



h e a l t h   s c i e n c e s   a u t h o r i t y   a n n u a l   r e p o r t   2 0 0 2 / 0 3

**building**  
**momentum**



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

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

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

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

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***Vision*** To be world class for scientific  
and regulatory expertise in Health  
Sciences

***Mission*** To excel in applying science  
to: • Support healthcare services and  
regulation • Serve the administration  
of justice • Enhance safety in our  
community

***Values*** We are committed to  
professional excellence • We create  
value for our clients • We uphold our  
professional integrity • We value and  
nurture our staff • We encourage  
innovation and enterprise

chairman's statement



Prof Lim Mong King  
Chairman

*Lim Mong King*

**chairman's statement** ■ 2002 was an exciting time to be at HSA. In our second year, we forged ahead to build up the critical capabilities and strategic alliances that would position us to respond effectively to the rapid changes at the local level and on a global scale.

### Challenges and Opportunities

New therapeutic goods, technologies, techniques and tools that emerge ever more rapidly than before, have offered numerous opportunities and shaped expectations for an improved quality of life. The pace of globalisation and information technology advancement further allows information to flow seamlessly and virtually across geographical boundaries resulting in heightened consumer demand for shorter time-to-market and a greater diversity of health products.

We can be sure that just as certainly as science, medicine and technology will advance, threats and risks will develop and proliferate at a similar pace. In recent times, the widespread concern on terrorism, including potential bio-terrorism, calls for better measures to protect public health and safety. Equally alarming has been the emergence of new infectious diseases, which requires us to respond quickly, for instance, with new screening measures to protect the integrity of the national blood supply from Severe Acute Respiratory Syndrome (SARS). And as economies become challenged with declining growth and unemployment, the lure of counterfeit and substandard health products will put greater pressures on our post-market surveillance and analytical testing capabilities.

Risks abound in the community and in the world of regulatory and scientific activities. Too much regulation stifles enterprise

and progress but too little regulation exposes the community to unnecessary hazards. Too cautious a scientific approach is resource-consuming without effectiveness but too little attention to scientific methodology undermines confidence and objectivity.

### Building Momentum

These challenges have significantly shaped our future directions and actions, strengthened our systems and processes, and also propelled us to forge new frontiers in strategic alliances in our second year of operation.

As a science-based agency, we have identified enterprise risk management as a primary strategic tool to address the increasing complexity of challenges yet exploiting each opportunity to fulfil our role to safeguard public health and safety and serve the administration of justice. Our enterprise risk register and individual risk registers at the centres' and departments' levels have enforced systematic decision-making and contributed to a greater insight into risks and their impacts, thereby improving our safety, quality and business performance.

In 2002, we gained momentum in establishing strategic alliances with our stakeholders and international benchmark regulatory counterparts as well as being an integral part of regional and global harmonisation initiatives.

These efforts serve to develop a more robust and responsive regulatory framework and scientific capabilities that are in line with current international best practices and trends. Through strategic alliances and collaborations, we also expand the breadth and depth of information and expertise that we can draw upon to make not just timely regulatory decisions, but also cutting-edge scientific judgements. There is no doubt that such ties serve the optimal use of limited resources for maximum public protection.

I am happy to highlight that in May 2002, we have taken a significant step forward by our first major collaboration with one of our key counterpart regulatory agencies, the Therapeutic Goods Administration (TGA) of Australia.

Signing the Memorandum of Intention of Co-operation with TGA marked an important milestone in the regulatory arena as it sealed the already strong ties between HSA and TGA, and served as a model for regulatory co-ordination in the Asia Pacific region. In addition, the Memorandum enhanced initiatives to harmonise regulatory standards amidst the diversity of regulatory approaches across national borders.

Amongst the many harmonisation initiatives which we are actively involved in, I am particularly pleased to note that we played a

key organising role in the 9th Global Harmonisation Task Force Conference held in May 2002 in Singapore. This conference saw a congregation of global key decision-makers from the industry and governments in the regulation of medical devices. There were eminent representatives from the US Food and Drug Administration, Australia TGA, Canada Therapeutic Products Directorate, UK Medicines and Healthcare products Regulatory Agency and European Commission. This participation has significantly raised our global profile in the regulatory arena and affirmed our commitment to forge a common direction for the harmonisation of medical device regulation in Asia via the Asian Harmonisation Working Party.

### Concluding Remarks

In our second year, I am gratified to note that we have continued the momentum built up from the previous year. It gives me great pleasure to convey my appreciation to the management and staff of HSA for their commitment, professionalism and contribution to the organisation and the delivery of our public mission. I would also like to express my heartfelt gratitude to the Board Members for their advice and guidance in our journey to our strategic designation in being world class for scientific and regulatory expertise in health sciences.

ceo's report



Dr Clarence Tan  
Chief Executive Officer



*Clarence*

**ceo's report** ■ This year, HSA has advanced in our journey towards our strategic designation in being world class for scientific and regulatory expertise in health sciences.

### Coming of Age

We have made good progress in developing our new regulatory capability in the evaluation of new drugs not previously approved in other countries. Building this regulatory capability complements the growth of research and development in the pharmaceutical industry in Singapore insofar as to make Singapore the origin of new and innovative quality drugs. This strategic direction is an integral part of the infrastructure to develop Singapore as a regional medical hub and as a world hub for the biomedical sciences research and development.

Being in our early developmental stage, I am proud to note that during the year, we have evaluated 8 new drug applications not previously approved in other countries. This represented the highest number of completed evaluations in a year, a few of which were completed ahead of other overseas benchmark regulatory agencies.

As with developed countries, our regulatory framework is based on a risk management approach designed to ensure public health and safety, while at the same time freeing the industry from any unnecessary regulatory burden.

As efficient and effective risk managers, who strategically apply science and law to protect consumers, we need to balance the rewards of biomedical and technological advancement with the inherent risk every breakthrough carries. During the year, we strengthened our regulatory framework for clinical trials to enhance the safety of trial subjects and improve process and accountability within the institutions undertaking the trials. In anticipation of more biologics as the noble innovations of biomedical research and development, we have proactively set up a biologics unit for the consolidation of expertise to evaluate such products.

Further in our role as risk managers, we need to weigh the risk and benefits of every regulatory decision, and knowing that every therapeutic product in the market has the potential of adverse reactions, we engage post-market surveillance measures for comprehensive ongoing vigilance.

During the year, we saw promising outcomes of our efforts in the enhancement of the pharmacovigilance programme. We received a record number of 801 adverse drug reaction (ADR) reports from the healthcare professionals, a 40% increase of reports compared to 2001. The increase was a good indicator of the continual

effort made to promote the reporting of any suspected ADR encountered by our health professionals for collation and further investigations at HSA, as well as the enhancement of the infrastructure for reporting that leveraged on the wide applications of information technology.

Spontaneous ADR reporting and monitoring has been recognised internationally as a powerful and effective tool for the detection of potential drug safety problems that may arise after the drugs have been marketed and used widely in the general population. In 2002, through the local ADR reports received, drug safety problems associated with Slim 10 and jarem encok were detected and subsequently tested and found to be adulterated with synthetic western drugs.

In the case of Slim 10, it was a defining regulatory event in the year that signified the coming-of-age of the awareness on the interplay of regulation in a globalised world. Our quick action from detection to its market removal illustrated the effectiveness and timeliness of our regulatory performance. The successful prosecution of the importer and distributor of the product also drove home the message on the importance of fulfilment and compliance to the statutory obligations defined in the regulatory framework.

As similar products, though packaged and marketed differently, were also found in other countries, there was much information

exchange and collaboration among a few regulators who were also confronted with the challenge to race against time to establish the causation of the ADR observed in their countries. There was no doubt that this incident highlighted the need for and benefits of our close co-operation in post-market surveillance, investigation and enforcement with our overseas counterparts in an ever growing globalised market.

### **Building Capabilities**

The roadmap to our strategic destination of being a world class regulator for health products and a one-stop centre of excellence in transfusion medicine, forensic and analytical expertise, depends on continued investments in building our people expertise, equipment and technological infrastructure, and modernised facilities that keep pace with best practices and rapidly emerging technologies.

Over the last two years, we invited world renown experts to teach and share their domain knowledge and audit our systems. In 2002, we sent more of our best to learn from benchmark agencies and participate in global professional and industry events.

In a move to meet the high expectations of our stakeholders to provide more complex and higher value-added forensic, investigative and analytical services, we invested in new state-of-the-art equipment that would yield rapid, sensitive and specific analysis.

The delivery of efficient and effective services must also rest on a strong and modern infrastructure. Exploiting information technology is one of our cornerstones in maximising resource utilisation and operational efficiency. During the year, we upgraded our network infrastructure and worked towards e-enabling many services by harnessing the power of the internet to make regulatory dealings more convenient for our industry players and blood donations more accessible to our blood donors.

Facility development and upgrades also continued during the year, and they were done with a strong commitment to serve our customers first and well. A new Apheresis Suite at our Bloodbank@HSA has enhanced the environment for our altruistic blood donors, and likewise, a more conducive and comfortable reception area at the Mortuary@HSA for distressed next-of-kin. Emphasis was also placed on improving occupational safety system at our facilities to handle Bio-Safety Level 3+ type of autopsy cases. This initiative would increase our capability capacity to handle situations of mass disaster, infectious disease outbreaks and bio-terrorism.

### Achieving Excellence

The ability to learn and put into practice what has been learnt is the competitive edge. Thus, we are proud to have attained the People Developer Standard, another milestone in our organisational excellence journey. It means that our people development and training system is comparable to the best in Singapore.

We also recognise that a culture of innovation and enterprise is one of the key critical success factors in driving our workforce behaviour and ensuring robustness in performance in a challenging operating environment which is becoming more sophisticated each day.

In 2002, we unveiled an integrated innovation framework that is built upon our vision, mission and core values to harness creativity through various strategies like risk management, value management and corporate excellence systems. Our innovation framework, based on three guiding principles *viz focus on vision, freedom with responsibility and frontier –boldly going forward*, aims to build up a self-propagating and self-sustaining pool of innovation that will sustain our journey towards excellence. We are seeking recognition of our innovation capability development via the application of the Singapore Innovation Class by FY 2003.

In our second year, we were pleased to achieve more third-party endorsements of our systems and processes. Our Centre for Analytical Science has not only attained the Singapore Quality Class, but also upgraded its Singapore Accreditation Council – Singapore Laboratory Accreditation Scheme accreditation to ISO/IEC 17025 in chemical, biological and environmental testing fields. The latter is a testimony that we have met the international standards for the competence of testing laboratories, and our clients can therefore exploit this accreditation strategically for their overseas markets.

In April 2002, the United Nations International Drug Control Programme (UNDCP) invited our Narcotics II Laboratory in our Centre for Forensic Science to be a reference laboratory for the biological specimen group. This added to the list of international recognition in which in June 2001, our Narcotics I Laboratory was made the reference laboratory for analysis of controlled drugs for seized materials group. As the reference laboratories, we provide the baseline information that is used to evaluate results reported by participating laboratories in UNDCP's bi-annual international collaborative exercises.

I am pleased to highlight that our pursuit of professional excellence has led to a unique application of existing investigative processes and methodologies by our forensic scientists, resulting in the prompt apprehension of the perpetrator of a high-profile local murder case. Our forensic scientists have cleverly applied conventional investigative techniques to create a new application, a first in the world, to prove that the exhibit found at the scene of crime matched that found in the criminal's dwelling.

In the domain of transfusion medicine, our internationally renowned Centre for Transfusion Medicine conducted a 17-day training course in April 2002, and shared our cutting-edge system of quality management in blood banking to senior blood bank officers from 11 countries in the Western Pacific region. This course was the first of a regular series in the World Health Organisation's initiatives to enhance a safer global blood standard and supply.

### Looking Ahead

I am proud that the HSA family has evolved into a cohesive and committed whole over the last two years as we worked together steadily and prevailed in the face of difficult challenges and changes.

We have achieved some progress towards realising our objectives in our second year. We will continue to persevere and ensure we remain a ready, relevant and responsive organisation that can deliver our mission to excel in applying science to support healthcare services and regulation, serve the administration of justice and enhance safety in our community.

leadership changes



Prof Hang Chang Chieh



Dr Tan Chor Hiang

**leadership changes** ■ HSA would like to express its deepest appreciation to Professor Hang Chang Chieh who relinquished his position as Chairman of HSA on 1 February 2003. He is succeeded by Professor Lim Mong King.

HSA also welcomes Dr Tan Chor Hiang, appointed Chief Executive Officer from 1 August 2003. Dr Tan, who succeeds Dr Clarence Tan, was the Deputy Director of Medical Services, Health Regulation at the Ministry of Health.

our board



# 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 Corporate Ltd & Singapore Land Ltd
- 08 Professor Low Teck Seng**  
Principal/Chief Executive Officer, Republic Polytechnic
- 09 Mr Ng Wai Choong**  
Director, Enterprise Division, Ministry of Trade and Industry
- 10 Mr Stephen Yeo**  
President, EDS International (Singapore) Ptd Ltd

## *BOARD COMMITTEES*

### *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 Swan 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



## highlights of the year

### 2002

#### April

- The Authority celebrated “One Family. One Vision. One Future.” in its 1st Anniversary Celebration cum Dinner & Dance held on 6 April 2002.
- The Authority organised its 1st HSA Scientific Seminar, held on 12 April 2002, with the aim to develop a vibrant research culture and boost the research capability.
- CTM organised the 1st Quality Management Training Course in Blood Transfusion Services in the Western Pacific Region from 15 April to 3 May 2002 in its capacity as the World Health Organisation Regional Training Centre for the Quality Management Programme. Dr Balaji Sadasivan, Minister of State (Health and the Environment) was the Guest-of-Honour at its Opening Ceremony that was held on 15 April 2002.
- On the same day, the fully dedicated Apheresis Suite@HSA was also officially launched.
- CAS filed a second patent on the novel extraction of chemical compounds from botanical and herbal preparations using pressurised hot water as a solvent and at temperatures below boiling point.
- CFS’ Narcotics II Laboratory was invited by the United Nations International Drug Control Programme to be a reference laboratory for the biological specimens group.
- CMDR introduced the Voluntary Product Registration Scheme for higher-risk medical devices. The Scheme, an interim measure to statutory controls, offered all stakeholders a foretaste of the various levers of the regulatory control.
- CPA
  - recalled Slim 10, a listed Chinese proprietary medicine, that generated a series of adverse drug reaction reports as the product was adulterated with synthetic western drugs.
  - participated in the raids on the illegal sale of cough mixture containing codeine together with the Singapore Police Force, Singapore Immigration and Registration Department (since reorganised into the Immigration and Checkpoints Authority) and Central Narcotics Bureau.
- CRP collaborated with the Health Promotion Board to ensure that all mammography X-ray facilities have the necessary quality control programme in place.

