outlets' licensees who are responsible for their respective outlets' compliance. Regardless of whether the licensees or their employees commit the offence, demerit points will be given to the licensee of the retail outlet where illegal sales of tobacco products to the underaged took place. The tobacco retail licence will be suspended or revoked depending on the points accumulated for the outlet.



Regional Harmonisation Efforts

• ASEAN Healthcare Integration

In 2003, the ASEAN Economic Ministers identified 11 priority sectors and agreed to accelerate the integration of these sectors to remove barriers to trade and investment to enhance ASEAN's competitiveness. Singapore has been assigned, through its lead agency, the Ministry of Trade and Industry, to lead the Healthcare sector. HSA has been proactively involved in various regional harmonisation working groups' meetings in pharmaceuticals, cosmetics, traditional medicines and health supplements, under the auspices of the ASEAN Consultative Committee for Standards and Quality (ACCSQ).

• ACCSQ Pharmaceutical Product Working Group (PPWG)

HSA represented Singapore at the 8th PPWG Meeting in July 2004 at Bangkok and the 9th PPWG Meeting in February 2005 at Manila. Singapore chairs the Implementation Working Group of the ACCSQ PPWG with Indonesia as the co-chair. We have been actively working with our ASEAN partners to achieve the goals related to the ASEAN Healthcare Integration roadmap, including the Mutual Recognition Arrangement Taskforce on GMP Inspection and the formalisation of the Post-Marketing Alert system.

• ASEAN Harmonised Cosmetic Regulatory Scheme

The Agreement on the ASEAN Harmonised Cosmetic Regulatory Scheme for cosmetic products, signed by the ASEAN Economic Ministers in September 2003, will be fully implemented by January 2008. HSA continued to be in the second and third meetings of the ASEAN Cosmetic Committee. We are the lead country on Product Safety Evaluation & Post Marketing Surveillance including the Post-marketing Alert system for defective or unsafe cosmetic products.

• ACCSQ Product Working Group (PWG) On Traditional Medicines and Health Supplements

The ACCSQ PWG for Traditional Medicine and Health Supplements was formed to look into the implementation of measures for traditional medicines and health supplements and the harmonisation of their technical requirements in the ASEAN region. HSA represented Singapore at the 2nd PWG meeting in January 2005 held in Malaysia.

• Assistance Rendered under the European Commission - ASEAN Economic Co-operation Programme on Standards, Quality and Conformity Assessment

Under the EC-ASEAN Economic Co-operation Programme, Singapore provided assistance as ASEAN Experts to lead in a number of sub-programme training activities in the Pharmacy and the Cosmetics sectors.

International Alliances and Activities

• Memoranda of Understanding (MOU)

In 2004, Singapore carried out a number of co-operation activities under the MOU with China's State Food and Drug Administration (SFDA) and the Australia's Therapeutic Goods Administration (TGA).

Under the MOU on drug administration signed with SFDA in September 2003, a Plan of Co-operation (POC) on Traditional Chinese Medicine (TCM) was established. The Singapore-China Workgroup on TCM Co-operation formed under the POC held a series of meetings in April 2004 to discuss various areas of co-operation, including regulation of Chinese Medicinal Materials (CMM), CMM clinical trials, post-marketing activities and adverse reactions monitoring.

We established a Joint Confidentiality Agreement with the US Food and Drug Administration (FDA) in August 2004. In 2005, we will ratify an MOU with the FDA related to the FDA-HSA Medical Products Working Group. We are also working towards impending MOU with Health Canada and the Malaysia's National Pharmaceutical Control Bureau (NPCB).

• Other Activities with Regulatory Partners

We also hosted a number of meetings and visits with other health authorities over the past year including officers from TGA in April 2004, FDA in June 2004, Indonesia's National Agency for Drug and Food Control in October 2004, and Health Canada in September and November 2004. We hosted a visit by the Fijian Minister of Health in September 2004 and visits by WHO representatives in October 2004 and March 2005.

Under the WHO Fellowship Programme, two officers from the Bangladesh Health Authority visited HSA for a 1-week GMP training attachment in January 2005.

To forge closer ties with our overseas regulatory counterparts, we made an inaugural visit to Malaysia's NPCB from 20 to 21 May 2004 to explore bilateral collaboration. As part of a wider trade agreement initiative under the India-Singapore Comprehensive Economic Co-operation Agreement, we made a visit to the Drugs Controller General of India in November 2004.

WHO appointed Singapore as a consultant for several projects, including a workshop for the SFDA on Post Marketing Regulation of Medicines held in Shenyang, China, in September 2004. Another project under the WHO Prequalification Project was a Good Clinical Practice Inspection of an Indian Clinical Research Organisation in November 2004.

• International Obligations and Commitments

We continued to observe our national obligations and commitments in a number of regional and international agreements and fora. These included the Mutual Recognition Agreement on GMP Inspections with Australia, the Singapore-Japan Joint Statement on Medicinal Product GMP Inspection under the Japan-Singapore Economic Partnership Agreement, the Pharmaceutical Inspection Co-operation Scheme (PIC/S), the Permanent Forum for International Pharmaceutical Crime, the WHO-supported Western Pacific Regional Forum for the Harmonisation of Herbal Medicines, the Regional Emerging Disease Intervention (REDI) Centre, the Brunei Malaysia Indonesia Singapore Thailand (BMIST) Public Health Conference, and the ASEAN Working Group on Technical Co-operation in Pharmaceuticals.



- **Conferences and Related Activities**

We participated in international conferences and related activities to keep abreast with the latest regulatory developments and trends. Such conferences included the Asia-Pacific Economic Co-operation (APEC) Life Sciences Programme, International Conference on Harmonisation, International Conference of Drug Regulatory Authorities, International Federation of Pharmaceutical Manufacturers and Associations, International Society for Pharmaceutical Engineering, Centre for Medicines Research. We also spoke at fora organised by the National University of Singapore, Nanyang Technological University, Singapore Polytechnic, Singapore Medical Association and Pharmaceutical Society of Singapore.

- **Going Forth**

We will continue to forge ahead in developing closer relationships and potential MOU with various benchmarked health authorities while deepening existing good ties with regional regulators. The bridging role that we can play between developed and developing regulators is one of the important value-adding contributions that we can bring to the region. At the same time, we must also be mindful of the goals and targets which we need to support and achieve under the ASEAN Healthcare Integration roadmap.

Bearing in mind that the implementation of the ASEAN roadmap will have significant implications and impact for Singapore, we strive to incorporate the ASEAN harmonised requirements into the local regulations.

Several challenges for CDA in the coming year include:

- **Implementation of the ASEAN Cosmetic Directive**

The ASEAN Cosmetic Directive will be implemented with effect from 1 January 2008. With the increased pace of ASEAN integration for cosmetic products, we will be assisting the cosmetic manufacturing industry in providing interpretation and training on the ASEAN Guidelines for Cosmetic Good Manufacturing Practices over the next one to two years.

The challenges ahead will include communicating the requirements of the ASEAN Cosmetic Directive to our stakeholders and building up our stakeholders' capacity to ensure that cosmetic products imported and manufactured meet the Directive's requirement for safety and GMP. In addition, we will also need to enhance the existing system of post-marketing surveillance for cosmetic products.

- **Good Manufacturing Practice Certification**

With the impending implementation of the successive phases of the Overseas Audit Programme, EC-ASEAN Pharmaceutical GMP Programme, ASEAN Cosmetic Product Harmonisation Programme and the potential development of biomedical manufacturing industry, there will be an expected rise in requests for GMP certification and Certificate of Pharmaceutical Products.

- **Development and Enhancement of Pharmaceutical Registration and Information System (PRISM)**

Moving along with the e-government initiatives in Singapore, PRISM, an electronic licensing and information management system, has been developed to facilitate paperless transactions for the benefit of the public, and to improve regulatory efficiency. We will be reviewing and building on our system capabilities of PRISM so as to provide greater convenience and ease of use for our clients. We aim to fully launch PRISM in phases for the various application modules in the coming years.

- **Counterfeit Medicines**

The problem of counterfeit medicines is a global phenomenon. In Singapore, the incidence of counterfeit medicines is mainly confined to products that exist outside the legal supply chain and has, so far, been limited to small quantities sold by illegal peddlers, originating from stocks smuggled or hand-carried into the country

in small consignments. With the rising counterfeiting activities around the world, it is a challenge to curb such activities in Singapore. We have taken proactive steps to tackle this area by collaborating and working in partnership with pharmaceutical industries and other enforcement agencies. Other action plans are being formulated to address this rising challenge.

- **Blood and Plasma-Derived Pharmaceutical Products**

Given the importance of blood and plasma-derived pharmaceuticals, there is a need to revise the guidelines for regulatory requirements relating to this special group of biologic products. This will ensure an appropriate and adequate risk management approach that is consistently applied and takes into account significant technology advances in manufacturing, development and testing. We hope to complete the review process and formulate a new set of guidelines by the end of the year.



Our Centre for Medical Device Regulation (CMDR) ensures that medical devices meet the requirements of safety, efficacy and quality so as to protect public health and safeguard the interests of the patients and users.





REGULATING MEDICAL DEVICES

Our **Centre for Medical Device Regulation (CMDR)** is entrusted with the responsibility of regulating medical device products available in the Singapore market. Our objective is to safeguard public health and safety by implementing regulatory controls through a programme of pre-market assessment of devices, manufacturing controls and post-market vigilance. Since 1 April 2002, we have been carrying out a range of assessment and monitoring activities to ensure medical devices available in Singapore are of an acceptable standard under a Voluntary Product Registration Scheme. The promulgation of a medical device regulation is targeted for 2006.

The proposed regulatory framework is based on a risk management approach designed to achieve a balance between providing an assurance of device product quality, safety and performance on one hand, and ensuring that the public have timely access to beneficial device products on the other.

CMDR also administers the Contact Lens Practitioners Act through the registration and licensing of Contact Lens Practitioners and the enforcement of the Act and its Regulations. As at end March 2005, there were 468 licensed Contact Lens Practitioners in Singapore.

Voluntary Product Registration (VPR) Scheme

The VPR Scheme for higher-risk medical devices was implemented in 2002 and it serves as an interim phase while transiting to a regulated environment. This interim phase allows for a period of confidence building and also learning about the various levels of regulatory control. It also offers stakeholders a window of opportunities to address any concerns that might present as obstacles to trade facilitation. A risk-based regulatory framework will be developed through the feedback obtained from market trials and partnerships with the industry.

By end March 2005, this scheme has been in operation for three years and it has received encouraging response and support from the medical device industry. Out of 3,309 applications received involving 5,310 devices, 91.2% of these applications have been cleared. During the year, CMDR was notified of eight product recalls and 59 adverse incidents relating to medical devices worldwide and locally. Appropriate corrective actions including recalls of products that were sold in Singapore were duly taken.

Enhancing Work Processes

We introduced a Project Management approach in November 2004 to the VPR Scheme, which serves as our business transformation strategy in our commitment to speed up the labour-intensive evaluation of VPR applications for marketing clearance. Basically, we developed an online system for our staff to monitor and track key lead indicators and limiting processes. The improved standard operating procedures and tracking mechanisms significantly boosts the efficiency and greatly reduces the backlog of pre-market review under the VPR scheme.

Singapore Medical Device Register (SMDR)

We have completed the development work of the online SMDR to capture database information of legally available devices and establishments dealing with devices. The SMDR module had a soft launch in May 2004. It will be ready for access by the public when the medical device regulation is enacted.

A Medical Device Information and Communication System (MEDICS@hsa) is being developed to support and enhance the operational efficiency for the regulation of medical devices. More customisation and e-services have been introduced to suit the different needs of establishments for applications, registration and licensing and information sharing among clients to promote connectivity between HSA and the industry.

Regular Dialogue Sessions

We continued our series of regular dialogue sessions and consultations with local distributors, importers and manufacturers of medical devices. We also updated them on the pending regulatory changes on an ongoing basis.

In May and June 2004, about 12 sessions were arranged for the industry to be briefed on the MEDICS, registrations of medical devices and listing in SMDR. The briefings to industry focussed on the first phase of implementation of MEDICS, its features and benefits and the various e-services it offers. A pilot implementation of additional e-services in MEDICS was introduced on 1 March 2005.

Contact Lens Licensing System (COLLINS)

We have developed an integrated electronic licensing system which was launched on 12 October 2004. COLLINS, a system for licensing and registration of contact lens practitioners (CLPs), is commissioned and fully operational. It aims to provide an effective online system for licensing CLPs and their associated places of practices. Applicants can now apply online for registration to be a CLP and access a host of other e-services and information round-the-clock through the Internet.



Owing to the ease of online transactions, there is an increase in the number of applicants who apply, renew, cancel, pay or order for or change particulars of their annual licences. Once these transactions are completed, there will be an immediate updating to an online CLP Register containing a list of names and particulars of all registered CLPs. The Register is now available in the public domain for viewing and search purposes.

Training Programme

We have finalised a training programme to meet the training needs of the local industry, which is facing a constant influx of new personnel with limited knowledge of regulatory affairs on medical devices. In addition, small businesses may not have dedicated personnel dealing with regulation affairs. The lack of understanding of medical device regulations, in turn, affects our implementation of regulatory initiatives and work plans. Hence, this training programme is part of our overall strategy to be a contemporary regulator in partnership with the industry. The aim of the training programme is to build up a core group of personnel from local industry and authorised representatives conversant with local regulatory requirements and other medical device regulatory affairs.

Regional Harmonisation of Medical Device Regulation

• Asian Harmonisation Working Party (AHWP)

CMDR acts as the Secretariat AHWP, for the regional harmonisation grouping on medical devices. At the 3rd AHWP Technical Committee Meeting held in Taipei from 29 to 30 April 2004, seven member economies indicated their interest in the development of a common pre-market submission dossier as a collaborative regional harmonisation project. CMDR is playing a key role in the development of such a common submission dossier template.

ASEAN Consultative Committee for Standards and Quality (ACCSQ) Medical Device Product Working Group

Another regional development in 2004 was CMDR's participation in the activities of the ACCSQ Medical Device Product Working Group (PWG). This PWG aims to promote integration of the healthcare sector through harmonisation of the technical regulations for the regulatory control of medical devices within ASEAN. Integration within the healthcare sector is a prioritised outcome of the Road Map for ASEAN Integration and ASEAN Economic Community 2020.

International Professional Participation

- **SPRING Singapore Industry Consultation, 23 February 2005**

At the SPRING Singapore Industry Consultation - Technical Reference 7:2002 Parts 1 & 2, Quality Management System Standard for Medical Device Components - for the medical device components industry, our Centre Director chaired the panel discussion at the invitation of the organising committee. This technical reference has been developed with inputs from CMDR.

- **Regional Harmonisation Activities – ACCSQ Product Working Group on Medical Devices, 3 to 4 March 2005**

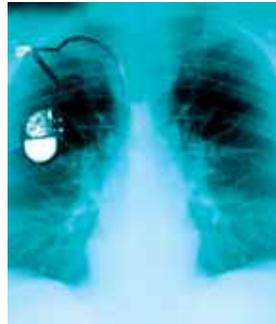
We are actively involved in a new regional initiative geared towards trade facilitation and integration of medical device regulatory control. Two of our officers participated at the inaugural meeting of the ACCSQ Product Working Group on medical devices. Our Centre Director is currently the co-chairman of this working group.

Going Forth

Our main challenges in 2005 include consultation and open communication with the industry, leading to the introduction of a new medical device regulatory framework based on a risk management approach. A great deal of dialogue is necessary to ensure that our objectives are achieved with minimal negative impact on industry and consumers. Dialogue with key stakeholders on the regulatory framework will continue into the coming year.

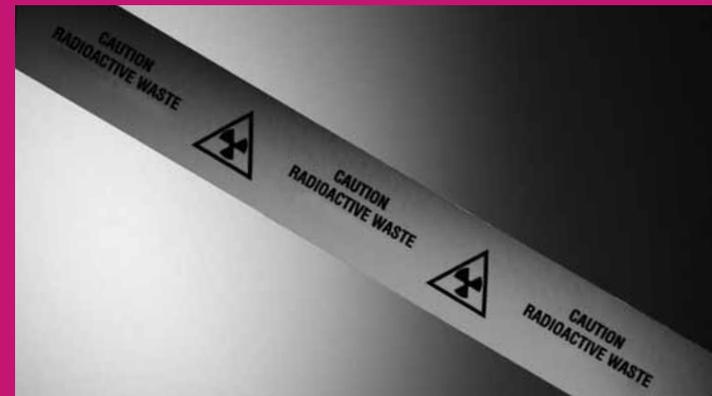
We will also continue to review and fine-tune the device evaluation and marketing clearance processes to provide differentiated pathways for those products which have obtained prior regulatory approval or clearance from benchmarked countries, without compromising safety, quality and performance of the device products for local commerce.

