

looking ahead  
health sciences authority  
**Ahead**  
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looking ahead  
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**LOOKING**  
**AHEAD**  
health sciences  
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looking ahead  
health sciences authority  
**looking**  
**ahead**

**Health Sciences Authority**



**annual report:2003/04**

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**"Dream the dream,**  
find that extraordinary vision,  
and keep it in focus."

- d e w i t t j o n e s



**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.

# vision

to be world class for scientific and regulatory expertise in Health Sciences

# mission

to excel in applying science to:

- support healthcare service 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



**chairman's insights**

**Prof Lim Mong King**  
Chairman

**chairman's insights**

The year 2003 had been a challenging one and, with the experiences gained, we are convinced that we need to constantly remake ourselves to adapt to the fast changing external environment. Moving ahead, we must continue to press on and remain steadfast in what we set out to do.

We have set our sight on our strategic destination, which is to be a leader in regulatory expertise, administering and enforcing a regulatory framework for products and materials which affect human health. As a national agency for scientific services, we strive to provide premium scientific, investigative and analytical testing and consultancy services to various government regulatory and enforcement agencies in an integrated manner. We also provide leadership in blood banking and transfusion medicine for the nation.

Our mission is to support healthcare services and regulation, serve the administration of justice and enhance safety in our community. To accomplish this, our professional expertise must be able to withstand critical scrutiny. We therefore continue to benchmark ourselves against the best in the world.

We need to stay focused on rapid scientific development and technological progress. This is especially critical in the new operating order, where recognising our vulnerabilities to emerging diseases and pathogens,

security risks and declining global economic robustness, we have to rise up to these unprecedented challenges. Keeping vigilant, expanding our radar scans and monitoring our risks is one essential strategic response. Enhancing our capability for business continuity and emergency preparedness is another. Keeping our sight on track of rapid scientific development and technological progress to build our professional capabilities will better ensure global and latest solutions to protect public health and safety in such risky environments.

The road to professional excellence is through the delivery of our national role, and by meeting increasing public expectations in a volatile knowledge-based and globalised economy. We can be sure that with a better informed public, there will be more demands for a higher level of products, services and satisfaction. There is a need to make sure that our efforts to enhance safety in our community are timely in nature, and are in step with the new technologies, techniques and tools.

As we strive to serve the population better through attaining new benchmarks and operationalising new standards and requirements based on the best and latest science, our outlook should also be one that is committed to keeping a fine balance. Economic enterprise should not be stifled with unnecessary burdens and costs, and resource consumption should be moderated. We must do more with less, by adding more value at the lowest possible cost.

Further, to achieve greater scientific synergy and excellence, we will better integrate and synergise, consolidate and strengthen our diverse capabilities as well as develop and nurture new ones to meet the challenges of the future. We have a good head-start. We have plugged ourselves into new networks in the past years and made good progress in forging strategic alliances with international, regional and local partners with whom we share knowledge, expertise and resources and explore ways to strategically and productively strengthen and develop our capabilities. Recognising that to achieve greater scientific synergy effectively, we engage key

stakeholders on an ongoing basis. This will only ensure that our moves are congruent with the state of development and meeting the needs of our stakeholders. Enhancing organisational resilience through building a strong workforce and a strong identity, and applying corporate and organisational excellence models to aid our progress and to track our accountabilities is another area which we must not lose sight of.

Professional and organisational excellence is impossible without a committed body. I would like to acknowledge the support and contribution of all HSAians and the management. I would also like to express my appreciation to the Board Members for their advice in our journey as we work together to reach our strategic destination in being world class for scientific and regulatory expertise in health sciences.



Prof Lim Mong King  
Chairman



**CEO's review**

**Dr Tan Chor Hiang**  
Chief Executive Officer

**CEO's review**

At HSA, we strive to meet expectations for better public health and safety to be delivered through our mission. Besides being plugged into an exciting time of scientific and technological innovations, Singapore's commitment to become a biomedical science hub of Asia has also helped us to focus on our mission better.

To deliver our mission as a one-stop agency for scientific and regulatory expertise, we are adopting a global outlook in addition to our health- and science-based focus in order to stay relevant and responsive in a rapidly changing environment.

### Looking Beyond

Advances in science and technology are moving at a quick pace worldwide, with new discoveries, applications and therapeutics emerging frequently. Such rapid advances on a global scale have made our world more interconnected than ever, and our access to knowledge and learning easily within reach, thereby creating a more sophisticated and challenging operating environment. Since our formation in 2001, we have worked steadily to set our standards at international benchmarked levels. This continues to be an essential approach so that the outcomes of our regulatory, scientific and investigative performance are timely and be of high standing, as well as meet the increasing expectations of the population by providing the citizenry with good public health and safety in the areas under our purview.

As with scientific and technological advances and the globalisation of diseases, crime and terrorism has also taken place concomitantly. Within just a year, we have seen threats of new emerging infectious diseases as well as new and sophisticated forms of criminal activities like counterfeiting and terrorism that are posing threats to the world. The fight to thwart threats posed by biomedical and technological developments would, likewise, require international and local collaboration, and collective actions across continents and within each jurisdiction.

At HSA, forging strategic alliances is one strategy in going forward to address such challenges. In addition, in our journey to be world class, we are looking beyond our geographical boundaries, as it is no longer possible for us to work in isolation.

I am pleased that in the year under review, we have successfully signed Memoranda of Understanding with Australia's Victorian Institute of Forensic Medicine and China's State Food and Drug Administration. Both strategic alliances facilitate and enhance reciprocal exchanges of information, development of professional competencies and scientific collaborations.

The alliance with the Victorian Institute of Forensic Medicine provides the forensic pathologists from both sides greater exposure than the narrow range of cases scoped by the community, thereby promoting stronger mutual professional ties useful for crisis response in our current operating environment.

With the long historical usage of Traditional Chinese Medicines (TCM) and the rapid advancement of TCM research in China, we embrace the State Food and Drug Administration as our key strategic partner in the regulation of TCM in Singapore. Through the Plan of Cooperation, we also map out common technical requirements on the safety and quality of TCM. Both agencies are set to benefit in two main areas, namely, timely access to regulatory information and broadening our pools of expertise and knowledge especially in the area of TCM.

Alliance with the United States Food and Drug Administration (FDA) was also forged through a Working Group on Medical Products, under the auspices of the United States-Singapore Free Trade Agreement. We look forward to close consultations with FDA on matters related to the regulation of medical products including medical devices, for the promotion and protection of public health through transparent and science-based procedures.

I am proud to share the fruits of our alliance, formalised in May 2002, with the Therapeutic Goods Administration (TGA), our Australian regulatory counterpart. Through the timely information provided by TGA, our Centre for Drug Administration managed a major recall of about 250 health supplements manufactured by the Pan Pharmaceuticals Ltd, expeditiously and without undue alarm amongst Singapore's consumers and trade members. Further, the alliance has added to the robustness of drug safety monitoring in Singapore as we exchange, on a regular basis, safety information arising from the use of prescription medicines in our communities. Another spin-off has been the enhancement of our training and capability development in important areas under the purview of our Centre for Drug Administration such as good manufacturing practice, product evaluation, enforcement, as well as regulatory subjects under our Centre for Medical Device Regulation.

We will, no doubt, continue to build on the strategic alliances we have forged in our journey ahead. We will also keep our eyes focused on another strategic undertaking in attaining professional accreditation for some of our key essential services.

In the area of blood banking, our Centre for Transfusion Medicine, already renowned for its blood safety standards, is relentless in its quest to be in the world class league. It has embarked on the journey to align its systems and processes to satisfy the high standards required for accreditation with the American Association of Blood Banks and the American Society of Histocompatibility and Immunogenetics. Similarly, our Centre for Forensic Medicine is targeting for accreditation with the National Association of Medical Examiners, the only known international standard that accredits Offices of Forensic/ Medical Examiners in an integrated holistic manner.

### Looking Back

On 11 July 2003, HSA was the first public healthcare agency and among the first few organisations to be conferred the Singapore Innovation Class status. The Singapore Innovation Class award is conferred to organisations that have acquired a commendable level of innovative capabilities and the award recognises the organisations for their commitment to better serve customers through innovative solutions.

Innovation does not occur randomly, but a result of sustained effort. At HSA, we consistently apply our innovation framework, defined based on our three guiding principles, *focus on vision*, *freedom with responsibility*, and *frontier – boldly going forward*, as part of our strategy to sustain our journey towards excellence.

Also in July 2003, our Centre for Analytical Science obtained excellent results in the annual assessment of Singapore Quality Class organisations. This recognition marked the second consecutive year of the Centre's achievement of its performance and eventually fulfilling its aim to be a top-notch business centre.

During the year, the Centre also developed and launched 26 new testing capabilities to cater to our clients' requirements and to keep pace with new and emerging demands. Our Pharmaceutical Laboratory successfully obtained accreditation in October 2003 by the Singapore Accreditation Council – Singapore Laboratory Accreditation Scheme to screen 156 western drugs categorised with 28 different pharmacological effect groupings such as analgesics, androgenic steroids, erectogenic agents and others.

At our Centre for Forensic Science, we took pride in delighting our clients – the Centre started a new cost effective and efficient urine screening test for ketamine abuse which enabled the Central Narcotics Bureau to conduct large scale operations to stamp out ketamine abuse. The Centre also successfully applied a novel technique application of electrostatic detection apparatus to lift fingerprints from documents of anonymous nature for a Hong Kong firm and enabled a key suspect to be identified.

In our continuous efforts to expand our horizons and encourage professional synergy, we organised a joint scientific seminar with the Department of Chemistry, National University of Singapore, where a total of 24 papers and 13 poster presentations was presented. It was a useful platform to share and gain valuable insights into the latest developments and forge closer cross-disciplinary collaboration.

Like many agencies, the severe acute respiratory syndrome (SARS) outbreak last year underscored the importance of emergency and crisis preparedness. In the early stage when there was lacking knowledge of the disease, our forensic pathologists from the Centre for Forensic Medicine were tasked to carry out autopsies on SARS victims under the Infectious Diseases Act. From their autopsies, recovered materials were sent for further investigations by different specialists so as to understand and establish the nature and pathological mechanism of the disease. An emergency implementation of strict protocols and safety audit was adhered to for the handling of SARS cases. The Centre received the President's Certificate of Commendation (for overcoming SARS) with two of its officers receiving the Commendation Medal (for overcoming SARS).

While still reeling from the experience, and with a strong commitment to learn from it, the Centre's officers successfully worked with an engineering firm to establish an innovative alternate engineering solution to meet the need for a higher bio-safety level autopsy suite. The new suite has an improvised biohazard air filtration system for waste air before its discharge into the environment. This innovation has been filed for intellectual property protection.

Also in the early SARS period, our Centre for Transfusion Medicine took immediate additional precautionary measures to proactively protect the safety of the national blood supply to minimise any risk of SARS-transmitted transfusions. The far-sightedness of our initiatives was confirmed when FDA and World Health Organisation (WHO) later recommended similar measures to be implemented to protect the blood stock. We faced a new challenge of reduced blood donor attendance during the SARS period, and blood collection levels dipped by more than 50%. Our blood donor recruiters worked hard to encourage blood donation and the collections subsequently returned to a steady state to support the national blood needs.

### Looking Within

Reviewing organisational structure is part of our strategic journey to improve systems and approaches. In the year under review, we merged our Centre for Drug Evaluation with our Centre for Pharmaceutical Administration to form the new Centre for Drug Administration. The merger was in line with our objective to provide a seamless regulatory service with streamlined systems and processes for the evaluation and registration of western medicinal products in Singapore. Further, the Innovative Therapeutics Group within our Centre for Drug Administration was set up for the full evaluation of new, innovative chemical entities and biological products.

Instilling financial stewardship throughout the entire organisation was another initiative pushed ahead in the year. We focused on cost savings through optimal use of resources and best sourcing, without any compromise on our service delivery.

Building a cohesive and healthy workforce remains our priority. Our organisation policies were refined to create a supportive environment and to equip staff with skills to adopt a healthier lifestyle under our new integrated workplace health promotion programme that targets for an optimum level of staff's physical, mental and social well-being. To further strengthen existing ties and establish common platform to address staff's welfare issues and concerns, we signed the 1st Collective Agreement with the Amalgamated Union of Statutory Board Employees on 25 March 2004.

As part of our ongoing effort to build a people-focused organisation and to create the desired working environment, we commissioned the Organisational Capability Survey in September 2003 where 92.5% of staff gave their frank assessment and opinions. The survey provided good feedback to the management on several dimensions to help review past initiatives and progress with a view to improve existing initiatives and to planning new ones to gear us for the next phase of our journey. A 2-day senior management retreat was held in November 2003 to address key issues based on findings identified through the Organisational Capability Survey.

Going forward, seven teams of innovative and committed individuals were identified to champion the priority areas in employee-management relations, performance and rewards, customer focus, living the core values, innovation and continuous improvement, scenario and strategic planning, and last but not least, work efficiency and

interfaces. We are confident that an enhanced future awaits us as we will strive hard in our organisational excellence effort, and we are committed to make HSA a workplace of challenges, creativity and celebrations.

### Looking Ahead

We have made some progress in building professional and organisational excellence as well as forging greater and more key strategic alliances in our third year. We have charted good outcomes in the critical area of building a shared culture and common identity, which is an ongoing process since our inception.

Our operating environment will continue to evolve and pose us new and varied challenges, and some may throw us into uncharted waters to test our organisational resilience. The rapid development and volatility of the global and national environment reminds us that change is a constant. We must continue to strengthen and review our regulatory frameworks in keeping with the evolving business industry and increasing sophisticated, yet varied, populace. Likewise, our essential service arm that provides scientific, investigative and analytical services must keep abreast of the relevant specialised fields so as to meet emerging consumer needs and new standards.

We are aware that meeting these challenges requires a disciplined and focused outlook – and we remain committed to achieving our mission to excel in applying science to support healthcare services and regulation, serve the administration of justice and enhance safety in our community.



Dr Tan Chor Hiang  
Chief Executive Officer

## our board members

### Chairman

- 01 **Professor Lim Mong King**  
Deputy President, Nanyang Technological University

### Board Members

- 02 **Mr Boon Swan Foo**  
Advisor, ST Engineering Ltd  
Executive Chairman, Exploit Technologies Pte Ltd  
Managing Director, Agency for Science, Technology and Research
- 03 **Dr Arthur Chern**  
Director, Health Service Development, Ministry Of Health
- 04 **Mr Giam Chin Toon**  
Senior Counsel, Wee Swee Teow & Company
- 05 **Mr Khoo Chin Hean**  
Chief Executive, Energy Market Authority
- 06 **Professor Edmund Lee**  
Professor of Pharmacology, Faculty of Medicine  
National University of Singapore
- 07 **Mr Lim Hock San**  
President & Chief Executive Officer,  
United Industrial Corporation Ltd & Singapore Land Ltd
- 08 **Professor Low Teck Seng**  
Principal/Chief Executive Officer, Republic Polytechnic
- 09 **Mr Ng Wai Choong**  
Deputy Secretary, Industry, Ministry of Trade and Industry
- 10 **Mr Stephen Yeo**  
President, EDS International (Singapore) Ptd Ltd



**our board members**



## board changes

We would like to express our deepest appreciation to Mr Boon Swan Foo and Mr Stephen Yeo who relinquished their positions as Board Members of HSA on 1 April 2004.

We also welcome [Associate Professor Kong Hwai Loong](#), Executive Director of the Biomedical Research Council, and [Ms Olivia Lum](#), Chief Executive Officer and President of Hyflux Ltd to the HSA Board.



[Associate Professor Kong Hwai Loong](#)  
Executive Director  
Biomedical Research Council



[Ms Olivia Lum](#)  
Chief Executive Officer and President of Hyflux Ltd

## HSA board committees

### 1 April 2003 to 31 March 2004

#### Staff Establishment Committee

Mr Giam Chin Toon - Chairman  
Prof Edmund Lee  
Prof Low Teck Seng  
Dr Arthur Chern

#### Audit Committee

Mr Lim Hock San - Chairman  
Mr Boon Suan Foo  
Mr Stephen Yeo  
Mr Ng Wai Choong

#### Cost and Price Review Task Force

Mr Khoo Chin Hean - Chairman  
Mr Stephen Yeo  
Dr Arthur Chern

### With effect from 1 April 2004

#### Regulatory Oversight Committee

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

Prof Edmund Lee	Chairman
Dr Arthur Chern	Member
Mr Giam Chin Toon	Member
A/Prof Kong Hwai Loong	Member
Mr Lim Hock San	Member

#### Service Provision Oversight Committee

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

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

#### Audit Committee

Mr Lim Hock San	Chairman
A/Prof Kong Hwai Loong	Member
Ms Olivia Lum	Member
Mr Ng Wai Choong	Member

#### Staff Establishment Committee

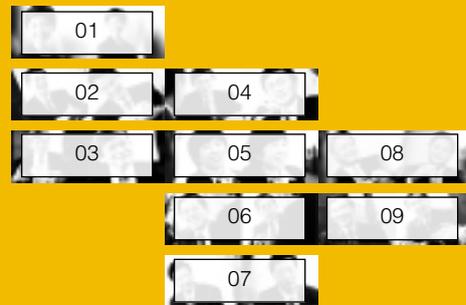
Mr Giam Chin Toon	Chairman
Dr Arthur Chern	Member
Prof Edmund Lee	Member
Prof Low Teck Seng	Member

#### Cost and Price Review Task Force

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

## 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 **Dr Diana Teo**  
Director, Centre for Transfusion Medicine
- 06 **Dr Paul Chui**  
Director, Centre for Forensic Medicine
- 07 **Dr Chow Shui Tse**  
Director, Centre for Forensic Science
- 08 **Dr Bosco Chen Bloodworth**  
Director, Centre for Analytical Science  
Quality Service Manager
- 09 **Mr Vincent Fong**  
Director, Corporate Management Group



**senior management**



## list of principal officers

### CENTRE for DRUG ADMINISTRATION

- Director  
Dr John Lim
- Senior Clinical Pharmacology Advisor  
Prof Vernon Oh
- Product Evaluation & Registration Division**
  - Deputy Director & Head, New Chemical Entities, Innovative Therapeutics Group  
Dr Gerald Wong
  - Senior Assistant Director & Head, Clinical Trials Branch  
Dr Kerwin Low
  - Head, Biologics, Innovative Therapeutics Group  
Dr Philip Ngai
  - Acting Head, Drug Registration Branch  
Ms Lee Hui Keng
- Compliance & Complementary Medicines Division**
  - Senior Deputy Director & Head, Prosecution  
Mr Yee Shen Kuan
  - Deputy Director, Complementary Medicines Branch & Head, Cosmetics Control  
Mrs Marie Tham
  - Head, Chinese Proprietary Medicines Unit  
Ms Chu Swee Seng
  - Head, Health Supplements Unit  
Mr Chao Ye Peng
  - Head, Investigation & Surveillance Unit  
Mr R Sivalingam
  - Head, Tobacco Regulation Unit  
Mr Tham Lup Hong
- Manufacturing & Quality Audit Division**
  - Deputy Director & Head, Good Manufacturing Practice Unit  
Mr Sia Chong Hock
  - Head, Certification Unit  
Dr Lai Weng Fai
  - Head, International Operations Unit  
Mr Boon Meow Hoe
  - Acting Head, Good Distribution Practice Unit  
Ms Hui Foong Mei
- Pharmacovigilance, Communications & Research Division**
  - Deputy Director  
Mdm Suvarin Chaturapit
  - Head, Pharmacovigilance & Head, Information & Research  
Ms Chan Cheng Leng
- International & External Programmes**
  - Deputy Director  
Mrs Marie Tham
  - Head, Regulatory Support Unit  
Mr Ho Yu Nam