## highlights of the year



### May

- The Authority signed a Memorandum of Intention of Co-operation with the Therapeutic Goods Administration of Australia to further collaborate on the regulation of pharmaceuticals, medical devices and complementary health products.
- The Authority collaborated with the Singapore Science Centre and organised a series of talks on "Excellence in Applying Science".
- CMDR played a key organising role in the 9th Global Harmonisation Task Force Conference and the 2nd APEC Seminar on Harmonisation of Medical Device Regulations.
- CAS submitted the application for the Business Excellence Assessment for Continuous Improvement to seek the Singapore Quality Class recognition.

### June

- CFS' Document Examination Laboratory was appointed by a high court in Berlin, Germany to examine Chinese signatures in a civil case involving business agreements.
- CTM organised a symposium on Haemovigilance, which was held on 15 June 2002 in conjunction with the Annual Meeting of Hospital Transfusion Committees.
- CPA
  - tested and confirmed that 45 locally listed Chinese proprietary medicines marketed for slimming and weight loss were free from adulteration of synthetic western drugs.
  - developed an online reporting programme to enable the healthcare professionals to report adverse drug reactions through the Internet in a timely and convenient manner.

### July

- CAS
  - was awarded the accreditation under the new ISO/IEC 17025 by the Singapore Accreditation Council – Singapore Laboratory Accreditation Scheme for meeting the new international requirements for the competence of testing laboratories.
  - was conferred the Singapore Quality Class award, thereby joining the top 5% rank of organisations that have achieved commendable levels of performance in their journey to becoming a world class business organisation.
  - one of its scientists was appointed as a WHO Temporary Advisor, in the WHO Expert Meeting held in Geneva, to review the guidelines for the certification of pharmaceutical starting materials moving into the international market and the guidelines on good trade and distribution practice.

## highlights of the year



- CFS' forensic scientist was invited by the American Society of Crime Laboratory Directors / Laboratory Accreditation Board as an inspector to audit the Contra Costa County Sheriff's Forensic Services Division.

- CTM

- implemented the revised Medical Benefits Scheme for Blood Donors and Nominees.

- revised the blood donor criteria as part of the precautionary measures to prevent the variant Creutzfeldt Jakob Disease in our national blood supply.

- CPA

- prosecuted TV Media Pte Ltd, the distributor of Slim 10, for 20 counts of unlicensed wholesale dealing and 8 counts of selling Slim 10 after it was recalled. The company was fined a total of \$64,000.

- established an e-mail address database of more than 4,000 doctors and pharmacists in Singapore to facilitate the dissemination of urgent drug safety information to the healthcare professionals in a timely manner.

### August

- 14 HSA officers were presented the 2002 National Day Awards for their contributions towards nation building. Of the 14 awards, there were one Commendation Medal, three Efficiency Medals and ten Long Service Medals.

- The HSA family celebrated National Day together with activities that encouraged community involvement and supported welfare organisations.

- CPA conducted a one-off sampling and testing of 163 health supplements marketed for slimming and weight control and found these samples free from adulteration of synthetic western drugs including a comprehensive range of western pharmaceutical agents related to slimming.

- The Minister for Health announced additional measures to enhance the regulatory control of Chinese proprietary medicines.

- The Authority's senior management attended a retreat to review the past year's work with the focus to establish future objectives and directions for inculcating two of the HSA's core values, viz to value and nurture our staff and encourage innovation and enterprise.

## highlights of the year



### September

- The HSA family got together at the Bukit Timah Nature Reserve for a brisk walk-and-run up the Bukit Timah Hill to celebrate good health, fun and company on the HSA Active Day.
- CAS
  - participated in the WHO collaborative study on the development of screening tests and the validation of a pharmacopoeia monograph for a new 4-fixed-dosed combination tuberculosis drug containing rifampicin, isoniazid, pyrazinamide and ethambutol HCL.
  - one of its scientists was invited by the Singapore Accreditation Council – Singapore Laboratory Accreditation Scheme to carry out a joint assessment with the Bureau of Accreditation, Vietnam on two national laboratories located in Ho Chih Minh City and Camau City to accredit them under ISO/IEC 17025.

- CFS collaborated with the Chemistry Department, National University of Singapore to initiate joint research and harness each other's scientific capabilities.
- CTM initiated a pilot Haemovigilance programme with majority of the hospitals through the Hospital Transfusion Committees.
- CPA
  - was invited, at the 6th meeting of the ASEAN Consultation Committee for Standards and Quality Pharmaceutical Product Working Group, to chair the Implementation Working Group to oversee the two-year trial period for the ASEAN Common Technical Dossier from January 2003 to December 2004.

- revoked Health Biz Pte Ltd's Import and Wholesale Dealer's Licences, following its conviction of 9 counts of violating the Medicines Act in its importation and sale of Slim 10. Health Biz Pte Ltd had pleaded guilty to all charges and was fined a total of \$45,000.

### October

- The Authority introduced the HSA Innovation Framework and embarked on the quest for the Singapore Innovation Class.
- CFS' Narcotics II Laboratory, in collaboration with the Central Narcotics Bureau, successfully completed a project on the detection of opiates in hair which resulted in a pilot study on the feasibility of using hair testing in drug monitoring.

## highlights of the year



- CRP conducted a training course on radiation protection for industrial radiographers to raise the general standard of radiation safety in industrial radiography and to minimise the radiation exposure to the workers.

### December

- The Authority achieved the People Developer Standard.
- The HSA family ended the year with an organisation-wide competition that promoted "HSA Core Values in Motion". Each competing centre designed, constructed and paraded its small-scale mobile structure that creatively depicted the Authority's core values.

## 2003

### January

- The Authority's corporate video "Celebrating Excellence" won a WorldMedal in the prestigious New York Festivals 2002. It was an outstanding orientation show in the competitive category "International Film and Video (Non-Broadcast)".
- CTM implemented the Haemovigilance programme with hospitals following the success of its pilot programme held in September 2002.
- CPA
  - implemented the new requirement that all Chinese proprietary medicine products should carry an additional label "Allowed for sale as a Chinese Proprietary Medicine" on the outer sales packs in both English & Chinese so as to help consumers to better differentiate Chinese proprietary medicine products from western drugs.

- set up a working group with the Agri-Food & Veterinary Authority to address issues of concern pertaining to product classification of "grey area" food products, which might be fortified with herbal ingredients.

### February

- The Authority was invited by the Public Service for the 21st Century, Prime Minister's Office and the Civil Service College to share on HSA's leadership in innovation as well as our innovation journey in the "Innovation Expedition for Public Service Officers" programme.
- CFS
  - its DNA Database Laboratory was launched in collaboration with the Singapore Police Force, after the Parliament has passed the amendment of Registration of Criminals Act.

## highlights of the year



- its Criminalistics Laboratory found, through its testing, that tube sparklers were dangerous, and successfully initiated the inclusion of tube sparklers as dangerous fireworks in the Dangerous Fireworks Act.

- CPA

- implemented the requirement that all indirect medical advertisements and consumer education materials of Prescription Only Medicine be classified as medical advertisements. This was to distinguish genuine consumer education materials from indirect advertisements of prescribed medicines.

- gazetted the amendments to the Smoking (Control of Advertisements and Sale of Tobacco) Act. Among the various amendments, licensing of importers and distributors would be required, cigarettes imported or sold in Singapore would list other constituents in addition to tar and nicotine, and the fine quantum of under-aged smoking offences would be increased.

### March

- The Authority carried out an enterprise-wide risk management study and developed risk registers at the organisation and centres' levels so as to enhance our capability for business continuity, emergency preparedness and crisis management.

- The HSA family celebrated its second Family Day at the Sapphire Beach, Sentosa. Officers and their spouses, children and friends had a fun-filled day packed with many activities like tele-matches, variety shows and games.

- CAS' Centre Director was invited to participate as a WHO Temporary Advisor at the WHO Expert Committee Meeting on Specifications for Pharmaceutical Preparations held in Geneva.

- CFS

- its Criminalistics Laboratory signed an agreement with the Royal Canadian

Mounted Police Edmonton Forensic Science Laboratory, marking our entry as a partner in the International Forensic Automotive Paint Data Query programme.

- its DNA Profiling Laboratory successfully passed the bi-annual external accreditation audit which was conducted by the American Society of Crime Laboratory Directors / Laboratory Accreditation Board.

- CPA set up a Grey Area Products Task Force to look into health products that did not fit clearly under the existing classifications.

- CTM implemented additional precautionary measures, following the SARS outbreak in Singapore, to safeguard the national blood supply and protect the blood donors and patients in the hospitals.

- CFM carried out autopsies on SARS victims under the Infectious Diseases Act during the SARS outbreak.



CPA

CDE

CMDR

CRP

CFM

CFS

CTM

CAS

**keeping watch** ■ At HSA, we safeguard public health by administering a robust and responsive regulatory system to ensure the appropriate standards of safety, quality and efficacy in western drugs, Chinese proprietary medicines, medical devices and health-related products available in Singapore. We also make sure that health supplements, cosmetics and medical and consumer products do no harm, including those products that emit radiation. Our work is to strategically apply science and law to protect consumers in Singapore. As with developed countries, our regulatory framework is based on a risk management approach designed to ensure public health and safety, while at the same time allowing the industry to develop without unnecessary regulatory burden.



“Compliance plays an important role in serving public health and reinforcing our reputation internationally as a medical hub that offers safe and authentic medical products to the industry and the public.”

**Yee Shen Kuan**  
Senior Deputy Director, Compliance & Complementary Medicines  
Centre for Pharmaceutical Administration

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Full Dossier Evaluations of New Drug Applications

**8**

Abridged Evaluations and Licensing of Western Medicinal Products

**2,525**

Site Inspections for Good Manufacturing and Good Distribution Practices

**522**

Listed Chinese Proprietary Medicines

**1,392**

Adverse Drug Reaction Reports

**801**

Recalled Medicinal / Health-related Products and Medical Devices

**43**

Voluntary Product Registration Applications for Medical Devices

**1,047**

Licences for Irradiating Apparatus and Radioactive Materials

**20,904**

Improved Consumer Access to Medicines, Enhanced Regulatory Control of Chinese Proprietary Medicines, Investigations into Adulteration of Slim 10 and Prosecution Actions, Adverse Drug Reaction Reporting Programme, Voluntary Product Registration Scheme for Medical Devices, X-Ray Mammography Quality Assurance Programme, Nuclear Safety and Emergency Planning



## REGULATING PHARMACEUTICALS AND HEALTH-RELATED PRODUCTS

Our **Centre for Pharmaceutical Administration (CPA)** safeguards public health by ensuring that medicinal and health-related products in Singapore meet the appropriate standards of safety, quality and efficacy.

We carry out pre-marketing evaluation of medicinal products before they can be marketed in Singapore. The products currently regulated include western medicinal products, Chinese proprietary medicines and cosmetic products. The regulatory framework for health supplements is being developed. We are also responsible for the regulation of clinical trials in Singapore and the provision of unbiased drug information to health professionals and the public. In addition, we administer and enforce the Smoking (Control of Advertisements and Sale of Tobacco) Act in support of the government's efforts to discourage smoking and promote public health.

We regulate medicinal and other health-related products under the Medicines Act, the Poisons Act, the Sale of Drugs Act, the Medicines (Advertisement and Sale) Act and the Misuse of Drug Regulations. Post-marketing regulatory activities include quality surveillance programmes, routine inspections and investigations into contraventions of legislation. When necessary, legal action is taken against the offenders by way of compounding or prosecution in court.



The spontaneous reporting of adverse drug reactions by doctors and other health professionals is another important tool used to keep continued vigilance on the safety of all marketed drugs in Singapore.

In addition, we inspect and license pharmaceutical manufacturers and importers/wholesale dealers in accordance with current international Good Manufacturing Practice and Good Distribution Practice standards respectively. This ensures the production of good quality medicines and preservation of their quality down the supply chain from the manufacturers to distributors and retailers.



Our **Centre for Drug Evaluation (CDE)** is an integral part of the infrastructure to develop Singapore as a regional medical hub and as a world hub for the life sciences research and development. Funded by the Agency for Science, Technology and Research, CDE complements the regulatory role of CPA in drug evaluation with the primary focus on the evaluation of new drugs not previously approved in other countries. This regulatory capability will help the pharmaceutical industry grow its research and development in Singapore and make Singapore the origin of new and innovative quality drugs. We aim to complete evaluation within timelines similar to those of benchmark agencies such as the US Food and Drug Administration.