Clear policies and guidelines that address all elements related to medical devices will be established and aligned to international standards and harmonisation. A level of scrutiny appropriate to the risk represented by each medical device will be applied to medical devices available on the Singapore market, and this will be achieved through a balance of the key elements - quality systems, pre-market review and post-market surveillance.



Our Centre for Radiation Protection (CRP)

excels in radiation science so as to enforce and promote the radiation safety of workers, the public and the environment; and ensure that irradiating apparatus and nuclear materials meet the statutory requirements of quality, safety and efficacy





ENSURING RADIATION SAFETY

Our **Centre for Radiation Protection (CRP)** is the national regulatory authority for the safe use of ionising and non-ionising radiation in Singapore. We administer and enforce the Radiation Protection Act, which controls all radioactive materials and irradiating apparatus such as X-ray machines, linear accelerators, electron beam welders, ion implanters, magnetic resonance imaging and ultrasound apparatus, lasers for medical, industrial and entertainment purposes.

Services provided by our six laboratories at CRP include personal monitoring for all radiation workers, testing for radioactive contaminants in imported food and industrial samples, testing for leakage in sealed radioactive sources, calibration of radiation measuring instruments, consultancy on radiation safety matters and education on radiation safety.

Administration and enforcement of the Radiation Protection Act and its subsidiary regulations are conducted through a system of licensing and inspections. Licence application forms are available for download via our website, providing convenience and cutting red tapes for our stakeholders. Import and export licences and endorsements are processed electronically and automatically through the TradeNet System, ensuring that applications are dealt with speedily and efficiently.

Radiation Control: Licensing and Inspections

The Radiation Protection Act (Chapter 262) controls all radioactive materials and irradiating apparatus. Licences are issued for the purposes of import, export, sale, possession, use and dealing in radioactive materials and irradiating apparatus and for the transport of radioactive materials. Ionising radiation irradiating apparatus include X-ray machines, linear accelerators, cyclotrons, gamma irradiators and electron beam welders, whereas non-ionising radiation irradiating apparatus include magnetic resonance imaging, ultrasound apparatus, lasers for medical, industrial and entertainment purposes, microwave ovens and UV sun tanning lamps.

In 2004, 26,008 licences were issued, an increase of about 15% compared to 2003. Altogether, 1,666 endorsements were given for the import/export of components of irradiating apparatus without the radiation emitting components, while 118 endorsements were given for ships carrying nuclear consignments such as nuclear fuel rods, uranium hexafluoride with natural uranium or enriched uranium, and large shipments of Cobalt-60 for irradiators or radiotherapy machines, to transit in Singapore.

We inspect all new facilities using ionising radiation before they are allowed to operate. Existing radiation facilities are re-inspected every one to three years depending on the nature of usage of the radiation equipment. Inspection includes checking that the facility and radiation equipment are in good operating condition and that radiation levels at locations accessible to the public are within limits

specified in the Regulations. For mammography X-ray machines and Computed Tomography (CT) scanners, there are additional checks for quality assurance (QA). In 2004, we made 438 inspections at medical, dental and veterinary practice premises and industrial and educational institutions.

For non-ionising radiation, 66 inspections were conducted to measure the radio frequency (RF) radiation levels for base stations of mobile phone service providers. We also conducted 11 surveys of RF facilities as well radio and television transmitting stations to ensure that regulations were complied with. In addition, CRP attended to various complaints from members of the public whose homes were near to these base stations.

To ensure that radiation leakage from microwave ovens sold in Singapore is below that specified in the Regulations, we checked 12 new models of microwave ovens from different manufacturers.

X-ray Mammography and CT Quality Control Programme

We continued to provide Quality Control (QC) checks for X-ray mammography services in clinics taking part in the national mammography screening programme. During the year, we inspected and certified 24 clinics with mammography X-ray facilities and embarked on QC programmes for CT scanners.

In August 2004, our chief radiographer underwent a 2-month practical training programme on QA/QC procedures for various types of medical diagnostic X-ray at the Westmead Hospital, New South Wales, Australia, to value-add to our current knowledge base.

Personal Monitoring

We provide the necessary personal monitoring service to all radiation workers in Singapore. Under the Radiation Protection (Ionising Radiation) Regulations, all workers performing ionising radiation work are required to wear personal dosimeters for monitoring of the amount of ionising radiation they are exposed to in the course of their work.

The personal monitoring provided is in the form of thermoluminescent dosimeters (TLDs), which are worn on the trunk of the body*. In 2004, more than 8,000 TLDs were issued and processed monthly to ensure that the radiation doses received by the workers were within limits specified in the regulations. Dose reports were generated to companies on the doses received by the workers. The number of the overdose cases investigated by us was 18, no change from the previous year. These overdose cases were mainly radiation workers in industrial radiography.

*For radiation workers handling radioactive materials which emit beta radiation or low energy gamma radiation, the TLDs are in the form of rings.

Wipe Test for Sealed Sources

During the year, we performed 360 wipe tests at sealed radioactive sources used in industrial, medical and research applications to ensure that there were no leakages. The wipe samples were brought back to our laboratory and tested for the presence of radioactivity using Sodium Iodide (NaI) and Geiger Muller (GM) detectors. None of these sealed radioactive sources were found to be leaking.



Radioactivity Analysis

We use very sensitive equipment, designed specifically to detect low levels of radioactivity in environmental samples such as soil and water; and industrial samples such as ilmenite sands, copper and tin slags, steel rebars, marble and granite. A total of 265 samples was analysed in FY 2004/05.

NaI detectors with multi-channel analysers are used to conduct radioactivity analysis on food samples. During the year, the number of food samples tested and certified free from radioactive contaminants was 1,607.

Ionising Radiation Dosimetry

Our Secondary Standards Dosimetry Laboratory (SSDL) was established with the support of the International Atomic Energy Agency (IAEA) and the World Health Organisation (WHO) as part of the international network of secondary reference laboratories. The SSDL acts as a national reference centre for radiation protection and environmental dosimetry. Inter-country comparisons to ensure accuracy of measurement of radiation dose among participating countries were periodically conducted by IAEA and the results obtained by CRP were well within acceptable limits.

In 2004, the reference dosimeters maintained by CRP calibrated a total of 379 radiation monitoring devices used by companies and hospitals in Singapore.

Consultancy Services

During the year, we provided 234 consultancy services on all aspects of ionising and non-ionising radiation protection to industries, government agencies, hospitals and the public.

Our services cover a wide spectrum of which include:

- Radioactive waste management
- Radiation accident procedures and emergency planning
- Radiation shielding requirements
- Radiation exposure limits
- Choice and use of radiation instruments
- Analysis of radioactivity in building materials and industrial raw materials
- Levels of RF radiation levels from base stations of mobile phone service providers and
- Detection of extremely low frequency (ELF) fields from transformer and High Tension switch rooms.

Training and Education

Training and education have become our key areas in establishing effective national radiation protection programmes.

In 2004, we conducted seven training courses on radiation safety. Two training courses on radiation safety were held for 48 participants training to be industrial radiographers. The other five courses on radiation safety were conducted for 105 participants using ionising radiation for various work purposes. These training courses aimed to equip workers with sufficient knowledge of the radiation hazards and the awareness of appropriate protective measures to minimise the occurrence of radiation accidents.

In 2004, 310 tests were conducted for applicants of ionising radiation safety licences, while 741 tests were conducted for applicants of laser safety licences.

Regional Training Centre in Radiation Protection

Under the Singapore-IAEA MOU, signed in March 2000, CRP has been playing an important role in the provision of training on radiation protection to professionals from countries in the region. From 1 February to 31 March 2005, three IAEA fellows from Myanmar and Bangladesh were attached to CRP for an on-the-job training programme on radiation protection and quality assurance in radiodiagnostic.

We also hosted the IAEA Regional Training Course on the Safe Transport of Radioactive Materials held in Singapore from 5 to 16 April 2004 for 30 participants from 15 countries. Our Centre Director was nominated by IAEA to be the Training Course Director.

International Professional Participation

During the year, we took part in a number of IAEA-related international events such as the IAEA 48th General Conference, the Preparatory Meeting of Contracting Parties to the Convention of Nuclear Safety, held for the planning of the 3rd Review Meeting to be held in 2005. In the area of safety and security of radiation sources, we were invited by IAEA to participate in a seminar for decision makers in USA dealing with issues involving nuclear threats from terrorism. As a member of the WHO International Advisory Committee on the International Electromagnetic Field (EMF) Project, we took part in its annual meeting and workshop on children's sensitivity to EMF exposure.

Going Forth

As part of our ongoing efforts in upholding radiation safety, we remain committed to promote radiation protection training locally and regionally. We will continue to keep abreast of the latest global developments and concerns in radiation safety and nuclear terrorism.

We will work with other relevant government agencies such as Singapore Civil Defence Force and Singapore Customs to strengthen the safety and security of radiation sources in Singapore. We will initiate actions on the possible implementation of the IAEA's Code of Conduct and other related conventions on nuclear security.

For the year ahead, we will strengthen our post-market inspections and radiation safety checks to safeguard both users and members of the public. We will introduce codes of practice to educate licensees on how to perform radiation work in a safer manner. Information and guidance documents on ionising radiation and non-ionising radiation protection topics will be identified and drafted for public information. These will be posted on the HSA website as well.

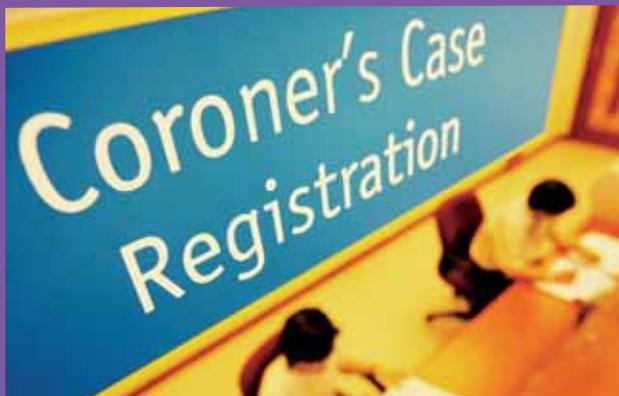
We will continue our ongoing quest for ISO 17025 Accreditation of Calibration Services and will also look at ISO 9001:2000 for our regulatory system.



adding value

Our Centre for Forensic Medicine (CFM) excels in applying forensic medicine and related sciences to serve law enforcement and the administration of justice; support healthcare services, medical audit, medical education and health regulations; and enhance safety in the community.





PROVIDING FORENSIC PATHOLOGICAL AND INVESTIGATIVE SERVICES

Our Centre for Forensic Medicine (CFM) undertakes the sole responsibility in Singapore to provide forensic medical consultancy services in Coroner’s cases, which include the conduct of autopsies on cases so authorised by the Coroner.

We also provide similar consultancy services to private clients, both local and regional. The medico-legal impact of the work is not only limited to death investigations, but also extends to areas such as criminal liability, medical negligence, malpractice, product liability, insurance compensation, safe working practices and workmen's compensation.

In addition, we work with the Singapore Police Force in crime scene investigations involving homicides and suspicious deaths, as well as support the national response to infectious diseases outbreaks in the conduct of examinations authorised by the Director of Medical Services under the Infectious Diseases Act. The outcome of our work provides essential feedback in closing the loop on medical quality and failures.

In transferring and applying our professional expertise in trauma and injury in the dead to the living, we also offer our expertise to clinical practice, in areas such as spousal and child abuse, and the investigation of sexual offences.

During the year, we handled 3,451 Coroner’s cases and, of these, we conducted 1,947 autopsies at our Mortuary@HSA. Our forensic death investigators attended to 42 cases.

CFM Workload Statistics for FY 2004/05

No. of coroner's cases	3,451
No. of coroner's autopsies	1,947
No. of forensic death investigator’s cases	42

Focusing on Core Capabilities

An ongoing review of our work processes continues to ensure a sharp focus on core capabilities and divestment of non-essential services. This is aimed at ensuring effective and efficient deployment of resources and manpower in delivering quality service to our clients.

Improved Facility and Capabilities

The emphasis on biosafety continues so as to minimise biohazard risks to staff and users of the mortuary facilities. The facility is now capable of handling cases potentially infected with Risk Group 2 and 3 biological agents.

Regional Involvement in Asian Tsunami Relief Efforts

In close coordination with the Ministry of Health and Ministry of Home Affairs, we participated in the Singapore Police Force-led Disaster Victims Identification (DVI) operations in Phuket during the Asian Tsunami crisis in December 2004.

Two forensic medicine teams, comprising forensic pathologists, forensic dentists, a forensic death investigator and mortuary technicians, were deployed as part of the Singapore contingent to

Phuket from end December 2004 to end January 2005 to assist in the DVI efforts. They carried out a range of tasks from the tagging of bodies, fingerprinting, examination of bodies, collection of information such as physical unique features, dental charting and taking of bone marrow samples for DNA profiling.

For our active participation in the international DVI efforts, members of our forensic teams were awarded commendation medals and certificates in recognition of their contribution to the relief efforts.

Customer Care at Mortuary@HSA

We are conscious that the needs of the next-of-kin (NOK) of each Coroner's case should be handled with care and sensitivity.

Whilst efforts have been made to provide a calm and comfortable environment, work processes have been reviewed to reduce waiting times. Body releases are scheduled so as to minimise uncertainty surrounding the claiming processes. Information regarding Coroner's cases is disseminated at the waiting area. Further staff training continues to improve the level of care during interaction with the NOK. Body release areas have been sequestered to provide greater privacy.

Quest for NAME Accreditation

To benchmark our professional services, we continued our quest to achieve accreditation with the National Association of Medical Examiners (NAME). NAME is the only known international standard that accredits Offices of Forensic / Medical Examiners in an integrated and holistic manner.

The achievement of NAME accreditation by an Office of Forensic / Medical Examiners signifies that the highest standards in medico-legal investigation and compliance in biosafety of its system is present, and well serves its jurisdiction.

To align with international best practice and to achieve structural compliance with NAME standards, we reviewed and refined all our biosafety work procedures and processes. We are expected to undergo inspection for NAME accreditation in May 2005.

Collaborations with Australia's Victorian Institute of Forensic Medicine (VIFM)

Following the Memorandum of Understanding signed with Australia's VIFM in July 2003 to further strengthen the strategic co-operation between both agencies, further discussions have been held in the areas of enhancing professional quality and cross-department interactions.

Going Forth

The year ahead will see us continuing to forge ahead in adding value to our jurisdiction system, strengthening our professional capability and gaining recognition for professional excellence in the field of forensic medicine. We will also focus on expanding our core capabilities by building on strong foundations with our counterparts and developing further collaborations with our partners and stakeholders.



*Our Centre for Forensic Science (CFS)
excels in forensic science for the purpose of law enforcement,
medico-legal investigations and administration of justice.*





PROVIDING FORENSIC, INVESTIGATIVE AND ANALYTICAL SERVICES

Our **Centre for Forensic Science (CFS)** provides a one-stop forensic and consultancy service to law enforcement agencies, government ministries, hospitals, private organisations and individuals to aid in criminal as well as medico-legal investigations, and civil dispute.

Since 1996, CFS has been accredited by the American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB). In addition, 12 of our forensic scientists are qualified ASCLD/LAB inspectors.

Our seven laboratories under CFS provide specialised scientific, investigative and analytical expertise in the areas of criminalistics, deoxyribonucleic acid (DNA) profiling, DNA database, narcotics, toxicology and document examination.

Our **Criminalistics Laboratory** examines physical and trace evidence such as arson accelerants, explosives, fibres, paints, glass, soils, gases, firearms, tool marks, physical fits, damages, shoeprints, tyre prints, suspicious powders, unknown organic and inorganic substances, and crime scene evidence.

Our **DNA Profiling Laboratory** examines biological evidence to establish individual characteristics and biological relationships for criminal investigations as well as for individual clients.

Our **DNA Database Laboratory** collaborates with the Singapore Police Force, operating a fully automated system for DNA analysis, to establish a database that provides "intelligence" information to assist the Police in criminal investigations.