### CENTRE for MEDICAL DEVICE REGULATION

- Director  
Mr Wong Yew Sin

### CENTRE for RADIATION PROTECTION

- Director  
Mr Stephen Chong
- Head, Environmental Radiation & Waste Management  
Mr Stephen Chong
- Head, Ionising Radiation Control  
Ms Annie Tan
- Head, Ionising Radiation Dosimetry  
Ms Annie Tan
- Head, Non-Ionising Radiation Control  
Dr Phua Tan Tee
- Head, Non-Ionising Radiation Dosimetry  
Dr Phua Tan Tee
- Head, Nuclear Safety & Emergency Planning  
Mr Stephen Chong

### CENTRE for TRANSFUSION MEDICINE

- Director  
Dr Diana Teo
- Deputy Director, Blood Resources  
Dr Tan Hwee Huang
- Deputy Director, Clinical Service  
Dr Mickey Koh
- Nursing Administrator  
Mrs Chua-Öng Chye Leng
- Head, Blood Processing & Inventory  
Mr Ng Kok Quan
- Head, Quality Control  
Ms Sally Lam
- Head, Hospital Services  
Dr Marieta Chan
- Head, Blood Programme Support  
Ms Koh Geok Tin
- Quality Manager  
Ms Tan Meng Kee

### CENTRE for FORENSIC MEDICINE

- Director  
Dr Paul Chui
- Deputy Director  
Dr Gilbert Lau
- Head, Professional Training & Education  
Dr George Paul
- Principal Consultant Forensic Pathologists  
Dr Clarence Tan  
Dr Wee Keng Poh

### CENTRE for FORENSIC SCIENCE

- Director  
Dr Chow Shui Tse
- Physical Evidence Division**
  - Deputy Director  
Dr Michael Tay
  - Head, Criminalistics Laboratory  
Dr Michael Tay
  - Head, DNA Profiling Laboratory  
Mrs Tan Wai Fun
  - Head, DNA Database Laboratory  
Mrs Tan Wai Fun
  - Head, Document Examination Laboratory  
Ms Lee Gek Kwee
- Drugs & Toxicology Division**
  - Deputy Director  
Dr Lee Tong Kooi
  - Head, Narcotics I Laboratory  
Dr Lee Tong Kooi
  - Head, Narcotics II Laboratory  
Dr Lui Chi Pang
  - Head, Toxicology Laboratory  
Dr Danny Lo

### CENTRE for ANALYTICAL SCIENCE

- Director  
Dr Bosco Chen Bloodworth
- Head, Food Laboratory  
Ms Joanne Chan
- Head, Pharmaceutical Laboratory  
Ms Low Min Yong
- Head, Industrial Health Laboratory  
Dr Chow Yue Thong
- Head, Cosmetics Laboratory  
Mrs Wong Geok Eng
- Head, Cigarette Testing Laboratory  
Dr Chow Yue Thong
- Head, Environment Laboratory  
Mr Ng Soon
- Head, Research & Development  
Ms Cheah Nuan Ping

### CORPORATE MANAGEMENT GROUP

- Director, Corporate Management  
Mr Vincent Fong
- Deputy Director, Corporate Services  
Mr Chua Hong Tong
- Deputy Director, Finance  
Mr Philip Ngiam
- Deputy Director, Human Resource  
Mrs Sarojini Padmanathan
- Deputy Director, Information Management  
Mr Andrew Chong

### CEO'S OFFICE

- Quality Service Manager  
Dr Bosco Chen Bloodworth
- Deputy Director, Corporate Communications  
Ms Jeannie Thng
- Deputy Director, Corporate Planning Office  
Ms Lim Peck Seah

## HSA at a glance

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 pharmaceuticals, biological 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 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 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 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).

## bird's eye view



### April 2003

- The Authority celebrated its 2nd Anniversary on 5 April 2003 with a Dinner & Dance graced by Dr Balaji Sadasivan, Minister of State (Health) and Minister of State (Environment). Registration fees collected for the event were matched dollar-for-dollar by HSA. A total of \$20,000 was raised for the Community Chest.
- The Authority collaborated with the Department of Chemistry, National University of Singapore to organise its 1st HSA-NUS Joint Scientific Seminar held on 9 April 2003. A total of 24 papers and 13 poster presentations was presented at the seminar. Based on the theme "Collaborative Research in Health Sciences", it was a platform for both agencies to explore and forge closer research and cross-disciplinary collaboration.
- CDA recalled a total of 244 health supplement products, marketed in Singapore, that were manufactured by Australian contract manufacturer, Pan Pharmaceuticals Ltd. This was in response to the suspension of Pan Pharmaceuticals' manufacturing licences by Australia's Therapeutic Goods Administration due to serious manufacturing breaches that affect the quality and safety of its health products.
- CAS
  - participated in the Multinational Collaborative Study organised by the International Pharmaceutical Federation in assessing the dosing reproducibility in the administration of amoxicillin/clavulanic acid suspensions.
  - in response to changing market environment, the functions of its Custom Laboratory were subsumed under its Food Laboratory with effect from 1 April 2003

- CFS introduced a new service to clinical trials and research units to screen for drugs of abuse and cotinine (metabolite of nicotine) in urine samples of pre-clinical trial volunteers.

### May 2003

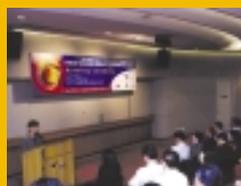
- CDA commenced the administration of the increased penalty for underaged youths caught smoking to a flat ceiling of \$300 on 1 May 2003 so as to achieve a stronger deterrent impact.

### June 2003

- A ceremony was held on 18 June 2003 in Canberra, Australia to mark the Authority's special recognition of Australia's approval of prescriptive medicines by its Australian counterpart, Therapeutic Goods Administration.

### July 2003

- The Authority was the first public healthcare agency and among the first few organisations to be conferred the Singapore Innovation Class status. This award is conferred by SPRING Singapore to organisations that have acquired a commendable level of innovative capabilities.
- CDA
  - introduced the licensing of all importers and wholesalers of tobacco products before they could supply tobacco products, with effect from July 2003. This extension of the retailer-licensing scheme would allow better control of the supply and distribution chain of tobacco products from licensed importers and wholesalers to the licensed retailers.



- signed an agreement on 8 July 2003 to participate in the Pharmaceutical Inspection Co-operation Scheme (PIC/S)-sponsored International Medicinal Inspectorates Database (IMID) as a contributor and user of GMP Inspection reports relating to overseas manufacturers which have been audited and certified by PIC/S member authorities.
- CAS
- received the 2003 Public Service Award for Organisational Excellence on 29 July 2003 during the 13th PS21-Managing For Excellence Forum on Organisational Excellence.
- participated in the 11th Asian Collaborative Study on ISO Tar and Nicotine involving 42 Laboratories from 18 countries in the Asia-Pacific region and Europe. Five different brands of cigarette samples with tar levels ranging from 1mg – 15mg were tested. The study report received in July 2003 indicated that the Laboratory's performance compared favourably from the best laboratories present at the Study.
- developed a new method to determine Sudan I colour in chilli products and chloramphenicol in shrimp products. Owing to the stringent import requirements from the European Union, chilli samples and other shrimp-based products from around the ASEAN region were sent to CAS for testing.
- CFS was awarded an open tender by the Defence Science and Technology Agency to provide urine screening service to national servicemen for drugs of abuse.
- CFM signed a Memorandum of Understanding with Australia's Victorian Institute of Forensic Medicine on 29 July 2003 to further strengthen the strategic co-operation between the two agencies.

### August 2003

- The Authority formalised its commitment to care for the community and the environment with a Societal and Environment Policy. Various initiatives were actively launched during the year to promote its corporate social responsibility.
- HSAians came dressed in red and white to celebrate the nation's birthday on 9 August 2003 with fund-raising activities organised for the less fortunate.
- 14 HSA officers were presented the 2003 National Day Awards for their contributions towards nation building.
- CFM received the President's Certificate of Commendation (for overcoming SARS) with two of its officers receiving the Commendation Medal (for overcoming SARS).
- CDA gazetted new tobacco health warnings under the Smoking (Control of Advertisements and Sale of Tobacco) (Labelling) Regulations on 1 August 2003. The implementation of pictorial health warnings would commence 12 months from the gazette.
- CAS was invited to participate in the Asia Pacific Laboratory Accreditation Cooperation (APLAC) proficiency testing programme organised by Hong Kong Laboratory Accreditation Service (HOKLAS) on the Analysis of Chlorpheniramine Maleate and Pseudoephedrine Hydrochloride Oral Solution.
- CFS started a new cost effective and efficient urine screening test for ketamine abuse which enabled the Central Narcotics Bureau to conduct large scale operations to stamp out ketamine abuse.

## bird's eye view



- CTM
- launched DonorCare@HSA, an online service for blood donors in Singapore as part of the services provided within the National Blood Donor Programme.
- hosted the 2nd World Health Organisation Quality Management Training Course in Blood Transfusion Services for the second consecutive year from 11 to 30 August 2003.

### September 2003

- The Authority launched an integrated workplace health promotion programme that would encourage and enable all staff to achieve an optimum level of physical, mental and social well-being. Organisational policies were refined to create a supportive environment and to equip staff with skills to adopt a healthier lifestyle.
- The HSA family came together for a FISH! Sticks Mid-Autumn Gathering on 10 September 2003. Highlights included a Lantern Making Contest with a FISH! Philosophy theme for staff to incorporate the Guiding Principles of Innovation.
- The Authority signed a Memorandum of Understanding (MOU) with the State Food and Drug Administration, People's Republic of China on 12 September 2003 to formalise and further strengthen the strategic alliance and co-operation between the two agencies in drug administration. Under the MOU, a Plan of Co-operation on traditional Chinese medicines was signed.
- CFS successfully applied a novel technique application of Electrostatic Detection Apparatus to lift fingerprints from documents of anonymous nature for a Hong Kong firm which enabled a key suspect to be identified.
- The HSA family got together on A.C.T.I.V.E Day at the MacRitchie Reservoir for a scenic trek to celebrate the fun of healthy living.

### October 2003

- In a continuing effort to build a people-focused organisation and to create the desired working environment for HSAians, the Authority commissioned the Organisational Capability Survey. A total of 520 staff took part in the survey which accounted for 92.5% of the HSA family. The survey served as a feedback to the senior management on several dimensions to help review past initiatives and progress with a view to improve existing initiatives and to planning new ones to gear HSA for the next phase of its journey.
- CAS
- its Centre Director participated in the International Laboratory Forum on Counterfeit Medicines (ILFCM) held in San Francisco. Singapore was the only non-European country invited to participate in the Forum.
- successfully achieved accreditation by Singapore Accreditation Council – Singapore Laboratory Accreditation Scheme to screen 156 western drugs categorised with 28 different pharmacological effects groups such as analgesic, androgenic steroids, erectogenic agents and others.
- CMDR's Centre Director received a Merit Award from SPRING Singapore in recognition of his contribution to the standardisation activities for the medical device industry in the Medical Technology Standards Committee.
- The HSA family came together for a fun, friendly and creative 'Shoot Me, I Am Innovative!' photo contest. HSAians from various centres and departments struck their poses and gave their best shots to depict the FISH! philosophy. 12 winning images were picked to be featured in the HSA 2004 corporate diary.



### November 2003

- CDA
  - and the Health Promotion Board introduced the additional conditional requirement with effect from 1 November 2003 for all second and third time underaged smoking offenders to attend smoking cessation counselling before they could pay their composition fine of \$30.
  - organised its first public Drug Safety Seminar for more than 160 healthcare professionals to enhance the awareness and reporting of adverse drug reactions
  - represented Singapore in the First Standing Committee Meeting of the Western Pacific Regional Forum for the Harmonisation of Herbal Medicines held in China from 26 – 28 November 2003. It was proposed at the meeting that HSA could co-chair with Australia's Therapeutic Goods Administration for the newly-formed expert workgroup on adverse drugs reactions relating to herbal medicine.
  - established a Medical Product Working Group with US Food & Drug Administration under the US-Singapore Free Trade Agreement to promote the protection of public health through expeditious, science-based regulatory procedures for new medical products.
- CAS' scientist was appointed as a WHO Temporary Advisor to the WHO Consultation Meeting on "Specifications for Medicines and Quality Control Laboratory Issues" held in Geneva.
- CMDR developed a core training program on medical device regulation. It received two regulators from Philippines under the auspices of WHO Fellowship Program for a 3-week training.

- CFS scientists shared their experience in 'Fighting Crime with Science' with about 200 secondary school students as part of the Authority's community outreach programme at the 2003 Faraday Lecture organised by the Singapore Science Centre.
- A 2-day Senior Management Retreat with a leadership workshop on "Synergy Through Transition" was held on 21 and 22 November 2003, for the management team, to address key issues and develop action plans based on findings identified from the Organisation Capability Survey conducted during the year.
- The Annual IDEAS Forum with the theme "IDEAS@Work That Work" was held on 28 November 2003 to encourage and inspire HSAians to be creative in their work. Various awards such as Best Work Innovation Projects, Best Staff Suggestions and NEMO (Nurturing, Enterprising, Mastery and Organisation@Heart) awards were given to staff in recognition of their commendable efforts in work improvement, ideas and for their role modelling of HSA core values.

### December 2003

- CDA implemented the prohibition of sale of cigarette packs containing fewer than 20 sticks with the objective of making cigarettes less affordable to youths and to discourage experimentation of tobacco products by young people, with effect from 1 December 2003.
- The HSA family ended the year with a party specially themed *A Walk Down Memory Lane* held at the premises of CDA before its move to Biopolis in 2004.
- CRP's Centre Director was engaged by International Atomic Energy Agency (IAEA) as an expert member of a 7-member consultant group to review its Radiation Protection Model Projects in East Asia and the Pacific Region.

## bird's eye view



### January 2004

- CDA
- in line with HSA's objective of providing a seamless regulatory service, CPA and the CDE merged to form the Centre for Drug Administration (CDA). CDA's formation would allow the further rationalisation and streamlining of the systems and processes for the evaluation and registration of western medicinal products in Singapore. The CDE entity was re-named as CDA's Innovative Therapeutics Group (ITG) in order to highlight its capability to conduct full evaluation of new, innovative chemical entities and biological products.
- With effect from 1 January 2004, CDA
  - enhanced the regulatory control of CPM by recognising only test reports issued by accredited laboratories for selected CPM assessed to be at a higher risk of adulteration.
  - implemented the control of aristolochic acids and their salts as poisons under the Poisons Act in view of significant reported toxicities of products containing aristolochic acids in various countries.
  - implemented the legislative provisions to enable the licensing, importation, sale and supply of therapeutic chewing gums under the US-Singapore Free Trade Agreement.
- CTM completed a research project on "Evaluation study in a Commercial Malaria PCR Test Kit for Future Application on Blood Donor Screening" in collaboration with the National University Hospital.

### February 2004

- The Authority organised a health screening exercise for staff as part of its Workplace Health Promotion's initiatives to promote a healthy workforce.
- The HSA family participated in a *Sports For Life* fitness assessment at the Labrador Beach Front on 12 February 2004 to gauge its overall fitness level.

### March 2004

- The Authority signed the 1st Collective Agreement with the Amalgamated Union of Statutory Board Employees on 25 March 2004 to further strengthen existing ties and establish common platform to address staff's welfare issues and concerns.
- The HSA family had *Fun in the Park* at the Pasir Ris Park at its third Family Day. A variety of activities, including game stalls, tele-matches, sand-sculpturing competition, stage entertainment, and lucky draw were planned for some 450 staff and family members.
- CAS participated in the inter-laboratory comparison study on various studies on drug related physical measurement activities, with the Official Laboratories and Medicines Control services, part of a multinational co-operation committee.
- CRP's Centre Director was further engaged IAEA as an expert in a working group of international experts to evaluate the status of radiation safety programme implementations in the participating countries including those in the African, European and the East Asia Regions.



## INTERNATIONAL OUTLOOK:

playing host to the world's regulatory, health, scientific & investigative agencies

Date	Visits By
11 August 2003	Ms Melinda Plaisier, Assistant Commissioner, US Food and Drug Administration
1 September 2003	Delegation led by Dato Haji Zainal Momin, Permanent Secretary, Ministry of Health, Brunei
11 September 2003	Delegation from China's State Food and Drug Administration led by Mr Zheng Xiaoyu, SFDA Commissioner
17 September 2003	A team of medical specialists from India under the auspices of the Singapore Medicine's initiative spearheaded by the Singapore Tourism Board
25 September 2003	Delegation from Shanghai State Drug Administration led by Mr Fang Yuming, Director of Shanghai Institute for Drug Control
9 October 2003	Delegation from Institute for Health Policy and Systems Research led by Dr Geoffrey Lieu, Chairman of Hong Kong Health Corporation Ltd
15 October 2003	Delegation from Shanghai Municipal Health Bureau led by Ms Liu Xin Xin, Deputy Director (Human Resource Division)
28 - 29 October 2003	Delegation from China National Accreditation Board for Laboratories led by Ms Yuan Songhong, Director (General Affairs)
11 November 2003	Delegation from Korea National Institute of Scientific Investigation led by its Section Chief, Mr Dong-Wook Kim
26 - 28 November 2003	Delegation from Vietnam's Drug Administration led by Director-General Tran Cong Ky
1 - 2 December 2003	Delegation from Taiwan Criminal Investigation Bureau led by its Director, Cheng Sheaw-Guey
15 December 2003	Delegation by Shandong Province Health Division led by its Deputy Head, Mr Zuo Yi
17 December 2003	Major General Mohamad A Sedki and Major Humaid Khalid from the Dubai Police Department under the auspices of the Singapore Medicine's initiative spearheaded by the Singapore Tourism Board
17 February 2004	Delegation from China's Ministry of Health led by Mr Zhang Ben, Director of Foreign Loan Office
16 March 2004	Delegation from Beijing Department of the Supreme People's Court led by Mr Song Jianchao, Senior Judge



a vigilant eye



At HSA, we implement a wide range of regulatory measures to safeguard public health from the potential risks of medicines, complementary health products, cosmetics, medical devices and other medical and consumer health products, including those that emit radiation. We adopt varied approaches for different product categories to ensure that the appropriate standards of safety, quality and efficacy are met. We apply science and law to protect consumers in Singapore. As in developed countries, our regulatory framework is based on a risk management approach designed to ensure public health and safety, while allowing the industry to develop without unnecessary burden.