### Evaluations of New Drug Applications

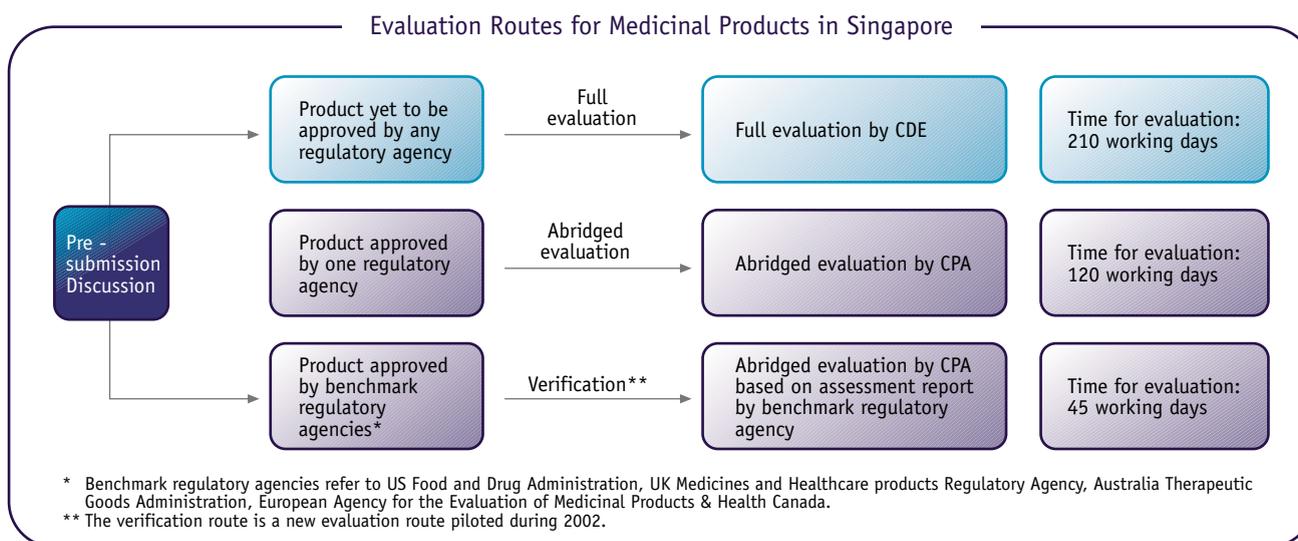
During the year, we evaluated 8 new drug applications that were not previously approved in other countries, bringing the total number of completed evaluations to 18 since 1998. This represented the highest number of completed evaluations in a year, a few of which were completed ahead of other overseas benchmark regulatory agencies. An example was Cialis, an erectile dysfunction prescription drug that we approved in January 2003, ahead of US approval. In closely tracking evaluation timelines, we continued to ensure that the science-based assessment of product safety, quality and efficacy to safeguard public health was not compromised through a system of closely coordinating the inputs of our expert evaluators, peer reviews and the Medicines Advisory Committee.



### Pre-market Abridged Evaluation and Licensing of Medicinal Products

Pre-market abridged evaluations are required if a western medicinal product has already been approved by at least one drug regulatory agency or if a generic medicinal product is manufactured locally. Once these abridged evaluations ensure that the product meets the criteria of safety, quality and efficacy, a product licence for the Singapore market will be granted.

The total number of product licences (including renewals and variations) issued for the year was 2,525. Of these, 390 licences were issued within an average of 3.2 months.



### Improving Consumer Access to Medicines

As at end-March 2003, 7,591 western medicinal products were licensed in Singapore, according to the following forensic classification:

Forensic Classification	No. of Registered Products	Percentage
Prescription Only Medicines (POM)	5,240	69.03%
Pharmacy Only Medicines (P)	1,034	13.62%
General Sale List Medicines (GSL)	1,317	17.35%
<b>Total</b>	<b>7,591</b>	<b>100%</b>

With the aim of improving public access to effective and safe drugs, 32 products were reclassified during the year.

### Reclassification of Medicinal Products

#### From Prescription Only Medicines to Pharmacy Only Medicines

These products are generally regarded as appropriate for self-medication under the supervision of a pharmacist.

30 products declassified, including

- 23 ibuprofen preparations, which provide alternatives to paracetamol and aspirin for pain and fever relief in self-medication settings
- Kenalog® in Orabase for mouth ulcer
- Regain® Topical Solution 5% for hair loss
- Nicorette® Inhaler for smoking cessation
- Bisolvon® Tablet & Elixir and Mucosolvon® Tablet & Liquid, for thinning of mucus

#### From Pharmacy Only Medicines to General Sale List Medicines

These products are now obtainable by the public without medical supervision in view of long history of use and wide safety margins.

2 products declassified, including

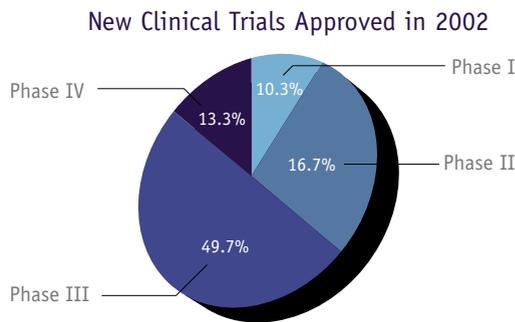
- Nizoral® Shampoo Conditioning Shampoo 1%
- Voltaren® Emulgel



A review of the Poisons Act led to the declassification of coenzyme Q10, which was allowed for sale as a health supplement from 16 September 2002. This was subject to cautionary labeling on adherence to a daily maximum dose and allowable indications.

### Regulation of Clinical Trials

In the year under review, 195 new clinical trial certificates were issued. The more common clinical trials conducted were for oncology, gastroenterology, cardiology and anti-infective products.

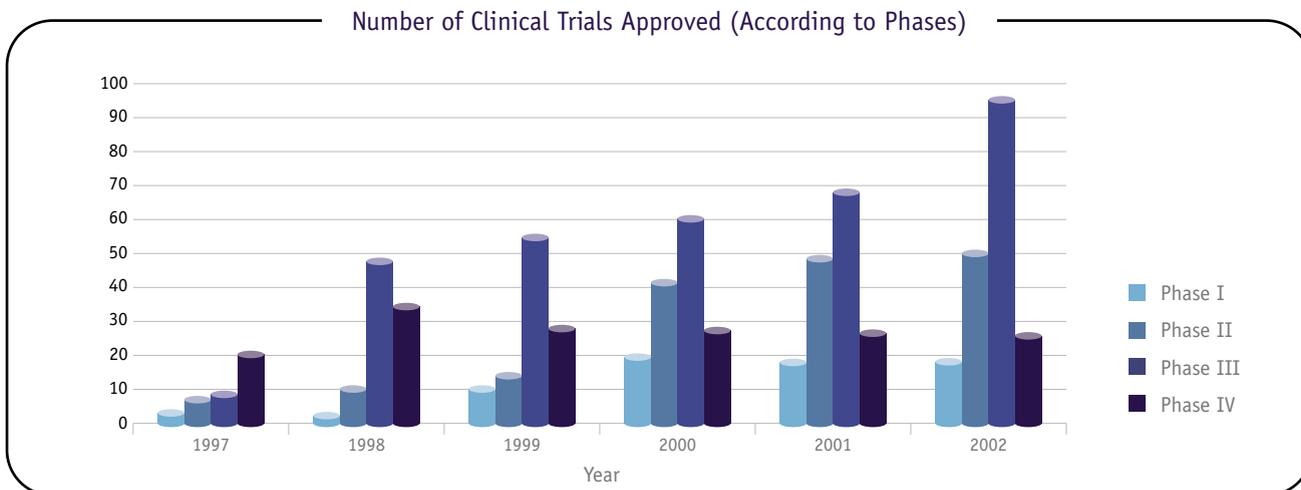


### Licensing of Manufacturers, Assemblers, Importers, Wholesale Dealers and Pharmacies

During the year, we issued 61 licences to manufacturers and assemblers of western medicinal products, Chinese proprietary medicines, cosmetic products and controlled drugs.

In the same period, 297 wholesale dealers' licences, 427 Form A\*, 260 pharmacy certificates and 8 Good Manufacturing Practice (GMP) certificates were issued. We inspected 522 sites to ensure that products were being manufactured, stored and distributed in compliance with GMP and Good Distribution Practice (GDP) standards. These standards were based on rigorous science and sound quality-assurance principles. Compliance with GMP and GDP would reduce the probability of defective or hazardous products entering the distribution system.

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





Other licences issued were 542 import licences, 88 export licences, 671 Form C\*, 448 certificates of pharmaceutical products and free sales certificates for Chinese proprietary medicines. An additional 212 import licences and 29 export licences were issued for psychotropic substances and narcotic drugs.

*\* 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

In April 2002, CPA was invited to participate in the Pharmaceutical Inspection Co-operation Scheme (PIC/S) delegation assessing Taiwan's application for PIC/S membership. The objective was to assess the GMP Inspection and Licensing system of its National Laboratories of Food and Drug.

In addition, we also participated in a PIC/S Joint Audit, arranged by PIC/S and Australia's Therapeutic Goods Administration. A PIC/S Joint Audit is intended to harmonise and calibrate the GMP audit approach, knowledge and skills of the auditors to establish consistency of GMP audits throughout the various PIC/S member authorities.

### Regulation of Chinese Proprietary Medicines

As at 31 March 2003, the total number of licensed Chinese proprietary medicine (CPM) importers, manufacturers, repackers and wholesalers stood at 194, 23, 30 and 289 respectively, and the total number of CPM products listed was 10,224. During the year, there were 3,495 applications for CPM product listing, and 1,392 products were allowed to be listed.

### Enhanced Regulatory Control of CPM

In August 2002, the enhancement of the control of CPM was announced, comprising the following additional measures:

- From 1 January 2003, CPM products should carry an additional label "Allowed for sale as a Chinese Proprietary Medicine" on the outer sales packs in both English and Chinese. This move would help consumers differentiate CPM from western drugs.
- From 1 January 2004, only test reports issued by accredited laboratories will be recognised and accepted by HSA for high-risk CPM products. This will enhance the reliability of test reports at the pre-marketing assessment stage for high-risk CPM products and for their subsequent imports.
- Our existing quality surveillance programme has been strengthened. The testing protocol has been enhanced in terms of risk assessment, with more targeted testing based on product indications and claims. All local and overseas CPM manufacturers will eventually be subject to periodic GMP audits according to international standards to weed out unreliable sources, including overseas on-site audits for manufacturers not already subject to PIC/S standards.



### Regulation of Health Supplements

Pending the implementation of regulatory control of health supplements in 2004, an enquiry service was established to handle enquiries relating to health supplements from the trade and the public. We managed a total of 5,221 enquiries in the year under review.

In January 2002, we issued a guidance letter to health supplement traders for the voluntary withdrawal of piper methysticum – commonly known as kava-kava – products, following overseas adverse drug reaction reports of hepatic toxicity associated with its consumption. Subsequently in July 2002, we banned the import and sale of kava-kava products altogether. This precautionary move was made after consideration of the German Federal Institute for Drugs and Medical Device’s completion of a safety review of kava-kava and its subsequent action to ban products containing kava-kava. Legislative amendments to include kava-kava and its constituents under the control of the Poisons Act were also instituted that month.

### Regulation of Cosmetics

During the year, we issued 11,101 cosmetic product licences. These included new cosmetic product licences, renewed licences and amended product licences. During the same period, 490 import licences were also issued.

In February 2002, we reviewed the cosmetic licensing processes to provide the industry flexibility in applying for a single licence for palettes of fixed colours, in addition to the current system of a single licence for each cosmetic product. Companies could now choose either scheme to apply for their cosmetic licences to optimise the fee quantum to be paid.

### Adverse Drug Reaction Reporting Programme

In 2002, we received a record number of 801 adverse drug reaction (ADR) reports from the healthcare professionals, a 40% increase compared to 2001. The increase was a good outcome indicator of the continual effort made to promote the reporting of any suspected adverse drug reactions encountered to the Pharmacovigilance Unit for collation and further investigation when necessary. Spontaneous ADR reporting and monitoring has been recognised internationally as a powerful and effective tool for the detection of potential drug safety problems that may arise after the drugs have been marketed and used widely in the general population. Through local ADR reports received in 2002, drug safety problems associated with Slim 10 and jarem encok were detected. They were found to be adulterated with synthetic western drugs when tested subsequently.

5 “Dear Healthcare Professional” letters on new safety information including hormone replacement therapy, Eprex, and pure red cell aplasia, kava-kava and liver toxicities and Slim 10 were issued to inform the healthcare professionals and the public on major drug safety issues that had resulted in significant regulatory actions.

Leveraging on the wide applications of information technology, we established an e-mail address database of more than 4,000 doctors and pharmacists in Singapore to facilitate the dissemination of urgent drug safety information to our healthcare professionals in a timely manner. In addition, to facilitate reporting of ADR by the healthcare professionals, an online reporting channel was developed to enable these professionals to submit reports electronically through the Internet.



### Regulation of Medical Advertisements and Sales Promotions

We regulate medical advertisements and sales promotion for medicinal products to ensure that the information presented is accurate and not misleading. During the year, we issued 1,468 permits for medical advertisements out of 1,536 applications received.

Following a comprehensive review conducted from November 2002 to February 2003, all indirect advertisements and consumer education materials for Prescription Only Medicine (POM) would be classified as medical advertisements to distinguish genuine consumer education materials from indirect advertisements of POM. This followed some cases of indirect or “consumer education” advertising that were construed as POM advertising.

As a council member of the Advertising Standards Authority of Singapore, we continued to provide advice for the clarification of issues related to the advertisement of medicinal and health-related products. We also worked with the Singapore Association of Pharmaceutical Industries to explore the role of the industry in co-regulating medical advertisements and sales promotions.