Our **Document Examination Laboratory** carries out expert analyses, provides opinions and training in handwriting, signatures, typewriting, tampering and alteration, ink and paper analysis and other related materials encountered in criminal investigations, civil disputes for government agencies and private organisations.

Our two **Narcotics Laboratories** conduct analysis of narcotic drugs in drug seizures and urine of drug addicts in support of the Central Narcotics Bureau.

Our **Toxicology Laboratory** provides analytical services for drugs and other toxic substances for patients and post-mortem specimens.

During the year, a total of 93,173 exhibits was examined by our laboratories.

Laboratories	Exhibits/Cases Completed
Criminalistics Lab	856
DNA Database Lab	18,740
DNA Profiling Lab	2,298
Document Examination Lab	293
Narcotics I Lab	3,249
Narcotics II Lab	50,694
Toxicology Lab	17,043

ASCLD/LAB Accreditation

Our DNA Database and Profiling Laboratories underwent an audit by ASCLD/LAB in March 2005 and were accredited by the ASCLD/LAB Board.

All our other forensic laboratories also passed the annual ASCLD/LAB audit.

Development of New Automated Gunshot Residue (GSR) Software

Our Criminalistics Laboratory collaborated with Jeol (Japan) engineers and software programmers between March 2004 and January 2005, to create a new automated GSR analysis software, fully integrated with the Jeol scanning electron microscope and Jeol energy-dispersive X-ray detector. This customised software was based on direct laboratory inputs from our years of experience working with GSR analysis. It reduces analysis time for a GSR stub from eight hours to four hours. The significant reduction in analysis time means greater throughput and lower examination costs.

Seizure of "Erimin 5" Tablets in Singapore

There were several large seizures, totalling more than 93,000 tablets, of "Erimin 5" in the year, by the enforcement agencies in FY 2004/05. In 2004, "Erimin 5" tablets made up about 63% of the benzodiazepine exhibits received by our Narcotics I Laboratory. In 2003, about 87% of the "Erimin 5" tablets analysed contained nimetazepam alone. In 2004, this figure decreased to about 45%. The rest of the "Erimin 5" tablets were found to contain a mixture of nimetazepam and nitrazepam (37%), and nitrazepam (18%) alone.

Detection of Cocaine Abuse in Singapore

In October 2004, our Narcotics I Laboratory received about 58 grams of cocaine exhibits for analysis. This was the single largest seizure of cocaine in Singapore. Also, for the first time in Singapore, our Narcotics II Laboratory detected cocaine and its metabolite in the urine of a number of persons suspected to have abused cocaine. Both analyses led to the successful prosecution and conviction of the cocaine abusers.

Collaboration with the Central Narcotics Bureau (CNB)

During the year, our two Narcotics Laboratories completed several projects for the CNB. These collaborations included the validation of CNB's newly acquired urine screening instruments and the evaluation of its saliva testing kits and the pupillometer to detect drug abuse. Two survey projects were also carried out to establish the profile of drugs abused in Singapore and to determine the consumption patterns of ketamine and nimetazepam ("Erimin 5"), respectively. This collaboration underscores the close working relationship between CNB and CFS.

New Testing Services for the Enforcement Agencies

In June 2004, our Narcotics II Laboratory started to test for the presence of benzodiazepines in urine for the various enforcement agencies. Since then, more than 3,500 cases were submitted for the analysis of nimetazepam, a Class C controlled drug. From November 2004 onwards, the laboratory also provided a new testing service for lysergide (LSD) and its metabolite. The detection of these drugs, which occur in the urine in trace amounts, was made possible by the newly acquired liquid chromatograph / tandem mass spectrometer (LC/MS/MS).



New Toxicology Services

With the acquisition of a new LC/MS, our Toxicology Laboratory started a new service in May 2004 to provide screening and confirmation of buprenorphine and its metabolite norbuprenorphine. Buprenorphine is available in Singapore since 2002 as substitution treatment for opioid dependence. This substitution programme, however, may lead to abuse, either orally or intravenously. Since the introduction of this service, a total of 176 biological samples was found to be positive for buprenorphine and/or its metabolite.

First Murder Case Solved through DNA Database

Our DNA Database Laboratory was launched in 2003 in collaboration with the Singapore Police Force. Through the retroactive DNA samples of all persons convicted of registrable offences, a murder committed in 1996 was solved when a DNA profile developed from a cigarette butt left at the murder scene was matched to a DNA profile in our DNA database. This is the first murder case in Singapore which was solved through the DNA Database.

Participation in Asian Tsunami Disaster Victims Identification (DVI) Efforts

Two forensic scientists from our DNA Profiling Laboratory joined the Singapore DVI Team in Phuket to assist the relief team in identifying Singaporean victims from 4 to 14 January 2005. Our forensic scientists also assisted the International Tsunami Victim Identification Committee to ensure the accurate transcribing of DNA profiles of the victims' next-of-kin (NOK) into the Interpol documentation forms.

Our DNA Profiling Laboratory was also involved in the profiling work of 28 personal effects collected from 11 Singaporean tsunami victims who perished in Phuket. DNA profiles were successfully developed from the personal effects of 10 victims. The successfully developed DNA profiles were then transmitted electronically to the Thai authorities for comparison purposes.

Our DNA Database Laboratory participated in the DVI work by expediting the processing of 50 blood samples collected from NOK of the victims. These results were submitted to the overseas identification centre for comparisons with the DNA profiles obtained from post-mortem samples.

Nurturing Young Talents

We partnered the Nanyang Technological University's (NTU) School of Biological Sciences to organise the NTU-HSA-JC Challenge held from November 2004 to February 2005. The 3-month long challenge saw about 160 students representing all 15 junior colleges, exploring the field of life sciences and conducting their own Research & Development projects. During the period, our scientists gave lectures on forensic science and we also hosted a visit by some 40 students to our forensic laboratories.

International Alliances

Under the Memorandum of Understanding signed between HSA and Australia's Victorian Institute of Forensic Medicine (VIFM) in July 2003, toxicologists from VIFM and our Toxicology Laboratory were attached to each other's laboratory during the year to exchange ideas and advances in toxicology.

Two scientists from the Taiwan Criminal Investigation Bureau were attached to our Criminalistics Laboratory and Narcotics I Laboratory from 2 to 14 March 2005 and to our Document Examination Laboratory from 2 to 30 March 2005, respectively.

Our forensic scientists have been invited by the ASCLD/LAB to participate in two accreditation inspections.

In addition, our officers have attended and presented several papers at international forensic conferences throughout the year.

Going Forth

In the coming year, we will continue to create new capabilities and provide value-added forensic services for the administration of justice.

An extensive study will be carried out on the effectiveness of saliva testing of suspected drug abusers in the next financial year. Our Narcotics II Laboratory will also be revising its laboratory's work procedures to provide a faster turn-around-time in the analysis of drugs of abuse in urine, in order to better serve our clients from the enforcement agencies.

Our Criminalistics Laboratory has recently purchased a dual ion chromatograph to simultaneously identify trace level cations and anions in post-blast explosives residue, and this enhances our investigative capabilities to deliver more value-adding services to our stakeholders.



delivering value

Quality service is another key focus in our drive for excellence - as we come to grips with an increasingly informed public in a knowledge-based economy - HSA, as a forward-looking service provider, must seek to understand our customers' needs well and deliver outstanding service and solutions beyond their expectations.

Our Centre for Transfusion Medicine (CTM) excels in transfusion medicine to ensure a safe and adequate national supply of blood and blood products, the appropriate use of blood and blood products and to provide high quality blood banking services.





ENSURING AN ADEQUATE AND SAFE NATIONAL BLOOD SUPPLY

Our **Centre for Transfusion Medicine (CTM)**, which operates the Bloodbank@HSA, is the national agency responsible for collecting, processing, testing and distributing safe blood and blood products to all hospitals in Singapore, in both public and private sectors.

We partner with the Singapore Red Cross (SRC), the National Blood Donor Recruiter, to promote altruistic, voluntary, non-remunerated blood donation. We work hand-in-hand to develop appropriate national awareness strategies and recognition programmes targeted at recruiting and retaining blood donors.

As a World Health Organisation (WHO) Collaborating Centre for Transfusion Medicine since 1992, we contribute to improving the standards and practice of transfusion medicine and promoting blood safety and quality in the Western Pacific Region. Since 2002, we have been appointed as the WHO Regional Centre for Quality Management Programme on Blood Transfusion Services in the Western Pacific Region.

As the national blood service, we ensure an adequate and safe national blood supply through stringent pre-donation screening and testing with state-of-the-art technology. We operate five main laboratories, namely, Component Processing Laboratories, Infectious Disease Testing Laboratory, 24-hour Cross Matching Laboratory, Red Cell Reference Laboratory and White Cell Reference Laboratory.

We provide specialised services in transfusion sciences such as immunohaematology and tissue typing. Our transfusion medicine specialists also provide professional advice and consultations to clinicians in Singapore and the region, so as to promote good clinical practice in transfusion medicine and to ensure that every blood donation is optimally and safely used.

During the year, we collected a total of 79,057 whole blood donations. These were processed into 194,144 blood components, of which 151,407 units were used by the local hospitals. A total of 8,438 apheresis procedures was carried out.

We also performed 815,171 diagnostic tests using state-of-the-art testing technologies to screen for transfusion transmissible diseases like Human Immuno-deficiency Virus infection, Hepatitis B, Hepatitis C and Syphilis, as well as performed specialised Immunohaematology tests for patients with red-cell-serological problems and tissue typing for patients undergoing organ or bone marrow transplantation.

First HSA-Network for Advancement of Transfusion Alternatives (NATA) Joint Symposium

The first Asia-Pacific HSA-NATA Joint Symposium on Transfusion Medicine and Alternatives was held in Singapore on 18 and 19 September 2004.

The mission and agenda of NATA strongly complement our purpose and duty in delivering high quality transfusion medicine services for Singapore and in our role as the WHO Collaborating Centre for Transfusion Medicine in the Western Pacific Region.

Featuring 20 international and local expert speakers from a wide range of clinical specialties, the 2-day symposium covered nearly 30 topics ranging from blood transfusion safety to the legal, ethical and economic considerations in transfusion needs and practice.

Attended by almost 160 delegates from 15 countries, the symposium provided an excellent platform for physicians and clinicians to keep up-to-date on current issues and practices in transfusion medicine.

1st Advanced Quality Training Course in Blood Transfusion Services

As a WHO Regional Training Centre for the Quality Management Programme (QMT) on Blood Transfusion Services (BTS), we hosted the QMT in BTS for the third consecutive year, from 4 to 16 October 2004.

The 2-week comprehensive training course, organised jointly with WHO and with the strong support of the Ministry of Health and Ministry of Foreign Affairs through its Singapore Co-operation Programme, this 3rd QMT Course was an Advanced Quality Management Course. A total of 24 delegates from 16 countries attended the advanced course conducted by local and overseas facilitators.

The first advanced QMT in BTS course aimed to review the progress made in implementing quality management on blood transfusion services in the participating countries. It also provided advanced training in specific key areas of quality management, such as training and competency assessments, equipment and process validations as well as donor management.

Quest for Accreditation by the American Association of Blood Banks (AABB)

In our continuing quest for excellence in blood banking standards, our efforts towards accreditation by the AABB have made good progress in 2004.

Dr. Cees Th. Smit Sibingar, Vice President of AABB, conducted a series of training and lectures in June 2004 to provide direction on our AABB accreditation preparations. Following the training completion, measures were taken to step up the requirements and specifications outlined by the AABB. We aim to attain the AABB accreditation by end of 2005.

Expansion of Apheresis Programme

The number of apheresis donations performed during the year increased from 6,626 in 2003 to 8,438 in 2004. Our long-term plan of converting all platelet products to apheresis platelets has enabled more platelets to be provided to patients as single donor platelets in FY 2004/05. To further improve the efficiency and yields of the



platelet collection procedure, we implemented new systems in May 2004, which shortened the donation interval from six weeks to four weeks to meet increased need in blood products and make platelet donation more convenient for our donors.

New Methods of Testing

In November 2004, we implemented Hepatitis B Nucleic Acid Test (NAT) for the screening of presence of Hepatitis B viral genes in donated blood and Malaria Polymerase Chain Reaction testing on blood donated by donors with Malaria risk. These are additional precautionary measures taken to safeguard the integrity of the national blood supply.

We also looked into the feasibility of introducing new methods of testing platelets for bacterial contamination in March 2005 to further enhance safety of platelet transfusion.

Increasing our Quality Service Notch

We launched our newly renovated Donors' Refreshment Lounge in October 2004, specially dedicated to all blood donors, in recognition of their selfless commitment of time and effort to give the gift of life to save those in need. Blood donors can now look forward to having their own private corner to enjoy their post-donation refreshments. A main feature of the Lounge is the River of Life which pays tribute to about 1,500 champion blood donors from 2002 to 2003 who have donated between 50 and 150 times. More names will be added annually to the River of Life, which is able to hold 5,000 names.

DonorCare@HSA Enhanced

We continued to enhance DonorCare@HSA, an online service for blood donors that was introduced in August 2003.

All blood donors are able to book donation appointments not only at the Bloodbank@HSA but also at the nearest mobile blood drive at anytime of the day. Further, waiting time for donation is also reduced for those who make appointments as the online system tracks and avoids peak hours for the appointments. With these features, DonorCare@HSA makes it more convenient for the altruistic and committed donors, and enables the Bloodbank@HSA to enhance the blood donation experience for donors.

In addition, potential blood donors are able to determine if they are suitable for blood donations by doing an online health assessment check, which is available in the four official languages, via the 'Health Assessment Questionnaire'. This obviates the need for donors to make unnecessary trips to the Bloodbank@HSA or the mobile blood drives if they are unsuitable for blood donation.

As part of our ongoing efforts to reach out to the communities, regularly updated information will be made available so that both donors and non-donors can learn more about the blood donation process and better understand the importance of donating regularly and of how they can contribute to blood safety.

Strategic Partnership with the Singapore Red Cross

During the year, we continued to work in close partnership with SRC to recruit, retain and recognise blood donors.

We celebrated the inaugural World Blood Donor Day on 14 June 2004 with SRC to thank blood donors and to promote the importance of voluntary, non-remunerated blood donations.

Champion Blood Donor Award Ceremonies were held with SRC as part of the Donor Recognition Programme. In 2004, a "Champion of Champions" Award was presented for the first time to a donor who made his 150th donation.

Various blood drives targeted at young donors to donate blood, such as "Vibrant Blood" and "Red Challenge Award 2004", were successfully organised during the year. To inject fun and to spread the joys of blood donation at the same time, we worked with SRC to organise thematic and festive blood donation drives such as Halloween Party and major festivals at the Bloodbank@HSA. The festive decorations, along with the staff dressing in traditional costumes, have also received positive responses from blood donors who welcome the refreshing change from the usual corporate uniforms.

Clinical Teachings and Staff Training

Several international experts were invited during the year to share their knowledge, expertise and experiences with our staff. We hosted Professor D J Anstee, who is our Ministry of Health's Health Manpower Development Programme Expert for Transfusion Medicine for two weeks from 26 July to 8 August 2004. Prof Anstee is also an international expert in immunohaematology and molecular biology.

We also invited another expert, Dr Albert Farrugia, Senior Principal Research Scientist and Head of the Blood and Tissues Unit, Australia's Therapeutic Goods Administration, who gave a series of lectures on immunohaematology, blood safety and transfusion science. These were attended by haematologists and blood banking personnel.

Our staff also attended the International Society of Blood Transfusion Conference in July 2004 held at Edinburgh, Scotland, and put up two poster presentations.

Going Forth

We continue to seek the highest standards in transfusion medicine to attain AABB accreditation by end 2005.

In the coming year, we target to complete the challenging task of streamlining and upgrading our operation to satisfy the high standards required for accreditation with the AABB and the American Society of Histocompatibility and Immunogenetics.

As part of our ongoing commitment to providing quality donor care, we will continue to introduce new initiatives to make blood donation more convenient and enjoyable, with the objective of encouraging more Singaporeans to donate blood. Plans in the pipeline for 2005 include the revision of opening hours at the Bloodbank@HSA so as to reach out to more donors.



*Our Centre for Analytical science (CAS)
excels in applying analytical science to safeguard public health by
providing high quality, cost-effective and timely service to our clients.*





PROVIDING SCIENTIFIC ANALYTICAL AND CONSULTING SERVICES

Our **Centre for Analytical Science (CAS)** is Singapore's leading government provider of scientific consulting services to law enforcement agencies, government ministries, hospitals, private organisations and individuals.