CDA



CMDR



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CTM



CFM



CFS



CAS

## REGULATING PHARMACEUTICALS AND HEALTH-RELATED PRODUCTS

To streamline the evaluation processes for western medicinal products, the Centre for Pharmaceutical Administration (CPA) and Centre for Drug Evaluation (CDE) were consolidated on 1 January 2004 to form the Centre for Drug Administration (CDA). With this consolidation, the former CDE entity was established as the Innovative Therapeutics Group (ITG) of CDA.

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 (CPM) based on set criteria for safety and quality;
- Good Manufacturing Practice (GMP) inspection/audit and licensing of manufacturers/assemblers of products regulated;
- Good Distribution Practice (GDP) 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 and licensing of tobacco importers and dealers;
- 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.

It should be noted that in spite of this spectrum of activities, 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 should always aim to obtain as much information 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. To continue building our evaluation capability, our ITG (formerly CDE) continues to be funded by the Agency for Science, Technology and Research as part of the infrastructure to develop Singapore into a vibrant biomedical research hub.

### Evaluation And Licensing Of Medicinal Products

During the year under review, we issued a total of 283 new product licences and renewed 1,055 existing product licences for medicinal products. In addition, a total of 2,749 applications of variation in product licences for medicinal products was processed and approved.



The medicinal products approved in 2003, and which contain new active ingredients or new ingredient combinations, are listed below:

No.	New Medicinal Products Approved in 2003
1	Actos® Tablets 15 mg and 30 mg ( <i>Pioglitazone</i> )
2	Agrylin® Capsule 0.5 mg ( <i>Anagrelide</i> )
3	Amscan DMSA® Agent for Injection 1 mg/vial ( <i>Dimercaptosuccinic Acid</i> )
4	Avage® Cream 0.1% ( <i>Tazarotene</i> )
5	Avodart® Capsule 0.5 mg ( <i>Dutasteride</i> )
6	Bifril® Tablet 30 mg ( <i>Zofenopril</i> )
7	Duratocin® Injection 100 mcg/ml ( <i>Carbetocin</i> )
8	Ebixa® Tablet 10 mg Ebixa® Oral Drops 10 mg/g ( <i>Memantine</i> )
9	Emend® Capsules 80 mg and 125 mg Emend® Tri-pack Capsule 80 mg with 125 mg ( <i>Aprepitant</i> )
10	Evra® Transdermal Patches 6 mg/600 mcg and 6 mg/750 mcg ( <i>Norelgestromin, Ethinylestradiol</i> )
11	Ezetrol® Tablet 10 mg ( <i>Ezetimibe</i> )
12	Gadovist® Injection 1.0 mmol/ml ( <i>Gadobutrol</i> )
13	Hepsera® Tablet 10 mg ( <i>Adefovir</i> )
14	Humira® Solution for Injection 40 mg/0.8 ml Vial Humira® Solution for Injection 40 mg/0.8 ml Pre-fill Syringe ( <i>Adalimumab</i> )
15	Iressa® Tablet 250 mg ( <i>Gefitinib</i> )
16	Iruxol Mono® Ointment 1.2 u/0.24 u ( <i>Clostridiopeptidase A, Proteases</i> )
17	Lexapro® Tablets 5 mg, 10 mg, 15 mg and 20 mg ( <i>Escitalopram</i> )
18	Multihance® Injections 529 mg/ml 10 ml, 15 ml and 20 ml ( <i>Gadobenate Dimeglumine</i> )
19	Optimark® Injection 0.5 mmol/ml ( <i>Gadoversetamide</i> )
20	Recombinat® for Injections 250 iu, 500 iu and 1000 iu/vial ( <i>Recombinant Antihemophilic Factor</i> )
21	Resovist® Injection 0.5 mmol Fe/ml ( <i>Ferucarbotran</i> )
22	Reyataz® Tablets 100 mg, 150 mg and 200 mg ( <i>Atazanavir</i> )
23	Totelle® Cycle Tablet 2 mg/0.5 mg ( <i>Estradiol Hemihydrate, Trimegestone</i> )
24	Valcyte® Tablet 450 mg ( <i>Valganciclovir</i> )
25	Vfend® Tablets 50 mg and 200 mg Vfend® for Infusion 200 mg/vial ( <i>Voriconazole</i> )
26	Yasmin® Tablet 3 mg/0.03 mg ( <i>Drospirenone, Ethinylestradiol</i> )

During the year, the drug registration guide and application form were revised to enhance clarity and transparency of our drug registration process and requirements. The ASEAN Common Technical Dossier, resulting from the ongoing harmonisation efforts amongst the ASEAN member countries, was also incorporated into the revised drug registration guide.

The verification route was formally incorporated into the drug registration guide after its trial implementation. This new evaluation route is applicable to products which are proposed to be marketed in Singapore for the same indications and approved by at least two of the following benchmark agencies: the US Food and Drug Administration (FDA), the UK Medicines and Healthcare Products Regulatory Agency, the European Medicines Evaluation Agency, the Australian Therapeutic Goods Administration (TGA), and Health Canada.

### Improving Consumer Access To Medicines

As part of our initiative to facilitate greater public accessibility to effective and safe drug treatment, 14 products were reclassified during the year. Of these, five were reclassified from Prescription-Only-Medicine (POM) to Pharmacy-Only-Medicine (P). Nine were reclassified from Pharmacy-Only-Medicine (P) to General Sale List (GSL).

### Reclassification of Medicinal Products

#### Reclassification from POM to P:

- Aleve (Naproxen Sodium) Tablet 220mg
- Growell (Minoxidil) Scalp Lotion 3%
- Growell (Minoxidil) Scalp Lotion 5%
- Minox 5 (Minoxidil) Topical Solution 5%
- Oral-T (Triamcinolone Acetonide) Oral Paste 0.1%

#### Reclassification from P to GSL:

- Almiral (Diclofenac ) Gel 1%
- Lamisil (Terbinafine) Cream 1%
- Lamisil (Terbinafine) Dermgel 1%
- Lamisil (Terbinafine) Solution 1%
- Lamisil (Terbinafine) Spray 1%
- Rhewlin (Diclofenac ) Gel 1%
- Tinaderm (Tolnaftate) Cream 1%
- Tinaderm (Tolnaftate) Solution 1%
- Toesring (Tolnaftate) Cream 1%



As at 31 March 2004, the number of medicinal products registered in Singapore totalled 7,550. The forensic classification of products registered is shown below:

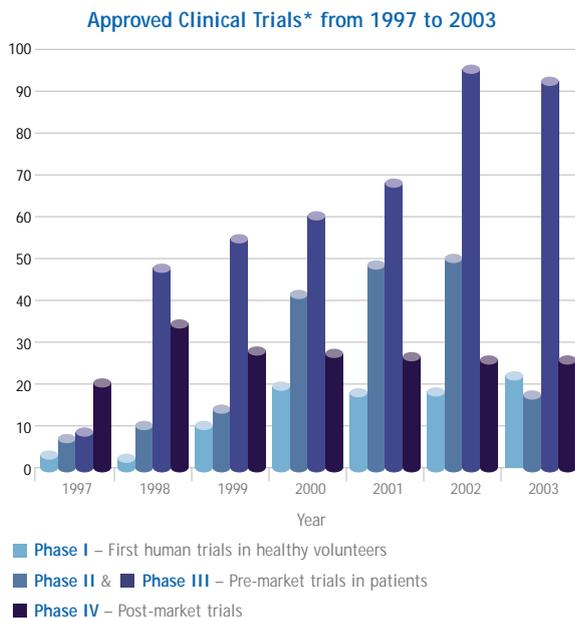
Forensic Classification	No. of Products	Percentage
Prescription-Only-Medicines (POM)	5,209	69%
Pharmacy-Only-Medicines (P)	1,033	14%
General Sale List Medicines (GSL)	1,308	17%
Total	7,550	100%

To allow access to critical medicines not registered in Singapore, we granted 1,492 approvals for unregistered medicinal products to be imported for use by individual patients during the year and administered under the supervision and responsibility of the attending doctors.

### Certification Of Clinical Drug Trials

During the year, we granted 160 clinical trial certificates\* (CTC) to various institutions. Of these, more than half (57%) was for phase III trials. Earlier phase trials (phase I and II) accounted for 27% of CTCs, with phase IV trials accounting for the remaining 16%.

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



\* Number of clinical trial certificates issued.

^ 1 January to 31 December of stated year.

As part of the ongoing safety monitoring of clinical trials, all adverse drug reactions that are both serious and unexpected are subject to expedited reporting to HSA. In 2003, we received a total of 3,757 initial reports from January to December 2003 and 1,123 follow-up reports from June to December 2003. These reports were captured in the clinical trial safety database for phase I-IV trials.

The monitoring of clinical trials was further strengthened in 2003. A more comprehensive clinical trial safety database was developed to allow for early signal detection so that interventions could be initiated as soon as possible.

To ensure consistency in the reporting of serious and unexpected adverse drug reactions by sponsors of clinical trials, a draft guidance for safety reporting in clinical trials was issued to the industry for consultation in September 2003. Inputs from industry on the draft guidance were collated and incorporated into the final Guidance for Industry - Safety Reporting Requirements for Clinical Drug Trials. The final guidance incorporating industry inputs was implemented in March 2004.

### Licensing Of Manufacturers, Assemblers, Importers, Wholesale Dealers And Pharmacies

During the year, we issued 83 licences to manufacturers and assemblers of medicinal products, CPM and cosmetic products. In the same period, 317 wholesale dealer licences, 559 import licences and 262 pharmacy certificates were processed and issued. These licences and certificates were granted to manufacturers and dealers only when they were found to be in compliance with relevant GMP, GDP and other quality system standards and regulatory requirements.



In addition, we issued other licences and certificates to the trade. These included 98 export licences, 442 Forms A\*, 721 Forms C\*\*, 206 certificates of pharmaceutical products, 92 GMP certificates and 64 free sales certificates for CPM as well as 12 statements of licensing status.

\* 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 Manufacturing Practice

We signed an agreement on 8 July 2003 to participate in the Pharmaceutical Inspection Co-operation Scheme (PIC/S)-sponsored International Medicinal Inspectorates Database as a contributor and user of GMP inspection reports relating to overseas manufacturers which have been audited and certified by PIC/S member authorities.

In July 2003, we participated in the PIC/S reassessment of TGA. This is one of several ongoing obligatory calibration programmes to ensure continual improvement in the quality system and consistency in regulatory practices in the field of GMP inspection by all PIC/S participating authorities. We were the co-rapporteur in this reassessment.

We participated in the 69th PIC/S Committee of Officials Meeting cum 18th PIC/S Committee Meeting held in Geneva from 11 to 12 November 2003. At this meeting, HSA was appointed as the rapporteur for the Joint Reassessment of the National Regulatory Authority, the Dipartimento per la Valutazione dei Medicinali e la Farmacovigilanza of Italy in 2004. During this meeting, the PIC/S also decided that HSA Singapore shall host the PIC/S Seminar 2007 with the theme "Inspection of Manufacturers of Solid Dosage Forms".

### Regulation Of Chinese Proprietary Medicines

During the year, we received a total of 1,439 applications for CPM product listing, of which 799 products were approved for listing based on the assessment of safety and certain aspects of quality requirements, but for which efficacy claims were not considered. As at 31 March 2004, the total number of CPM listed was 10,819.

Between 1 January 2003 and 31 March 2004, 39 CPM were rejected due to harmful content, objectionable names or inability to fulfil documentation requirements. Out of these, 38 CPM contained prohibited substances.

In addition, by sending suspicious samples of products submitted for enquiry for testing, we successfully screened out close to 20 products which contained chemical adulterants, at the pre-marketing stage, hence preventing the entry of unsafe products into Singapore.

HSA introduced the following additional measures to tighten control of CPM:

- (a) With effect from 1 January 2004, certain categories of CPM that have been assessed to have higher risks, including slimming products and male sexual performance enhancers, must be tested by an accredited laboratory.
- (b) Herbs and CPM containing aristolochic acids were not allowed for sale in Singapore with effect from 1 January 2004 following the gazetting of aristolochic acids under the Poisons Act. The measure was taken in view of the reported risks of renal toxicity and potential carcinogenicity of herbs containing aristolochic acids.



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### Regulation Of Health Supplements

Pending the implementation of the specific regulatory framework for health supplements, we issued the Health Supplements Guidelines to assist the health supplements industry to comply with the existing legal requirements. In addition, the guidelines prepare the industry to meet future requirements when the framework is introduced. We also worked in cooperation with the industry to advise consumers on the need to exercise personal responsibility in the selection and usage of health supplements.

#### Recall of health supplements manufactured by Australia's Pan Pharmaceuticals Ltd

In April 2003, we carried out a major recall of 244 health supplements manufactured by Pan Pharmaceuticals Ltd.

The recall was initiated in response to the suspension of the manufacturing licence of Pan Pharmaceuticals Ltd by TGA. The manufacturer was found to have serious manufacturing breaches that affect the quality and safety of its health products.

The products affected included vitamins, minerals and herbal products sold under 26 brands in the local market. All the affected products were withdrawn by the local distributors within a few days. Inspections were carried out at major retail outlets of health supplements to ensure that all affected products were no longer available to consumers.

There were no reports of adverse reactions due to the affected products. During the recall, enquiry hotlines were established to address public concern and more than 3,000 enquiries were handled. In addition, daily updates of the recall were issued to the media.

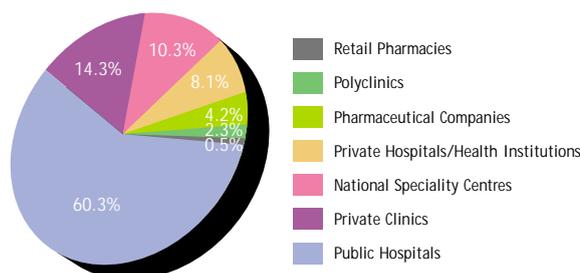
### Regulation Of Cosmetics

We issued a total of 10,209 cosmetic product licences for the year. These included 4,775 new cosmetic product licenses, 5,238 renewed licenses and 198 amended product licences. Eight applications were rejected due to the presence of banned ingredients.

Under the US-Singapore Free Trade Agreement, Singapore agreed to allow the importation and sale of chewing gums with therapeutic value, subject to laws and regulations relating to health products. With effect from 1 January 2004, we implemented the legislative provisions for the licensing, importing, sale and supply of oral dental gums which contain ingredients for oral and dental hygiene purposes such as gums for tooth whitening and reducing tooth decay. As the overall ban for the import and sale of chewing gum remains in force, certain restrictions are imposed on the retail access to approved gums.

### Adverse Drug Reaction (ADR) Monitoring

We received a record number of 1,100 ADR reports in 2003 - an increase of 38% compared to the previous year. The public hospitals contributed the majority of reports (60.3%), followed by private clinics (14.3%), national speciality centres (10.3%), private hospitals/health institutions (8.1%), pharmaceutical companies (4.2%), polyclinics (2.3%) and retail pharmacies (0.5%).

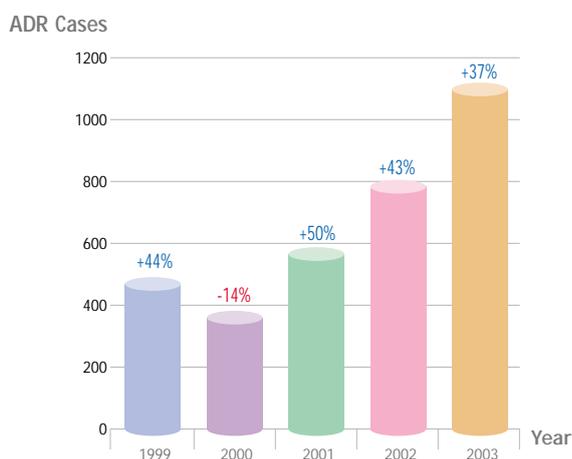




As spontaneous reporting of ADR is key to the post-market monitoring of drug safety, we conducted regular talks to promote ADR reporting in various health institutions, including community pharmacies. In addition, ADR news bulletins are published to provide regular updates on drug safety issues and distributed to more than 7,000 healthcare professionals in Singapore.

In view of Singapore's small population base, there is a need for us to tap into ADR signals reported in other countries. We have benefited much from our participation in regular bi-monthly teleconferences initiated by our ADR monitoring counterparts in Australia and New Zealand.

### ADR Reports Received From 1999 To 2003



\*Percentage of change over previous year

### Assessment Of Major Drug Safety Issues

During the year, several safety concerns that emerged from overseas reports or local signals were reviewed. The major safety issues reviewed in 2003 are shown below:

Affected Drug	Safety Concerns/Signals	Review Outcome
Epoetin alpha	Emerging reports of a form of blood disorder (pure red cell dysplasia) in chronic renal failure patients who were receiving the drug via the subcutaneous route.	The package insert of the product was revised. A Dear Healthcare Professional letter was issued to advise doctors of this risk and how it can be minimised.
Nefazodone	Emerging reports of liver toxicities suspected to be associated with the drug.	The product was voluntarily withdrawn due to low local demand and usage.
Oxaliplatin	Local reports of serious occurrence of infusion related adverse events.	The package insert of the product was revised to include these possible adverse events.
Selective Serotonin-Reuptake Inhibitors (SSRIs)	Emerging reports of increased risk of suicidal ideation in children and adolescents treated with this class of drugs.	HSA's position on the risk of SSRIs in children and adolescents was issued. The package inserts of SSRIs are being revised.
Combined Hormone Replacement Therapy (HRT)	Clinical trial data revealed an increased risk of breast cancer, cardiovascular disease in postmenopausal women taking the drug on a long term basis.	HSA's position on benefits and risks of HRT was issued. The package inserts of products indicated for HRT are being revised.
Atypical antipsychotics	Epidemiological data revealed increased risk of hyperglycaemia and diabetes in patients taking this class of drugs.	The package inserts of affected products were revised to reflect these new risks.
Granulocyte Stimulating Factors	Isolated reports of possible risk of blood disorders in healthy donors given the drug to stimulate blood cell production for bone marrow transplantation.	A Dear Healthcare Professional Letter was issued to oncologists and haematologists to highlight this possible risk.

### Regulation Of Medical Advertisements And Sales Promotions

Of the 1,238 applications received during the year, 1,136 were granted advertising permits, 92 were withdrawn, and 10 were rejected.

As a council member of the Advertising Standards Authority Of Singapore (ASAS), we continued to provide advice and professional inputs to ASAS in the assessment of advertisements relating to medicinal and health-related products. During the Severe Acute Respiratory Syndrome (SARS) outbreak, we worked with ASAS to evaluate SARS-related advertisements to ensure that they did not mislead consumers.