### Investigation, Surveillance and Prosecution

Like our benchmark regulatory agencies, we detect health fraud through a variety of ways. We may identify a violation or a suspected fraudulent product through our inspectors’ routine market-place



surveys, searches on the Internet, ADR reports, complaints from consumers, healthcare professionals and trade competitors, or through referrals from other government authorities.

During the year, 401 cases from various sources were investigated which led to the recall of 28 products. Of these, 19 cases were prosecuted in court resulting in \$231,500 of total fines imposed and two cases with two-week and six-week imprisonment terms imposed, respectively.

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### Investigations into Adulteration of Slim 10 and Prosecution Actions

Slim 10, listed as a CPM, generated a series of ADR reports from end March 2002. These reports of suspected liver injury and hyperthyroidism rapidly triggered a cascade of investigations and regulatory actions against the product, including the withdrawal of the product from the market on 19 April 2002. Publicity was used to warn consumers and health professionals on the adulterated batches that entered the market.

Following the investigations, the importer, Health Biz Pte Ltd, was prosecuted for 9 charges under the Medicines Act, namely 8 counts of selling Slim 10 without having first confirmed that the imported consignments were free from poisons and other synthetic substances, and one charge for failing to keep import records of Slim 10 brought into Singapore. The importer, who pleaded guilty to the charges, was convicted and sentenced to the maximum fine of \$5,000 on each of the nine charges in September 2002. Following the conviction, we also revoked the importer's Import licence and Wholesale Dealer's licence.

The local distributor, TV Media Pte Ltd, was also prosecuted for its role in the distribution and sale of Slim 10. The distributor was fined \$64,000 in July 2002, after it had pleaded guilty to 20 counts of unlicensed wholesale dealing and, more significantly, 8 counts of charges relating to its sale of Slim 10 after HSA had recalled the product.

The findings of our investigations and regulatory actions also featured in a Coroner's Inquiry into a death suspected to be caused by Slim 10. The Inquiry subsequently ruled that the death was caused by negligence on the part of the importer of Slim 10.

To allay public concerns on slimming products following the recall of Slim 10, we tested all 45 locally listed CPM marketed for slimming and weight loss in June 2002, and 163 health supplements and 11 popular jamu products marketed for slimming in August 2002. All test results indicated that the samples were free from adulteration of synthetic western drugs including a comprehensive range of western pharmaceutical agents related to slimming.

During the year, we also conducted raids, after a period of close surveillance on peddlers involved in the sale of illegal medicines near markets, MRT stations, temples and other roadside areas.

Legal actions against the offenders were taken as some unlisted CPM and unregistered medicinal products seized were found to contain sildenafil (active ingredient in Viagra®), steroid ointments and anti-fungal preparations.

To address the growing concern of illegal imports of medicinal preparations, we enhanced our co-operation with other government agencies. A guideline on procedures for the clearance of hand-carried medicinal and health-related products was issued to the Customs and Excise Department (since reorganised into the Immigration and Checkpoints Authority) officers to help them in



identifying products controlled by HSA and to prevent their illegal import. We investigated the cases surrounding such seizures for further information and leads, so as to stem out the source of the illegal imports.

We also reviewed the illegal sale of codeine-containing cough mixtures with the Singapore Police Force, the Singapore Immigration and Registration Department (since reorganised into the Immigration and Checkpoints Authority) and the Central Narcotics Bureau. In April 2002, these government agencies, in a co-ordinated effort, conducted raids in the vicinity of North Bridge Road and Stamford Road, nightspots in the city centre and at Balestier Road. The joint operation led to the arrest of 56 immigration offenders as well as abusers and peddlers of cough mixtures containing codeine. Large quantities of codeine-containing cough mixtures were seized from these offenders.

As an agency that protects public health and safety, we keep in touch with the various stakeholders and respond swiftly to



alerts and feedback. Following media feedback in July 2002, we promptly deterred a range of luohan kuo health supplements from making medicinal claims in their promotional materials, and the media highlighted the misleading and medicinal claims made for the products.

### Tobacco Regulation

During the year, we granted 7,489 tobacco retailer licences, and took to task 7 retailers for selling cigarettes without valid licences.

We intensified our enforcement efforts to prohibit smoking by youths under 18 years old. The increased surveillance resulted in a total of 4,153 underage youths caught smoking or possessing cigarettes. Some 1,554 young offenders were compounded and 253 were prosecuted in court.

In FY 2002, 384 cigarette samples were sampled from the market and tested. The results showed 99% compliance rate of the legal limit of tar and nicotine contents in cigarettes retailed locally. Out of these samples, one product indicated a tar content level that exceeded the legal limit, and with our confirmatory laboratory test results, we took enforcement action against the distributor involved.

During the year, we met regularly with the Customs and Excise Department to provide advice and assistance on health warning exemptions and approvals for checks on imported cigarettes. These sessions reaffirmed our commitment to support the government's initiative for mandatory health warning labels for tobacco products as a means to inform the public of the health hazards from the use of tobacco.



Based on the recommendation of the Committee on Smoking Control that provided overall policy direction for the National Smoking Control Programme, the amendments to the Smoking (Control of Advertisements and Sale of Tobacco) (Amendment) Bill were proposed and passed by the Parliament on 31 October 2002. Among the various amendments, licensing of importers and distributors would be required and powers of investigation for authorised officers under the Act would be refined. Cigarettes imported or sold in Singapore would list other constituents in addition to tar and nicotine and the fine quantum of under-aged smoking offences would be increased.

### Grey Area Products Task Force

In January 2003, we formed a working group with the Agri-Food & Veterinary Authority to address issues of concern pertaining to product classification of “grey area” food products, which might be fortified with herbal ingredients.

We also set up a Grey Area Products Task Force in March 2003 to look into other health products that did not fit clearly under existing classifications.

### Biologics Task Force

Research and development in new technologies in biotechnology and genomics has been leading to an increasing scientific complexity of products including more biologics in the pipeline. In order to accurately assess the readiness of these products to be marketed in Singapore and help these innovative products reach our patients as quickly as possible, we proactively set up a Biologics Task Force to address the regulation and evaluation of biological products.

### Compliance and Complementary Medicines Division

In August 2002, we realigned our organisational structure to form a new Compliance & Complementary Medicines Division in order to meet the new challenges in regulating complementary medicines like traditional medicines and health supplements. The reorganisation would serve to optimise the use of resources and the collective knowledge and experience to better respond to the needs of the various stakeholders in Singapore.

### The Year Ahead

As part of our ongoing broader efforts to strengthen and modernise our pharmaceutical and health-related products regulatory system to protect public health and safety as well as to make safe and effective drugs available to Singaporeans, we have lined up several new initiatives in the coming year. Looking ahead, some of these include:

- The implementation of a new verification route that offers faster assessment timelines for certain categories of medicinal products that are already registered in benchmark agencies. The pilot phase is currently underway.
- A new drug registration guide and application form that will be in line with the new International Conference of Harmonisation and ASEAN common technical dossier requirements and formats. This initiative will facilitate the objective of the ASEAN Free Trade Area through a common template for the submission of drug applications.



- The implementation of a new clinical trials regulatory framework based on a risk-based approach. The new framework aims to ensure high standards of clinical research and safety to protect the trials' subjects without impeding trials' timelines and the progress of research in Singapore.
- The implementation of the health supplements regulatory framework in phases.
- The launch of the Pharmaceutical Registration and Information System (prism@hsa), an integrated electronic licensing system to support various activities in the regulatory systems. The prism@hsa system will enable the electronic submission of all licence, permit and certificate applications from trade representatives dealing in western medicinal products, Chinese proprietary medicines, health supplements, cosmetics and tobacco. In addition to facilitating the application process, which can be carried out during out-of-office hours, prism@hsa will allow applicants to track the approval status of their applications online.

## REGULATING MEDICAL DEVICES

Our **Centre for Medical Device Regulation (CMDR)** keeps a close tab 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 2003, there were 406 licensed contact lens practitioners in Singapore.



### Voluntary Product Registration Scheme

In April 2002, a Voluntary Product Registration Scheme for higher-risk medical devices was introduced. By end-March 2003, we had received 1,047 case applications and encouraging response and support from the medical device industry.

The scheme, which was introduced as an interim measure to statutory controls, offered all stakeholders a foretaste of the various levers of regulatory controls. During this phase, we maintained regular dialogues and interactions to guide and educate the industry and to receive valuable feedback to improve the regulatory process. Each industry stakeholder also had the opportunity to evaluate the feasibility of the proposed medical device regulation framework and to participate in the strategic development of the programme.

The regulatory framework would also consist of maintaining an efficient and effective post-market surveillance system. This would include the analysis and prompt investigation of adverse incident reports relating to medical devices and taking any necessary action to safeguard public health. To date, the industry has shown good support for the vigilance programme through the increased reporting of adverse incidents under the voluntary scheme. During the year, medical device manufacturers submitted incident reports of 15 product recalls and 4 adverse incidents relating to medical devices worldwide. These companies also duly followed up with the appropriate corrective actions including recalls of products that were sold in Singapore.

### The Year Ahead

In the next year, we will continue with the preparatory works following the introduction of a statutory framework for medical devices. As in the voluntary scheme, our main focus is to continue to engage, consult and communicate with the industry stakeholders on the regulations and procedures, while closely monitoring outcomes and performance.

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. Looking ahead, the medics@hsa will provide a web-based channel for business partners to make convenient transactions 24 hours a day for product applications, registration and licensing. medics@hsa will also feature a useful online medical device register.



## ENSURING RADIATION SAFETY

Our **Centre for Radiation Protection (CRP)** administers and enforces 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 our 7 laboratories include personal monitoring of all radiation workers, testing of imported food and industrial samples for radioactive contaminants, testing for leakage of sealed radioactive sources and calibration of radiation measuring instruments.



## Ionising and Non-ionising Radiation Licensing and Inspections

During the year, 20,904 licences were issued, for the purposes of import, export, sale, possession and use of irradiating apparatus and radioactive materials and for the transport of radioactive materials. 1,467 endorsements were given for the import / export of components of irradiating apparatus without the radiation emitting components, and 101 endorsements were made for ships carrying nuclear consignments such as nuclear fuel rods, uranium hexafluoride with natural uranium or enriched uranium to transit in Singapore.

We also made 419 inspections at medical, dental and veterinary practice premises and industrial and educational institutions, compared to 397 inspections in 2001. The inspections were required for premises using ionising radiation (IR) irradiating apparatus or radioactive materials. Checks were made to assess that the facilities and equipment were in proper condition and that radiation levels at places accessible to the public were within limits specified in the regulations.

We conducted a further 26 inspections for premises using non-ionising radiation (NIR) apparatus and 14 surveys at handphone base-stations and radio / television transmitting stations.

Further, to ensure that radiation levels emitting from microwave ovens sold in Singapore were below that specified in the Regulations, we checked 29 new models of microwave ovens from different manufacturers.



### **X-Ray Mammography Quality Assurance Programme**

As part of our continuing effort in ensuring radiation safety, we placed emphasis on quality control and assurance in medical applications of X-rays. In July 2002, we collaborated with the Health Promotion Board to ensure that all mammography X-ray facilities had the necessary quality-control programme in place at the clinics. By year-end, we inspected and certified more than 10 clinics with mammography X-ray facilities.

### **Personal Monitoring Service**

As part of the regulatory control, we monitor all radiation workers in Singapore closely. During the year, more than 72,000 thermoluminescent dosimeters were issued to these workers. These dosimeters were processed monthly to ensure that the radiation doses were within limits specified in the regulations. The number of overdose cases investigated by us decreased to 40 this year, from 46 cases in 2001, occurring mainly in industrial radiography.

Additional dosimeters in the form of rings were issued to monitor the radiation dose to the fingers for those workers handling radioactive materials that emitted beta radiation or low energy gamma radiation.

### **Wipe Tests and Radioactivity Analysis**

During the year, we performed a total of 515 wipe tests, compared to 470 tests in 2001, at establishments that use sealed radioactive sources in industrial, medical and research applications.

We also conducted radioactivity analysis on food samples. In 2002, the number of food samples tested and certified free from radioactive contaminants increased by 415 to 1,770 samples.

In addition, we were involved in the detection of radioactivity levels in environmental samples, such as soil and water, copper and tin slags, steel rebars, marble, granite, etc.

### **Ionising Radiation Dosimetry**

Our Secondary Standards Dosimetry Laboratory calibrated a total of 347 radiation-monitoring devices used by companies and hospitals in Singapore. Our laboratory, the national reference centre for radiation protection and environmental dosimetry, was established with the support of the International Atomic Energy Agency and the World Health Organisation as part of the international network of secondary reference laboratories.

### **Nuclear Safety and Emergency Planning**

During the year, we were engaged as the project consultant for the new remote radiation monitoring system that was successfully installed and commissioned at Changi Naval Base.

We are now able to access dose readings of detectors at two monitoring stations at Changi and Sembawang wharves via computers and telephone lines. These stations provide 24-hour monitoring to give early warning in the event of a radiological accident during the visits of nuclear powered warships. In 2002, 8 such warships visited Singapore.



### Radiation Consultancy and Training

We provided a total of 79 consultancy services on all aspects of ionising and non-ionising radiation protection to industries, ministries, statutory boards, hospitals and the general public. The services covered 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.

To raise the general standard of radiation safety in industrial radiography, we started a training course in October 2002 on

radiation protection for industrial radiographers. The course aimed to provide sufficient knowledge of the radiation hazards associated with the industrial radiographers' work and the awareness of appropriate protective measures so as to minimise the occurrence of radiation accidents.