Our five specialised laboratories provide scientific and analytical expertise in the areas of food, pharmaceutical, cosmetic, cigarette and environmental analysis.

We continue to benchmark ourselves against our counterparts in leading analytical institutions abroad. In 2002, we became a Singapore Quality Class (SQC) organisation. Since 1997, CAS has also attained the continuous recognition by the Singapore Accreditation Council - Singapore Laboratory Accreditation Scheme (SAC-SINGLAS) under ISO/IEC Guide 25, which was further upgraded to ISO/IEC 17025 in July 2002. We have seven senior analytical scientists who are appointed as qualified ISO/IEC technical assessors.

We take a special interest to protect our community and environment. An integrated approach with stringent protocols is in place to ensure that solvents and acids used for experiments do not pollute the environment and are within safety limits.

During the year, a total of 12,432 exhibits was examined by our laboratories.

Laboratories	Exhibits/Cases Completed
Food Lab	5,566
Pharmaceutical Lab	2,256
Industrial Health Lab	3,171
Cosmetic Lab	305
Cigarette Testing Lab	601
Environmental Lab	533

New Analytical Science Capabilities

In January 2005, our Pharmaceutical Laboratory successfully expanded its existing accredited adulterants' list for Chinese Proprietary Medicines (CPM) screening by another 52 adulterants (*vide infra*).

In July 2004, our Cosmetic Laboratory added two new tests to identify oestrogens and tretinoin in skin care cosmetic in the scope of accredited tests.

Our Food Laboratory launched a new analytical service to screen irradiated food by photostimulated luminescence in January 2005. Samples have been received from both the public and private sectors.

Annual Assessment by SAC-SINGLAS

There was an annual renewal assessment for all our laboratories by SAC-SINGLAS on 30 March 2005.

An internal laboratory audit was conducted on all our laboratories in August 2004. Corrective actions for the non-compliance items observed in the respective laboratories during the audit were all completed by end September 2004.

Following the internal audit exercise, we arranged for an audit of our Pharmaceutical and Food Laboratories by SAC-SINGLAS in October and November 2004, respectively, for an enlargement of the scope of accredited tests.

Our Pharmaceutical Laboratory successfully expanded its accredited scope of CPM screening by another 52 western drug adulterants in January 2005. To date, we have been accredited by SAC-SINGLAS for the testing of 208 western drugs categorised into 37 different pharmacological effect groupings. Our Food Laboratory also successfully completed the SAC-SINGLAS accreditation assessment to expand the existing scope of analysis by two new tests.

In November 2005, we jointly organised a Proficiency Testing Seminar with SAC-SINGLAS for local laboratories, and this received overwhelming response from the industries.

Asia Pacific Laboratory Accreditation Co-operation (APLAC) Proficiency Testing Programme

We were invited in March 2005 to participate in the APLAC proficiency testing programme organised by Hong Kong Laboratory Accreditation Services on the Analysis of Lead in Herbal Medicine.

ASEAN Reference Laboratories

Under the EC-ASEAN Economic Co-operation Programme on Standards, Quality and Conformity Assessment, our Food Laboratory was designated in June 2004 as an ASEAN reference laboratory for mycotoxin analysis, while our Cosmetic Laboratory was selected as ASEAN leading laboratory under cosmetics sub-programme. Our Cosmetic Laboratory was involved in building up the capacity for laboratory expertise of ASEAN member countries for post-marketing surveillance purposes. We were also selected to conduct a workshop in cosmetic analysis in which we provided hands-on laboratory training to 10 ASEAN delegates from 11 to 15 October 2004 on two ASEAN Harmonised Cosmetic Methods for colorants and tretinoin. An instructional video was produced on these methods and would be distributed as training material to the ASEAN countries.

Our Pharmaceutical Laboratory completed the testing of bulk substances, Hydrocortisone, Trimethoprim and Diazepam, which will be adopted as ASEAN reference standards in the coming 13th Meeting on Production and Utilisation of ASEAN Reference Substances, to be held in Thailand by the second quarter of 2005. The Laboratory also hosted the training in the conduct of proficiency tests in January 2005 for 11 delegates from around the region.



ASEAN Experts

Under the same EC-ASEAN programme, two of our scientific officers were appointed as ASEAN Senior Experts, and one of them assessed the laboratories in Indonesia, Malaysia, Cambodia and Laos from 2 to 11 August 2004. In addition, two officers attended the Harmonisation Workshop for ASEAN Cosmetic Test Methods in Malaysia from 13 to 17 September 2004 as ASEAN Senior Expert and Junior Expert, respectively.

Further, two scientific officers were invited as ASEAN experts to attend the Regional Workshop on Access to Reference Substances, held in Bangkok from 21 to 22 October 2004, and another officer attended the training in the conduct of proficiency tests, held in Malaysia from 17 to 18 January 2005.

Collaborations with the World Health Organisation

Our two WHO collaborating centres, the Pharmaceutical Laboratory and the Food Laboratory, continued to work closely with WHO on activities associated with their terms of reference. Our Food Laboratory was also re-designated as a WHO Collaborating Centre for Food Contamination Monitoring during the year.

In February 2005, our Pharmaceutical Laboratory re-examined three chemical reference substances, namely Indomethacin, Fluorouracil and Methorexate, for WHO Collaborating Centre for Chemical Reference Substances in Sweden.

Our Centre Director attended the WHO Consultation on Assessing Safety and Quality of Herbal Medicines held in Italy from 12 to 14 July 2004 as an expert.

A WHO Fellow from Sri Lanka was attached to our Pharmaceutical Laboratory for training in pharmaceutical analysis from 4 to 31 October 2004. Three WHO Fellows from the China Academy of Traditional Chinese Medicine and State Administration of Traditional Chinese Medicine of China visited our Pharmaceutical Laboratory from 6 to 7 December 2004.

12th Asia Collaborative Study on ISO Tar and Nicotine

In May 2004, our Cigarette Testing Laboratory participated in the 12th Asia Collaborative Study on ISO Tar and Nicotine in Cigarettes together with 55 laboratories from 20 countries in the Asia-Pacific region and Europe. Each participating laboratory tested five different brands of cigarette samples with tar levels ranging from 1mg to 15mg per cigarette.

The analytical data from the collaborative study was sent to CAS for collation and statistical analysis in November 2004. We have completed the testing of cigarette samples and are carrying out the statistical analysis of the data for the study. The reports of our analysis will be sent to the participants in April 2005.

International Laboratory Forum on Counterfeit Medicines (ILFCM)

In May 2004, our Centre Director was invited to participate in the ILFCM, which aimed to share information on scientific techniques used to detect counterfeit drugs and harmful substances in dietary supplements. The forum also sought to highlight possible sources of counterfeit, law enforcement actions and collaboration on the development of new methodologies and analysis of samples.

Collaboration on Research Studies

In May 2004, we collaborated with the National University Hospital's Division of Gastroenterology on a 5-year project "Clinical Course of Patients with Drug-Induced Liver Injury in a Tertiary Liver Centre".

We also continued our ongoing collaborations, which started since 2003, with the National University of Singapore's Departments of Chemistry and Pharmacy on the analysis of hepatotoxic alkaloids and sildenafil analogues in herbal preparations.

Our Pharmaceutical Laboratory was invited by the British Pharmacopoeia Commission Secretariat in September 2004 to contribute towards the development of the British Pharmacopoeia monographs for Traditional Chinese Medicines and Ayurvedic Medicines.

Going Forth

Having attained the SQC in July 2002, we will embark on our journey for the Service Excellence Class in the coming year. We will continue to support the public agencies' regulatory activities by developing new capability and keeping abreast with new developments in order to exceed the needs of our clients.

New initiatives in the pipeline include a \$0.6 million investment plan to expand resources and procure new equipment such as High Performance Liquid Chromatography – Mass Spectrometry, Gas Chromatography – Mass Spectrometry and PhotoStimulated Luminescence detector.

Key challenges for our various laboratories in the coming year include the following:

- Our Pharmaceutical Laboratory will continue to assist the local and overseas laboratories in attaining accreditation for screening of common adulterants in CPM. This is part of our efforts in ensuring availability of sufficient accredited laboratories in the region for

traders, especially in China, Taiwan and Hong Kong, where most of the CPM originated. Expansion of analytical scope on naturally occurring toxic alkaloids and pesticide residues in CPM is part of our plan to keep pace with new and emerging demands. Our collaboration with WHO continues and there are plans to work with WHO in the development of draft monographs for International Pharmacopoeia on anti-HIV/AIDS drugs.

- Our Food Laboratory will be renewing a 5-year contract with Agri-Food Veterinary Authority of Singapore for the analysis of chemicals in processed food and in food packaging material. We also plan to further develop our testing capability on irradiated food and plastics, particularly in the area of migration studies of plastic additives into food. In the coming year, we will be organising our first EC-ASEAN proficiency testing programme as well as a hands-on training on the technique on mycotoxin analysis.

- Our Cosmetic Laboratory will continue to validate the ASEAN Harmonised Cosmetic Methods as well as participate in the Proficiency Test where samples will be sent from France to four other leading ASEAN countries, including Singapore. We will also continue to carry out research projects on prohibited and restricted substances in cosmetic products.

- Our Cigarette Testing Laboratory intends to start a research project on the survey of tar and nicotine in cigars on sale in Singapore and carry out the mainstream smoke analysis for other constituents.

- Our Environmental Laboratory will continue to determine and review the Measurement Uncertainty determination for all of our analytical tests. We have adopted a cost-effective way of analysing bottled water samples to deliver better value and more savings in analyses fees for our stakeholders.



nurturing value

We recognise our people as our greatest asset. HSA believes in nurturing value by building a work culture that is collaborative, creative and innovative and to develop an engaged and committed workforce ready to embrace change and compete in a fast-changing operating environment.

PROMOTING ORGANISATIONAL EXCELLENCE

Our relentless pursuit for organisational excellence at HSA has led us towards achieving the People Developer Standard (PDS) in 2002 and Singapore Innovation Class (I-Class) in 2003.

In 2004, focussed efforts were channelled to bridge the gaps in the key improvement areas identified based on the Singapore Quality Award Framework and from our earlier achievements of the two organisational excellence accolades.

HSA needs to ensure that we have the right people, with the right mindset, talent and expertise for the job. We will also need to continuously build and sustain an engaged and committed workforce ready to embrace change and respond quickly to opportunities in the operating environment.

Hence, priority was given to strengthen the HSA Way as the desired corporate culture that is innovative, creative and professional, and that would enable us to surmount the challenges as we strive towards our vision to be world class for scientific and regulatory expertise in health sciences.

Through a comprehensive Organisational Capability Survey carried out by an independent external consultant in 2004, extensive feedback and many useful ideas were received from our staff to strengthen the internal processes. Taskforces were formed to look into areas of concerns and to review organisational processes that would help to bring about a high level of operational efficiency and staff satisfaction in the workplace.

Living Core Values, the HSA Way

In September 2004, the HSA Living Core Values Programme, spearheaded by the Living Core Values Taskforce, was launched, where a full month was dedicated to the promotion of each HSA's five core values. In addition to the monthly awareness activities, a series of attractive and colourful in-house designed posters featuring each core value was introduced to inspire and motivate our staff.



The HSA Living Core Values Recognition Programme was concurrently launched to recognise HSA officers who are living examples of "the HSA Way" and who are role models for the particular core value. A total of 24 officers was honoured and presented the HSA Living Core Values Award.

In January 2005, we published the first issue of the Living Core Values Newsletter to profile our Award winners and to further deliver the core value messages.

Embracing Innovation

At HSA, innovation is one of our key drivers of promoting organisational excellence. Our Innovation framework, built upon our vision, mission and core values, is based on three guiding principles: *focus on vision, freedom with responsibility* and *frontier – boldly going forward*.

Three F words for Our Innovation Journey

Based on HSA's core value on "Encouraging innovation and enterprise", these F words serve as guiding principles to inspire and challenge each and every HSAian to think and act out of the box.

- **Focus on Vision**

Innovation & Enterprise (I & E) begins with looking out for something with a purpose or special meaning. Focusing on a vision promotes strategic movement, helps sustain the drive and keeps one moving towards a shared goal.

- **Freedom with Responsibility**

I & E is work, serious work. I & E cannot be seen as wasting money or time. It is about investing wisely in the future today. Sowing for tomorrow, today.

- **Frontier – Boldly going Forward**

I & E involves taking risks. It is about learning from the mistakes and striving again to excel. Be bold – by possessing the "never say die" attitude, new frontiers can be forged and conquered.

FISH! Sticks, the sequel to the FISH! Philosophy, was introduced to HSAians in October 2004. More than 85% of HSAians attended the in-house workshops, which emphasised the importance of commitment to our corporate vision.

Throughout the year, other innovation activities were also organised to sustain the momentum to keep the HSA vision alive. In May 2004, we collaborated with the National University of Singapore to organise the 2nd HSA-NUS Scientific Seminar. A total of 22 papers and 17 posters was presented based on the seminar theme "Health through Scientific Research".

In November 2004, the annual IDEAS Forum was held to encourage and inspire HSAians to be creative in their work and to showcase their award-winning projects. A series of creative and fun-filled activities such as learning journeys, creativity workshops and cerebral challengers was also organised in March 2005 as part of the HSA Innovation Month. The theme, PASSION, which stands for 'Pass Innovation On', serves to remind all that it is PASSION that fuels the fire of inspiration, awakes the amber of ideas and sparks off the light of innovation to be shared by all.



We continuously encourage our staff to take part in Research and Development, Work Innovation team (WIN) projects and contribute staff suggestions to improve processes. During the year, 17 research projects were simultaneously worked on and 40 WIN projects were completed. Out of 1,632 staff suggestions submitted, 355 suggestions were implemented.

With its efforts in innovation, HSA bagged Gold for the Best Staff Suggestion Award, Gold for the Distinguished Work Improvement Teams (WITs) Effort (Team) Award, Gold for Outstanding WITs Leader Award and Bronze for Outstanding WITs Facilitator Award at the MOH Annual PS21 EXCEL Awards 2004.



HSA Innovation Award

The HSA Innovation Award recognises HSAians who have shown innovation and effectiveness in developing innovative and successful products, services and approaches in the areas of health products and radiation protection regulations, transfusion medicine, forensic medicine as well as analytical and forensic science services.

• New Autopsy Trolley

The need to create another weighing facility in our Centre for Forensic Medicine's Mortuary@HSA led to a winning idea from a cross-functional Work Innovation (WIN) team project.

The WIN team, working within existing constraints of space and physical infrastructure, successfully created an autopsy trolley with weighing function suitable for use in Biosafety Level 3 autopsy suites. This trolley not only helps to increase the efficiency and work process for the morticians, it also reduces the chances of work-related injuries in the mortuary. This invention is estimated to have resulted in cost savings of at least \$10,000 per trolley. This team was awarded the HSA Innovation Distinction Award.

• Improved DNA Profiling Method

HSA also recognised another innovative project by its forensic scientists from the DNA Database Laboratory, Centre for Forensic Science (CFS). Aiming to better serve and create value for the Singapore Police Force - specifically, the Criminal Investigation Division - the CFS' DNA Laboratory developed a method which increased the laboratory's operational efficiency and reduced the use of test reagents and consumables without compromising the quality and reliability of the DNA profiling tests. This improved DNA profiling method, which has been validated to meet international standards, resulted in an annual savings of approximately \$600,000 and was subsequently translated into a reduction in testing charges and savings for the Police by at least 15%.

Developing & Nurturing our People

Given the high level of competent staff required to uphold professional excellence in our professional services, priority is given to develop and nurture our staff's potential to their fullest. Staff competency level is evaluated twice yearly. Detailed learning analyses are also carried out for all levels of staff on an annual basis to identify areas for further development.

Apart from the formal training programmes and sponsorship for overseas conferences, our staff are given many avenues to upgrade themselves. Some programmes in place include the Staff Development Fund (SDF) and the Professional Development Programme (PDP) where we encourage our staff to share the responsibilities of personal development and skills upgrading either through committing to joint course funding or through a minimum serving period.

Under programmes such as the Ministry of Health's Health Manpower Development Programme (HMDP), our staff are posted overseas to countries such as USA and UK for training and attachment. Opportunities are arranged for them to further share the knowledge gained from such postings with the other colleagues and to apply the knowledge learnt to improve HSA's professional standards.