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To prevent indirect advertising of POM to members of the public through disease awareness campaigns, we developed a set of guidelines for pharmaceutical companies to comply with. The Singapore Association of Pharmaceutical Industries' inputs were sought and incorporated into the guidelines.

#### Investigation, Surveillance And Prosecution

During the year, we investigated 480 cases which arose from various complaints and reports received. A total of 275 products was recalled, inclusive of 244 products manufactured by Australia's Pan Pharmaceuticals Ltd.

We also completed 25 prosecution cases in court, which resulted in total fines of \$134,000 being imposed by the Courts. In addition to the fines, seven offenders were also given prison terms. In addition, we issued 61 composition notices amounting to a total of \$53,550 in fines.

In line with this year's focus on increased surveillance of internet sites offering medicinal products for sale, we participated in an International Internet Sweep, organised jointly by Australian Competition and Consumer Commission and the International Consumer Protection and Enforcement Network from 10 to 12 February 2004. The theme of this year's sweep was "*Too Good To Be True*". All participating agencies surveyed the sites in their respective countries that offered products and services making claims that appeared to be exaggerated. A total of 3,000 local websites were screened and some 20 sites were identified for further investigation for possible illegal sales of medicinal products. From the investigations, none of the sites were found to reflect illegal activities.

To curb the illegal entry and sale of unregistered and counterfeit medicines, we continued to expand our collaboration with other agencies, namely the Immigration and Checkpoints Authority, Singapore Post, Singapore Police Force and Central Narcotics Bureau. As a result, a number of joint operations with these agencies was conducted.

#### Tobacco Regulation

During the year, 7,488 tobacco retailer licences were issued. In addition, we intensified our efforts to curb smoking by youths under 18 years old. A total of 6,009 youths was caught smoking or in possession of cigarettes.

The Smoking (Control of Advertisements and Sale of Tobacco) (Amendment) Act 2002 was gazetted on 28 February 2003. The significant amendments include:

- Amendment of penalty for underaged smokers to a flat rate of \$300
- Licensing of tobacco importers and wholesalers
- Introduction of mandatory counselling for underaged smokers caught
- Prohibition of sales of cigarette packs containing fewer than 20 sticks per pack
- Introduction of new Health Warning Labels

With effect from 1 July 2003, licensing of tobacco importers and wholesalers was implemented to better regulate the supply and distribution of tobacco products and to make them more accountable for ensuring regulatory compliance. As at 31 March 2004, 59 importers and wholesalers of tobacco products have been licensed.

The sale of cigarette packs containing fewer than 20 cigarettes was prohibited from 1 December 2003 so as to make cigarettes less affordable and to discourage experimentation by youths.



### **International Collaboration And Regional Harmonisation Efforts**

Under the auspices of the ASEAN Consultative Committee for Standards and Quality (ACCSQ), which aims to develop harmonisation schemes for pharmaceutical regulations within the region, we chair the Implementation Working Group which oversees the trial implementation period for the ASEAN Common Technical Requirements and ASEAN Common Technical Dossier from January 2003 to December 2004. The findings of the survey on the ASEAN Harmonised Documents were presented to the Pharmaceutical Product Working Group (PPWG) at the 7th ACCSQ PPWG Meeting held from 1 – 3 July 2003 in Penang, Malaysia.

The ASEAN Economic Ministers signed the Agreement on the ASEAN Harmonised Cosmetic Regulatory Scheme at the 35th ASEAN Economic Ministers' Meeting held in Phnom Penh, Cambodia on 2 September 2003. We will be modifying Singapore's cosmetic regulatory framework to implement the ASEAN Cosmetic Directive from 1 January 2008.

Since its formation in 2002, we have been actively involved in the Western Pacific Regional Forum for the Harmonisation of Herbal Medicines (FHH) to establish common technical guidelines on herbal medicines, including CPM, among member countries. We participated in the First Standing Committee Meeting of the FHH held in November 2003. HSA and TGA will be co-chairing the new expert working group on ADR relating to herbal medicines.

### **LOOKING AHEAD**

As part of our ongoing efforts to strengthen our pharmaceutical and health-product regulatory system to protect public health and to enhance public access to safe and effective drugs, several new initiatives will be rolled out in the coming year. Looking ahead, some of our ongoing plans include:

- **Quality Medicines Harmonisation Programme (QMHP)**

From 1 April 2004, we will be implementing the first phase of QMHP which covers new product licence applications. QMHP aims to harmonise Singapore's regulatory requirements and standards for new and existing medicines with current ASEAN and international standards. It comprises three key components, i.e. GMP audit of overseas manufacturers not already audited according to international standards (like the PIC/S); enhanced pharmaceutical data review; and bioequivalence study requirements for generic products.

- **New Clinical Trials Regulatory Framework**

To strengthen the regulatory oversight of clinical trials and enhance protection of clinical research participants in Singapore, we will be implementing a new Clinical Trial Regulatory Framework in phases. The strengthened framework will increase stakeholder accountability through trial centre licensing and institutional review board verification. A Good Clinical Practice inspection/audit program will also be introduced.

- **International Collaboration In Pharmacovigilance**

Cooperation and sharing of information among regulatory authorities in the area of pharmacovigilance is important in enabling the faster detection of potential drug safety problems. We are working towards enhancing pharmacovigilance cooperation with our Asian counterparts over the next 1- 3 years.

- **Good Distribution Practice Certification Scheme**

Conformance to GDP standards by companies involved in the distribution of medicinal and health-related products have been gaining regulatory importance worldwide. In Singapore, importers and wholesale dealers of medicinal products have been required to comply with GDP standards since 1998. We are also considering introducing a voluntary GDP Certification Scheme to facilitate the distribution of medicinal products by the biomedical science logistic industry.



## REGULATING MEDICAL DEVICES

Our **Centre for Medical Device Regulation (CMDR)** keeps a close watch on the rapidly advancing technologies that result in a proliferation of new medical devices. Our objective is to protect public health and safety by discharging regulatory controls through a programme of pre-market assessment of products, manufacturing controls and post-market monitoring. We take all necessary and reasonable steps to ensure that medical devices in Singapore are safe, of appropriate quality, perform as intended and are properly used. We seek to ensure that the valuable new technologies are made available to the clinical community, patients and consumers expeditiously while preventing unsafe or ineffective devices from reaching the market.

We also administer 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 2004, there were 443 licensed contact lens practitioners in Singapore.

### Voluntary Product Registration Scheme

Introduced in 2002, the Voluntary Product Registration Scheme for higher-risk medical devices serves as an interim phase while transiting to a regulated environment. This interim phase allows for a period of confidence building where one learns about various levels of regulatory control and it offers stakeholders a window of opportunities to address issues that are obstacles to trade facilitation.

By end March 2004, this scheme has been in operation for two years and received encouraging response and support from the medical device industry. About 76% of the 1,908 applications received, involving 3,394 devices, have been cleared. Of these, about 46% were cleared within the target turnaround time of four to six weeks.

During the year, manufacturers under the voluntary scheme submitted incident reports of 27 product recalls and three adverse incidents relating to medical devices worldwide and locally. Appropriate corrective actions including recalls of products that were sold in Singapore were duly taken.

### Regular Dialogue Sessions

We hold regular dialogues and consultations with local distributors and manufacturers of medical devices, which include updating them of pending regulatory changes on an ongoing basis. During the year, we also worked in partnership with SPRING Singapore to develop and promote two technical references for the medical device industry.

### Singapore Medical Device Register

During the year, we completed much of the development work of an online Singapore Medical Device Register (SMDR) to capture database information of legally available devices and establishments dealing with devices. The SMDR will be ready when the regulation of medical devices is enacted.

A Medical Device Licensing and Control System (medics@hsa) is being developed to support and enhance the operational efficiency for the regulation of medical devices. More customisation and e-services will be 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.



### Core Training Programme Developed

CMDR developed a core training programme on medical device regulation. We received two regulators from Philippines under the auspices of WHO Fellowship programme for a 3-week training. Five trainees from the region also benefited from the programme.

### SPRING Singapore Award

CMDR's Centre Director received a Merit Award by SPRING Singapore in recognition of his contribution to the standardisation activities for the medical device industry in the Medical Technology Standards Committee.

### LOOKING AHEAD

During the year, key management and staff positions have been filled gradually, standard operating procedures and tracking mechanisms have been improved; the backlog of pre-market review under the Voluntary Product Registration Scheme has been reduced; and a risk-based regulatory framework has been developed.

Looking ahead, CMDR will continue to review and make improvements to the device evaluation and marketing clearance processes to provide differentiated pathways for those which have prior regulatory approval or clearance from benchmarked countries, without compromising safety, quality and performance of the device products for local commerce. Clear policy and guidelines that will address all elements related to medical devices are established which are aligned to international standards and harmonisation and a level of scrutiny appropriate to the risk they represent will be applied to medical devices available on the Singapore market. The scrutiny will be achieved through a balance of the key elements – quality systems, pre-market review and post market surveillance.

Our main challenges in 2004 include consultation process with the industry, leading to the introduction of new regulations on medical devices based on risk, and transition to cost recovery. A great deal of dialogue is necessary to make sure our objectives are achieved with minimal negative impact on industry and consumers. Dialogue with key stakeholders on the regulatory framework began two years ago and will continue in the coming year.





## ENSURING RADIATION SAFETY

Our **Centre for Radiation Protection (CRP)** is the national controlling authority for the safe use of ionising and non-ionising radiation in Singapore. We administer and enforce the Radiation Protection Act (Chapter 262), 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, microwave ovens and ultra-violet sun tanning lamps.

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

### Radiation Control: Licensing And Inspections

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.

In 2003, 22,632 licences were issued, an increase of more than 8% compared to 2002. Altogether, 1,775 endorsements were given for the import/export of components of irradiating apparatus without the radiation emitting components, while 147 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. 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.

In 2003, we made 424 inspections at medical, dental and veterinary practice premises, industrial and educational institutions. For premises using non-ionising radiation apparatus, we conducted 26 inspections to ensure compliance. In addition, 14 surveys at handphone base-stations and radio/television transmitting stations were conducted.

To ensure that radiation levels emitting from microwave ovens sold in Singapore are below that specified in the Regulations, we checked 33 new models of microwave ovens from different manufacturers in 2003. All complied with the requirements specified in the Radiation Protection (Non-Ionising Radiation) Regulations 1991.

### X-Ray Mammography Quality Control Programme

For mammography X-ray machines, we continue to provide quality assurance and control service to X-ray clinics taking part in the national mammography screening programme. Our chief radiographer attended a training course on the techniques of performing quality control tests using the latest test equipment. In 2003, we inspected and certified 22 clinics with mammography X-ray facilities. Minor non-compliances like field collimation, roller marks on films and dark room light leakage, were detected in 10 of these clinics.



### Personal Monitoring Service

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

Personal monitoring is in the form of thermoluminescent dosimeters (TLDs) worn on the trunk of the body. To monitor the radiation dose to the fingers for those workers handling radioactive materials which emit beta radiation or low energy gamma radiation, the dosimeters are in the form of rings, which are worn on the fingers.

In 2003, about 80,000 TLDs were issued and processed monthly to ensure that the doses received by the workers are within the dose limits specified in the Regulations. Dose reports were generated and sent to each company to show the doses received by the workers. The number of overdose cases investigated by CRP decreased to 18, from 40 cases in 2002. These overdose cases occurred mainly in industrial radiography.

### Wipe Tests For Sealed Sources

Wipe tests are conducted annually at establishments that use sealed radioactive sources in industrial, medical and research applications. The wipe samples are brought back to CRP's laboratory and tested for the presence of radioactivity using Sodium Iodide and Geiger Muller detectors. In 2003, we performed 387 of such wipe tests. None of these sealed radioactive sources were found to be leaking.

### Radioactivity Analysis

Sodium Iodide detectors with multi-channel analysers are used to conduct radioactivity analysis on food samples. In 2003, the number of food samples tested and certified free from radioactive contaminants was 1,578.

We also use very sensitive equipment designed specifically to detect low level radioactivity in environmental samples such as soil and water, and industrial samples such as ilmenite sands, copper and tin slags, steel bars, marble, granite, etc. Of the 14 samples analysed during the year, we detected six samples with elevated readings.

### 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-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 2003, our reference dosimeters calibrated a total of 366 radiation monitoring devices used by companies and hospitals in Singapore.



### Nuclear Safety And Emergency Planning

There are two remote radiation monitoring systems under our vigilance, Changi Naval Base and Sembawang Wharves. We can access the dose readings of all the detectors at any time via computer and phone lines. An alarm system has been programmed at CRP and at the monitoring stations if the dose rate exceeds a pre-set value. These stations provide 24-hour monitoring to give early warning in the event of a radiological accident during the visits of Nuclear Powered Warships (NPWs). In 2003, nine NPWs visited Singapore.

### Radiation Consultancy Services, Training And Education

We provide consultancy services on all aspects of ionising and non-ionising radiation protection to industries, ministries, statutory boards, hospitals and the general public. The service covers a wide spectrum from radioactive waste management system, radiation accident procedures and emergency planning, radiation shielding requirements, radiation exposure limits, choice and use of radiation instruments, radioactivity in building materials and industrial raw materials and extremely low frequency fields from transformer and High Tension switch rooms.

In 2003, we expanded on the number of training courses conducted on radiation safety. Two training courses on radiation safety were held for industrial radiographers, four training courses on radiation safety were held for those using ionising radiation for various other purposes and one course on laser safety was conducted.

These training courses aim to provide the workers with sufficient knowledge of the radiation hazards associated with their work and the awareness of appropriate protective measures so that the occurrence of radiation accidents will be minimised.

Lectures and training on radiation safety were provided for medical doctors, dentists, undergraduates and radiation workers in hospitals, universities and commercial companies. We conducted a total of 303 tests on knowledge of ionising radiation safety and 469 tests on knowledge of laser safety to ascertain the workers' competency prior to the issuing of licences.

### Regional Training Centre in Radiation Protection Under Singapore-IAEA MOU

Under the Singapore-IAEA MOU signed in March 2000, our CRP became a key regional player in radiation protection training. However, owing to the SARS outbreak, a number of regional training programmes was rescheduled or cancelled in 2003.

Two IAEA Fellows from Mauritius were attached to CRP from on a technical visit program on radiation protection in medical and industrial practices in February 2004.

### Expert Missions To IAEA

Our CRP's Centre Director was engaged by IAEA in December 2003 as an expert member of a 7-member consultant group to review its Radiation Protection Model Projects in East Asia and the Pacific Region. He was further engaged by IAEA in March 2004 with a group of international experts to evaluate the status of radiation safety programme in participating countries including those in African, European and East Asia Regions.

During the two expert missions, recommendations were made on how to accelerate the implementations of the five milestones under the Radiation Protection Model Projects. The recommendations will be tabled for approval by the IAEA Board of Governors in its coming meetings.

### International Professional Participation

During the year, some of the key international events we participated in were:

- **International Conference on Radiation Protection Infrastructure, Morocco, 1 to 5 September 2003**

This event is part of a series of conferences and activities aimed at facilitating the implementation of international standards for radiation safety and the security of radioactive sources. Various strategies for building and strengthening radiation safety infrastructure, including strategies for education and training in the safety and security of radiation sources were discussed and formulated.

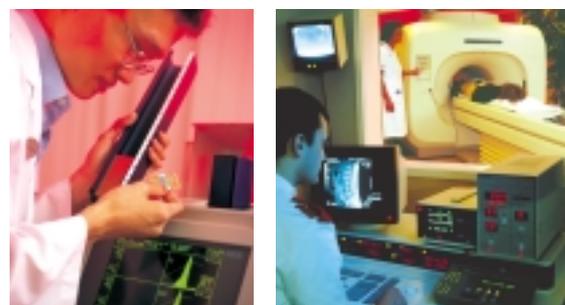
- **IAEA 47th General Conference, 15 To 19 September 2003**

The key issues discussed included the nuclear programmes of the Democratic People's Republic of Korea and Iran, implementation of measures against nuclear terrorism, and on the safe transport of nuclear materials.

### LOOKING AHEAD

Globally, there is an increasing need to ensure that regulatory bodies and emergency response organisations have resources in place for dealing with nuclear or radiological emergencies. We will be working with IAEA on the strengthening of our regulatory infrastructure and capabilities for emergency response. We will also look into the possibilities of organising training courses for exercises for first responders and officials.

In view of the broad spectrum of radiation applications using a wide variety of radiation sources, education and training will remain a priority in order to meet the diverse needs of users. We will continue to adopt the "train the trainers" concept in order to increase the number of skilled people and thereby promote infrastructure sustainability.





an investigative eye



CDA



CMDR



CRP



CTM



CFM



CFS



CAS

HSA is committed to serving the administration of justice in Singapore. We provide forensic pathological, scientific, investigative and analytical services and expertise in performing autopsies, conducting crime scene investigations to provide forensic analysis in the areas of controlled substances, toxicology, serology, DNA profiling and database, trace evidence, firearms, toolmarks, explosives, arson, fireworks, shoe-prints, tyre-prints and impressions, chemical analyses, physical examinations and questioned documents.



## PROVIDING FORENSIC PATHOLOGY AND INVESTIGATIVE SERVICES

Our **Centre for Forensic Medicine (CFM)** is the sole provider of services to examine Coroner's cases, and perform autopsies that are authorised by the Coroner. We also carry out autopsies requested by private clients, including hospitals and other countries in the region.

We also provide crime scene investigative services to the Singapore Police Force (SPF), in cases of homicides, or cases of suspicious deaths. These services help the SPF in their investigations by providing preliminary inputs, early leads and direction in which their investigations should take shape.

In addition, we support the Ministry of Health in autopsies required under the Infectious Diseases Act and authorised by the Director of Medical Services. We administer the ethical use of unclaimed bodies authorised by the Director of Medical Services under the Medical Therapy Education and Research Act in a transparent manner. Medical educators and researchers depend on these anatomical materials for further training as well as research, in order to extend the scope of medical knowledge and understanding, so that living patients might benefit in due course. In 2003, CFM participated in the fight against the Severe Acute Respiratory Syndrome (SARS) by carrying out autopsies on deaths suspected to have been caused by SARS.

We offer clinical forensic medical consultations, by transferring and applying our professional expertise gained in understanding trauma and injury in the dead, to the living cases on subjects of violence resulting from child abuse, sexual offences and spousal abuse. Further, as part of our one-stop service to next-of-kin, we act as an agent of the Registry of Births and Deaths, providing the death certification services for Coroner's cases.

During the year, we handled 3,507 Coroner's cases, and of these performed 1,885 autopsies. Our forensic death investigators attended to 124 cases.