Lectures and training on radiation safety were also delivered to medical doctors, dentists, undergraduates and radiation workers in hospitals, universities and commercial companies. Under a memorandum with the International Atomic Energy Agency, we also provided training to a consultant radiologist from the Myanmar General Hospital in radiation protection, quality assurance in radio-diagnostic and planning and preparedness for radiological emergency in the event of an accident or incident.

### The Year Ahead

As part of our ongoing efforts in upholding radiation safety, we will continue to promote radiation protection training and education locally and regionally. In our efforts to ensure quality control and assurance in medical applications of X-rays, we will continue our collaborations with the Health Promotion Board so that all mammography X-ray facilities have the necessary quality control programme in place. For the year ahead, we will also work towards raising the general standard of radiation safety in industrial radiography and minimising the level of radiation exposure to workers.



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**serving justice** ■ 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 providing 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.



“We progress and keep pace in serving the changing requirements of justice by streamlining our processes, investing in the latest equipment, developing new capabilities and raising our professional standards.”

**Elliot Lau**  
Manager, Special Investigations  
Centre for Forensic Medicine

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Coroner's Cases

3,325

Clinical Forensic Medicine Cases

323

Forensic Science Exhibits / Cases

64,343

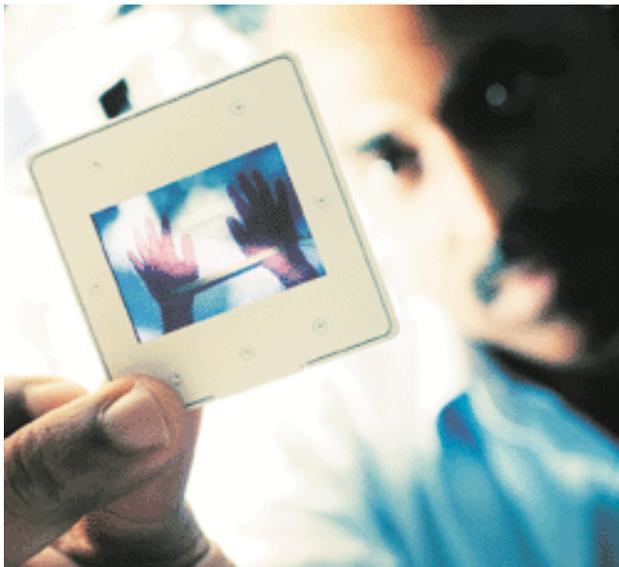
Quest for NAME Accreditation, Improved Customer Care at  
Mortuary, Performing Autopsies on SARS Victims,  
New Forensic Science Capabilities, New DNA Database Laboratory,  
International Reference Laboratory for  
Biological Specimen



## PROVIDING FORENSIC PATHOLOGICAL AND INVESTIGATIVE SERVICES

Our **Centre for Forensic Medicine (CFM)** undertakes the sole responsibility in Singapore to examine Coroner’s cases and perform autopsies that are authorised by the Coroner. We also carry out autopsies requested by private clients including parties from hospitals and regional countries.

We provide crime scene investigative services to the Police in cases of homicides or cases of suspicious deaths. These services help to provide preliminary inputs that assisted the Police in their investigations.



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.

Also applying our professional expertise in trauma and injury to the living, we offer clinical forensic medical consultations 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 death certification services for Coroner’s cases.

During the year, we handled 3,325 Coroner’s cases and of these, we conducted 2,050 autopsies. We also investigated 323 clinical forensic medicine cases.

### CFM Workload Statistics for FY 2002

No. of Coroner's cases	3,325
No. of Coroner's autopsies	2,050
No. of private autopsies	18
No. of forensic death investigator's cases	410
No. of clinical forensic medicine cases	323
No. of DNA Profiling cases	189



### Quest for NAME Accreditation

In order to benchmark our professional services, we embarked on the quest to achieve accreditation with the National Association of Medical Examiners (NAME). NAME is the only known international standard that accredits Offices of Forensic / Medical Examiners in an integrated holistic manner. As an ongoing effort for accreditation with NAME, we participated in its annual meeting in September 2002 and visited three NAME-accredited centres for further insights into the operations of accredited centres.

To align with international best practice and to achieve structural compliance with NAME standards, an operational plan was devised which included a major renovation initiative that commenced in March 2003. We would be upgrading our isolation autopsy suite and general autopsy suite to handle Bio-Safety Level 3+ cases. These initiatives would increase our capability to cope with situations of mass disaster, infectious disease outbreaks and bio-terrorism.

### Improved Customer Care at Mortuary@HSA

The public waiting area at the Reception of our mortuary for the next-of-kin was extensively renovated to provide a clean, comfortable, well-lit and pleasant area, promoting an environmental sense of calmness and serenity at a time of distress. We also created an interview room to allow for meetings with the next-of-kin in privacy. Counter officers were also sent for enhanced customer care training.



### Performing Autopsies on SARS Victims

March 2003 saw the outbreak of Severe Acute Respiratory Syndrome (SARS) in Singapore. Our forensic pathologists were tasked to carry out autopsies on SARS victims under the Infectious Diseases Act. An emergency implementation of strict protocols and safety audit was adhered to for the handling of SARS cases.

### Medical Audit and Health Regulation

We conduct a monthly mortality review for all perioperative (iatrogenic) deaths and fatal adverse drug reactions that have been reported as Coroner's cases. The results of the internal review are provided to support the Ministry of Health's clinical audit. In August 2002, a paper on "Lessons in Trauma from the Mortuary" was presented at the 1st National Health Group Scientific Congress.



### Clinical Learning and Teaching

In August 2002, Dr Michael Baden, a world renowned medical examiner, provided an enriching two-week training and consultancy to the Centre and its key stakeholders. Held under the Ministry's Health Manpower Development Plan, this training complemented our regular programme of continuing medical education and systematic programme of training for doctors aspiring to become forensic medical experts.

To foster regional goodwill and networking, two doctors were attached for training for a period of 10 weeks from September 2002 under the Philippines-Singapore Action Plan. An Australian medical student was also attached to the Centre for three weeks to pursue a project on comparing deaths related to drugs in Singapore and the State of Victoria in Australia. We also hosted the visit by a forensic delegation of three doctors from Vietnam in October 2002.

### The Year Ahead

Looking forward, we will work towards a Memorandum of Understanding with our Australian counterpart, the Victorian Institute of Forensic Medicine. This alliance will enhance reciprocal exchanges of information and resources and facilitate the development of professional competencies and scientific collaboration between the two centres.

## PROVIDING FORENSIC SCIENTIFIC, INVESTIGATIVE AND ANALYTICAL SERVICES

Our **Centre for Forensic Science (CFS)** provides a one-stop forensic science service and consultancy to law enforcement agencies, government ministries, hospitals, private organisations and individuals for criminal and medico-legal investigations and civil disputes. Our 7 laboratories provide specialised scientific, investigative and analytical expertise in the areas of criminalistics, DNA profiling, DNA database, narcotics, toxicology and document examination.





**CFS Workload Statistics for FY 2002**

	Criminalistics Lab	DNA Database Lab	DNA Profiling Lab	Document Examination Lab	Narcotics I Lab	Narcotics II Lab	Toxicology Lab	Total
Exhibits / Cases Completed	1,051	1,282	3,260	385	5,638	35,847	16,880	<b>64,343</b>
Revenue (SGD)	1,900,876	175,634	2,817,074	1,023,757	3,998,028	2,824,409	3,095,922	<b>15,835,700</b>
Work Value (Man Hours)	5,971	641	18,763	4,114	28,557	23,537	25,801	<b>107,384</b>

During the year in review, we completed a total of 64,343 cases yielding a total revenue of \$15.84 million. Compared to the previous year, the number of exhibits and cases had dropped by 12.2%, mainly due to a 33.9% drop in urine specimens for opiates screening. The revenue, however, increased by 6.6% as a result of a 10.5% growth in the number of other cases and the low cost of opiates screening.

Since 1996, CFS has been accredited by the American Society of Crime Laboratory Directors / Laboratory Accreditation Board (ASCLD/LAB), an international benchmark accreditation scheme for forensic laboratories. We have 14 senior forensic scientists who are qualified ASCLD/LAB inspectors. Apart from the DNA Database Laboratory, which was set up only in February 2003, all our laboratories have passed the annual internal ASCLD/LAB accreditation audit. Our DNA Profiling Laboratory also successfully passed the bi-annual ASCLD/LAB external accreditation audit.

**New Forensic Science Capabilities**

During the year, we developed the following new capabilities to cater for our clients' requirements and to keep pace with new and emerging technologies:

**Criminalistics Laboratory**

- Completion of the validation of the Renishaw Confocal Raman Microspectrophotometer in October 2002. This powerful new technique would greatly extend our capabilities in identifying and comparing a wide range of unknown organic and inorganic materials: paints, surface coatings, pigments, paper, fibres, polymers, explosives, propellants, soils, minerals, gemstones, aqueous solutions, and unknown organic and inorganic substances.





- Physical comparison of packaging materials and containers such as plastic bags, paper bags, envelopes and plastic bottles using macroscopic class features and microscopic manufacturing defects to ascertain their origins and establish connections in drug trafficking cases and criminal cases.
- Microstructure study of soft gold alloys, and acquired competencies in grinding, wet-polishing, etching and the SEM/EDX (scanning electron microscope with an energy-dispersive X-ray analyser) analysis and interpretation of phases which could be applied to determine the causes of failure and fractures of metal objects and structures.

#### ***DNA Profiling Laboratory***

- Real-time polymerase chain reaction method for the quantification of DNA recovered from casework, which would be faster, more specific and more informative than the chemiluminescent method.

#### ***Narcotics I Laboratory***

- Information from the study on “Characterisation and Profiling of Illicit Methamphetamine Tablets Abused in Singapore” to help drug enforcement agencies to establish possible links between different seizures of the methamphetamine tablets or different distribution networks.

#### ***Narcotics II Laboratory***

- Screening of ketamine and its metabolite, norketamine, in urine using an ELISA test kit has greatly reduced the number of confirmatory tests needed, thus saving costs and time for our clients.



#### ***Toxicology Laboratory***

- Screening method based on the kinetic interaction of micro-particles in solution for workplace drug testing and for clinical trial urine sample testing.
- Analytical method to differentiate the enantiomers *d*- (dextro) and *l*- (levo) methamphetamine and *d*- and *l*-amphetamine, useful in determining if a urine donor has been using a prescription medication or abusing an illicit drug.



### **New DNA Database Laboratory**

Our new DNA Database Laboratory was launched in February 2003 in collaboration with the Police after the amendment of the Registration of Criminals Act was passed in Parliament in December 2002. This amendment empowered retroactive sampling of all persons convicted of registrable offences. In February 2003, 13,243 samples were taken from inmates at 14 prison centres. The daily submissions from the various Police divisions ranged from 41 to 129 samples, averaging about 80 samples.

### **Inclusion of Tube Sparklers in Dangerous Fireworks Act**

Our Criminalistics Laboratory successfully initiated the inclusion of tube sparklers as dangerous fireworks in the Dangerous Fireworks Act after conducting laboratory testing in February 2003. With effect from 1 April 2003, any sparkler that comprised a tube containing pyrotechnics and was designed to propel a flame resembling the pyrotechnics of a flare would be classified as dangerous fireworks.

### **Overseas Cases on Handwriting and Signature Examination**

Our Document Examination Laboratory received several cases from overseas on handwriting and signature examination, including one case appointed by a high court in Berlin, Germany to examine Chinese signatures in a civil case involving business agreements. The court made its judgement based on the report submitted by our laboratory.

### **International Forensic Automotive Paint Data Query Program**

Our Criminalistics Laboratory signed an agreement with the Royal Canadian Mounted Police Edmonton Forensic Science Laboratory, marking its entry as a partner in the International Forensic Automotive Paint Data Query programme. This collaboration was strategic to our forensic investigations as we could now gain access to a comprehensive searchable paint database for nearly 13,000 vehicles and more than 46,000 paint layers.

### **International Reference Laboratory for Biological Specimen Group**

In April 2002, our Narcotics II Laboratory was invited by the United Nations International Drug Control Programme to be a reference laboratory for the Biological Specimen Group. This followed an earlier invitation in June 2001 to the Narcotics I Laboratory to be a reference laboratory for the Seized Material Group. The Programme organises bi-annual International Collaborative Exercises where test samples from the seized material and the biological specimen groups are sent to the participating laboratories. Results from the reference laboratories provide the baseline information that will be used to evaluate results reported by the participating laboratories.



### Collaborative Research Projects

During the year, our Narcotics II Laboratory collaborated with the Central Narcotics Bureau on a project to detect the presence of opiates in hair. The results of the project, which was completed in October 2002, showed that 6-monoacetylmorphine and codeine could be detected in hair samples of opiate abusers. A pilot study was further initiated to look into the feasibility of using hair testing in drug monitoring.

In September 2002, we also collaborated with the National University of Singapore's Chemistry Department to initiate joint research and to leverage on each other's scientific capabilities.

### The Year Ahead

For the coming year, we aim to expand our scientific and analytical capabilities to better serve our stakeholders.

We will be investing in new state-of-the-art equipment to further advance our core capabilities and to position ourselves as a world class centre of excellence for forensic science. Our future assets will include:

- liquid chromatography / tandem mass spectrometry systems for narcotics and toxicological analysis
- another scanning electron microscopy to reduce the turn-around-time of gun shot residue analysis
- a GRIM 3 to replace the old GRIM 2 for glass refractive analysis
- a new voltammetry system for the quantitative analysis of a wide range of metal ions (including oxidation states), specific analysis of organic compounds and determination of anions

- another 3100 DNA sequencer to reduce the turn-around-time for DNA profiling.