To encourage our nurses to upgrade their skills, we also started sponsoring two enrolled nurses to a 3-year Diploma in Nursing course offered by the Nanyang Polytechnic for the first time.

Much emphasis had also been placed on in-house training which includes on-the-job trainings and other in-house sharing sessions such as the Balanced Scorecard Roadshows, Professional Centres' Roadshows, Moot Court Sessions, Journal Club Presentations and Professional Seminars. In FY 2004/05, each of our 578* staff achieved an average of 95 training hours.

* staff strength as at 31 March 2004.

During the year, 67 officers were promoted in recognition of their excellent performance. Long Service Awards were also bestowed upon 66 staff.

Seven HSA officers received the National Day Awards in 2004. These included five Long Service Medals, one Commendation Medal and an Efficiency Medal.

Integrating Fun & Fitness at Work

We are also fully committed to promoting an integrated workplace health promotion programme that will encourage and enable all staff to lead balanced and healthy lifestyles. Initiatives are taken to continuously improve and maintain the health of our staff, thereby making HSA a great place to work in and to work out at.

Activities such as Family Day, recreational outings, sports activities, competitions, talks and workshops were held to strengthen staff bonding and the importance of healthy living. The monthly Fruits Day and the Active Day were just some of the regular features to help staff stay in the pink of health.

During the year, we also started a 4-Colour House Teams Programme to encourage camaraderie and esprit de corps among our staff. Each staff is assigned to a house team. Some of the House events organised for the year include the Innovative Cooking Competition, the National Day Singing Competition and the HSA Games Day.



As a result of the continuous efforts in promoting staff well-being and workplace health, HSA was awarded the Singapore Family Friendly Employer Award and a silver H.E.A.L.T.H award for the Workplace Health Programme in 2004.

Harnessing IT

In 2004, we continued to implement and enhance the customer-focussed solutions identified in our 3-year Information Technology (IT) Master Plan in July 2002.

These five application systems identified in the IT Master Plan are:

- System for Transfusion Medicine Analysis and Management (STREAM)
- Donor Care and Management System (DonorCare)
- Pharmaceutical Regulation and Information System (PRISM)
- Medical Device Licensing and Control System (MEDICS)
- Contact Lens Licensing System (COLLINS)

We also planned ahead to upgrade some of the other older systems in HSA. Our team had also been working with other government agencies in order to support the Government's initiatives to provide secure and streamlined e-services.

Development and implementation of STREAM had been a key focus in 2004. Our team worked closely with the users and vendor in order to derive the functional and design specification of the system. We completed the first phase of user acceptance test and will be embarking on the second phase of testing in the coming year. The Queue Management System for DonorCare was also tested. We will be interfacing DonorCare and STREAM in order to provide a complete platform for the management of blood products and our blood donors.

Phase One of PRISM was completed and we began progressively rolling out the various electronic licensing modules to our customers.



With the completion of Phase Two of PRISM, we were able to leverage on the Integrated Search and Retrieval System to enhance CDA's regulatory work processes. The Quality Enforcement and Surveillance System would support our quality enhancement and surveillance programme. Development of the module for electronic submission of dossiers for evaluation was also completed.

Both MEDICS and COLLINS are operational. Practitioners as well as traders are now able to access the systems online to register their products, apply for and renew their licences.

To enhance these main application systems, we implemented an Interactive Voice Response System (iCall@HSA). This system provides an alternative avenue for users of our electronic services to access them. By interfacing iCall@HSA with DonorCare@HSA, our blood donors can now find out their next eligible donation date by just calling us. We are currently exploring the feasibility of interfacing this system with the other regulatory systems to enable our licensees to find out the expiry date of their licences by calling us, in addition to accessing the licensing system via the Internet.

To align HSA to the Government's directives on electronic services, we have been actively working with the Online Business Licensing System team to make available our electronic services on this seamless and fully integrated platform. We have also been awarded a provisional award for the accreditation of TrustSg. We hope to give our electronic service users the confidence that HSA is providing secure and reliable electronic services.

With most of the projects identified under the 3-year IT Master Plan nearing completion in July 2005, we hope to embark on the next 4-year IT Master Plan for FY 2005-08. We will work with our various professional centres on IT planning to align their various initiatives with HSA's strategic objectives of improving effectiveness and efficiency as well as providing premium professional services. This

would involve replacement and enhancement of some of our existing application systems. The enhancement to our One-Stop Centre Web Portal would also take place in order to align it to the Government's new standard of web page design.

We will continue to exploit IT development in order to provide streamlined, user-friendly and cost efficient systems, to our stakeholders.

Delivering Quality Customer Service

In the face of growing public expectations, several service improvement initiatives were rolled out during the year to continuously nurture the quality culture at HSA and to ensure greater responsiveness in our customer service. These included:

- Participating in a quarterly PS21 Mystery Customer Audit programme which paired us with Singapore Customs and Agri-Food & Veterinary Authority to cross-audit each other's service standards. On average, we attained 98% and 80% of compliance rate, respectively, for service indicators such as response time for telephone calls, and email queries in the cross audits.
- Organising an HSA Quality Day in February 2005 to enhance awareness of the quality efforts and to recognise quality service providers within HSA. Nine officers received the Outstanding Service to Customer Awards (OSCA) which are awarded to those who have demonstrated high customer service level. As at 31 March 2005, 22 individuals and two teams were presented with the OSCA, while eight teams have been presented with the Outstanding Quality Improvement Award (OQIA) for their contributions in improving the quality of work and operations.
- Conducting a second* Customer Satisfactory Survey in March 2005 to measure our service quality and customer satisfaction on services provided by our seven professional centres and HSA as a whole. Appropriate service indicators were specially designed for the survey

questionnaires to cater to the specialised services provided by each professional centre and the unique customer group serviced by the respective centre. The survey is targeted to be completed by June 2005

*The first Customer Satisfaction Survey was conducted in 2002.

- Publishing a quarterly e-Quality Service Bulletin where customer feedback is collated and disseminated to our staff to reflect on our service quality. Staff are also provided monthly updates of customer feedback received. During the year, we received 1,372 and 778 feedback responses through emails and feedback forms, respectively. We also continued with the quarterly issue of the Voice of Customer (VOC) report for all staff as a platform to continuously review our feedback system and to improve our responses to our customers.

Caring for the Community and Environment

At HSA, we recognise our responsibility not only to our immediate clients and stakeholders, but also to the environment and community at large.

Our Societal and Environmental Policy that was formalised in 2003 highlighted four key thrusts:

- Conserve natural resources
- Advocate environmental awareness and workplace safety to our stakeholders
- Reduce, recycle and manage wastes effectively
- Encourage our staff to contribute to the development and dissemination of scientific knowledge, and to the well-being of our community



During the year, various activities were organised to promote our corporate social responsibility and were actively participated by HSAians. These included fundraising programmes through charity walks and runs, selling of donation tickets and collection of old clothing; paper recycling efforts; and community outreach projects such as bringing underprivileged children for island hopping trip.

Playing an active role in nation-building, our staff also participated in the development and dissemination of scientific knowledge through the Ministry of Education's learning journey programmes for students of secondary schools and junior colleges. Many of our professional staff also served as subject experts in various international and local scientific agencies and committees.

Going Forth

In the year ahead, we will be gearing up for the People Developer re-certification audit in October 2005 by SPRING Singapore and working towards the next challenge and target of achieving the People Excellence Award.

In our knowledge-based economy, it is important for HSA to develop a renewed focus on our people, to keep vital knowledge within the organisation, to enhance expertise and develop new skills and capabilities to compete in a more demanding and fast-changing business environment.

We will remain committed to building a collaborative culture that motivates and empowers HSAians to work towards an excellent HSA that is customer-focussed and people-oriented.



our customer service standards

The Health Sciences Authority is a Statutory Board dedicated to regulatory, scientific and service excellence.

We aim to deliver a high standard of customer service in serving with courtesy, accessibility, responsiveness and effectiveness.

We are committed to

- Treat all our customers with courtesy and consideration •
- Provide customer service in a positive, helpful and timely manner •
- Handle customer feedback and complaints with sensitivity and honesty •
- Provide accurate and current information to the public •

We will

- Set appropriate target turn-around-times for our professional services •

We will

- Conduct regular consultations with our stakeholders and customers to continuously develop and improve our services •

We will

- Reply to customers' enquiries within 7 days •
- Reply to urgent requests within 3 working days •

We aim to

- Attend to customers within 10 minutes of appointment time •

We aim to

- Answer all telephone calls within 10 seconds •

All of us at HSA pledge to uphold these standards to provide the best service to our customers.

research papers and projects

REGULATING PHARMACEUTICALS AND HEALTHCARE PRODUCTS

TITLE OF RESEARCH PAPER	AUTHOR(S)	PROFESSIONAL PUBLICATION
A Mechanistic Perspective On The Specificity And Extent Of Cyclooxygenase-2 Inhibition In Pregnancy	Dr Vivian Chan	Drug Safety, 27(7), 421-426, 2004
The Use of Toxicogenomic Data In Risk Assessment: A Regulatory Perspective	Drs Vivian Chan & Mette Due Theilade	Journal of Toxicology - Clinical Toxicology, 43(2), 121-126, 2005
Regulatory Control Of Chinese Proprietary Medicines In Singapore	Yee Shen Kuan, Chu Swee Seng, Xu Yi Min & Choo Peck Lin	Health Policy, 71(2), 133-149, 2005
Analysis Of Adverse Drug Reactions For Year 2003	Ang Pei San, Dr Ting Kang Nee, Tan Bee Him & Chan Cheng Leng	Drug Safety; 27(12), 914, 2004
Complementary Medicine: Case Report Of Adverse Drug Reactions Due To Adulteration	Dr Ting Kang Nee, Ang Pei San, Tan Bee Him & Chan Cheng Leng	Drug Safety; 27(12), 962, 2004
How Singapore Regulates Safety Reporting From Clinical Trials	Dorothy Toh, Dr Kerwin Low, Dr John C W Lim, Julia Leong & Foo Yang Tong	The Regulatory Affairs Journal-Pharma, October 2004, 15 (10), 725-731

TITLE OF RESEARCH PRESENTATION	AUTHOR(S)	PROFESSIONAL EVENT
Recent Advances On The Use Of Toxicogenomic Data In Risk	Drs Vivian Chan & Mette Due Theilade	2 nd HSA-NUS Scientific Seminar, 19 May 2004
Assessment: Regulatory Perspective Analysis Of ADR Reports For Year 2003	Ang Pei San, Dr Ting Kang Nee, Tan Bee Him & Chan Cheng Leng	2 nd HSA-NUS Scientific Seminar, 19 May 2004
Risk Assessments Arising From Drug Safety Concerns	Ang Pei San, Dr Ting Kang Nee, Tan Bee Him & Chan Cheng Leng	2 nd HSA-NUS Scientific Seminar, 19 May 2004

TITLE OF RESEARCH PROJECT	PRINCIPAL INVESTIGATOR(S)
Use of Genetically Modified Viruses And Genetically Engineered Virus-vector Vaccines: Environmental Effects	Dr Vivian Chan
Regulatory Control Of Aristolochia Herbs In Singapore	Yee Shen Kuan, Chu Swee Seng, Tee See Yee, Li Chunwei & Choo Peck Lin
Survey On The Use Of Package Insert As A Source Of Drug Information By Healthcare Professionals In Singapore	Dr Ting Kang Nee, Ang Pei San, Tan Bee Him & Chan Cheng Leng

PROVIDING FORENSIC PATHOLOGICAL AND INVESTIGATIVE SERVICES

TITLE OF RESEARCH PAPER	AUTHOR(S)	PROFESSIONAL PUBLICATION
Homicidal And Dyadic Falls From Heights : Rarities In Singapore	Associate Professor Gilbert Lau	Medicine, Science & Law 2004; 44:93-106
Cholecystokinin-B Receptor Gene Expression In Cerebellum, Pre-Frontal Cortex And Cingulated Gyrus And Its Association With Suicide	Sherrin T, Heng KYC, Drs Zhu Y Z, Tang Y M, Associate Professor Gilbert Lau & Dr Tan CH	Neuroscience Letters 2004: 357:107-110
Slim 10 – Slim Chance. A Fatal Case Of Hepatic Failure Possibly Induced By N-nitrosufenfluramine	Associate Professor Gilbert Lau, Dr Danny Lo, Dr Yao Yi Ju, Leong Hsiao Tung, Chan Cheng Leng & Chu Swee Seng	Medicine, Science & Law 2004, 44(3): 252-263
Injury Patterns And Outcome Of Falls From Heights In Two Teaching Hospitals	Drs Ong A, Lau P, Yeo A, Koh M P & Associate Professor Gilbert Lau	Medicine, Science & Law 2004; 44:201-5

PROVIDING FORENSIC PATHOLOGICAL AND INVESTIGATIVE SERVICES (CONT'D)

TITLE OF RESEARCH PRESENTATION	AUTHOR(S)	PROFESSIONAL EVENT
Fatal Road Accidents	Associate Professor Gilbert Lau	World Health Seminar, Singapore, 20 April 2004
Death May Have Its Benefits : The Role Of Forensic Pathology In Medical Audit	Associate Professor Gilbert Lau	15 th World Congress On Medical Law, Melbourne, Australia, 2 August 2004
Fatal Adverse Drug Reactions (ADR) : A Forensic Perspective On The Use Of Anti-microbial And Anti-neoplastic Agents	Associate Professor Gilbert Lau	World and Ehrlich Conference On Magic Bullets Nürnberg, Germany, 9 September 2004
Sudden Death And Buprenorphine And Benzodiazepine Toxicity	Dr Wee Keng Poh	National Association Of Medical Examiners, Memphis, Tennessee, USA, 11 September 2004
Scene Investigations Of Suspicious Deaths In Singapore	Dr Wee Keng Poh	National Association Of Medical Examiners, Memphis, Tennessee, USA, 15 September 2004

TITLE OF RESEARCH PROJECT	PRINCIPAL INVESTIGATOR(S)
An Extensive Literature Review Of Iatrogenic Injury From A Forensic Perspective, Undertaken Upon An Invitation To Contribute A Chapter On The Subject To Forensic Pathology Reviews (Vol 3), Humana Press, edited by M Tsokos (Hamburg, Germany) (Completed in July 2004)	Associate Professor Gilbert Lau
An Interim, Follow-up Study On Maternal Deaths, Covering The Period 2000 - 2003 (Completed In July 2004)	Associate Professor Gilbert Lau
An Interim, Follow-up Study On Fatal Adverse Drug Reactions, Covering The Period 2001 - 2003 (Completed In August 2004)	Associate Professor Gilbert Lau

PROVIDING FORENSIC SCIENTIFIC, INVESTIGATIVE AND ANALYTICAL SERVICES

TITLE OF RESEARCH PAPER	AUTHOR(S)	PROFESSIONAL PUBLICATION
Investigation of Class Characteristics In English Handwriting Of The Three Main Racial Groups: Chinese, Malay And Indian In Singapore	Lee Gek Kwee, Nellie Cheng, Yap Bei Sing, Lee Lee Tiang, Tan Sock Kim & Tan Koon Puay	Journal Of Forensic Science, 50(1): 177-184, 2005
A Fatal Case Of Hepatic Failure Possibly Induced By Nitrosufenfluramine: A Case Report	Associate Professor Gilbert Lau, Chan Cheng Leng, Chu Swee Seng, Leong Hsiao Tung, Drs Danny Lo Siaw Teck & Yao Yi Ju	Medicine, Science & Law, 44(3): 252-263, 2004
Performing Toxicology Under The Threat Of SARS	Leong Hsiao Tung, Drs Yao Yi Ju & Danny Lo Siaw Teck	Bulletin Of The International Association Of Forensic Toxicologists, XXXIV (2): 35-36, 2004
Genetic Data For The 13 CODIS STR Loci In Singapore Indians	Simon Lim Eng Seng, Tan-Siew Wai Fun, Ang Hwee Chen, Drs Chow Shui Tse, Christopher Syn & Bruce Budowle	Forensic Science International 148: 65-67, 2005
STR Data For The 13 CODIS Loci In Singapore Malays	Ang Hwee Chen, Simon Lim Eng Seng, Tan-Siew Wai Fun, Drs Chow Shui Tse, Christopher Syn, R Sornarajah & Bruce Budowle	Forensic Science International 148: 243-245, 2005