### CFM Workload Statistics for FY 2003

No. of coroner's cases	3,507
No. of coroner's autopsies	1,885
No. of forensic death investigator's cases	124

### Ensuring Professional Focus

An internal review of the scope of work within CFM was carried out from June to October 2003. To sharpen the overall focus on core professional capabilities, work processes were simplified, streamlined and documented. CFM exited the embalming service industry with effect from 1 April 2003.

### Improved Facility And Capabilities

With the increased awareness arising from the SARS outbreak in 2003, a concerted effort was made to improve biosafety in the mortuary and reduce biosafety risk to the staff and the public who came to the facility.

In April 2003, major renovations were initiated in the Autopsy Suites and Body Handling and Storage Areas to upgrade the mortuary to handle potentially more infective cases than the routine Coroner's cases. We overhauled the ventilation systems and waste management systems as well as re-routed our work processes to enable reduction of biosafety risks. In addition, to improve physical security at the mortuary, a surveillance system is being installed in phases to monitor activities in and around the premises.



In the course of dealing with SARS' autopsies, an innovative idea of conducting autopsies within a self-contained mobile suite was conceived. This idea was further developed to enable the development of a containerised fully self-contained mobile autopsy suite to handle Biosafety Level 4 type of cases. The idea forms the core of a patent pending.

#### MOU With Victorian Institute Of Forensic Medicine Of Australia

We signed an MOU with Australia's Victorian's Institute of Forensic Medicine on 29 July 2003.

This MOU facilitates and enhances reciprocal exchanges of information and resources, development of professional competencies and scientific collaborations between the two agencies. It also promotes stronger mutual professional ties useful for crisis response. It seeks to facilitate the sharing of expertise and practices so that lessons of public safety can be learnt and shared, which in turn advances the common goal of enhancing safety in the community.

#### President's Certificate Of Commendation (For Overcoming SARS)

Our role in supporting the Ministry of Health in autopsies required under the Infectious Diseases Act was recognised when our Centre was awarded the President's Certificate of Commendation (for overcoming SARS). In addition, two officers from our Centre were awarded the National Day Commendation Medal (for overcoming SARS).

#### Improved Customer Care At Mortuary@HSA

To reduce biosafety risks and mental distress caused to the next-of-kin during the body identification process, viewing is now carried out with greater privacy.

In October 2003, we re-defined and segregated the death registration process, which was previously shared with the Singapore General Hospital's non-Coroner's cases. This enabled quicker handling of Coroner's cases and had further increased customer service efficiency. By the same effort, better physical security of bodies and shorter processing times were also achieved.

#### LOOKING AHEAD

The year ahead will see us strengthening our collaborations with our Australian counterpart, the Victorian Institute of Forensic Medicine under the MOU signed in 2003. This is a first step towards strengthening professional capability and gaining recognition for professional excellence in the field forensic medicine, both locally and abroad.





### PROVIDING FORENSIC SCIENTIFIC, INVESTIGATIVE AND ANALYTICAL SERVICES

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

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

Since 1996, CFS has been accredited by the American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB). We have 14 forensic scientists who are qualified ASCLD/LAB inspectors.

During the year, we examined a total of 100,116 exhibits yielding a total revenue of \$19.2 million.

#### CFS Workload Statistics For FY 2003

	Exhibits/ Cases Examined	Work Value (Man hours)	Revenue (SGD)
Criminalistics Lab	890	5,711	1,722,339
DNA Database Lab	32,506	12,290	4,868,021
DNA Profiling Lab	3,100	24,070	3,745,826
Document Examination Lab	385	3,950	1,023,727
Narcotics I	3,830	18,680	2,831,782
Narcotics II	43,070	17,529	2,118,237
Toxicology Lab	16,335	23,368	2,894,502
<b>TOTAL</b>	<b>100,116</b>	<b>105,598</b>	<b>19,204,434</b>

### Enhancing Forensic Capabilities

In FY 2003, we acquired the following new instruments to enhance our forensic capabilities and to keep pace with new and emerging technologies:

- one scanning electron microscope
- one liquid chromatograph/tandem mass spectrometer
- one liquid chromatograph/mass spectrometer
- three gas chromatograph/mass spectrometers
- one automated glass refractive index measurement system
- one advanced voltammetry system
- two stereo microscopes
- one fibre optic videoscope
- upgraded an existing gas chromatograph/mass spectrometer to tandem mass spectrometer

### Three Cold-Hits Achieved Within The First Year Of Operation

Our DNA Database Laboratory, launched in February 2003, completed more than 32,000 offender and crime scene profiles. Three cold-hits (i.e. an unsolved crime scene profile matches an offender not under investigation for the case) have been confirmed. These three cases involved a murder, a burglary cum sexual molesting and a vehicle break-in. This is a significant achievement and proves the investigative values of DNA database beyond any doubt.

### A Novel Application Of Electrostatic Detection Apparatus

In September 2003, our Documentary Examination Laboratory successfully applied a novel technique of using Electrostatic Detection Apparatus to lift fingerprints from documents of anonymous nature received by a Hong Kong investment company. Based on the fingerprints lifted, the company was able to identify the suspect.



### **New Forensic Applications Using Raman Microspectrophotometer**

Our Criminalistics Laboratory completed a validation of the Raman microspectrophotometer in May 2003. In June 2003, the new technique was successfully applied to caseworks involving the analyses of paints, polymers and explosives. In an investigation involving an explosion activated by an improvised explosive device, oxidising agents, potassium chlorate, potassium nitrate and barium nitrate were detected using the Raman microspectrophotometer.

### **New DNA Extraction Method**

A new DNA extraction method for crime stains using Qiagen columns was introduced into casework by our DNA Profiling Laboratory in August 2003. This method shortens the turnaround time significantly from six days to three days, especially in cases where the results are needed urgently by the enforcement agencies for intelligence purposes.

### **New Toxicology Services**

In FY 2003, our Toxicology Laboratory started two new services upon requests from our clients.

In April 2003, we provided screening service of drugs of abuse and cotinine (metabolite of nicotine) in urine samples of pre-clinical trial volunteers for two clinical trials & research units. The drugs of abuse screened include amphetamine, barbiturates, benzodiazepines, cannabinoids, cocaine, methadone, opiates and phencyclidine (PCP). A total of 462 urine samples was screened in FY 2003.

In December 2003, we started a service to screen for and to confirm, the presence of nimetazepam (a Class C controlled drug listed in the Misuse of Drugs Act) in urine samples from the Central Narcotics Bureau. A total of 523 urine samples was analysed in FY 2003.

### **Profiling Of Methamphetamine Abused In Singapore**

Our Narcotics I Laboratory completed a study in December 2003 on the profiling of methamphetamine ("ice") abused in Singapore. The study examined "ice" exhibits seized over a period of ten years to determine whether there were any changes in the origins or synthetic pathways of this illicitly-produced drug. The information is useful to the enforcement agencies in their investigations.

### **Service Contract On Urine Testing For Controlled Drugs**

In July 2003, we were awarded an open tender by Defence Science and Technology Agency to provide urine screening service to the Singapore Armed Forces (SAF) to screen urine of national servicemen for controlled drugs. This allows our Narcotics II Laboratory to provide a one-stop service for both screening and confirmatory tests for the SAF.

In August 2003, we introduced a cost effective and efficient urine screening test for ketamine abuse which enabled the Central Narcotics Bureau to conduct large scale operations to curb ketamine abuse.

### **LOOKING AHEAD**

In the coming year, we will continue to create and provide value-added forensic services surpassing our clients' requirements and expectations. We plan to:

- seek ASCLD/LAB accreditation for our DNA Database Laboratory
- set up a clandestine laboratory investigation capability
- improve our target turnaround time to 85%
- promote our forensic expertise and services to local, regional and international clients
- conduct a joint Fire Research with Singapore Civil Defence Force (SCDF)
- start casework using mitochondrial DNA and Y-chromosome profiling.



a critical eye



At HSA, we exploit science and technology to deliver essential services in blood banking and analytical investigations. We protect the national blood supply by applying the best of science, technology and quality management at every step, from blood collection to processing and distribution of blood and blood products to all hospitals in Singapore. We are also the largest single-site testing laboratory facility in Singapore and the national reference agency providing scientific, analytical and consulting services in the areas of food and drug safety, cosmetics, environmental and industrial health protection, and the testing of cigarettes and tariff items.



## 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 blood and blood products to all hospitals in Singapore, in both the public and private sectors.

In ensuring an adequate and safe national blood supply, we face the challenge of meeting Singapore's daily blood needs during peacetime as well as during national and civil emergencies. We maintain disaster preparedness at all times with contingency plans developed for disaster scenarios requiring large amounts of blood.

We work closely with Singapore Red Cross (SRC), the National Blood Donor Recruiter, to promote altruistic, voluntary, non-remunerated blood donation. Appropriate national awareness strategies and recognition programmes targeted at recruiting and retaining blood donors have been developed and implemented.

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 of blood transfusion services in the Western Pacific Region. During the year, we also received blood banking professionals and health officials from the region on study tours of Singapore's healthcare system and our blood banking quality system.

In FY 2003, we collected a total of 67,927 whole blood donations from 43,251 donors. These were processed into 162,306 blood components and which 128,033 units were used by the local hospitals. A total of 6,844 apheresis procedures was carried out.

We also performed 711,888 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 specialised immunohaematology tests performed for patients with red-cell-serological problems and tissue typing for patients undergoing organ or bone marrow transplantation.

## Protecting The National Blood Supply During SARS Outbreak

We had to act proactively during the Severe Acute Respiratory Syndrome (SARS) outbreak in 2003 to ensure blood safety.

Additional precautionary measures were implemented to minimise any risk of transfusion-transmitted SARS infection. This included deferring donors who were at risk of having been exposed to SARS, and deferring patients who had recovered from SARS. These measures were put in place before the recommendations by the US Food & Drug Administration and WHO, which later also recommended similar measures for blood programmes in other countries. During the course of the SARS outbreak, we regularly reviewed and updated the donor screening criteria to ensure that donors were not unnecessarily deterred from donating blood and that any potential risk of SARS transmission through blood transfusion was reduced to a minimum.



Another major impact of the SARS outbreak was its devastating effect on blood donor attendance at the Bloodbank@HSA and at mobile blood drives. The national blood collection dropped by more than 50% which led to the postponement of elective surgeries at hospitals. Together with our strategic partner, SRC, we stepped up recruitment efforts and media strategies to urge the public to continue donating blood and managed to collect adequate blood for emergency needs during the outbreak.

We also contributed to the national and worldwide battle against SARS. Our Apheresis teams were sent to Tan Tock Seng Hospital to collect plasma from convalescent SARS patients for treating severely ill SARS patients.

In the WHO Global Conference on SARS held on 17 and 18 July 2003 at Kuala Lumpur, Malaysia, our Centre Director presented a paper on the "Response of CTM (Singapore) to SARS and the Lessons Learnt".

Although the spectre of SARS has receded, our CTM continues to be prepared. Measures remain in place to ensure the continued safety and adequacy of the national blood supply should another outbreak come around.

### **2nd Regional Quality Management Training Course in Blood Transfusion Services**

For the second consecutive year, we hosted the 2nd WHO Quality Management Training (QMT) Course in Blood Transfusion Services from 11 to 30 August 2003. Our CTM specialist consultants conducted the QMT course together with the WHO experts.

Delegates from 15 countries in the region participated in the 17-day course which imparted the fundamentals of quality management in blood transfusion services so that they could implement quality system essentials in their respective countries.

### **Launch Of DonorCare@HSA**

In August 2003, we launched DonorCare@HSA, an online service for blood donors, as part of the services provided within the National Blood Donor Programme.

With DonorCare@HSA, existing blood donors would be able to book donation appointments at the Bloodbank@HSA 24 hours a day and at anytime from the comfort of their home or any place with Internet connection. Depending on donors' preferences, confirmations and reminders on appointments would be disseminated through short messaging service (SMS) or email.

Donors would also be able to update their personal particulars and check the latest blood donation information. These features were aimed at making blood donation as convenient as possible so as to enhance the blood donation experience for donors and to better serve them.

### **Quest for Accreditation by the American Association of Blood Banks**

In our continuing quest for excellence, our efforts towards accreditation by the American Association of Blood Banks (AABB), a world renowned body in blood banking, have made good progress in 2003.

In March 2003, visiting expert Dr Cees Th. Smit Sibinger under the Ministry of Health's Health Manpower Development Plan (HMDP) conducted a series of lectures which provided new direction on further fine-tuning of our blood banking quality standards in anticipation of the forthcoming AABB audit and accreditation.



### Expansion Of Apheresis Programme

The number of apheresis donations performed has increased from 6,150 in 2002 to 6,626 in 2003. The 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 2003. To further improve the efficiency and yields of the platelet collection procedure, we also evaluated new systems which shortened the donation procedure time and made platelet donation more convenient for the donor.

### Clinical Teaching And Staff Training

In keeping with our commitment to staff training and skills upgrading, several training programmes and upgrading initiatives were started.

Under the Ministry of Health's Health Manpower Development Plan, international expert speakers and local clinical experts were regularly invited to complement the regular teaching programme for all levels of staff.

Our donor aides were successfully trained to perform haemoglobin testing and phlebotomy during in-house skills upgrading courses. From end 2003, our donor aides were upgraded to perform all haemoglobin testing during mobile sessions.

We held a 1-day seminar and workshop on Blood Grouping on 27 February 2004 for in-house staff as well as various personnel from the healthcare sector in Singapore. We also conducted a talk for student nurses from the Institute of Technical Education in March 2004 to share with them the services and programmes of CTM.

We played an active role in continuing medical education in Singapore. In May 2003, we started a programme of 3-monthly training attachments for haematology registrars from the National Healthcare Group.

Other training plans in the pipeline include certification of CTM as an On-The-Job Training Centre (CoJTC), as well as development of training curricula in transfusion sciences for nurses in collaboration with the polytechnics.

### Strategic Partnership With Singapore Red Cross

Our ongoing strategic partnership with the SRC has continued to reap rich rewards. SRC's emphasis on volunteerism and its strength in community outreach has successfully enhanced the blood donor recruitment and retention programme.

Numerous novel donation campaigns conducted jointly with SRC during the year helped to boost blood collection numbers. A series of blood drives and activities was organised from February to June 2004 to commemorate the inaugural World Blood Donor Day.

### Supporting Singapore Medicine

With a good international reputation of high standard of safety in our blood supply, the Singapore Tourism Board sought our participation in its Singapore Medicine programme. From September 2003, we conducted tours and briefings of our blood banking facilities for healthcare professionals and media from those countries targeted in the Singapore Medicine programme.



### LOOKING AHEAD

The year ahead will be a pivotal year for CTM.

We target to complete the challenging task of streamlining and upgrading our operations to satisfy the high standards required for accreditation with the AABB and the American Society of Histocompatibility and Immunogenetics.

We plan to have a publication 'National Clinical Guidelines For The Use Of Blood Components' as a service to the medical community. Clinicians and laboratory technologists will find these guidelines invaluable during treatment of patients.

Exciting new technologies in blood banking await evaluation in the coming year. These include new methods of testing platelets for bacterial contamination, new pathogen inactivation technology, automated red cell testing systems for pre-transfusion testing and flow cytometers for Human Leucocyte Antigen antibody screening. Additional tests for Hepatitis B and malaria will be introduced to further improve blood supply safety.

We look forward to breaking new grounds in research and academia in FY2004. Plans include hosting the 1st Asia-Pacific Joint Symposium on Transfusion Medicines and Alternatives with the Network for Advancement of Transfusion Alternatives and the conduct of new studies on issues such as the impact of transfusion on iron stores of regular blood donors.

Donor services will be upgraded substantially in the coming months. Plans in the pipeline include implementing Phase 2 of the DonorCare system and providing a more conducive environment to enhance the blood donation experience for donors.



### PROVIDING SCIENTIFIC ANALYTICAL AND CONSULTING SERVICES

Our **Centre for Analytical Science (CAS)** is Singapore's leading government provider of analytical and scientific consulting services for health-related products.

We provide scientific, analytical and consultancy services to law enforcement agencies, government ministries, hospitals, private organisations and individuals.

Our six\* specialised laboratories in CAS provide scientific and analytical expertise using the state-of-the-art instrumentation in the areas of food, pharmaceutical, cosmetic, cigarette, industrial health and environmental analysis.

\* The CAS' Customs Laboratory was subsumed under the Centre's Food Laboratory on 1 April 2003.

In 1997, CAS was the first government laboratory to have been accredited by the Singapore Laboratory Accreditation Scheme - Singapore Accreditation Council (SINGLAS-SAC) 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.

Our CAS also joined the ranks of Singapore Quality Class organisations in July 2002 and set an industry benchmark in the journey for world class business excellence.

In July 2003, CAS received the 2003 Public Service Award for Organisational Excellence. At present, we hold two patents on the extraction methods of bioactive ingredients from herbal medical products.

### CAS Workload Statistics For FY 2003

	Exhibits/ Cases Completed	Revenue	Workvalue (hours)
Food Lab	5,640	\$4,162,000	28,191
Pharmaceutical Lab	2,332	\$2,732,000	15,049
Industrial Health Lab	1,958	\$738,000	2,859
Cosmetic Lab	304	\$312,000	1,546
Cigarette Testing Lab	522	\$355,000	1,537
Environment Lab	476	\$435,000	2,335
<b>TOTAL</b>	<b>11,232</b>	<b>\$8,734,000</b>	<b>51,517</b>

During the year under review, we carried out a total of 11, 232 tests, yielding a total revenue of \$8.73 million.

### New Analytical Science Capabilities

During the year, we developed and launched 26 new testing capabilities to cater to our clients' requirements and to keep pace with new and emerging demands.

In July 2003, we developed a new method to determine Sudan I colour in chilli products and chloramphenicol in shrimp products. Owing to the stringent import requirements of the European Union, chilli samples and other shrimp-based products from around the ASEAN region were sent to CAS for testings.

Our Pharmaceutical Laboratory successfully obtained accreditation by Singapore Accreditation Council – Singapore Laboratory Accreditation Scheme (SAC-Singlas) in October 2003 to screen 156 western drugs categorised into 28 different pharmacological effect grouping such as analgesic, androgenic steroids, erectogenic agents and others.



### International Pharmaceutical Federation

Our Pharmaceutical Laboratory participated in a multinational collaborative study organised by the International Pharmaceutical Federation in April 2003. In this study, the dosing reproducibility in the administration of amoxicillin / clavulanic acid suspensions was assessed.

### Collaboration 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 as well as provided advanced training to WHO scholars in the region. In July 2003, we provided a 1-month advanced training on advanced techniques in drug analysis for three WHO Fellows from Nepal.

The WHO Collaborating Centre for Drug Quality Assurance will be developing new monographs for the International Pharmacopoeia in areas relating to analytical procedures. It will also examine candidate reference materials for adoption as WHO standards.

The WHO Collaborating Centre for Food Contaminants Monitoring will continue to participate in the Joint United Nations Environment Programme/Food and Agriculture Organisation of the United Nations/WHO Contamination Monitoring to enable governments, the Codex Alimentarius Commission, other relevant institutions to monitor the levels and trends of contaminants in food.