In order to meet the challenges of the 21st Century, we plan to:

- encourage staff to adopt innovative approaches and rethink current processes
- nurture and train staff to foster professionalism and improve performance
- benchmark critical measures and processes, setting competitive and comparative targets
- harness advanced technology for more rapid, sensitive and specific analyses
- streamline procedures
- develop new capabilities to fill gaps and diversify into other evidence types
- conduct regular dialogue sessions to build understanding and garner rapport and support from our clients to better meet and shape their needs and expectations.





CPA

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CFM

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CTM

CAS

**delivering services** ■ At HSA, we exploit science 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 the point of blood collection to processing and issuing 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.



“Applying the best of science, technology and discipline in our processes and systems and building up our blood donor base ensure our nation will have a safe and adequate blood supply even through emergency situations.”

**Dr Tan Hwee Huang**  
Head, Blood Resources  
Centre for Transfusion Medicine

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Whole Blood Donations

**68,406**

Apheresis Donations

**6,504**

Diagnostic Screening Tests on Donated Blood

**713,462**

Processed Blood Products

**165,902**

Analytical Tests for Laboratory Samples

**57,335**

Turnaround Time for Laboratory Samples

**8 days**

1st Regional Quality Management Training Course in Blood Transfusion Services, Apheresis Suite@HSA, Swift Response to SARS Outbreak, Accreditation of Laboratories under ISO/IEC 17025, Singapore Quality Class, Second Patent Filed, Accredited Laboratories for Chinese Proprietary Medicine Testing



## PROVIDING ESSENTIAL BLOODBANKING SERVICES

Our **Centre for Transfusion Medicine (CTM)**, which operates the Bloodbank@HSA, is responsible for ensuring a safe and adequate national blood supply. Dedicated to serving the public interest, we achieve our mission by upholding medical, ethical, regulatory and professional standards, and by supporting research in the fields of blood services and transfusion medicine.

We partner and leverage on the Singapore Red Cross Society's humanity programme to promote the importance of donating blood to help those in need. Through the Red Cross, which plays the role of National Blood Donor Recruiter, we develop and implement appropriate national awareness strategies and recognition programmes targeted at recruiting and retaining blood donors.

As a WHO Collaborating Centre for Transfusion Medicine, we contribute to improving the standards and practice of transfusion medicine and promoting blood safety and quality in the Western Pacific Region.



During the year, we collected 68,406 whole blood donations from donors and processed these into 165,902 blood components. A total of 6,504 apheresis procedures was carried out.

We further performed 713,462 diagnostic tests including screening tests on blood donations for transfusion transmissible diseases like Human Immunodeficiency 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 bone marrow and organ transplantation.

### 1st Regional Quality Management Training Course in Blood Transfusion Services

As a WHO Regional Training Centre for the Quality Management Programme, we organised the 1st Quality Management Training Course in Blood Transfusion Services in the Western Pacific Region from 15 April to 3 May 2002. Attended by senior blood bank and health officers from 11 countries in the region, the 17-day course imparted the fundamentals of quality management in blood safety so that participants could implement the system in their respective countries. The Opening Ceremony was graced by Dr Balaji Sadasivan, Minister of State (Health and the Environment) as the Guest-of-Honour.

### Apheresis Suite@HSA

As part of our continuing efforts to provide quality donor care, a newly renovated and fully dedicated state-of-the-art Apheresis Suite@HSA was also officially launched on 15 April 2002 during the Opening Ceremony of the 1st Quality Management Training Course in Blood Transfusion Services.

## delivering services



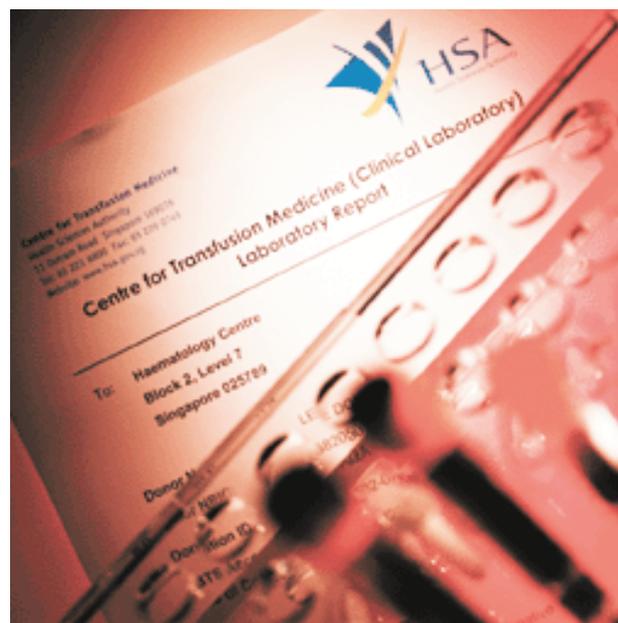
The new Apheresis Suite@HSA provides a more comfortable and relaxed environment for our regular donors who not only sacrifice more time at each donation, but also make more frequent donations of up to 6 times a year. Each apheresis donor can now enjoy his personal choice of the latest movies and full terrestrial networks via the individual TV monitor attached to each apheresis donation couch.

### Haemovigilance Programme

In our broader efforts to further enhance the integrity of our blood safety and clinical utilisation programme, a symposium on Haemovigilance was organised on 15 June 2002 in conjunction with the Annual Meeting of Hospital Transfusion Committees. This was followed by initiation of a pilot Haemovigilance programme from September 2002, which was formally implemented in January 2003.

### Revised Criteria for Variant Creutzfeldt Jakob Disease & Medical Benefits Scheme for Blood Donors and Nominees

On 1 July 2002, we revised our donor criteria to exclude people who had lived in the United Kingdom for more than three months



or in Europe for more than five years. These moves were taken as precautionary measures to prevent the variant Creutzfeldt Jakob Disease in our national blood supply. The revised Medical Benefits Scheme for Blood Donors and Nominees was also implemented.

### Leveraging on Information Technology

In the continuous journey to make blood donation convenient for the modern-day blood donors, we embarked on an e-service initiative, DonorCare@HSA. The objective of DonorCare@HSA is to provide an easy, accessible and user-friendly interface with busy donors.

We also exploited IT to streamline and improve the process of approval and issue of blood and blood components. This project was completed in March 2003.



### Swift Response to SARS Outbreak

The year posed additional challenges with the outbreak of Severe Acute Respiratory Syndrome (SARS) in mid-March 2003. We promptly implemented precautionary measures from 18 March 2003 to ensure the continued safety of the national blood supply and to minimise our blood donors' exposure to SARS. Donor health questionnaires contained questions on possible SARS exposure risks, which were updated regularly as the outbreak developed. Additionally, our staff were vigilant in monitoring their own health closely to safeguard the health of blood donors.

### Clinical Learning and Teaching

Through the Ministry's Health Manpower Development Plan, we continued to invite international expert speakers to complement the regular teaching programme for all levels of staff, where local clinical experts also conducted tutorials and lectures.

In June 2002, Dr Paul Holland, an international transfusion expert, provided enhanced learning on haemovigilance to our officers and clinical stakeholders through a series of lectures and round table discussions.

In March 2003, Dr Cees Th. Smit Sibinger, Director, WHO Collaborating Centre and Academic Institute for International Development of Transfusion Medicine, Netherland, and Vice-President, American Association of Blood Banks, conducted a series of lectures in the area of Quality Systems in Transfusion Medicine. Dr Sibinger also delivered the keynote address at the HSA-NUS Joint Scientific Seminar held in April 2003.



### The Year Ahead

Our journey to align with the highest standards in transfusion medicine is on track as we plan for an audit and accreditation by the American Association of Blood Banks. Similarly, the Transplant Support Unit in our laboratories will be undergoing audit and accreditation with the American Society of Histocompatibility and Immunogenetics, which will ensure that our results are recognised by transplant networks worldwide.

The 2nd Quality Management Training Course in Blood Transfusion Services in the Western Pacific Region is also planned for August 2003 where we anticipate participants from various countries.

## delivering services



Also in the pipeline is our plan to co-host the 1st Asia-Pacific Symposium of the Network for Advancement of Transfusion Alternatives, as part of our educational programme in clinical transfusion medicine. This symposium, which aims to improve the clinical use of blood, is targeted at all doctors, nurses and para-medics with an interest in transfusion medicine and who use blood and blood products in their work.

Other plans to enhance the safety of the blood supply include introducing the evaluation of nucleic acid tests for Hepatitis B virus, pathogen inactivation technology for fresh blood components, and testing of platelets for bacterial contamination. Within the field of immunohaematology and tissue typing, further development and implementation of tests using molecular technology are expected.

In the area of donor recruitment strategy, we will continue to work in partnership with the Singapore Red Cross Society. Donors can look forward to a more conducive donation environment and the introduction of the DonorCare@HSA initiative.



## PROVIDING SCIENTIFIC ANALYTICAL AND CONSULTING SERVICES

Our **Centre for Analytical Science (CAS)** is the largest single-site testing laboratory facility for health-related products in Singapore. It combines both highly qualified and experienced scientific expertise with state-of-the-art instrumentation.

Through our 7 laboratories in CAS, we provide analytical and consulting services to regulatory agencies and private organisations on a wide variety of products to safeguard public health and safety. These include the quality and safety of food, drugs and cosmetics, the statutory limits for tar and nicotine in cigarettes, environmental and industrial health standards and classification of liquors.

During the year in review, 57,335 tests were carried out compared to 61,893 tests in the previous year. Turn-around time of samples however, improved from 11.5 days to 8 days.

We were proactive in meeting the high expectations of clients for more complex and higher value-added analytical services. We thus invested \$1.7 million in state-of-the-art equipment and placed emphasis on specialist training for both professional and technical staff. Recognising the importance of research as integral to the continuing development of a world class laboratory for analytical testing, a Research and Development Unit was also set up.

Our two WHO Collaborating Centres continued to work very closely with the WHO on international activities. The WHO Collaborating Centre for Food Contamination Monitoring submitted 12,632

## delivering services



results of food contaminants from the national food surveillance programme to WHO in 2002. These results provided useful information for WHO to make global comparison with other participating countries and to minimise risks to consumers. The WHO Collaborating Centre for Drug Quality Assurance evaluated three articles and re-examined three international reference substances (Cisplatin, Methyldopa and Azathioprine) submitted by the WHO Collaborating Centre for Chemical Reference Substances in Sweden to validate them as international standards.

### Accreditation of Laboratories under ISO/IEC 17025

Our CAS was the first government laboratory to have been accredited by the Singapore Accreditation Council – Singapore

Laboratory Accreditation Scheme (SAC-SINGLAS) under ISO/IEC Guide 25 in 1997. In 2002, our laboratories obtained accreditation under the new ISO/IEC 17025 after a rigorous two-week surveillance assessment by independent technical assessors and officials of SAC-SINGLAS. This achievement means that we have met the highest international standards for the competence of testing laboratories and are on par with the best in the world.

### Singapore Quality Class

Our CAS joined the ranks of Singapore Quality Class organisations in July 2002. This recognition was accorded to organisations that had achieved commendable levels of performance in their journey to world-class business excellence. We were ranked top in the Health and Social Work Sector and credited to have 14 areas in which our relative strengths were higher than the industry average. These areas would serve as benchmark for others in the industry to follow.

### Second Patent Filed

Following the filing of a patent to extract bioactive ingredients from herbal medicinal products using pressurised liquid extraction in November 2001, we filed a second patent in 2002. The invention involves the extraction of bioactive components from materials such as botanical samples and herbal preparations using pressurised hot water as a solvent at temperatures below 100 degrees Celsius. The method utilises less energy than sub-critical water extraction methods and may be used under dynamic flow conditions with or without an organic solvent.



### Accredited Laboratories for Chinese Proprietary Medicine Testing

As part of the enhanced control measures of Chinese proprietary medicines announced on August 2002, all such products would require to be tested by accredited laboratories both at the pre-marketing assessment stage and at the point of all subsequent imports. To map out the implementation plan, a study team went to the national accreditation bodies of China, Taipei and Hong Kong in December 2002 to understand their accreditation systems and to visit their testing laboratories for Chinese proprietary medicines. We would be establishing a list of accredited laboratories in these countries to facilitate the testing of such products originating from them.

The Mutual Recognition Agreements that the overseas laboratories had signed with SAC-SINGLAS would be used as the basis for accepting their test results. In the meantime, we would assist them with all the technical information and test protocols. Similarly, local laboratories would be given such support for Chinese proprietary medicine testing.

### WHO Temporary Advisors

In July 2002, one of our scientists was appointed a WHO Temporary Advisor in the WHO Expert Meeting to review the guidelines for the certification of pharmaceutical starting materials moving into the international market and the guidelines on good trade and distribution practice. Further, in March 2003, our CAS Director was invited to participate as a WHO Temporary Advisor at the WHO Expert Committee Meeting on the Specifications for Pharmaceutical Preparations. Both meetings were held in Geneva, and Singapore was one of the 4 countries from Asia that were invited.

### Collaborative Study on the Development of Screening Tests

In recognition of our analytical capability and standards, the WHO invited us to participate in a collaborative study on the development of screening tests and the validation of a pharmacopoeia monograph for a new 4-fixed-dosed combination tuberculosis drug containing rifampicin, isoniazid, pyrazinamide and ethambutol HCl. Singapore was the only country in Asia invited to participate in the study that involved laboratories in Norway, Switzerland, Denmark and the United States.