TITLE OF RESEARCH PRESENTATION	AUTHOR(S)	PROFESSIONAL EVENT
Overview Of Forensic Science, Firearms And Toolmarks And Glass Examinations	Dr Tay Ming Kiong Michael	Defence Science & Technology Agency Technical Seminar, 30 April 2004.
Forensic Science in Singapore	Dr Chow Shui Tse	Korea Forensic Science Conference, 13 May 2004
A Study On The Levels Of Difficulty In The Simulation Of Individual Characteristics In A Signature	Yang Chiew Yung, Lee Gek Kwee, Yap Bei Sing, Lee Lee Tiang, Tan Sock Kim & Tan Koon Puay	2 nd HSA-NUS Scientific Seminar, 19 May 2004

PROVIDING FORENSIC SCIENTIFIC, INVESTIGATIVE AND ANALYTICAL SERVICES (CONT'D)

TITLE OF RESEARCH PRESENTATION	AUTHOR(S)	PROFESSIONAL EVENT
Illicit drugs For Erectile Dysfunction	Leong Hsiao Tung, Drs Yao Yi Ju & Danny Lo Siaw Teck	2 nd HSA-NUS Scientific Seminar, 19 May 2004
Study of "Erimin 5" Tablets Seized In Singapore	Dr Lee Tong Kooi, Wendy Lim Jong Lee, Merula Mangudi & Thiru Selvi	2 nd HSA-NUS Scientific Seminar, 19 May 2004
A Strand Of Evidence: Analysis Of 6-Monoacetylmorphine In Hair	Leong Huey Sze, Lim Cheng Min, Drs Lee Tong Kooi & Lui Chi Pang	2 nd HSA-NUS Scientific Seminar, 19 May 2004
Forensic DNA Profiling In Singapore	Dr Chow Shui Tse	CID Forensic Conference 2004, Singapore, 14 July 2004
Evaluation Of Ketamine Abuse Using Hair Analysis: Concentration Trends In A Singapore Population	Leong Huey Sze, Tan Ngak Lee, Drs Lui Chi Pang & Lee Tong Kooi	Joint Meeting of SOFT and TIAFT, Washington, DC, USA, 30 August – 3 September 2004
Raman Microscopy Of Low Explosives And Their Combustion Products	Dr Tay Ming Kiong Michael, Lim Chin Chin, Chia Poh Ling, Chow Yuen San Vicky & Su Wanjing	American Academy of Forensic Science 57th Annual Meeting, New Orleans, USA, 21 - 26 February 2005
Raman Microscopy Of Low Explosives Obtained From Sparkler Material	Dr Tay Ming Kiong Michael, Lim Chin Chin, Chia Poh Ling & Su Wanjing	American Academy of Forensic Science 57th Annual Meeting, New Orleans, USA, 21 - 26 February 2005
High Speed High Resolution GC/MS Of High Explosives	Lim Chin Chin, Chia Poh Ling, Irene Tan, Kuah Kim Lian & Dr Tay Ming Kiong Michael	American Academy Of Forensic Science 57th Annual Meeting, New Orleans, USA, 21 - 26 February 2005
Forensic Investigation Of A Gas Phase Explosion In A Building	Dr Tay Ming Kiong Michael, Chia Poh Ling & Kuah Kim Lian	American Academy Of Forensic Science 57th Annual Meeting, New Orleans, USA, 21 - 26 February 2005
The Amelogenin Sex Test – The Missing Y?	Simon Lim Eng Seng, Tan-Siew Wai Fun & Dr Christopher Syn	American Academy Of Forensic Science 57th Annual Meeting, New Orleans, USA, 21 - 26 February 2005
Verification Of STR Alleles By Alternative Primer Pairs Through A Singleplex PCR System	Simon Lim Eng Seng, Crystal Lai Liang Sung, Grace Law Chien Tien, Joyce Low Hui Koon & Tan-Siew Wai Fun	American Academy Of Forensic Science 57th Annual Meeting, New Orleans, USA, 21 - 26 February 2005
Trace Evidence: Its Value And Analysis	Dr Tay Ming Kiong Michael	International Forensic Science Symposium And 11th Annual Spring Meeting, Korean Society Of Forensic Science, Seoul, South Korea, 25 March 2005

TITLE OF RESEARCH PROJECT	PRINCIPAL INVESTIGATOR(S)
A Study Into The Analysis Of Inkjet Printer Inks By HPLC	Lee Gek Kwee, Yap Bei Sing, Yang Chiew Yung, Tan Joo Chin, Lee Lee Tiang, Tan Sock Kim & Tan Koon Puay

PROVIDING ESSENTIAL BLOODBANKING SERVICES

TITLE OF RESEARCH PAPER	AUTHOR(S)	PROFESSIONAL EVENT
Blood Donor's Arrival Time Preference	Noorhayati Rahman, Chong Tye Ling & Rohaidah Ramli	International Society Of Blood Transfusion, Edinburgh, 9 April 2004
Donors Deferral Due To nvCJD	Drs Diana Teo, Tan Hwee Huang, Syed Shu-Aib, Lawrence Kiong	International Society Of Blood Transfusion, Edinburgh, 13 April 2004
Disproportionate Number Of Group B Component (Whole Blood / Red Blood Cell) In The Centre For Transfusion Medicine. A Supply Or Demand Issue?	Michelle Peh	Workshop in Transfusion Medicine, Australian Red Cross Blood Services, Brisbane, 18 April 2004 2 nd HSA-NUS Scientific Seminar, 19 May 2004
Development And Validation Of The Mono-clonal Antibody-specific Immobilisation of Platelet Antigens Testing In The Centre For Transfusion Medicine	Drs Lela Seema, Lai Hock Chong, Diana Teo and Koh MBC	2 nd HSA-NUS Scientific Seminar, 19 May 2004
Prevalence Of Human T-lymphotropic Virus Among Blood Donors In Singapore	Siti Salbiah	21 st National Serology Reference Laboratory Workshop, Singapore, 18 - 20 August 2004

PROVIDING SCIENTIFIC ANALYTICAL AND CONSULTING SERVICES

TITLE OF RESEARCH PRESENTATION	AUTHOR(S)	PROFESSIONAL EVENT
The Proliferation Of Sildenafil As An Illicit Adulterant	Associate Professor Bosco Chen Bloodworth	2 nd HSA-NUS Scientific Seminar, 19 May 2004
Screening For Common Adulterants (Western Drugs) In Chinese Proprietary Medicines (CPM)	Low Min Yong	2 nd HSA-NUS Scientific Seminar, 19 May 2004
Sudan 1 Analysis On Chilli Products	Mohamed Sah Redha Hamzah	2 nd HSA-NUS Scientific Seminar, 19 May 2004
Chloramphenicol In Honey	Lee Lin Min & Yap Wee Kim	2 nd HSA-NUS Scientific Seminar, 19 May 2004
Acrylamide in Local Fried Food	Associate Professor Bosco Chen Bloodworth	7 th ASIAN Conference of Analytical Sciences (ASIA ANALYSIS VII), 28 – 31 July 2004
Chromatographic Determination Of Vinyl Chloride Monomer With Different Capillary Columns	Cheah Nuan Ping, Chan Sheot Harn Joanne & Lim Thye Hin	25 th International Symposium On Chromatography, 4 – 8 October 2004
Data Processing For Testing Programme	Kiang Kin Har	SAC-Singlas and CAS Proficiency Testing Seminar, 5 November 2004
The Optimisation And Identification Of Chloramphenicol In Royal Jelly Products Using HPLC Tandem MS	Chan Sheot Harn Joanne & Lee Lin Min	21 st LC/MS Montreux Symposium, 10 – 12 November 2004
Tandem MSMS Analysis Of Bisphenyl-A Diglycidyl Ether (BADGE) And Its Reaction Products In Canned Foods	Sun Cuilian, Matthew Grigg, Chan Sheot Harn Joanne & Lee Lin Min	21 st LC/MS Montreux Symposium, 10 – 12 November 2004
Detecting Mycotoxins: Overview Of Analytical Methods	Chan Sheot Harn Joanne	4 th ASEAN Food Safety Standards Harmonisation Workshop, Manila Philippines 29 – 30 December 2004

PROVIDING SCIENTIFIC ANALYTICAL AND CONSULTING SERVICES (CONT'D)

TITLE OF RESEARCH PROJECT	PRINCIPAL INVESTIGATOR(S)
Analysis Of Urinary t,t-muconic Acid By High Performance Liquid Chromatography (Completed in August 2004)	Dr Chow Yue Thong Patrick, Tan Buay Ting, Yeo Siew Lan, Audrey Ng & Poh Wee Koh
Developing Analytical Procedures For Identification Of Ethylene Dichloride In Cosmetic Products By Solid Phase Micro-extraction (SPME) And Gas Chromatography (GC)(Completed in September 2004)	Wong-Neo Geok Eng & See Phek Hah
Identification And Determination Of Prohibited And Restricted Dyes In Hair Dye Products (Ongoing)	Wong-Neo Geok Eng, See Phek Hah & Tang Kwai Fong
Rapid Quantitation Of Mercury Using Microwave Digestion In Cosmetic Product With Flow Injection-AAS (Ongoing)	Wong-Neo Geok Eng, Cheah Nuan Ping, See Phek Hah & Tang Kwai Fong
Development Of Turbo Ionspray Ionisation HPLC Tandem Mass Spectrometry Procedures To Determine Bisphenol A And Related Substances In Canned Foods (Ongoing)	Chan Sheot Harn Joanne, Dr Loke Swee Leng, Lee Lin Min, Mdm Yap Wee Kim & Sun Cuilian
Determination Of Pyrrolizidine Alkaloids In Chinese Herbs And Chinese Proprietary Medicine (Ongoing)	Kiang Kin Har, Low Min Yong, Oh Sze Yin, Tiong Chai Ling & Tan Oon Boon
Determination Of Organochlorine And Organophosphorus Pesticide Residues In Chinese Proprietary Medicine (Ongoing)	Low Min Yong, Oh Sze Yin, Kiang Kin Har, Tan Oon Boon & Len Shea Mei
Tar And Nicotine Survey Of Cigars On Sale In Singapore (Ongoing)	Dr Chow Yue Thong Patrick & Faridatul Akmam Morsed

financial statements

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AUDITORS' REPORT TO THE MEMBER OF HEALTH SCIENCES AUTHORITY

We have audited the accompanying financial statements of the Health Sciences Authority (the "Authority") as set out on pages 104 to 122 for the year ended 31 March 2005. These financial statements are the responsibility of the Authority's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with Singapore Standards on Auditing. Those Standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as, evaluating the overall financial statements presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion,

- a) the accompanying financial statements are properly drawn up in accordance with the provisions of the Health Sciences Authority Act (Chapter 122C) (the "Act") and Singapore Financial Reporting Standards so as to give a true and fair view of the state of affairs of the Authority as at 31 March 2005, and of the results, changes in reserves and funds, and cash flows of the Authority for the year ended on that date; and
- b) the accounting and other records required by the Act to be kept by the Authority have been properly kept in accordance with the provisions of the Act.

During the course of our audit, nothing came to our notice that caused us to believe that the receipt, expenditure and investments of funds, and the acquisition and disposals of assets by the Authority during the financial year have not been in accordance with the provisions of the Act.



Certified Public Accountants

Singapore
08 August 2005

HEALTH SCIENCES AUTHORITY

STATEMENT BY THE HEALTH SCIENCES AUTHORITY

In our opinion, the accompanying financial statements of the Health Sciences Authority (the "Authority") as set out on pages 104 to 122 are drawn up so as to give a true and fair view of the state of affairs of the Authority as at 31 March 2005 and of the results, changes in reserves and funds, and cash flows of the Authority for the financial year then ended.

On Behalf of the Authority



Prof Lim Mong King
Chairman



Dr Tan Chor Hiang
Chief Executive Officer

Singapore
08 August 2005

HEALTH SCIENCES AUTHORITY

BALANCE SHEET

As at 31 March 2005

	<u>Note</u>	<u>2005</u> \$'000	<u>2004</u> \$'000 (Restated)
CAPITAL ACCOUNT	4	48,124	-
ACCUMULATED DEFICIT		(2,176)	(1,154)
PRE-RESTRUCTURING FUNDS	5	-	233
		<u>45,948</u>	<u>(921)</u>
REPRESENTED BY:			
CURRENT ASSETS			
Cash and cash equivalents	6	14,700	12,974
Trade receivables		5,802	6,063
Other receivables, deposits and prepayments	7	4,233	9,454
Inventories	8	1,461	1,582
Total current assets		<u>26,196</u>	<u>30,073</u>
NON-CURRENT ASSET			
Plant and equipment	9	109,130	32,740
CURRENT LIABILITIES			
Trade payables		(3,760)	(4,619)
Other payables and accruals (Note below *)	10	(9,678)	(27,480)
Current portion of long term loans	11	(2,512)	-
Grants received in advance:			
Government	12	(2,769)	(1,992)
Non-government	13	-	(83)
Total current liabilities		<u>(18,719)</u>	<u>(34,174)</u>
NON-CURRENT LIABILITIES			
Deferred capital grant	14	(33,427)	(25,977)
Other payables and accruals	10	(4,431)	(3,583)
Long term loans	11	(32,801)	-
Total non-current liabilities		<u>(70,659)</u>	<u>(29,560)</u>
NET ASSETS (LIABILITIES)		<u>45,948</u>	<u>(921)</u>

* Note:

In 2004, this included an amount payable for the net assets of \$18,610,000 transferred from the Ministry of Health when the Authority was established on 1 April 2001. Pending the completion and finalisation of the mode of transfer (loan or equity) by the Ministry of Finance, the transfer was effected through a loan to the Authority in 2002 which had no fixed repayment terms or interest. The mode of transfer was finalised in 2005 (Notes 4 and 11).

The accompanying notes form an integral part of these financial statements.

HEALTH SCIENCES AUTHORITY

INCOME AND EXPENDITURE STATEMENT

Financial year ended 31 March 2005

	<u>Note</u>	<u>2005</u> <u>\$'000</u>	<u>2004</u> <u>\$'000</u> <u>(Restated)</u>
OPERATING INCOME			
Laboratory analysis fees		18,573	22,934
Blood processing fees		14,293	11,740
Patient laboratory testing fees		1,841	1,795
Forensic investigation fees		6,151	5,241
Licensing fees		6,127	5,729
Professional service fees		1,345	535
Miscellaneous income		180	175
		<u>48,510</u>	<u>48,149</u>
OPERATING EXPENDITURE			
Staff costs	15	37,000	34,959
Supplies and services		13,380	12,833
Rental of premises and equipment		5,396	6,339
Blood donor expenses		2,741	2,584
Repairs and maintenance		3,443	3,449
Depreciation of plant and equipment	9	7,210	5,966
Staff welfare and development		2,206	2,525
Professional services		2,671	4,184
Utilities		1,090	1,180
Transport, postages and communications	16	1,392	1,518
Impairment loss for plant and equipment	9	-	861
Publicity and public relations	16	142	306
Board members' allowances		68	50
Other expenses		1,006	950
		<u>77,745</u>	<u>77,704</u>
OPERATING DEFICIT		(29,235)	(29,555)
NON-OPERATING SURPLUS	17	425	411
DEFICIT BEFORE GRANTS		(28,810)	(29,144)
GRANTS			
Government grants	12	21,081	23,240
Non-government grants	13	1,798	1,643
Pre-restructuring funds	5	233	1
Development projects	18	-	380
Deferred capital grants amortised	14	4,676	3,319
		<u>27,788</u>	<u>28,583</u>
DEFICIT BEFORE CONTRIBUTION TO CONSOLIDATED FUND		(1,022)	(561)
CONTRIBUTION TO CONSOLIDATED FUND	19	<u>-</u>	<u>-</u>
DEFICIT FOR THE YEAR		<u>(1,022)</u>	<u>(561)</u>

The accompanying notes form an integral part of these financial statements.