### International Laboratory Forum On Counterfeit Medicines

In October 2003, our Centre Director was invited to participate in the International Laboratory Forum on Counterfeit Medicines (ILFCM). Singapore was the only non-European country to be invited.

The main objective of ILFCM was to share information on scientific techniques used to detect counterfeit drugs and harmful substances in dietary supplements. Information was also shared on possible sources of counterfeit, law enforcement actions and collaboration on development of new methodologies and analysis of sample.

### ASEAN Reference Substances

Our Pharmaceutical Laboratory continued to participate in the WHO programme for producing ASEAN Reference Substances for use in the region. During the year, we completed three tests from two participating countries, Philippines and Thailand in our collaborative programme.

### 11th Asian Collaborative Study On ISO Tar And Nicotine

We participated in the 11th Asian Collaborative Study on the ISO of Tar and Nicotine involving 42 laboratories from 18 countries in the Asia-Pacific region and Europe. Five different brands of cigarette samples with tar levels, ranging from 1mg to 15mg were tested. The study report received in July 2003 indicated that our performance compared favourably with the best laboratories present at the study.

### APLAC Proficiency Testing Programme

We were invited in August 2003 to participate in the Asia Pacific Laboratory Accreditation Cooperation proficiency testing programme organised by Hong Kong Laboratory Accreditation Service on the Analysis of Chlorpheniramine Maleate and Pseudoephedrine Hydrochloride Oral Solution.



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### WHO Temporary Advisor

In November 2003, a senior analytical scientist from our Pharmaceutical Laboratory was appointed as a WHO Temporary Advisor to the WHO Consultation Meeting on "Specifications for Medicines and Quality Control Laboratory Issues" held in Geneva.

### Inter-laboratory Comparison Study

In March 2004, we participated in the inter-laboratory comparison study on various studies on drug related physical measurement activities, within the Official Laboratories and Medicines Control Services, part of a multinational co-operation committee.

### Care for the Environment

We take an integrated approach to protect our community and environment. Stringent protocols are in place to ensure that solvents and acids used for experiments do not pollute the environment. An audit by the CAS safety committee, conducted between November 2003 to April 2004, on the level of organic solvent vapour in CAS' laboratories showed that these levels were within the safety limits.

### LOOKING AHEAD

CAS is committed to developing new capability and keeping abreast of new developments in order to exceed the needs of our clients. In the coming year, we will continue to support the regulatory activities by increasing our capability and expansion of analytical scope.

Our Pharmaceutical Laboratory will continue to assist the local and overseas laboratories in attaining accreditation for screening of common adulterants (western drugs) in Chinese proprietary medicines (CPM). This is part of our effort in ensuring sufficient accredited laboratories are available 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 Food Laboratory plans to develop its capability on migration studies on potentially harmful plasticisers and additives from food contact materials into the food. The area of cyanobacteria toxins has been largely under-developed locally and there are plans to develop these methods because of growing concerns of these toxins entering into the food chain.

Our Industrial Health Laboratory will work on a new method to analyse nickel in urine samples and mercury in blood. This is part of the national efforts, together with Occupational Health Department, Ministry of Manpower, to monitor occupational health levels in Singapore.

Our Cosmetic Laboratory will be expanding its testing capability by carrying out development work on androgens, oestrogens and progestogens suspected to be used in cosmetic products. There are creams containing high phyto-oestrogens, which may interface with the analysis, and development work will need to be carried out to rule out false positive results.

Our Cigarette Testing Laboratory will explore the testing of other cigarette smoke constituents, such as carbon monoxide, benzene, formaldehyde and hydrogen cyanide, in order to enhance its testing capability and provide better service to our regulatory arm in the Centre for Drug Administration.

Our Environmental Laboratory will develop a method for testing ammonia in water using other reagents such as hypochlorite, phenol and sodium nitropruside. This will do away with using mercury salt that is currently being phased out.





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At HSA, we believe that a cohesive, professional and innovative workforce is an integral factor in the making of an excellent organisation. In our pursuit of organisational excellence, we recognise and value our people as our greatest asset and take a proactive approach to invest in their personal development and to equip them to more than meet the expectations of our stakeholders and to take on future challenges with confidence. Having attained the People Developer Standards in 2002, we will focus on our next challenge and target of achieving the People Excellence Award by 2006.



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At HSA, we embrace the Singapore Quality Award as our organisational excellence development framework. While we focus on developing our officers and spurring them on to achieve greater heights, much of our efforts also concentrate on creating the right culture, setting the right conditions, providing an optimum environment and putting in place firm organisational structural building blocks to gear us towards developing an excellent HSA.

In July 2003, HSA was endorsed as a Singapore Innovation Class organisation by SPRING Singapore; one of the first in the public healthcare services and regulation sector. This award recognises HSA's contribution towards organisational excellence through outstanding innovation capability development and implementation of innovative solutions. It also reaffirms our commitment towards the various strategic initiatives undertaken to develop and nurture our people, to pursue innovation excellence, to strengthen strategic alliances, to create value for our customers, to exploit information technology and to fulfil our corporate citizenship role in contributing to the society and caring for the environment.



### Developing And Nurturing Our People

Our priority is to develop each staff to his or her fullest potential.

A host of initiatives was mapped out to build a shared vision with staff at all levels to enhance their individual potential while fostering unity among staff and creating a positive work culture and satisfied workforce.

As we seek to maximise staff potential through empowerment, sharing and continuous learning, we target for each of our total 578\* staff to commit to at least 100 hours of training per year. In FY 2003 our staff attended, on average, 120 hours of training each.

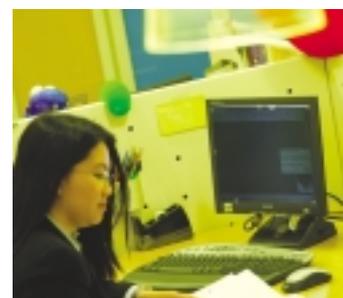
\* staff strength as at 31 March 2004.

Under the Ministry of Health's Health Manpower Development Plan (HMDP), opportunities are provided for our officers to be sent for overseas training and attachments. During the year, five officers from HSA were sent for training and attachments to USA, UK, Canada, Hong Kong and Japan.

In line with the mission of Human Capital development, we introduced the Professional Development Programme (PDP) in August 2002. The objective of PDP is to encourage and provide employees with the opportunity for distance learning to upgrade their knowledge and competencies. Upon attainment of the relevant qualifications, our officers would be deployed to the respective schemes of service. By so doing, the programme allows for a wider range of potential career development and advancement for our talents. This programme is a funding scheme that complements the HMDP. Currently, nine officers are undergoing the PDP scheme.

During the year, 87 officers were promoted in recognition of their excellent performance. Long Service Awards were bestowed to 75 staff.

Fourteen HSA officers received the National Day Awards. Two officers received the Public Administration Medal (Silver) and one officer was awarded the Public Administration Medal (Bronze). Two officers received the Commendation Medal (for overcoming SARS). In addition to eight Long Service Award recipients, we received a Commendation Medal and an Efficiency Medal. To make HSA a great place to work in and workout, an integrated workplace health promotion programme was introduced in September 2003.



Organisational policies were refined to create a supportive environment for our staff to lead balanced and healthy lifestyles. This included a Flexible Benefits Scheme which allows greater flexibility and presents more choices for our staff to participate in recreational and enrichment activities. In addition, activities like Family Day, recreational outings, sports activities, competitions, talks and workshops were held regularly to strengthen staff bonding and the importance of healthy living.

As part of our effort to build a people-focused organisation and create the desired working environment for HSAians, we commissioned the Organisational Capability Survey (OCS) in October 2003. A total of 520 staff, accounting for 92.5% of the HSA family, took part in the survey. The results of the OCS are used by senior management to review past initiatives and map out our progress to enhance employer-employee relations and operational processes. A 2-day senior management retreat was held in November 2003 to address key issues and develop action plans based on findings from the OCS.

In March 2004, we signed our 1st Collective Agreement with the Amalgamated Union of Statutory Board Employees, further strengthening existing ties and establishing a common platform to address staff's welfare issues and concerns.

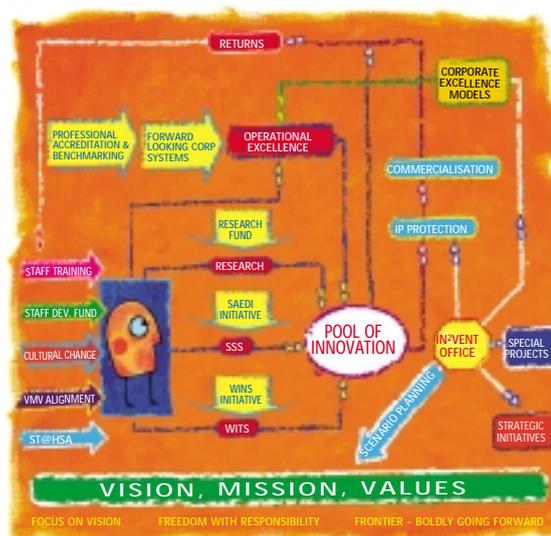
To attract young talents to join the HSA family, we offer scholarships annually to 'A' level high achievers. During the year, two undergraduate scholarships with a value of \$72,000 each were awarded for the pursuit of a Science Bachelor degree and a Pharmacology degree at the National University of Singapore. In the coming year, we will be working with Nanyang Polytechnic to offer diploma scholarships to attract their graduates to join our nursing professionals.

### Pursuing Innovation Excellence

Cultivating an innovative culture within our organisation is one of our key drivers of organisational excellence.

We aim to be an innovative organisation, robust and capable of reinventing our systems, processes and core competencies continuously.

We have developed a working strategy to foster a culture of vibrant innovation and enterprise at HSA. 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*.



HSA Innovation Framework



Our efforts in research and development, based on these guiding principles in our innovation framework, focused on projects that served to enhance the delivery of our mission. A total of 39 papers was presented in international, regional and local professional conferences, 9 papers were published in key professional journals and 14 research projects were completed during the year.

In April 2003, we collaborated with the National University of Singapore (NUS) to organise the 1st HSA-NUS Joint Scientific Seminar. A total of 24 papers and 13 poster presentations was presented based on the seminar theme "Collaborative Research in Health Sciences".

We jumpstarted with a series of FISH! camps in 2002 to ignite and energise our employees to be creatively engaged in the workplace. During the year, activity highlights included a Lantern Making Contest in August 2003 with a FISH! theme for staff to incorporate the Guiding Principles of Innovation and a fun and creative "Shoot Me, I Am Innovative!" photo contest in November 2003. HSAians from various centres and departments struck their poses and gave their best shots to depict the FISH! Philosophy. A total of 12 winning images was picked to be featured in HSA 2004 corporate diary.

#### FISH! Philosophy

The key to achieving HSA's vision to be world-class for scientific and regulatory expertise in Health Sciences lies in our human capital. We use the FISH! Philosophy to create an environment that attract and retain competent and motivated staff, to foster collaboration and sharing; and to develop a vibrant innovative culture in HSA.

The Fish! Philosophy is a tool to create an innovative and accountable work environment where a playful, attentive, and engaging attitude leads to more energy, enthusiasm, productivity, and creativity within HSA. The FISH! Philosophy focuses on 4 concepts:

- **Play:** It's about having fun, enjoying yourself, being spontaneous and creative, Figure out ways to have more fun and to install more energy in the workplace.
- **Make Their Day:** It's about involving customers/clients in on the energy and fun; creating unusual perks and incentives for customers and employees.
- **Be Present:** It's about being totally focused on the moment and on the person or task with which you are engaged. When we are fully present with our customers and with each other, we listen deeply and important opportunities do not escape us.
- **Choose Your Attitude:** It's about accepting full responsibility for all our choices, even our attitude at work. A positive attitude is a decision we make, moment to moment.

#### FISH! STICKS

As a continuous effort to keep HSA's vision alive and sustain the momentum that was built up from the Fish! camps and activities organised, Fish! Sticks was recommended as a follow-up to the Fish! camp that were conducted organisation-wide last year.

- **Commit:** Being willing to commit to a larger vision and allowing one to participate in creating the workplace of one's dreams.
- **Be It:** All who work at the fish market accept responsibility for recreating and renewing the market and its vision by the way they are being at the market. Every moment is an opportunity to be your organisation's vision and be one's vision for self.
- **Coach It:** The fishmongers all accept the responsibility to coach each other when they see something that is inconsistent with their mutual commitment to the vision. Effective coaching is never done in the spirit of making others feel wrong, but instead has the best interest of the person being coached and their work towards the vision at heart.

During the year, 130 new officers also attended the FISH! workshops to experience the FISH! principles in action. For the coming year, we will be launching FISH! STICKS, the next series of the FISH! Philosophy. To continue cultivating and sustaining the FISH! culture in our organisation, we will hold more innovative and creative workshops for our staff.

Our employees are encouraged to take part in the Work Innovation team (WIN) projects. In 2003, two WIN projects in our organisation were selected to present at the National Quality Circles Convention. The two teams received one silver award and one bronze award respectively. A total of 48 WIN projects was completed within the year.

At the MOH PS21 EXCEL Awards 2003, we were awarded First Prize in both the Distinguished Training Effort (Department) Award and Distinguished Work Improvement Teams (WITs) Effort (Department) Award for our training and work improvement efforts in 2002. We also won the MOH Outstanding Distinguished WITs Effort (Team) Award 2003 and MOH Outstanding WITs Facilitator Award 2003.



We continued to tap on our staff's creativity via the Staff Suggestion Scheme to refine our work systems, processes and environment. A total of 2,244 staff suggestions was received and out of these, 455 suggestions were implemented.

The annual IDEAS Forum with the theme "IDEAS@Work That Work" was held in November 2003 to encourage and inspire HSAians to be creative in their work. Various awards such as Best Work Innovation Projects, Best Work Innovation Projects, Best Staff Suggestions and NEMO (Nurturing, Enterprising, Mastery and Organisation@Heart) were given to staff in recognition of their commendable efforts in work improvements, ideas and for their role modelling of HSA core values.

### Strengthening Strategic Alliances

In our continuous effort to forge strategic alliances and to leverage on the strengths of our partners, we signed Memoranda of Understanding (MOUs) with the Australia's Victorian Institute of Forensic Medicine in July 2003 and the People's Republic of China's State Food and Drug in September 2003. These MOUs facilitate and enhance reciprocal exchanges of information and resources, development of professional competencies and scientific collaborations between our agencies.

### Delivering Value To Our Customers

Quality service is another key focus in our drive for excellence and is exemplified in one of our core values - we create value for our clients.

As we come to grips with an increasingly informed public in a knowledge-based economy, we must be a forward-looking service provider, always striving to exceed expectations of our stakeholders by consistently providing value-added services.

We seek to deliver quality service and promote an organisational culture that embodies such a standard. During the year, our Quality Service Committee continued to promote quality service through these efforts:

- HSA Quality Service Bulletin - a quarterly e-newsletter where customer feedback is collected and disseminated to our staff to reflect our service quality. The compiled feedback serves as a platform to review our service level and work procedures as well as to take preventive actions on issues which may create customer's dissatisfaction.
- Transparency of all feedback information; all feedback received are posted on our intranet to act as a reference of our customer service standards to all our staff.
- The celebration of quality service acts - awards such as the Outstanding Service to Customers Awards and the Outstanding Quality Improvement Award are given to deserving officers who have gone the extra mile for their customers.

#### 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 consultation with our stakeholders and customers to continuously develop and improve our services.

##### We will

Replay to customers' enquiries within 7 days.  
Replay 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.



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As part of our efforts to continuously explore ideas to enhance the efficiency of our operations and improve our service delivery to our clients, we also put in place a number of customer-focused solutions via exploiting information technology.

In July 2002, we began our implementation of a 3-year Information Technology (IT) Master Plan which serves as a computerisation blueprint to help us achieve our mission and the public service vision of "A Networked Government Connected With Our People".

Plans were rolled out for an infrastructural upgrade and the following five application systems were identified in the IT Master Plan:

- Pharmaceutical Regulation and Information System (prism@hsa)
- System for Transfusion Medicine Analysis and Management (stream)
- Medical Device Licensing and Control System (medics@hsa)
- Contact Lens Licensing System (collins)
- Donor Care Management System (DonorCare@HSA)

The upgrading of our IT infrastructure was successfully completed in November 2003. A later addition of an enterprise backup system, using the Storage Area Network infrastructure, was also incorporated into our system to support and consolidate the various servers into a centralised backup storage.

We also rolled out the final module on Performance Ranking and Promotion in our Human Resource information systems in November 2003. This Enterprise Resource Planning System was implemented to support our human resource and finance system processes.

With the successful development of a one-stop centre hosting platform for the HSA portal, we will be able to provide businesses and individuals a complete suite of e-services and applications.

Phase one of prism@hsa, an integrated online licensing system was implemented for cosmetic products in March 2003. About 400 online applications were received monthly, resulting in a significant reduction of submissions received over the counter by more than 70%. An internal pilot run for the other product categories (drugs, CPM and tobacco) was also launched during the year.

We started phase two of the prism@hsa, which involved the Integrated Search and Retrieval System to support our evaluation of the product and license application. A Quality Enforcement and Surveillance System to support quality surveillance programme as well as implementation of enforcement activities is expected to roll out with the completion of phase two.

During the year, we also implemented the second phase of medics@hsa, online licensing system for medical devices. The licensing system for contact lens practitioners, collins@hsa, is in the testing phase of the implementation cycle and should be operational by first quarter of 2004.

In August 2003, we launched DonorCare@HSA, an online service for blood donors which enables them to book donation appointments at the Bloodbank@HSA 24 hours a day and at anytime from the comfort of their home or any place with Internet connection. All phases of the DonorCare@HSA were successfully rolled out in the year.

For the coming year, we will focus on the detailed implementation of stream, a system which will assist us in the planning, administration and management of blood bank operations and new blood transfusion programmes. We will continue to harness IT to streamline our systems, workflow and processes to achieve greater operational efficiency and enhance our service delivery and connectivity with our stakeholders.



### Fulfilling Our Role As Corporate Citizen

We also strongly believe in contributing to the community and caring for the environment.

In August 2003, we formalised our commitment with a Societal and Environmental Policy Statement - HSA is committed to CARE for the community and the environment.

The Statement 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 initiatives were undertaken to promote our corporate social responsibility. These include raising funds for the Red Cross International Bazaar and sales of the HSA postcards to raise funds for the Singapore Children's Society. A total of \$2,114 was raised from the proceeds of the postcards.

Additionally, registration fees collected for the HSA 2nd Dinner and Dance in April 2003 were matched dollar-for-dollar. A total of \$20,000 was raised for the Community Chest.

In November 2003, we participated in the 2003 Faraday Lecture for students at the Singapore Science Centre as part of our community outreach programme. Our forensic scientists shared their experience in "Fighting Crime with Sciences" with 200 secondary school students.