### Production and Utilisation of ASEAN Reference Substances

At the ASEAN arena, we participated actively in the collaborative project to establish ASEAN reference standards for pharmaceutical testing. Stringent tests had to be carried out by at least three chosen member countries on candidate materials before they were formally adopted as ASEAN reference standards, and Singapore was involved in all of them. During the year, we coordinated studies on phenylpropanolamine hydrochloride, dextromethorphan hydrobromide and dequalinium chloride with Thailand and Malaysia; on methylparaban, propylparaben and riboflavin with Malaysia; on tetracycline hydrochloride with Thailand; and amoxicillin trihydrate and ibuprofen with the Philippines. To date, 154 low-cost standards have been produced for the benefit of the ASEAN region.

### Professional Learning and Teaching

Two analytical scientists were awarded overseas training scholarships during the year. This move was part of our aim to build advance knowledge and competencies, including in traditional Chinese medicines where their common popularity has been on the rise.

## delivering services



A visit was also made to the United Kingdom's Laboratory of the Government Chemist, Central Science Laboratory, Health and Safety Laboratory and the Food Research Institute to explore areas for future collaboration.

### The Year Ahead

As a service provider, we believe in creating value for our stakeholders. In the year ahead, we will continue to ensure relevance and remain competitive by exploiting new technology and advancing our working capabilities. The \$1.7 million invested on new state-of-the-art equipment will be exploited to carry out a number of specific initiatives to anticipate the needs of our customers.

Our Pharmaceutical Laboratory will seek accreditation for a new test protocol to screen 156 drugs covering 28 different pharmacological effects that are commonly encountered in Chinese proprietary medicines. Development on the advance testing of health supplements will also be actively pursued.

Our Food Laboratory plans to develop a number of new tests to support the Agri-Food & Veterinary Authority of Singapore in its role to ensure food safety. Among the tests to be established are ethyl carbamate in fermented food, acrylamide in baked food, chloramphenicol in royal jelly, quantitation of stevioside in food, analysis of plasticisers and multi-mycotoxin quantitation in cereals.

Our Industrial Health Laboratory will work on a new method to analyse mercury in blood samples, which will provide a better index on mercury level than the current test on urine samples. We will also develop new services in clinical trial to support the clinical trial programme.

The testing capability of our Cosmetics Laboratory will be expanded to meet the increase in pre-market evaluation and post-marketing samples and the impending harmonised ASEAN initiative for cosmetic products.

Our Cigarette Testing Laboratory will initiate studies of the analysis of benzene and formaldehyde in mainstream smoke, while the Environment Laboratory will explore more cost-effective analytical methods for testing bottled water in order to value-add to our customers.



CPA

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CAS

**forging partnerships** ■ Recognising the value of local and international alliances in information exchange, sharing of expertise, resources and training, we seek to build and maintain strong collaborative partnerships with key benchmark regulatory agencies, scientific bodies and industry leaders in the local and global communities.



“We believe that in the protection of public health and safety, all stakeholders have much to gain from working together as partners.”

**Suwarin Chaturapit**

Deputy Director  
Pharmacovigilance, Communications and Research  
Centre for Pharmaceutical Administration

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## **Establishing Strategic Alliances**

Contributing to Regional and Global

Harmonisation Initiatives

## **Attaining Professional Accreditation and Recognition**

Collaborating with the World Health Organisation

## **Increasing International Professional Representation, Participation and Exposure**

Collaborating with Local Industry

and Stakeholders

## forging partnerships



To achieve our mission to excel in applying science to support healthcare services and regulation, serve the administration of justice and enhance safety in our community, we need to look beyond our geographical boundaries. This will ensure that we meet the challenges of globalisation and rapid technological advancement.

Globalisation results in lowered market barriers and speedy access. To facilitate trade and promote technological innovation while protecting public health and safety, we participate in and support mutual recognition and harmonisation programmes, which can help reduce duplication of resources and promote strategic information exchange.

The explosive rate of scientific discovery results in new knowledge and a whole new range of technologies and innovative therapeutic products. Tapping on a range of international and regional expertise allows us to fulfil our public mission effectively as well as to build the depth and breadth of our professional capabilities.

Singapore has identified biomedical sciences as a key pillar of the economy to help propel the country forward to become a regional medical and life sciences hub. Our small geographical size makes it imperative for us to establish and strengthen global links.

Establishing strategic alliances with our stakeholders and international benchmark regulatory counterparts, and being an integral part of regional and global harmonisation initiatives, serve to develop a more robust and responsive regulatory framework and scientific capabilities that are in line with current international best practices and trends.

The quest does not stop here. We also strive for professional accreditation for our essential services in areas like blood banking, analytical services, forensic science and forensic medicine to attain recognised world class standards in our services to Singaporeans.

### ESTABLISHING STRATEGIC ALLIANCES

We have sought to formalise strategic alliances with our key stakeholders and international centres of repute by establishing Memoranda of Intention of Co-operation (MOI), Memoranda of Understanding (MOU) and Mutual Recognition Agreements (MRA) with these agencies.

The general scope of these agreements include the exchange of information and sharing of databases, sharing and leveraging on each other's expertise, development of professional competencies and collaborations in training, education and research. They cover areas such as the regulation of medicinal products including blood and blood products, Chinese proprietary medicines, other complementary health products and medical devices, forensic science and forensic medicine.

Since our formation in April 2001 till March 2003, we have formalised our collaborative partnerships with two countries and three organisations.

## forging partnerships



### **MOI with the Therapeutic Goods Administration of Australia**

We signed our first MOI with our Australian regulatory counterpart, the Therapeutic Goods Administration, on 15 May 2002 to jointly collaborate and co-operate in the regulatory framework for pharmaceuticals, medical devices and complementary health products.

This MOI, a significant milestone in the regulatory arena, not only seals the already strong ties between our two organisations, but also serves as a model for regulatory co-ordination in the Asia-Pacific region. In addition, the MOI enhances initiatives to harmonise regulatory standards amidst the diversity of regulatory approaches across national borders.

### **Singapore-Australia MRA on Medicinal Product Good Manufacturing Practice Inspection**

Signed in February 2001 between Singapore and Australia, the Singapore-Australia MRA would facilitate the export of medicinal products and reduce the duplication of resources. Australia's Therapeutic Goods Administration would accept conclusions and recommendations of audits of medicinal product manufacturers carried out by HSA's Good Manufacturing Practice (GMP) auditors and vice-versa without the need to re-conduct site audits.

### **Singapore-Japan Joint Statement on Medicinal Product GMP Inspection**

A joint statement was signed in January 2002 with Japan's Ministry of Health, Labour and Welfare to cover the exchange of GMP audit reports and certificates relating to pharmaceutical manufacturers located in Singapore and Japan. This would greatly reduce duplication of audit resources especially with the upcoming implementation of our overseas GMP conformity assessment programme.

### **MOU with Department of Chemistry, National University of Singapore**

An MOU was signed in March 2002 with the National University of Singapore to promote collaborations in research and development in the areas of nutraceuticals and functional food, forensic science, medicinal chemistry and drug evaluation.

### **MOU with Singapore Red Cross Society**

Through an MOU signed in April 2001, we formalised our partnership with the Singapore Red Cross Society as the National Blood Donor Recruiter. Since then, the Society has been developing and implementing national awareness programmes to heighten the importance of altruistic and voluntary blood donation and activities on donor recognition. On our part, we concentrate on building professional capability and expertise in transfusion medicine.

## forging partnerships



### The Year Ahead

Gaining momentum, in the year ahead, we are working towards establishing more strategic alliances with the following organisations, including overseas national agencies:

- Victorian Institute of Forensic Medicine, Australia
- The State Food and Drug Administration, The People's Republic of China
- US Food and Drug Administration, through the US-Singapore Free Trade Agreement
- National Serology Reference Laboratory, Australia



### CONTRIBUTING TO REGIONAL AND GLOBAL HARMONISATION INITIATIVES

Our involvement in regulatory harmonisation enables us to contribute as a regional and global player and achieve greater medical, pharmaceutical and radiation safety for Singaporeans. During the year, we continued to pave the way to build convergence at regional and global levels for the evolution of regulatory systems.

#### ASEAN Harmonisation of Pharmaceutical Regulations

We represent Singapore in the ASEAN Consultation Committee for Standards and Quality Pharmaceutical Product Working Group, which was formed in 1999. This Working Group aims to achieve the development of harmonisation schemes for pharmaceutical regulations of the ASEAN member countries. The initiative complements and facilitates the objective of the ASEAN Free Trade Area, particularly in the elimination of technical barriers to trade posed by these regulations, without compromising on drug quality, safety and efficacy.

We have also been chairing the Implementation Working Group to oversee the two-year trial period for the ASEAN Common Technical Dossier from January 2003 to December 2004 before the actual operationalisation.

## forging partnerships



### ASEAN Harmonisation of Cosmetic Regulations

To further the objectives of the ASEAN Free Trade Area, we also represent Singapore in the ASEAN Consultation Committee for Standards and Quality Cosmetic Product Working Group, which was formed in 1997 to achieve cosmetic regulatory harmonisation. So far, the Working Group has finalised the technical requirements for cosmetic products and is in the final stage of preparation of an Agreement on the ASEAN Harmonised Cosmetic Regulatory Scheme for signing by ASEAN ministers. The Scheme will provide for speedier time-to-market for cosmetics to be launched in ASEAN countries without compromising public safety.

### Western Pacific Regional Forum for Harmonisation of Herbal Medicines

We represent Singapore in the Western Pacific Regional Forum for Harmonisation of Herbal Medicines, which was formed in March 2002. The founding members are Singapore, China, Japan, South Korea, Hong Kong, Australia and Vietnam. With the support and involvement of the WHO, the Forum seeks to establish common technical guidelines on herbal medicines, including Chinese proprietary medicines, among member countries.

### Asian and Global Harmonisation of Medical Devices Regulations

In the arena of harmonisation of medical device regulations, we are actively involved as the Secretariat for the Asian Harmonisation Working Party. This Working Party is a voluntary forum of regulators and the medical device industry of Asian economies working towards the forging of a common direction for the harmonisation of medical device regulation in Asia. It also seeks to encourage greater understanding on the benefits of harmonisation and facilitate alignment with the Global Harmonisation Task Force guidance documents.

We played a key organising role in two events, held in May 2002 in Singapore, viz the 9th Global Harmonisation Task Force Conference and the 2nd APEC Seminar on Harmonisation of Medical Device Regulations. The latter provided training on medical device regulations for APEC member economies.

## forging partnerships



### Regional Harmonisation of Radiation Protection Regulations

We represent Singapore in the Regional Co-operative Agreement, formed under the auspices of the International Atomic Energy Agency, where the member states review and evaluate radiation protection infrastructure for the peaceful use of radiation and radioisotopes in member states.

### The Year Ahead

As we maintain a global perspective to stay relevant, ready and responsive, our commitment in the regional and global harmonisation programmes continues to remain strong even as these initiatives are likely to accelerate in the years ahead.

### ATTAINING PROFESSIONAL ACCREDITATION AND RECOGNITION

Striving for professional accreditation is an important step to elevate our overall professional practice standards, audit and check our deliverables and propel us towards professional excellence. Attaining recognition by accreditation bodies, international scientific/professional agencies and national certification authorities provides a strong endorsement of our standing by the local and international communities.

### Accreditation by American Society Of Crime Laboratory Directors / Laboratory Accreditation Board

Our CFS is accredited by the American Society of Crime Laboratory Directors / Laboratory Accreditation Board, an international benchmark accreditation scheme for forensic laboratories in the disciplines of controlled substances, toxicology, trace evidence, serology, DNA, firearms, toolmarks and questioned documents.

This accreditation is a demonstration of our high standards in forensic expertise and quality management as well as our commitment in providing world class services to meet clients' high expectations and requirements. Our CFS first obtained the accreditation in 1996 and was re-accredited again in June 2001 for another five years.

### Accreditation by Singapore Accreditation Council – Singapore Laboratory Accreditation Scheme

Our CAS was the first government laboratory to have been accredited by Singapore Accreditation Council – Singapore Laboratory Accreditation Scheme (SAC-SINGLAS) under ISO/IEC Guide 25 in 1997.

During the year in review, our laboratories went through a rigorous two-week surveillance assessment by independent technical assessors and officials of SAC-SINGLAS and obtained accreditation under the new ISO/IEC 17025. This achievement is a testimony that our CAS has met the highest international standards for the competence of testing laboratories and is on par with the best in the world.

## forging partnerships



### Singapore Quality Class

In July 2002, our CAS, the largest local single-site testing laboratory facility for health-related products, further attained the Singapore Quality Class. It is a national certification scheme recognising organisations that have strong business excellence in leadership, planning, information, people, processes, customers and results.

### Reference Laboratories for the United Nations International Drug Control Programmes

In July 2001, our Narcotics I Laboratory under CFS was invited by the United Nations International Drug Control Programme to be a reference laboratory for the seized material group. In April 2002, our Narcotics II Laboratory was also invited by the Programme to be a reference laboratory for the biological specimen group. As the reference laboratories, we provide the baseline information that is used to evaluate results reported by participating laboratories under the Programme's bi-annual International Collaborative Exercises.

### Pharmaceutical Inspection Co-operation Scheme

HSA was the first Asian member of the Pharmaceutical Inspection Co-operation Scheme. Accession to the Scheme has brought many benefits to Singapore and the pharmaceutical manufacturing sector. These include the enhancement of the status of Singapore as a regional pharmaceutical and life sciences hub, the facilitation of the process of mutual recognition on Good Manufacturing Practice inspection with countries under the Scheme and the global acceptance of the quality of pharmaceutical products manufactured and exported from Singapore.

### Permanent Forum on International Pharmaceutical Crime

By invitation, our CPA joined the exclusive membership of the Permanent Forum on International Pharmaceutical Crime, a forum aimed at exchanging information and ideas to foster mutual co-operation in combating pharmaceutical crime. Member agencies are drug regulatory authorities in the US, Canada, UK, Australia and other European countries. The Permanent Forum also works with other interested bodies including the World Health Organisation, the World Customs Organization, and INTERPOL. The networks via the Permanent Forum and its meetings are invaluable in tackling drug issues of both global and national concern.