HEALTH SCIENCES AUTHORITY

STATEMENT OF CHANGES IN RESERVES AND FUNDS

Financial year ended 31 March 2005

	<u>Capital account</u> \$'000	<u>Accumulated deficit</u> \$'000	<u>Pre- restructuring funds</u> \$'000	<u>Total</u> \$'000
Balance as at 31 March 2003				
- Previously reported	-	(806)	246	(560)
- Prior year adjustments (Note 23)	-	213	-	213
Balance as at 31 March 2003 - restated	-	(593)	246	(347)
Deficit for the year				
- Previously reported	-	(1,342)	-	(1,342)
- Prior year adjustments (Note 23)	-	781	-	781
Deficit for the year - restated	-	(561)	-	(561)
Transfer to deferred capital grants	-	-	(12)	(12)
Transfer to income and expenditure statement (Note 5)	-	-	(1)	(1)
Balance as at 31 March 2004 - restated	-	(1,154)	233	(921)
Issue of shares to Minister for Finance (Note 4)	48,124	-	-	48,124
Deficit for the year	-	(1,022)	-	(1,022)
Transfer to income and expenditure (Note 5)	-	-	(233)	(233)
Balance as at 31 March 2005	<u>48,124</u>	<u>(2,176)</u>	<u>-</u>	<u>45,948</u>

The accompanying notes form an integral part of these financial statements.

HEALTH SCIENCES AUTHORITY

CASH FLOW STATEMENT

Financial year ended 31 March 2005

	<u>Note</u>	<u>2005</u> <u>\$'000</u>	<u>2004</u> <u>\$'000</u> <u>(Restated)</u>
CASH FLOWS FROM GRANTS:			
Government grants received	12	39,831	26,395
Non-government grants received	13	981	1,194
Development projects	18	-	380
Total cash from grants		<u>40,812</u>	<u>27,969</u>
CASH FLOWS FROM OPERATING ACTIVITIES:			
Deficit before grants		(28,810)	(29,144)
Adjustments for:			
Depreciation of plant and equipment	9	7,210	5,966
Interest income	17	(60)	(44)
Impairment loss on plant and equipment	9	-	861
(Gain) Loss on disposal of plant and equipment	17	(6)	36
(Reversal) Allowance for doubtful trade receivables		(152)	152
Amount owing to MOH written off		139	-
Deficit before working capital changes		<u>(21,679)</u>	<u>(22,173)</u>
Changes in working capital excluding cash and cash equivalents:			
Trade receivables		413	(1,148)
Other receivables and prepayments		107	(310)
Inventories		121	96
Trade payables		(859)	309
Other payables and accruals		<u>(17,092)</u>	<u>961</u>
Cash used in operations		<u>(38,989)</u>	<u>(22,265)</u>
Contribution to Consolidated Fund paid during the year		-	(122)
Net cash used in operating activities		<u>(38,989)</u>	<u>(22,387)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:			
Proceeds from disposal of property, plant and equipment		18	-
Purchase of property, plant and equipment	9	(83,612)	(12,396)
Interest received		60	44
Net cash used in investing activities		<u>(83,534)</u>	<u>(12,352)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issue of shares to Minister for Finance		48,124	-
Proceeds from government loan		35,313	-
Net cash from financing activities		<u>83,437</u>	<u>-</u>
Net increase (decrease) in cash and cash equivalents		1,726	(6,770)
Cash and cash equivalents at beginning of year		<u>12,974</u>	<u>19,744</u>
Cash and cash equivalents at end of year		<u>14,700</u>	<u>12,974</u>

The accompanying notes form an integral part of these financial statements.

HEALTH SCIENCES AUTHORITY

NOTES TO THE FINANCIAL STATEMENTS

Financial year ended 31 March 2005

1 GENERAL

The Health Sciences Authority (the "Authority") is a statutory board established in Singapore under the Health Sciences Authority Act (Chapter 122C) (the "Act") on 1 April 2001. The address of the Authority is 11 Outram Road, Singapore 169078 and its principal place of business is in Singapore.

During the current year, the Authority issued 48,124,270 shares to the Minister for Finance, a body corporate incorporated under the Minister for Finance (Incorporation) Act (Cap. 183), upon finalisation of the debt-equity mode to effect the transfer of net assets from the Ministry of Health ("MOH") for the establishment of the Authority. Consequently, the Minister for Finance became a shareholder in HSA through its financing of part of the transfer of assets from MOH through equity.

The principal activities of the Authority are:

- a) to regulate the import, manufacture, sale, disposal, transport, storage, possession and use of cosmetics, medicines, medical devices and other health-related products, tobacco products, radioactive materials and irradiating apparatuses;
- b) to conduct technological assessments of medicines, cosmetics, medical devices and other health-related products for the purpose of determining their efficacy, safety and suitability for consumption and use in Singapore and to advise the Government thereon;
- c) to collect and co-ordinate the collection of blood from donors and to test, process and distribute such blood and the products thereof for the purpose of building and maintaining a safe and adequate national blood supply;
- d) to provide professional, investigative and analytical services in health sciences to the Government and to any other person or body (whether in Singapore or elsewhere);
- e) to conduct or engage any other person to conduct research in health sciences, and generally to promote the development of health sciences; and
- f) to act internationally as the national authority or representative of Singapore in respect of matters related to health sciences.

The financial statements of the Authority for the year ended 31 March 2005 were authorised for issue by the members of its Board on 08 August 2005.

HEALTH SCIENCES AUTHORITY

2 SIGNIFICANT ACCOUNTING POLICIES

a) Basis of accounting

The financial statements of the Authority, expressed in Singapore dollars, are prepared in accordance with the historical cost convention and are drawn up in accordance with the provisions of the Health Sciences Authority Act (Chapter 122C) and Singapore Financial Reporting Standards (“FRS”).

With effect from the current financial year, deferred capital grants has been presented as non-current liability in accordance with FCM M4/2005 to better reflect the underlying nature of the grants. Consequently, the comparatives have been reclassified to enhance comparability.

b) Financial assets

The Authority’s principal financial assets are bank balances and cash, trade and other receivables. Trade and other receivables are stated at their nominal values as reduced by appropriate allowances for estimated irrecoverable amounts.

c) Financial liabilities

Financial liabilities include trade and other payables which are stated at their nominal values.

d) Inventories

Inventories are measured at the lower of cost (first-in first-out method) and net realisable value. Cost includes all costs of purchase, costs of conversion and other costs incurred in bringing the inventories to their present location and condition.

e) Property, plant and equipment

Property, plant and equipment are carried at cost less accumulated depreciation and any impairment loss where the recoverable amount of the asset is estimated to be lower than its carrying amount.

Depreciation is charged so as to write off the cost of assets, over their estimated useful lives, using the straight-line method, on the following bases:

Leasehold land and building	60 years (based on lease period)
Building improvements	20 years (based on useful life of asset)
Computers	3 to 5 years
Motor vehicles	10 years
Scientific and medical equipment	5 years
Other equipment, furniture and fittings	5 to 10 years

Depreciation is not provided on work-in-progress.

Plant and equipment costing less than \$2,000 each, are charged to the income and expenditure statement in the year of purchase.

Fully depreciated assets still in use are retained in the financial statements.

HEALTH SCIENCES AUTHORITY

f) Impairment of assets

At each balance sheet date, the Authority reviews the carrying amounts of its assets to determine whether there is any indication that those assets have suffered an impairment loss. If any such indication exists, the recoverable amount of the asset is estimated in order to determine the extent of the impairment loss (if any). Recoverable amount is the greater of net selling price and value in use. If the recoverable amount of an asset is estimated to be less than its carrying amount, the carrying amount of the asset is reduced to its recoverable amount. Impairment losses are recognised as an expense immediately.

When an impairment loss subsequently reverses, the carrying amount of the asset is increased to the revised estimate of its recoverable amount, but only to the extent that the increased carrying amount does not exceed the carrying amount that would have been determined had no impairment loss been recognised for the asset in prior years. A reversal of an impairment loss is recognised as income immediately.

g) Leases

Leases are classified as finance leases whenever the terms of the lease transfer substantially all the risks and rewards of ownership to the lessee. All other leases are classified as operating leases.

Rental payable under operating leases are charged to the income and expenditure statement on a straight-line basis over the term of the relevant lease.

h) Foreign currency transactions

Transactions in foreign currencies are recorded using the rates ruling on the dates of the transactions. At each balance sheet date, recorded monetary balances and balances carried at fair value that are denominated in foreign currencies are reported at the rates ruling at the balance sheet date. All realised and unrealised exchange adjustment profits and losses are dealt with in the income and expenditure statement.

i) Income recognition

Income from the rendering of services that are of a short duration, such as laboratory analysis fees, patient laboratory testing fees, forensic investigating fees and professional services fees are recognised when the services are completed.

Income from blood processing fees are recognised when the processed blood products are used by the hospitals.

Licence fees income are recognised on an accrual basis over the licence period.

Fines and forfeitures are recognised on an accrual basis.

Interest income is accrued on a time proportionate basis, by reference to principal outstanding and at the interest rates applicable, on an effective yield basis.

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j) Grants

Contribution from the government for the establishment of the Authority are taken to the Capital Account.

Government grants for the purchase of depreciable assets are taken to the Deferred Capital Grants Account. The deferred grants are recognised in the income and expenditure statement over the periods necessary to match the depreciation of the assets purchased. Upon the disposal of these assets, the balance of the related deferred capital grants is recognised in the income and expenditure statement to match the net book value of the assets disposed of.

Government grants and contributions from other organisations to meet current year's operating expenses are recognised as income in the same year.

Both capital and operating grants are accounted for on an accrual basis.

k) Retirement benefit costs

Payments to defined contribution retirement benefit plans (including state-managed retirement benefit schemes, such as the Singapore Central Provident Fund) are charged as an expense when incurred.

Defined benefit retirement obligations due to pensionable officers are recognised in the balance sheet in accordance with the Pensions Act (Cap. 225, 2004 Revised Edition). The pension amounts payable are based on the last drawn salaries of the respective officers and the officers' cumulative service period served with the Authority at the time of retirement. The Authority does not need to bear any medical liabilities for pensionable officers upon their retirement.

l) Employee Leave Entitlement

Employee entitlements to annual leave are recognised when they accrue to employees. A provision is made for the estimated liability for annual leave as a result of services rendered by employees up to the balance sheet date.

m) Contribution to Consolidated Fund

The Authority is required to make contribution to the consolidated fund based on the net surplus of the Authority for each of the financial year at the prevailing corporate tax rate.

With effect from FY2005/2006, the contributions are based on the net surplus of the Authority (before donations) for the financial year adjusted for any accumulated deficits carried forward from the years that the Authority was under the contribution framework.

For the financial year ended 31 March 2005, the Authority did not recognise an asset in respect of such losses as management is uncertain of the future surpluses of the Authority.

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3 FINANCIAL RISKS AND MANAGEMENT

a) Foreign exchange risk

The Authority has limited exposure to foreign exchange risk as its operations are substantially transacted in Singapore dollars.

b) Interest rate risk

The Authority is exposed to interest rate risk as due to interest-bearing loans as disclosed in Note 11.

c) Credit risk

The Authority's credit risk is primarily attributable to its cash and cash equivalents, trade receivables and other receivables. The Authority places its cash and cash equivalents with creditworthy financial institutions. The credit risk with respect to receivables is low as the Authority mainly deals with creditworthy organisations such as government bodies and hospitals.

The Authority has no significant concentration of credit risk. Trade receivables are spread over a large base of organisations.

The maximum credit risk that the Authority is exposed to is represented by the carrying amounts of its financial assets as stated in the balance sheet.

d) Liquidity and funding risk

The Authority funds its operations through a mix of internally-generated funds, government and non-government grants. The Authority reviews regularly its liquidity reserves, comprising of cash flows from its operations and government grants, to ensure sufficient liquidity is maintained at all times.

e) Fair values of financial assets and financial liabilities

The carrying amounts of financial assets and financial liabilities reported in the balance sheet approximate the fair values of those assets and liabilities.

4 CAPITAL ACCOUNT

	<u>2005</u>	<u>2004</u>	<u>2005</u>	<u>2004</u>
	Number of shares of \$1 each		\$'000	\$'000
Issued and paid up:				
Issued during the year and balance at end of year	<u>48,124,270</u>	<u>-</u>	<u>48,124</u>	<u>-</u>

This consists of 48,124,270 shares of \$1 each issued to Minister for Finance as part of the debt/equity financing (Note 11).

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5 PRE-RESTRUCTURING FUNDS

	<u>2005</u>	<u>2004</u>
	\$'000	\$'000
Balance at beginning of year	233	246
Transfer to deferred capital grants (Note 5)	-	(12)
Transfer to income and expenditure statement	<u>(233)</u>	<u>(1)</u>
Balance at end of year	<u>-</u>	<u>233</u>

The pre-restructuring funds were granted by MOH for the expenditures incurred during the establishment of the Authority. Upon completion of the mode of transfer during the year, the remaining unused funds were transferred to income and expenditure statement.

6 CASH AND CASH EQUIVALENTS

Cash and cash equivalents included in the cash flow statement comprise the following:

	<u>2005</u>	<u>2004</u>
	\$'000	\$'000
Bank and cash balances	4,689	10,970
Fixed deposits	<u>10,011</u>	<u>2,004</u>
	<u>14,700</u>	<u>12,974</u>

The fixed deposits bear interest ranging from 1.3125% to 1.6875% (2004 : 0.25%). The fixed deposits will be maturing in April to June 2005 and can be readily converted to cash at the discretion of management.

7 OTHER RECEIVABLES, DEPOSITS AND PREPAYMENTS

	<u>2005</u>	<u>2004</u>
	\$'000	\$'000
		(restated)
Grants receivable - Government (Note 12)	1,993	8,095
Grants receivable - Non-government (Note 13)	1,293	305
Other receivables	62	57
Deposits	309	421
Advances to staff ^(a)	35	3
Prepayments	<u>541</u>	<u>573</u>
	<u>4,233</u>	<u>9,454</u>

^(a) These are festive advances given to staff which are interest-free and unsecured. The amounts are repayable over 2 months via deductions from the staff salaries.

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8 INVENTORIES

	<u>2005</u>	<u>2004</u>
	\$'000	\$'000
Gases, laboratory and medical supplies, at cost	<u>1,461</u>	<u>1,582</u>

9 PLANT AND EQUIPMENT

	Leasehold land and buildings \$'000	Building improvements \$'000	Computers \$'000	Motor vehicles \$'000	Scientific and medical equipment \$'000	Other equipment, furniture and fittings \$'000	Work- in-progress \$'000	Total \$'000
Cost:								
At beginning of year								
- as previously reported	-	6,523	10,515	75	16,149	4,343	11,517	49,122
- Prior year adjustment (Note 23)	-	-	-	-	-	-	(1,246)	(1,246)
- restated	-	6,523	10,515	75	16,149	4,343	10,271	47,876
Additions	70,195 ^(a)	34	506	-	1,203	56	11,618	83,612
Disposals	-	(844)	(5)	(13)	(81)	(117)	-	(1,060)
Transfer from work-in-progress	-	4,152	11,381	-	557	1,545	(17,635)	-
At end of year	<u>70,195</u>	<u>9,865</u>	<u>22,397</u>	<u>62</u>	<u>17,828</u>	<u>5,827</u>	<u>4,254</u>	<u>130,428</u>
Accumulated depreciation:								
At beginning of year	-	374	4,655	32	8,307	907	-	14,275
Depreciation for the year	117	406	3,520	6	2,613	548	-	7,210
Disposals	-	(65)	(5)	(13)	(72)	(32)	-	(187)
At end of year	<u>117</u>	<u>715</u>	<u>8,170</u>	<u>25</u>	<u>10,848</u>	<u>1,423</u>	<u>-</u>	<u>21,298</u>
Impairment loss:								
At beginning of year	-	779	-	-	-	82	-	861
Disposals	-	(779)	-	-	-	(82)	-	(861)
At end of year	<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>
Depreciation for last year	<u>-</u>	<u>294</u>	<u>1,784</u>	<u>79</u>	<u>3,301</u>	<u>508</u>	<u>-</u>	<u>5,966</u>
Carrying amount:								
At end of year	<u>70,078</u>	<u>9,150</u>	<u>14,227</u>	<u>37</u>	<u>6,980</u>	<u>4,404</u>	<u>4,254</u>	<u>109,130</u>
At beginning of year								
- as previously reported	-	5,370	5,860	43	7,842	3,354	11,517	33,986
- Prior year adjustment (Note 23)	-	-	-	-	-	-	(1,246)	(1,246)
- restated	<u>-</u>	<u>5,370</u>	<u>5,860</u>	<u>43</u>	<u>7,842</u>	<u>3,354</u>	<u>10,271</u>	<u>32,740</u>

(a) Included in leasehold land and buildings additions were \$68,250,000 for the acquisition from Singapore Land Authority as part of the asset transfer from Ministry of Health for the establishment of the Authority (Note 11).