### LOOKING AHEAD

To achieve our vision of being world class for regulatory and scientific expertise, we strive to be a best practice, dynamic organisation, focused on value innovation through our people and by embracing new learning opportunities.

As we face many challenges of today's knowledge-based economy, we remain committed to fostering a culture of learning, sharing, excellence and innovation to develop HSA into an excellent organisation that is customer focused and people oriented.



## Eye On Research

### research papers & projects

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## EYE ON RESEARCH

### RESEARCH PAPERS & PROJECTS

#### A. Regulating pharmaceuticals and healthcare products

title of reseach presentation	author(s)	professional event
Establishing The Right Chemistry Between The GMP (Good Manufacturing Practice) Auditor And The Pharmaceutical Manufacturer	Dr Lai Weng Fai, Sia Chong Hock, Boon Meow Hoe, Ng Liong Thiam, Toh Lay Mui, Terrence Ong, Vimal Sachdeva, Karen Teo, & Lim Na	HSA-NUS Joint Scientific Seminar, 9 April 2003
A Review Of Clinical Trials Conducted In Singapore	Dr Kerwin Low, Clarence Khoo, Marie Tham, Lee Hui Keng, Foo Yang Tong & Dorothy Toh	HSA-NUS Joint Scientific Seminar, 9 April 2003
The Risk Of Rhabdomyolysis With Statins	Chan Cheng Leng & Tan Bee Him	HSA-NUS Joint Scientific Seminar, 9 April 2003
Analysis Of ADR Reports For Year 2002	Chan Cheng Leng & Ang Pei San	HSA-NUS Joint Scientific Seminar, 9 April 2003
Impact Of ADR Reporting On Patient Safety: A 10-Year Experience	Chan Cheng Leng	Pharmaceutical Society of Singapore, Pharmacy Congress Singapore, 22 November 2004
Analysis Of ADR Reports For 2002 – The Singapore Experience	Chan Cheng Leng	WHO Programme for International Drug monitoring – National Centre Meeting, 8 – 10 December 2003

title of research project	author(s)
Decision Tree For Classification Of Health Products By The Health Supplements Unit	Christina Chay & Lim Lee San (Food Control Division, Agri-Food Veterinary Authority)
Research Into Approval Of New Chemical Entities In Singapore Compared To Other Countries	Pearle Liew
Survey On Doctors' Perception Of Product Information Inserts	Chan Cheng Leng & Dr Ting Kang Nee
Development Of Pharmaceutical Indicators	Lee Wei Yann & Eileen Lim

## B. Providing forensic pathological and investigative services

title of reseach presentation	author(s)	professional event
Death May Have Its Benefits: The Role Of Forensic Pathology In Medical Audit	Dr Gilbert Lau	International Conference On Risk Management For Prevention Medicine, Tokyo, 28 March 2003
Clinical Age Estimation Of Young Living Malaysian Subjects Compared With Young Indian Subjects By Radiological Epiphyseal And 3 <sup>rd</sup> Molar Changes	Dr George Paul	HSA-NUS Joint Scientific Seminar, 9 April 2003
Why Mothers Die	Dr Gilbert Lau	HSA-NUS Joint Scientific Seminar, 9 April 2003
Pathobiology Of SARS – Questions Looking For Answers	Dr Paul Chui	WHO Conference on SARS Research, Singapore, 19 June 2003
Did He Drown Or Was He Murdered?	Dr Gilbert Lau	3 <sup>rd</sup> European Academy of Forensic Science Triennial Meeting, Istanbul, Turkey, 26 September 2003
Sudden Death From An Intracranial Germinoma Complicated By Microvascular Disease Of The Heart	Dr Gilbert Lau	3 <sup>rd</sup> European Academy of Forensic Science Triennial Meeting, Istanbul, Turkey, 26 September 2003
Fatal Retroperitoneal Haemorrhage: An Unusual Complication Of Percutaneous Endoscopic Gastronomy	Dr Gilbert Lau	3 <sup>rd</sup> European Academy of Forensic Science Triennial Meeting, Istanbul, Turkey, 26 September 2003
Dead Men Do Tell Tales: A Story Of Unmanageable Trauma	Dr Gilbert Lau	2 <sup>nd</sup> NHG Annual Scientific Congress, Singapore, 5 October 2003
Slim 10 – Slim Chance. A Fatal Case Of Hepatic Failure Possible Induced By Nitrosfenfluramine	Dr Gilbert Lau	41 <sup>st</sup> International Meeting of the International Association of Forensic Toxicologists (TIAFT) Melbourne, Australia, 19 November 2003
New Teaching Methods In Forensic Medicine	Dr George Paul	XXV Conference of Indian Academy of Forensic Medicine, Silver Jubilee Forensic Medicine 2004, Bambolim, Goa, 7 – 9 February 2004

## B. Providing forensic pathological and investigative services

title of research paper	author(s)	professional publications
Lung Pathology Of Severe Acute Respiratory Syndrome (SARS): A Study Of 8 Autopsy Cases From Singapore	Dr Paul Chui	Human Pathology. 34(8): 743 – 8, August 2003
Falls From Heights	Dr Gilbert Lau	Forensic Medicine: Clinical & Pathological Aspects. London: Greenwich Medical Media, 2003
Female Trauma Patients In The Emergency Department: Should Their Injury Prevention Programme Be Different?	Dr Gilbert Lau	Hong Kong Journal of Emergency Medicine. 10:13 – 18, 2003
Fatal Pulmonary Thromboembolism In Singapore: Has Anything Changed?	Drs Gilbert Lau & Lai Siang Hui	Medicine, Science & Law. 43:307 – 314, 2003
A Case Of Sudden Death From Primary Intracranial Germinoma Complicated By Microvascular Disease Of The Heart	Dr Gilbert Lau	Forensic Science International. 137:1 – 5, 2003
Role Of Alcohol And Drugs In Safety	Dr George Paul	Safety Promotion and Injury Prevention, University of Malaya Press, 371 – 402, 2003
Hand, Foot and Mouth Disease In Singapore: A Comparison Of Fatal And Non-Fatal Cases	Dr Lai Siang Hui	Acta Paediatrica; 92(10):1163 – 1169 October 2003
Analysis Of Deaths During The Severe Acute Respiratory Syndrome (SARS) Epidemic In Singapore: Challenges In Determining A SARS Diagnosis	Dr Paul Chui	Archives of Pathology Laboratory;128(2): 195 – 204, February 2004

title of research project	author(s)
A Comparative Study On The Necropsy Incidence And Characteristics Of Deaths From Pulmonary Thromboembolism Between The Periods 1989-1993 And 1994-1998	Dr Gilbert Lau
A 10-Year Review Of Homicidal And Dyadic Falls From Heights In Singapore, During The Period Of 1991-2000	Dr Gilbert Lau

## C. Providing forensic scientific, investigative and analytical services

title of reseach presentation	author(s)	professional event
Abuse Of Amphetamine-Type Stimulants In Singapore	Dr Lee Tong Kooi, Mary Lim May May & Ng Kim Hui	3 <sup>rd</sup> European Academy of Forensic Science Meeting, Istanbul, Turkey, 22 – 27 September 2003
Quantitative Analysis Of Ketamine In Drug Seizures By Capillary Electrophoresis	Wong Yen Ling, Tan Siok Gim, Tan Ying Ying, Drs Lee Tong Kooi & Chen Shao Xing	3 <sup>rd</sup> European Academy of Forensic Science Meeting, Istanbul, Turkey, 22 – 27 September 2003
Analysis Of Methamphetamine In Drug Seizures By Capillary Electrophoresis	Dr Lee Tong Kooi, Nancy Phua Chiu Guay & Wong Yen Ling	3 <sup>rd</sup> European Academy of Forensic Science Meeting, Istanbul, Turkey, 22 – 27 September 2003
Analysis Of Ketamine And Norketamine In Urine Of Ketamine Abusers	Moy Hooi Yan, Drs Lee Tong Kooi & Lui Chi Pang	3 <sup>rd</sup> European Academy of Forensic Science Meeting, Istanbul, Turkey, 22 – 27 September 2003
Evaluation Of An ELISA Test Kit In The Screening Of Ketamine In Urine	Tan Moy Eng, Moy Hooi Yan, Drs Lui Chi Pang & Lee Tong Kooi	3 <sup>rd</sup> European Academy of Forensic Science Meeting, Istanbul, Turkey, 22 – 27 September 2003
The Occurrence Of Illicit Viagra In Singapore And The Detection Of Sildenafil In Routine Drug Screening	Leong Hsiao Tung, Drs Yao Yi Ju & Danny Lo Siaw Teck	3 <sup>rd</sup> European Academy of Forensic Science Meeting, Istanbul, Turkey, 22 – 27 September 2003
Detection Of Contaminants In Bunker Oil And Waste Oil Samples	Chia Poh Ling, Drs Angeline Yap Tiong Whei & Michael Tay Ming Kiong	3 <sup>rd</sup> European Academy of Forensic Science Meeting, Istanbul, Turkey, 22 – 27 September 2003
Background Interference From Clothing And The Effects Of Washing	Chia Poh Ling, Lim Chin Chin, Jonathan Chong, Drs Angeline Yap Tiong Whei & Michael Tay Ming Kiong	3 <sup>rd</sup> European Academy of Forensic Science Conference, Istanbul, Turkey, 22 – 27 September 2003
Forensic Investigation Of An Underground Gas Main Explosion	Lim Chin Chin, Chia Poh Ling & Dr Michael Tay Ming Kiong	American Academy of Forensic Science 56 <sup>th</sup> Annual Meeting, Dallas, USA, 16 – 21 February 2004
The Next Big Challenge For Quality Forensic Service	Lim Chin Chin & Dr Michael Tay Ming Kiong	American Academy of Forensic Science 56 <sup>th</sup> Annual Meeting, Dallas, USA, 16 – 21 February 2004
Forensic Application Of Analytical Instruments	Dr Michael Tay Ming Kiong	Naresuan University of Phitsanulok, Thailand, Faculty of Medical Science, 19 March 04
Profiling Of Methamphetamine Abused In Singapore	Tan Ying Ying, Deborah Liew, Ng Kim Hui, Wong Yen Ling & Dr Lee Tong Kooi	17 <sup>th</sup> International Symposium on the Forensic Sciences, Wellington, New Zealand, 28 March – 2 April 2004
A Study Of "Erimin 5" Tablets Seized In Singapore	Wendy Lim Jong Lee, Mangudi Merula, Thiru Selvi d/o Selvarajah & Dr Lee Tong Kooi	17 <sup>th</sup> International Symposium on the Forensic Sciences, Wellington, New Zealand, 28 March – 2 April 2004

## D. Providing essential bloodbanking services

title of research presentation	author(s)	professional event
Study On Donors Deferral Due To nvCJD	Drs Diana Teo, Tan Hwee Huang, Syed Shu-aid, Lawrence Kong	HSA – NUS Scientific Seminar, 9 April 2003
Blood Donor's Arrival Time Preference	Noorhayati Rahmat, Chong Tye Ling, Rohaidah Ramli	HSA – NUS Scientific Seminar, 9 April 2003
Highly Sensitised Patients	Dr Diana Teo	8 <sup>th</sup> Congress of the Asian Society of Transplantation, Kuala Lumpur 21 – 22 September 2003
MAIPA [Monoclonal Antibody Immobilization of Platelet Analysis] Testing On Platelets In Singapore	Sng Moi Moi, Toh Ching Lian, Foo Ken Juat, Seah Lee Yok, Amarjit Kuar & Dr Tan Swee Looi	Asia Pacific Conference of International Society of Blood Transfusion, New Delhi, 15 – 18 November 2003
Quality Control In Transfusion Medicine	Dr Diana Teo	5 <sup>th</sup> Asian Network for Clinical Lab Standardisation and Harmonisation Colloquium, 18 – 19 December 2003

title of research project	author(s)
Study On Donor Adverse Reactions In Apheresis	Drs Shawn Mah, Lawrence Kiong, Tan Hwee Huang & Ong Kiat Ho
MAIPA [Monoclonal Antibody Immobilization Of Platelet Analysis] Study	Drs Seema Lale, Lai Hock Choong, Mickey Koh & Diana Teo
Evaluation Study In A Commercial Malaria PCR Test Kit For Future Application On Blood Donor Screening	Sally Lam, Lim Gek Yee & Toh Chiew Yong

## E. Providing scientific analytical and consulting services

title of reseach presentation	author(s)	professional event
Development Of A Platform Using Liquid Chromatography/Mass Spectrometry (LC/MS) For Protein Based Drugs And Biomedical Applications	Ong Eng Shi	HSA-NUS Joint Scientific Seminar, 9 April 2003
Meeting The Challenges In Validation And Standardisation-Characterization Of Herbal Medicine	Ong Eng Shi	Nutraceutical, Complementary Medicines Wellness Asia 2003 Summit, Kuala Lumpur (Malaysia), 4 August 2003
Detection Of Acrylamide In Cooked Starch-enriched Food By HPLC Tandem MS – The Singapore Finding	Chan Sheot Harn Joanne, Lee Lin Min, Yap Wee Kim & Matthew Grigg	16 <sup>th</sup> International Mass Spectrometry Conference, Edinburgh (UK), 31 August – 5 September 2003
Study On Styrene Monomer Migration From Food Packaging Material Into Food	Chan Sheot Harn Joanne, Yap Wee Kim, Lee Lin Min, Ang Lay Kheng, Peh Hui Zhu & Dr Loke Swee Leng	Singapore International Chemical Conference, Singapore, 15 – 17 December 2003
Instruments And Techniques For Analysis Of Environmental Samples – Gases, Vapour And Aerosols	Cheah Nuan Ping & Dr Chow Yue Thong	NUS-MOM Joint Seminar on Environmental and Biological Monitoring and Analysis, Singapore, 30 March 2004

title of reseach paper	author(s)	professional publication
Evaluation Of Surfactant Assisted Pressurized Hot Water Extraction For Marker Compounds In <i>Radix Codonopsis Pilosula</i> Using Liquid Chromatography And Liquid Chromatography/ Electro spray Ionization Mass Spectrometry	Ong Eng Shi & Len Shea Mei	Journal of Separation Science, 26,1533 – 1540, May 2003

title of research project	author(s)
To Develop And Validate The Method For Determination Of Iodine In Food Products	Dr Bosco Chen Bloodworth, Joanne Chan, Cheah Nuan Ping & Lucilla Teo
Developing Analytical Procedures For Identification Of Ethylene Dichloride In Cosmetic By Solid Phase Micro-extraction (SPME) & Gas Chromatography (GC)	Wong-Neo Geok Eng, Ong Eng Shi & See Phek Hah
Identification And Determination Of Prohibited And Restricted Dyes In Hair Dye Products	Wong-Neo Geok Eng, See Phek Hah & Tang Kwai Fong
Determination Of Glucuronolactone In Tonic Drinks By HPLC	Mohamed Sah Redha, Joanne Chan, Lim Thye Hin, Yap Wee Kim & Lee Lin Min
Determination Of Protein-bound Nitrofurantoin Antibiotics In Food Using HPLC-Tandem Mass Spectrometry	Joanne Chan, Mohamed Sah Redha, Lee Lin Min, Yap Wee Kim & Ang Lay Kheng
Rapid Quantitation Of Mercury Using Microwave Digestion In Cosmetic Product With Flow Injection-AAS	Wong-Neo Geok Eng, Cheah Nuan Ping, See Phek Hah & Tang Kwai Fong

## Financial Review

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## AUDITORS' REPORT TO THE MEMBERS OF

### HEALTH SCIENCES AUTHORITY

We have audited the accompanying financial statements of the Health Sciences Authority (the "Authority") for the financial year ended 31 March 2004, as set out on pages 3 to 18. 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 of the Authority 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 2004, and of the results, changes in reserves and funds, and cash flows of the Authority for the financial 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 investment 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.



Deloitte & Touche  
Certified Public Accountants

Singapore  
12 August 2004

## HEALTH SCIENCES AUTHORITY

### STATEMENT BY THE HEALTH SCIENCES AUTHORITY

In our opinion, the accompanying financial statements of Health Sciences Authority (the "Authority") as set out on pages 3 to 20 are properly drawn up so as to give a true and fair view of the state of affairs of the Authority as at 31 March 2004 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  
12 August 2004

## HEALTH SCIENCES AUTHORITY

### BALANCE SHEET As at 31 March 2004

	Note	2004 \$'000	2003 \$'000 (Restated)
<b>ACCUMULATED DEFICIT</b>		(2,148)	(806)
<b>PRE-RESTRUCTURING FUNDS</b>	4	233	246
<b>DEFERRED CAPITAL GRANTS</b>	5	23,503	3,708
		<u>21,588</u>	<u>3,148</u>
<b>REPRESENTED BY:</b>			
<b>CURRENT ASSETS</b>			
Cash and cash equivalents	6	12,974	19,744
Trade receivables		6,063	5,067
Other receivables, deposits and prepayments	7	3,215	744
Inventories	8	1,582	1,678
Total current assets		<u>23,834</u>	<u>27,233</u>
<b>NON-CURRENT ASSET</b>			
Plant and equipment	9	33,986	14,426
<b>CURRENT LIABILITIES</b>			
Trade payables		(4,619)	(4,310)
Other payables and accruals (Note below *)	10	(27,506)	(27,013)
Grants received in advance:			
Government	11	(1,992)	(4,251)
Non-government	12	(83)	(227)
Contribution to Consolidated Fund		-	(122)
Total current liabilities		<u>(34,200)</u>	<u>(35,923)</u>
<b>NON-CURRENT LIABILITY</b>			
Other payables and accruals	10	(2,032)	(2,588)
<b>NET ASSETS</b>		<u>21,588</u>	<u>3,148</u>

**\* Note:**

This included an amount payable for the net assets of \$18,610,000 (2003 : \$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 capital grant) by the Ministry of Finance, the transfer was effected through a loan to the Authority in 2002 which has no fixed repayment terms or interest. Upon the finalisation of the mode of transfer, any subsequent adjustments, including any accrued interest, will be effected in the financial year in which the mode of transfer is finalised.

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

## HEALTH SCIENCES AUTHORITY

**INCOME AND EXPENDITURE STATEMENT**  
**Financial year ended 31 March 2004**

	Note	2004 \$'000	2003 \$'000 (Restated)
<b>OPERATING INCOME</b>			
Laboratory analysis fees		22,934	18,808
Blood processing fees		11,740	11,737
Patient laboratory testing fees		1,795	1,447
Forensic investigation fees		5,241	5,749
Licensing fees		5,729	5,300
Professional service fees		535	704
Miscellaneous income		175	137
		<u>48,149</u>	<u>43,882</u>
<b>OPERATING EXPENDITURE</b>			
Staff costs	13	33,909	30,777
Supplies and services		12,757	9,856
Rental of premises and equipment		6,339	5,768
Blood donor expenses		2,584	3,478
Repairs and maintenance		3,434	3,096
Depreciation of plant and equipment	9	5,966	3,060
Staff welfare and development		2,525	2,767
Professional services		3,109	1,722
Utilities		1,180	1,193
Transport, postages and communications	14	1,498	1,037
Impairment loss for plant and equipment	9	861	-
Publicity and public relations	14	306	522
Board members' allowances		50	38
Other expenses		916	925
		<u>75,434</u>	<u>64,239</u>
<b>OPERATING DEFICIT</b>		(27,285)	(20,357)
<b>NON-OPERATING SURPLUS</b>	15	<u>411</u>	<u>398</u>
<b>DEFICIT BEFORE GRANTS</b>		(26,874)	(19,959)
<b>GRANTS</b>			
Government grants	11	20,982	18,357
Non-government grants	12	1,643	1,382
Pre-restructuring funds	4	1	14
Development projects	16	380	-
Deferred capital grants amortised	5	2,526	33
		<u>25,532</u>	<u>19,786</u>
<b>DEFICIT BEFORE CONTRIBUTION TO CONSOLIDATED FUND</b>		(1,342)	(173)
<b>CONTRIBUTION TO CONSOLIDATED FUND</b>	17	<u>-</u>	<u>(122)</u>
<b>NET DEFICIT FOR THE YEAR</b>		<u>(1,342)</u>	<u>(295)</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 2004**

	Accumulated surplus (deficit) \$'000	Pre- restructuring funds \$'000
Balance as at 31 March 2002		
- previously reported	2,097	390
- prior year adjustments (Note 21)	(2,608)	-
Balance as at 31 March 2002 – restated	(511)	390
Surplus for the year		
- previously reported	431	-
- prior year adjustments (Note 21)	(726)	-
Deficit for the year – restated	(295)	-
Transfer to deferred capital grants	-	(130)
Transfer to income and expenditure statement (Note 4)	-	(14)
Balance as at 31 March 2003 – restated	(806)	246
Deficit for the year	(1,342)	-
Transfer to deferred capital grants	-	(12)
Transfer to income and expenditure statement (Note 4)	-	(1)
Balance as at 31 March 2004	(2,148)	233

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

## HEALTH SCIENCES AUTHORITY

**CASH FLOW STATEMENT**  
**Financial year ended 31 March 2004**

	Note	2004 \$'000	2003 \$'000 (Restated)
<b>CASH FLOWS FROM GRANTS:</b>			
Government grants received	11	26,395	37,266
Non-government grants received	12	1,194	1,589
Development projects	16	380	-
Total cash from grants		<u>27,969</u>	<u>38,855</u>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Deficit before grants		(26,874)	(19,959)
Adjustments for:			
Depreciation of plant and equipment	9	5,966	3,060
Impairment loss arising from plant and equipment	9	861	-
Allowance for doubtful trade receivables		152	-
Loss on disposal of plant and equipment	15	36	-
Interest income	15	(44)	(72)
Deficit before working capital changes		<u>(19,903)</u>	<u>(16,971)</u>
Changes in working capital excluding cash and cash equivalents:			
Trade receivables		(1,148)	819
Other receivables and prepayments		(310)	(357)
Inventories		96	(462)
Trade payables		309	(2,776)
Other payables and accruals		(63)	(3,861)
Cash used in operations		<u>(21,019)</u>	<u>(23,608)</u>
Contribution to Consolidated Fund paid during the year		(122)	(680)
Net cash used in operating activities		<u>(21,141)</u>	<u>(24,288)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Purchase of plant and equipment	9	(13,642)	(9,498)
Interest received		44	72
Proceeds from disposal of plant and equipment		-	35
Net cash used in investing activities		<u>(13,598)</u>	<u>(9,391)</u>
Net (decrease) increase in cash and cash equivalents		(6,770)	5,176
Cash and cash equivalents at beginning of year		19,744	14,568
<b>Cash and cash equivalents at end of year</b>		<u><u>12,974</u></u>	<u><u>19,744</u></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 2004

#### 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 registered office and principal place of business of the Authority is at 11 Outram Road, Singapore 169078.

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 2004 were authorised for issue by the members of its Board on 12 August 2004.

## 2 SIGNIFICANT ACCOUNTING POLICIES

### a) Basis of accounting

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

The Authority has adopted all the applicable new/revised FRS and INT FRS which became effective during the year. The adoption of the new/revised FRS and INT FRS does not affect the results of current or prior periods.

### b) Financial assets

Financial assets include cash and cash equivalents, 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 and other costs incurred in bringing the inventories to their present location and condition.

### e) Plant and equipment

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:

Building improvements	20 years
Computers	3 to 5 years (2003 : 3 to 8 years)
Motor vehicles	10 years
Scientific and medical equipment	5 years (2003 : 6 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.

Prior to 1 April 2003, computers and scientific equipment were depreciated over a maximum of 8 and 6 years respectively. In the current financial year, the Authority has re-evaluated the estimated useful lives applicable to computers and scientific equipment in view of the advancement in technology. The estimated useful lives for computers and scientific equipment have been revised to a maximum of 5 years to better reflect the estimated useful lives of the assets. The effect of the change in estimated useful lives has been applied prospectively and has increased the depreciation expense for the year by approximately \$946,000.

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). When it is not possible to estimate the recoverable amount of an individual asset, the Authority estimates the recoverable amount of the cash-generating unit to which the asset belongs. If the recoverable amount of an asset/cash-generating unit is estimated to be less than its carrying amount, the carrying amount of the asset/cash generating unit 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/cash-generating unit 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/cash-generating unit in prior years.

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 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.

j) Grants

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 state-managed 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 are recognised in the balance sheet based on a review and estimate of the valuation on the pension fund as determined and allocated by the Accountant-General's Department and adjusted by the Authority's estimates of the probable obligations with reference to the historical trends and the assumptions which are reflected in the actuarial report.

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

Contribution to Consolidated Fund is provided on an accrual basis. The contribution is based on the net surplus of the Authority for each of the financial year at the prevailing corporate tax rate.

### 3 FINANCIAL RISKS AND MANAGEMENT

#### a) 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.

#### b) Interest rate risk

The Authority has limited exposure to interest rate risk as interest-bearing assets are all short-term. The Authority does not have any interest-bearing liabilities.

#### c) Foreign currency exchange risk

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

#### 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 PRE-RESTRUCTURING FUNDS

	<u>2004</u>	<u>2003</u>
	\$'000	\$'000
Balance at beginning of year	246	390
Transfer to deferred capital grants (Note 5)	(12)	(130)
Transfer to income and expenditure statement	(1)	(14)
Balance at end of year	<u>233</u>	<u>246</u>

The pre-restructuring funds were granted by MOH for the expenditures incurred during the establishment of the Authority.

## 5 DEFERRED CAPITAL GRANTS

	<u>2004</u>	<u>2003</u>
	\$'000	\$'000
Balance at beginning of year	3,708	232
Transfer from pre-restructuring funds (Note 4)	12	130
Transfer from grants received in advance		
– IT Master Plan (Note 11)	6,030	3,379
– MDP Funds (Note 11)	3,478	-
– NMRC (Note 11)	20	-
Development projects transferred from MOH (Note 9)	12,781	-
Transfer to income and expenditure statement to match depreciation of related assets	(2,526)	(33)
Balance at end of year	<u>23,503</u>	<u>3,708</u>

## 6 CASH AND CASH EQUIVALENTS

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

	<u>2004</u>	<u>2003</u>
	\$'000	\$'000
Bank and cash balances	10,970	11,729
Fixed deposits	2,004	2,006
Short-term bank note (quoted, 2003: market value of \$6,009,000)	-	6,009
	<u>12,974</u>	<u>19,744</u>

In 2003, the short-term bank note was a fixed-rate secured note which bore interest at the rate of 1.08% per annum and matured on 14 May 2003.

7 OTHER RECEIVABLES, DEPOSITS AND PREPAYMENTS

	2004	2003
	\$'000	\$'000
Grants receivable – Government (Note 11)	1,856	-
Grants receivable – Non-government (Note 12)	305	-
Other receivables	57	237
Deposits	421	421
Advances to staff <sup>(a)</sup>	3	21
Prepayments	573	65
	<u>3,215</u>	<u>744</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.

8 INVENTORIES

	2004	2003
	\$'000	\$'000
Gases, laboratory and medical supplies, at cost	<u>1,582</u>	<u>1,678</u>

9 PLANT AND EQUIPMENT

	Building improvements	Computers	Motor vehicles	Scientific and medical equipment	Other equipment, furniture and fittings	Work- in-progress	Total
	\$'000	\$'000	\$'000	\$'000	\$'000	\$'000	\$'000
Cost:							
At beginning of year	2,000	3,367	186	11,012	1,526	3,452	21,543
Development projects transferred from MOH (Note 16)	3,458	6,782	-	-	2,541	-	12,781
Additions	1,065	157	-	4,136	219	8,065	13,642
Disposals	-	(2)	(97)	(140)	(19)	-	(258)
At end of year	<u>6,523</u>	<u>10,304</u>	<u>89</u>	<u>15,008</u>	<u>4,267</u>	<u>11,517</u>	<u>47,708</u>
Accumulated depreciation:							
At beginning of year	80	2,662	37	4,003	335	-	7,117
Depreciation for the year	294	1,784	79	3,301	508	-	5,966
Disposals	-	(2)	(70)	(138)	(12)	-	(222)
At end of year	<u>374</u>	<u>4,444</u>	<u>46</u>	<u>7,166</u>	<u>831</u>	<u>-</u>	<u>12,861</u>
Accumulated impairment loss:							
Impairment for the year and balance at end of year	<u>779</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u>82</u>	<u>-</u>	<u>861</u>
Depreciation for last year	<u>67</u>	<u>788</u>	<u>13</u>	<u>1,976</u>	<u>216</u>	<u>-</u>	<u>3,060</u>
Carrying amount:							
At end of year	<u>5,370</u>	<u>5,860</u>	<u>43</u>	<u>7,842</u>	<u>3,354</u>	<u>11,517</u>	<u>33,986</u>
At beginning of year	<u>1,920</u>	<u>705</u>	<u>149</u>	<u>7,009</u>	<u>1,191</u>	<u>3,452</u>	<u>14,426</u>

The impairment loss arose as a result of certain assets whose recoverable amounts were estimated to be lower than their carrying amounts due to limited use of such assets after office relocation.

## 10 OTHER PAYABLES AND ACCRUALS

	2004	2003
	\$'000	\$'000
Licence fees collected in advance	3,726	4,316
Amount payable to MOH for net assets transferred <sup>(a)</sup>	18,610	18,610
Accrual for staff costs	5,478	5,367
GST payable	271	163
Refundable security deposits	196	205
Other payables and accruals	1,257	940
	<u>29,538</u>	<u>29,601</u>
Non-current portion:		
Licence fees collected in advance	(505)	(1,036)
Obligations in respect of defined benefit retirement plan as included in accrual for staff costs <sup>(b)</sup>	(1,527)	(1,552)
	<u>(2,032)</u>	<u>(2,588)</u>
Current portion	<u>27,506</u>	<u>27,013</u>

(a) This represents 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 capital grant) by the Ministry of Finance, the transfer was effected through a loan to the Authority in 2002 which has no fixed repayment terms or interest. Upon the finalisation of the mode of transfer, any subsequent adjustments, including any accrued interest, will be effected in the financial year in which the mode of transfer is finalised.

(b) This represents the allocated portion of the pension fund (shared between the MOH and the Authority) to meet the ongoing service liability of pensionable employees. The pension amount to be paid to the employees upon retirement under this defined benefit retirement plan is dependent on, among other factors, the number of years of service and last drawn salary. The Authority is liable for the pension costs for the period of service completed by the employees with the Authority. Defined benefit retirement obligations are recognised in the balance sheet based on a review and estimate of the valuation on the pension fund as determined and allocated by the Accountant-General's Department and adjusted by the Authority's estimates of the probable obligations with reference to the historical trends and the assumptions which are reflected in the actuarial report.

## 11 GRANTS RECEIVED IN ADVANCE – GOVERNMENT

	IT Master Plan <sup>(a)</sup>		MDP Funds <sup>(b)</sup>		Operating Grants		HMDP <sup>(c)</sup>		SARs Funds <sup>(d)</sup>		NMRC <sup>(e)</sup>		Total	
	2004	2003	2004	2003	2004	2003	2004	2003	2004	2003	2004	2003	2004	2003
	\$'000	\$'000	\$'000	\$'000	\$'000	\$'000	\$'000	\$'000	\$'000	\$'000	\$'000	\$'000	\$'000	\$'000
Balance at beginning of year														
- Grants receivable as previously reported	-	-	-	-	-	(13,949)	-	-	-	-	-	-	-	(13,949)
- Prior year adjustments (Note 21)	-	-	-	-	-	2,608	-	-	-	-	-	-	-	2,608
<b>- restated</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>(11,341)</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>(11,341)</b>
- Grants received in advance as previously reported	325	-	-	-	412	-	180	62	-	-	-	-	917	62
- Prior year adjustments (Note 21)	-	-	-	-	3,334	-	-	-	-	-	-	-	3,334	-
<b>- restated</b>	<b>325</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>3,746</b>	<b>-</b>	<b>180</b>	<b>62</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>4,251</b>	<b>62</b>
Receipts during the year	6,648	3,704	1,645	-	17,459	33,312	266	250	259	-	118	-	26,395	37,266
Transfer to deferred capital grants (Note 5)	(6,030)	(3,379)	(3,478)	-	-	-	-	-	-	-	(20)	-	(9,528)	(3,379)
Transfer to income and expenditure statement as previously reported	-	-	(20)	-	(20,358)	(18,951)	(244)	(132)	(259)	-	(101)	-	(20,982)	(19,083)
- Prior year adjustments (Note 21)	-	-	-	-	-	726	-	-	-	-	-	-	-	726
<b>- restated</b>	<b>-</b>	<b>-</b>	<b>(20)</b>	<b>-</b>	<b>(20,358)</b>	<b>(18,225)</b>	<b>(244)</b>	<b>(132)</b>	<b>(259)</b>	<b>-</b>	<b>(101)</b>	<b>-</b>	<b>(20,982)</b>	<b>(18,357)</b>
Net	943	325	(1,853)	-	847	3,746	202	180	-	-	(3)	-	136	4,251
Presented as														
- Grants receivable (Note 7)	-	-	1,853	-	-	-	-	-	-	-	3	-	1,856	-
- Grants received in advance	943	325	-	-	847	3,746	202	180	-	-	-	-	1,992	4,251
Total grants received since establishment	10,352	3,704	1,645	-	56,471	39,012	719	453	259	-	118	-	69,564	43,169

- (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 IT Master Plan is scheduled to complete in 2005. 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.

## 12 GRANTS RECEIVED IN ADVANCE - NON-GOVERNMENT

	2004	2003
	\$'000	\$'000
Balance at beginning of year	227	20
Net receipts during the year	1,194	1,589
Transfer to income and expenditure statement	(1,643)	(1,382)
Net	<u>(222)</u>	<u>227</u>
Presented as		
- Grants receivable (Note 7)	<u>305</u>	-
- Grants received in advance	<u>83</u>	<u>227</u>
Total grants received since establishment	<u>3,560</u>	<u>2,366</u>

## 13 STAFF COSTS

	2004	2003
Number of employees at end of year	<u>578</u>	<u>494</u>
	2004	2003
	\$'000	\$'000
Staff costs	<u>33,909</u>	<u>30,777</u>
Cost of defined contribution retirement plans included in staff costs	<u>3,237</u>	<u>3,276</u>
Cost of obligations in respect of defined benefit retirement plan included in staff costs	<u>687</u>	<u>989</u>

14 TRANSPORT, POSTAGES AND COMMUNICATIONS,  
PUBLICITY AND PUBLIC RELATIONS

Transport, postages and communications, publicity and public relations include the following expenses:

	2004	2003
	\$'000	\$'000
Overseas travelling	123	65
Entertainment	<u>15</u>	<u>19</u>

15 NON-OPERATING SURPLUS

	<u>2004</u>	<u>2003</u>
	\$'000	\$'000
Interest income	44	72
Fines and forfeitures	328	258
Miscellaneous income	<u>115</u>	<u>189</u>
	<u>487</u>	<u>519</u>
Foreign currency exchange loss	(40)	(121)
Loss on disposal of plant and equipment	<u>(36)</u>	<u>-</u>
	<u>(76)</u>	<u>(121)</u>
Non-operating surplus	<u><u>411</u></u>	<u><u>398</u></u>

16 DEVELOPMENT PROJECTS

The development projects pertain 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 during the year.

17 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).

The contribution for the financial year ended 31 March 2003 was based on the net surplus (before prior year adjustments) of \$553,000, at the prevailing corporate tax rates for the Year of Assessment 2003 at 22%. No adjustment has been made for the contribution to consolidated fund for the year ended 31 March 2003 as a result of restatement of the prior year net surplus as the Authority is of the view that the probability of a refund is remote.

There is no contribution to consolidated fund for the current financial year as the Authority is in a net deficit position.

18 CONTINGENT LIABILITIES

	<u>2004</u>	<u>2003</u>
	\$'000	\$'000
Guarantees	<u>108</u>	<u>-</u>

19 CAPITAL EXPENDITURE COMMITMENTS

	2004	2003
	\$'000	\$'000
Estimated amounts committed for future capital expenditure but not provided for in the financial statements	<u>6,916</u>	<u>18,477</u>

## 20 OPERATING LEASE COMMITMENTS

	<u>2004</u>	<u>2003</u>
	\$'000	\$'000
Minimum lease payments under operating leases for rental of premises and equipment	<u>6,339</u>	<u>5,768</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>2004</u>	<u>2003</u>
	\$'000	\$'000
Within one year	5,186	5,758
In the second to fifth years inclusive	<u>6,398</u>	<u>315</u>

## 21 PRIOR YEAR ADJUSTMENTS

During the current financial year, the MOH made adjustments to transitional grants for prior years that were disbursed to the Authority for financial years ended 31 March 2001 to 2003. Accordingly, the comparatives have been restated as follows:

	Balance as previously reported	Prior year adjustments	Balance as restated
	\$'000	\$'000	\$'000
<u>Balance sheet as at 31 March 2003</u>			
Grants received in advance - Government	917	3,334	4,251
Accumulated surplus (deficit) as at 31 March 2003	2,528	(3,334)	(806)
<u>Income and expenditure statement for the financial year ended 31 March 2003</u>			
Government grants	<u>19,083</u>	<u>(726)</u>	<u>18,357</u>
Surplus (deficit) before contribution to Consolidated Fund	553	(726)	(173)
Contribution to Consolidated Fund	(122)	-	(122)
Accumulated surplus (deficit) as at 31 March 2002	<u>2,097</u>	<u>(2,608)</u>	<u>(511)</u>
Accumulated surplus (deficit) as at 31 March 2003	<u>2,528</u>	<u>(3,334)</u>	<u>(806)</u>



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