In prior year, the impairment loss arose as certain assets whose recoverable amounts were estimated to be lower than their carrying amounts due to limited used of such assets subsequent to the office relocation. These assets were disposed during the financial year.

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10 OTHER PAYABLES AND ACCRUALS

	<u>2005</u>	<u>2004</u>
	\$'000	\$'000
		(Restated)
Licence fees collected in advance	3,485	3,726
Amount payable to MOH for net assets transferred ^(a)	-	18,610
Accrual for staff costs	8,191	7,029
GST payable	222	271
Refundable security deposits	83	196
Other payables and accruals	<u>2,128</u>	<u>1,231</u>
	<u>14,109</u>	<u>31,063</u>
Non-current portion:		
Licence fees collected in advance	(329)	(505)
Obligations in respect of defined benefit retirement plan as included in accrual for staff costs ^(b)	<u>(4,102)</u>	<u>(3,078)</u>
	<u>(4,431)</u>	<u>(3,583)</u>
Current portion	<u>9,678</u>	<u>27,480</u>

^(a) In 2004, this represented an amount payable for the net assets transferred from MOH when the Authority was established on 1 April 2001. Pending the completion and finalisation of the mode of transfer (loan or equity) by the Ministry of Finance, the transfer was effected through a loan to the Authority in 2002 which had no fixed repayment terms or interest. The mode of transfer was finalised in 2005 (Notes 4 and 11).

^(b) There are currently 35 (2004 : 37) employees of the Authority who are under pension schemes other than the state-managed retirement benefit schemes, such as the Singapore Central Provident Fund. The pension amount to be paid to each employee upon retirement under this scheme is dependent on, among other factors, the number of years of service and last drawn salary. The total pension costs are shared between the Authority and the Accountant-General's Department. The Authority is only liable for the pension costs for the period of service completed by the employee with the Authority.

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11 LONG-TERM LOANS

	<u>2005</u>	<u>2004</u>
	\$'000	\$'000
Transfer of leasehold land and building loan	27,300	-
Transfer of assets loan	<u>8,013</u>	<u>-</u>
	<u>35,313</u>	<u>-</u>
Current portion	<u>2,512</u>	<u>-</u>
Non-current portion	<u>32,801</u>	<u>-</u>

Upon establishment of the Authority on 1 April 2001, net assets amounting to \$18,609,528 were transferred from the Ministry of Health ("MOH"). Pending the completion and finalisation of the mode of transfer by the Ministry of Finance ("MOF"), the transfer was effected through a loan to the Authority in 2002 which had no fixed repayment terms or interest (Note 10). Part of this payable amount was repaid to MOF from additional grants from MOH during the current financial year and the balance amount of \$11,957,117 for certain fixed assets and \$1,285,992 for inventories were refinanced as part of the debt/equity financing below.

During the current financial year, the mode of transfer was finalised by MOF resulting in an agreed loan/equity mix of 40% loan (\$32,082,847) and 60% equity (\$48,124,270) for total assets transferred of \$80,207,117. This consists of leasehold land and building of \$68,250,000 (excluding stamp duty of \$1,944,610) and other fixed assets transferred of \$11,957,117.

For the equity portion, the Authority had issued 48,124,270 shares of \$1 each to the Minister for Finance (Note 4).

For the loan portion, two loans were obtained from MOF as follows:

- a) Transfer of land and building loan - This is based on 40% of the leasehold land and building cost of \$68,250,000 as mentioned above. The loan is repayable over 15 years from 31 March 2005. Interest rate per annum is fixed at the Daily Average 10-year Singapore Government Securities Yield plus a premium of 0.9%.
- b) Transfer of assets loan - This is based on 40% of other fixed assets cost of \$11,957,117 as mentioned above; stamp duty of \$1,944,610 for alienation of leasehold land and building, and inventories of \$1,285,992 as mentioned above. The loan is repayable over 5 years from 31 March 2005. Interest rate per annum is fixed at the Daily Average 10-year Singapore Government Securities Yield plus a premium of 0.5%.

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12 GRANTS RECEIVED IN ADVANCE - GOVERNMENT

	IT Master Plan (a)		MDP Funds (b)		Operating Grants		HMDP (c)		SARs Funds (d)		NMRC (e)		Total	
	2005 \$'000	2004 \$'000	2005 \$'000	2004 \$'000	2005 \$'000	2004 \$'000	2005 \$'000	2004 \$'000	2005 \$'000	2004 \$'000	2005 \$'000	2004 \$'000	2005 \$'000	2004 \$'000
Balance at beginning of year:														
Grant receivables														
- as previously reported	-	-	(1,827)	-	(6,265)	-	-	-	-	-	(3)	-	(8,095)	-
- prior year adjustments (Note 23)	-	-	-	-	-	(5,227)	-	-	-	-	-	-	-	(5,227)
- restated	-	-	(1,827)	-	(6,265)	(5,227)	-	-	-	-	(3)	-	(8,095)	(5,227)
Grants received in advance	943	325	-	-	847	3,746	202	180	-	-	-	-	1,992	4,251
Receipts during the year	4,064	6,648	10,496	1,645	24,981	17,459	210	266	-	259	80	118	39,831	26,395
Transfer to deferred capital grants:														
- as previously reported	(5,211)	(6,030)	(6,660)	(3,478)	-	-	-	-	-	-	-	(20)	(11,871)	(9,528)
- prior year adjustments (Note 23)	-	1,208	-	38	-	-	-	-	-	-	-	-	-	1,246
- restated (Note 5)	(5,211)	(4,822)	(6,660)	(3,440)	-	-	-	-	-	-	-	(20)	(11,871)	(8,282)
Transfer to income and expenditure statements														
- as previously reported	(650)	-	(1,975)	(20)	(18,070)	(20,358)	(276)	(244)	-	(259)	(110)	(101)	(21,081)	(20,982)
- prior year adjustments (Note 23)	-	(1,208)	-	(12)	-	(1,038)	-	-	-	-	-	-	-	(2,258)
- restated	(650)	(1,208)	(1,975)	(32)	(18,070)	(21,396)	(276)	(244)	-	(259)	(110)	(101)	(21,081)	(23,240)
Net	<u>(854)</u>	<u>943</u>	<u>34</u>	<u>(1,827)</u>	<u>1,493</u>	<u>(5,418)</u>	<u>136</u>	<u>202</u>	<u>-</u>	<u>-</u>	<u>(33)</u>	<u>(3)</u>	<u>776</u>	<u>(6,103)</u>
Presented as														
- Grants receivable (Note 7)	<u>854</u>	<u>-</u>	<u>16</u>	<u>1,827</u>	<u>1,090</u>	<u>6,265</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u>33</u>	<u>3</u>	<u>1,993</u>	<u>8,095</u>
Presented as														
- Grants received in advance	<u>-</u>	<u>943</u>	<u>50</u>	<u>-</u>	<u>2,583</u>	<u>847</u>	<u>136</u>	<u>202</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u>2,769</u>	<u>1,992</u>
Total grants received since establishment	<u>14,416</u>	<u>10,352</u>	<u>12,141</u>	<u>1,645</u>	<u>81,452</u>	<u>56,471</u>	<u>929</u>	<u>719</u>	<u>259</u>	<u>259</u>	<u>198</u>	<u>118</u>	<u>109,395</u>	<u>69,564</u>

- (a) To help achieve the Authority's vision to be world-class in scientific and regulatory expertise in health sciences and fulfil its mission and desired outcomes, a 3-year IT Master Plan had been formulated to align the Authority's computerisation blueprint in 2003. This blueprint outlines the information systems required over a 3-year period. The capital cost of \$19,150,000 will be phased over a 5-year period and will be met from MOH's block budget.
- (b) The funds for the Minor Development Projects ("MDP") pertain to miscellaneous minor development projects embarked by the Authority which are funded by MOH.
- (c) The funds received under the Health Manpower Development Programme ("HMDP") relates to funds received from MOH for sponsoring professional staff for overseas training.
- (d) Severe Acute Respiratory Syndrome ("SARs") funds relate to funds received from MOH for reimbursement of SARs related expenditures incurred by the Authority during the SARs crisis period in 2003.
- (e) The funds received from NMRC are used to fund expenses relating to the implementation of the new Clinical Trials Regulatory Framework. The aim of this framework is to ensure high standards of safety for clinical trials in Singapore. This is a 3-year grant ending in FY2006/2007.

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13	GRANTS RECEIVED IN ADVANCE - NON-GOVERNMENT	<u>2005</u> \$'000	<u>2004</u> \$'000
	Balance at beginning of year	(222)	227
	Net receipts during the year	981	1,194
	A*STAR fund transfer to deferred capital grants	(254)	-
	Transfer to income and expenditure statement	(1,798)	(1,643)
	Net	<u>(1,293)</u>	<u>(222)</u>
	Presented as:		
	- Grants receivable (Note 7)	<u>1,293</u>	<u>305</u>
	- Grants received in advance	<u>-</u>	<u>83</u>
	Total grants received since establishment	<u>4,541</u>	<u>3,560</u>
14	DEFERRED CAPITAL GRANTS	<u>2005</u> \$'000	<u>2004</u> \$'000 (restated)
	Balance at beginning of year	25,978	3,708
	- prior year adjustment	-	4,513
	- restated	25,978	8,221
	Transfer from pre-restructuring funds (Note 5)	-	12
	Transfer from grants received in advance:		
	- IT Master Plan (Note 12)	5,211	6,030
	- prior year adjustment	-	(1,208)
	- restated	5,211	4,822
	- MDP Funds (Note 12)	6,660	3,478
	- prior year adjustment	-	(38)
	- restated	6,660	3,440
	- A*STAR fund (Note 13)	254	-
	- NMRC (Note 12)	-	20
	Development projects transferred from MOH (Note 18)	-	12,781
	Transfer to income and expenditure statement to match depreciation of related assets		
	- as previously stated	(4,676)	(2,526)
	- prior year adjustment (Note 23)	-	(793)
	Balance at end of year	<u>(4,676)</u> <u>33,427</u>	<u>(3,319)</u> <u>25,977</u>

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15	STAFF COSTS		
		<u>2005</u>	<u>2004</u>
	Number of employees at end of year	<u>563</u>	<u>578</u>
		<u>2005</u>	<u>2004</u>
		\$'000	\$'000
			(restated)
	Staff costs	<u>37,000</u>	<u>34,959</u>
	Cost of defined contribution retirement plans included in staff costs	<u>3,076</u>	<u>3,237</u>
	Cost of obligations in respect of defined benefit retirement plan included in staff costs	<u>1,287</u>	<u>1,738</u>
16	TRANSPORT, POSTAGES AND COMMUNICATIONS, PUBLICITY AND PUBLIC RELATIONS		
	Transport, postages and communications, publicity and public relations include the following expenses:		
		<u>2005</u>	<u>2004</u>
		\$'000	\$'000
	Overseas travelling	89	123
	Entertainment	<u>7</u>	<u>15</u>
17	NON-OPERATING SURPLUS		
		<u>2005</u>	<u>2004</u>
		\$'000	\$'000
	Interest income	60	44
	Fines and forfeitures	380	328
	Miscellaneous income	<u>33</u>	<u>115</u>
		<u>473</u>	<u>487</u>
	Foreign currency exchange loss	(54)	(40)
	Gain (Loss) on disposal of plant and equipment	<u>6</u>	<u>(36)</u>
		<u>(48)</u>	<u>(76)</u>
	Non-operating surplus	<u>425</u>	<u>411</u>

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18 DEVELOPMENT PROJECTS

The development projects for financial year ended 31 March 2004 pertained to implementation and setting up of the Authority's IT infrastructure (including professional fees) and renovation works which were previously carried out by the MOH for the establishment of the Authority and the related assets were transferred to the Authority in the previous financial year.

19 CONTRIBUTION TO CONSOLIDATED FUND

The Authority is required to make a contribution to the Consolidated Fund in accordance with the Statutory Corporations (Contributions to Consolidated Fund) Act (Chapter 319A) and in accordance with the Finance Circular Minute No M5/2005.

There is no contribution to consolidated fund for the current financial year as there is no accounting surplus.

20 CONTINGENT LIABILITIES

	<u>2005</u> \$'000	<u>2004</u> \$'000
Guarantees	<u>307</u>	<u>108</u>

21 CAPITAL EXPENDITURE COMMITMENTS

	<u>2005</u> \$'000	<u>2004</u> \$'000
Estimated amounts committed for future capital expenditure but not provided for in the financial statements	<u>951</u>	<u>6,916</u>

22 OPERATING LEASE COMMITMENTS

	<u>2005</u> \$'000	<u>2004</u> \$'000
Minimum lease payments under operating leases for rental of premises and equipment	<u>5,396</u>	<u>6,339</u>

At the balance sheet date, the commitments in respect of operating leases for rental of premises and equipment with a term of more than one year were as follows:

	<u>2005</u> \$'000	<u>2004</u> \$'000
Within one year	1,293	5,186
In the second to fifth years inclusive	<u>5,713</u>	<u>6,398</u>

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23 PRIOR YEAR ADJUSTMENTS

The following adjustments are made to the prior year financial statements:

- a) MOH made adjustments for the understatement of government grants and grants receivable of \$1,038,288 upon finalisation of the prior year transitional grants quantum that were disbursed to the Authority for financial year ended 31 March 2004.
- b) A net one-off grant of \$5,227,050 was received from MOH during the year to repay MOF for certain trade receivables transferred to the Authority on its establishment. As the funds received on settlement of these trade receivables were previously spent on fixed assets, prior year adjustments were made to restate the understatement of deferred capital grant by \$3,720,644 as at 31 March 2004. In addition, adjustments were made to correct the related understatement of the beginning accumulated deficit and deferred capital grant amortised of \$713,698 and \$792,709 respectively for financial year ended 31 March 2004.
- c) As a result of management's review of the expenditure under the IT Master Plan, an amount of \$1,246,085 were identified as incorrectly capitalised as work-in-progress in prior years, of which \$1,220,342 were incorrectly expensed and \$25,744 were incorrectly taken up twice as accruals for the financial year ended 31 March 2004.
- d) In the previous financial years, defined benefit retirement benefit obligations (ie. provision for pension costs) were recognised in the balance sheet based on a review and estimate of the pension fund as determined and allocated by the Accountant-General's Department ("AGD") and adjusted by the Authority's estimate of the probable obligations with reference to the historical trends and assumptions which were reflected in the actuarial reports. In the current financial year, management performed further reviews of the adequacy of the pension liability based on formulas used by the AGD for actual retirees. Based on this review, an under-provision of \$1,550,580 relating to previous financial years were identified of which \$1,050,220 and \$500,360 related to the understatement of the operating expenditure and understatement of the beginning accumulated deficit respectively for financial year ended 31 March 2004.

	Balance as previously reported \$'000	Prior year adjustments \$'000	Balance as restated \$'000
<u>Balance sheet as at 31 March 2004</u>			
Other receivables, deposits and prepayments	3,215 - -	1,038 ^(a) 5,227 ^(b) (26) ^(c)	4,253 5,227 (26)
	3,215	6,239	9,454
Deferred Capital Grants	(23,503) -	(3,720) ^(b) 1,246 ^(c)	(27,223) 1,246
	(23,503)	(2,474)	(25,977)
Plant and equipment	33,986	(1,246) ^(c)	32,740
Other payables and accruals - current liabilities	(27,506)	26 ^(c)	(27,480)
Other payables and accruals - non-current liabilities	(2,032)	(1,551) ^(d)	(3,583)
Accumulated deficit as at 31 March 2004	2,148	(994)	1,154

HEALTH SCIENCES AUTHORITY

Income and expenditure statement
for the financial year ended 31 March 2004

	Balance as previously reported \$'000	Prior year adjustments \$'000	Balance as restated \$'000
Government grants	(20,982) -	(1,038) ^(a) (1,220) ^(c)	(22,020) (1,220)
	(20,982)	(2,258)	(23,240)
Deferred capital grants amortised	(2,526)	(793) ^(b)	(3,319)
Operating expenditure	75,434 -	1,220 ^(c) 1,050 ^(d)	76,654 1,050
	75,434	2,270	77,704
	51,926	(781)	51,145
Deficit before contribution to Consolidated Fund	1,342	(781)	561
Accumulated deficit as at 31 March 2003	806 -	(714) ^(b) 501 ^(a)	92 501
	806	(213)	593
Accumulated deficit as at 31 March 2004	2,148	(994)	1,154

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