### Training Centre for Radiation Protection

Under the Singapore - International Atomic Energy Agency MOU signed in 2000, our CRP became a key regional player in radiation protection training. CRP hosted a number of fellows from countries in the region and provided training in radiation protection legal infrastructure, quality assurance and quality control in medical exposures, occupational exposures and various aspects of emergency preparedness and planning for radiological accidents. Our CRP also conducted courses on radiation safety for industrial radiographers to provide them 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 would be minimised.

## forging partnerships



### The Year Ahead

We are on track in our journey to align our systems and processes with the highest standards to achieve professional accreditation by the following accreditation bodies:

- American Association of Blood Banks – quest by CTM;
- American Society of Histocompatibility and Immunogenetics – quest by the Transplant Support Unit, CTM;
- National Association of Medical Examiners – quest by CFM.

## COLLABORATING WITH THE WORLD HEALTH ORGANISATION

### WHO Collaborating Centre for Transfusion Medicine WHO Regional Training Centre for Quality Management Project

As a WHO Collaborating Centre, our CTM has been playing an important role in assisting the WHO with promoting blood safety and quality in the Western Pacific Region. In recognition of its high standards and quality, our CTM is also a regional reference centre for immunohaematology and tissue typing in transfusion medicine.

Further, CTM was selected to host the first meeting, held in October 2001, on the Quality Management Project for Directors of the Blood Transfusion Services in the Western Pacific Region. Following the landmark meeting, our CTM was designated as a WHO Regional Training Centre for Quality Management Project and held the first training course in April 2002 for quality management personnel from blood transfusion services in the region.



### WHO Collaborating Centre for Food Contamination Monitoring WHO Collaborating Centre for Drug Quality Assurance

The Food Laboratory of CAS is a WHO Collaborating Centre for Food Contamination Monitoring and has been re-accredited in October 2000 for another 4 years. As a WHO Collaborating Centre, it establishes a food database, participates in quality assurance programmes and provides training on food contaminants.

The Pharmaceutical Laboratory of CAS is a WHO Collaborating Centre for Drug Quality Assurance and has been re-accredited in April 2001 for another 4 years. As a WHO Collaborating Centre, it reviews monographs for international pharmacopoeia, validates international chemical reference substances and provides training on pharmaceutical analysis.

## forging partnerships



### **WHO International Advisory Committee on Electromagnetic Fields**

As a member of the WHO International Advisory Committee on Electromagnetic Fields, our officers in CRP attend the annual meetings in WHO headquarters in Geneva. The Committee has established an International Electromagnetic Fields Project that assesses the scientific evidence of possible health effects of electromagnetic fields.

### **WHO Department of Essential Drugs and Medicines Policy**

Our CPA regularly provides inputs to the WHO Department of Essential Drugs and Medicines Policy on issues relating to herbal medicines such as the drafting of WHO herbal monographs and guidelines on traditional medicines.



### **WHO International Conference of Drug Regulatory Authorities**

Our CPA and CDE participate regularly in this bi-annual international meeting to discuss the latest approaches and best practices on drug regulation around the world. At the 2002 meeting in Hong Kong, we shared our perspectives on the regulatory challenges posed by the internet and also facilitated discussion on the issues related to the regulation of biological and biotechnology products.

### **The Year Ahead**

The collaborations with the WHO are ongoing. We remain committed to them so as to apply our expertise and knowledge to forge a better future for all.

## **INCREASING INTERNATIONAL PROFESSIONAL REPRESENTATION, PARTICIPATION AND EXPOSURE**

### **Global Professional and Industry Events**

To build and enhance our global profile, we played a key organising role in the 9th Global Harmonisation Task Force Conference held in May 2002 in Singapore. This conference saw a congregation of global key decision-makers from the industry and governments in the regulation of medical devices. There were eminent representatives from the US Food & Drug Administration, Australia Therapeutic Goods Administration, Canada Therapeutic Products Directorate, UK Medicines and Healthcare products Regulatory Agency, European Commission and Japan Ministry of Health, Labour and Welfare.

## forging partnerships



In addition, our officers were often invited to global professional and industry events as expert speakers or participants throughout the year. These representations served to build our global profile, enrich our knowledge and expertise and widen our international networks. In addition, study visits to benchmark agencies helped to build deeper understanding and closer links that were often strategic and useful in our efforts to meet emerging regulatory issues and challenges.

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

- the 16th International Symposium on the Forensic Sciences, Australia, May 2002
- the 16th Meeting of the International Association of Forensic Sciences, France, September 2002
- the Annual Meeting of National Association of Medical Examiners, US, September 2002
- the World Quality Congress, UK, September 2002, which provided insight on the attributes of world class organisations.
- the International Atomic Energy Agency 46th General Conference, Austria, September 2002, where some of the issues dealt with were on nuclear safety, safe transport of nuclear materials and nuclear terrorism. We co-sponsored Australia's draft resolution on "Measures to strengthen international co-operation in nuclear, radiation and waste safety".
- the 30th ASCLD/LAB Annual Conference, USA, October 2002
- the International Conference and Exhibition on the Modernisation of Traditional Chinese Medicine, China, November 2002

- the 55th Annual Meeting of the American Academy of Forensic Sciences, USA, February 2003
- International Conference on Security of Radioactive Sources, Austria, March 2003. This conference sought to raise awareness of the growing global security concern and was organised by the International Atomic Energy Agency, co-sponsored by the Russian Federation and the US in co-operation with the European Commission, European Police Office, the International Criminal Police Organisation and World Customs Organisation.

### Study Visits to Regulatory Counterparts

During the study visits to key regulatory counterparts, discussions on current regulatory issues and best practices in systems and processes were conducted. Further, the visits to research sites allowed the study teams to observe the latest cutting-edge technologies and research approaches and network with development and regulatory affairs personnel from industry and academia.

In the year under review, study visits were made to the following:

- Food and Drug Administration, US
- European Agency for the Evaluation of Medicinal Products
- Medicines and Healthcare products Regulatory Agency, UK
- Health Canada
- Therapeutic Goods Administration, Australia
- National Radiological Protection Board, UK
- Research and development facilities like the GlaxoSmithKline Harlow Site, The Institute of Cancer Research Sutton Site and the Eli Lilly Erlwood Research Centre

## forging partnerships



### Study Visits from Regulatory and Scientific Counterparts

At the same time, we hosted various familiarisation and study visits by senior officials from our regulatory and scientific counterparts. As part of our overall approach to forging partnerships, we ensured that each visit was an enriching and informative session for our overseas stakeholders.

During the year, some of the overseas stakeholders who visited us were:

- Food and Drug Administration, US
- Therapeutic Goods Administration, Australia
- Association of British Pharmaceutical Industries
- Life Sciences/Health Sub-Committee, Singapore-British Business Council
- Private companies like Merlion Pharmaceuticals PL, CSL Bioplasma, etc
- Institute of Forensic Science, Ministry of Public Security, The People's Republic of China
- Central Institute for Forensic Medicine, Vietnam
- Western Pacific Regional Office, World Health Organisation
- Different ministries from the health and justice sectors of the regional countries

### The Year Ahead

In the pipeline, we will co-host the 1st Asia-Pacific Symposium of the Network for Advancement of Transfusion Alternatives, an international group of world-renowned anaesthetists, intensive care specialists, surgeons and transfusion medicine specialists concerned with blood conservation techniques.

Looking ahead, the exponential increase in scientific development and regulatory issues necessitates continuous professional representation, participation and exposure so as to foster networks and exchange and build knowledge. The cumulative outcome will be a stronger team of high-calibre experts who keep in touch with the network and development of their specialised expertise to deliver our public mission effectively and efficiently.

## COLLABORATING WITH LOCAL INDUSTRY AND STAKEHOLDERS

Leveraging on local stakeholders from the different public agencies and the industry helps to extend our work and mission. During the year in review, some of the key partnerships with local stakeholders were:

### ▪ Agri-Food & Veterinary Authority

Our CPA formed a work group in January 2003 with representation from the Food Control Division, Agri-Food & Veterinary Authority to address issues pertaining to product classification of "grey area" food products, which might be fortified with herbal ingredients.

### ▪ Singapore Traditional Chinese Medicine Organisations Committee

Aimed at upgrading the standards of Chinese medicinal material dispensers in Singapore, a new training course for these dispensers was organised by the Singapore Traditional Chinese Medicine

## forging partnerships



Organisations Committee with the support of and facilitation by HSA and the Ministry of Health. Visiting experts from the prestigious Beijing University of Chinese Medicine were invited by the Ministry to assist in designing the course's syllabus. There was an overwhelming response of more than 400 applicants when the course began in July 2002.

### ■ Central Narcotics Bureau

During the year, our Narcotics II Laboratory in CFS worked together with the Central Narcotics Bureau on a project to detect the

presence of opiates in hair. The results of the project, which was completed in October 2002, showed that 6-monoacetylmorphine and codeine could be detected in hair samples of opiate abusers. A pilot study was further initiated to look into the feasibility of using hair testing in drug monitoring.

### ■ Singapore Police Force

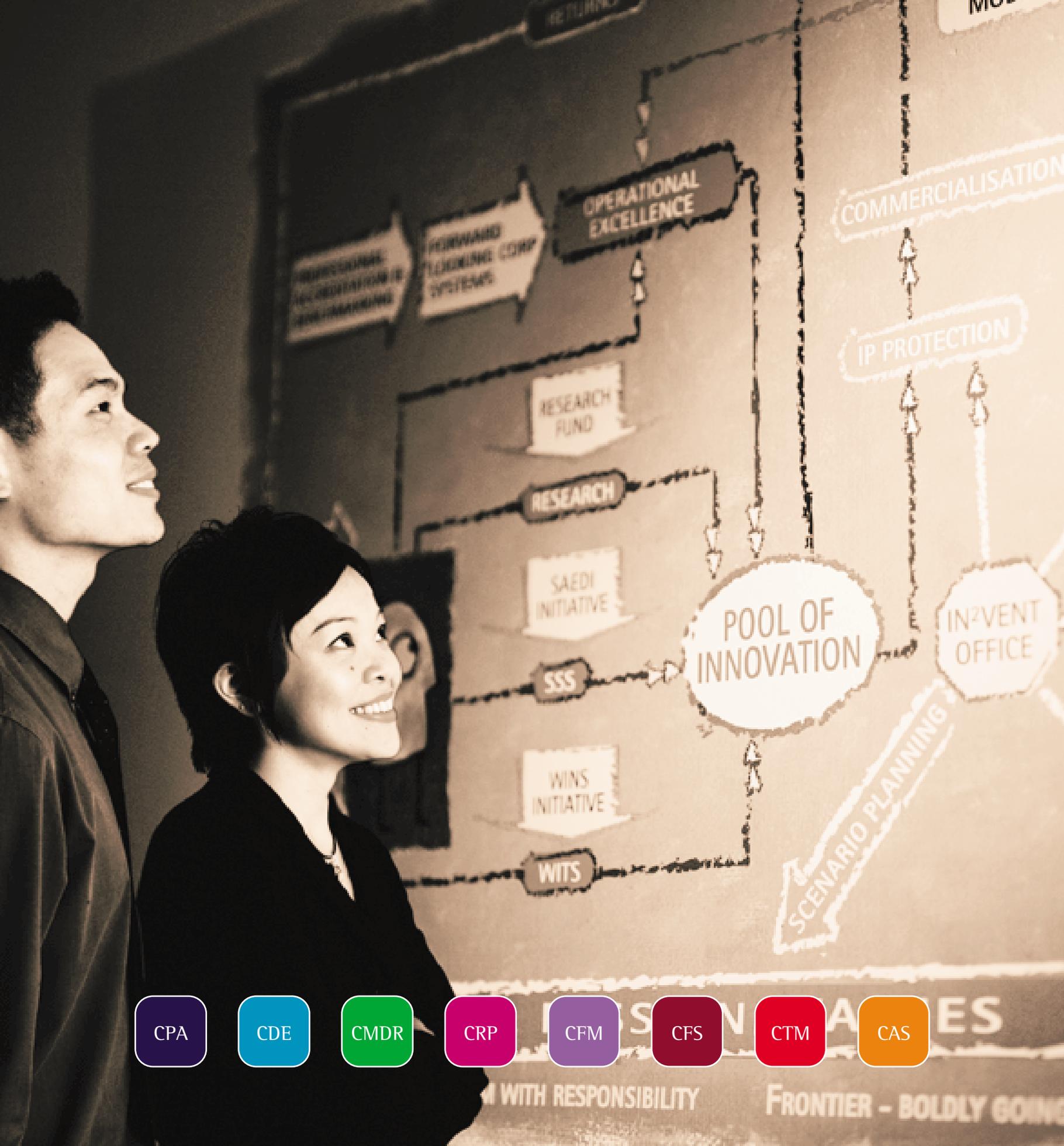
Our CFS collaborated with the Singapore Police Force to set up a new DNA Database Laboratory with dedicated DNA profiling facilities. The new laboratory was launched in February 2003.

### ■ Singapore Science Centre

As part of our corporate citizenship programme, we collaborated with the Singapore Science Centre on the "Excellence in Applying Science" programme. The programme serves to demonstrate, enhance the awareness and learning of the student population and the community on how we excel in applying science in the fields of forensic science and forensic medicine.

### The Year Ahead

As in every strategic partnership, collaboration with our local stakeholders helps to improve our systems and enable us to better meet the needs of our customers. In the year ahead, we will continue our commitment to forge stronger bonds with our stakeholders.



CPA

CDE

CMDR

CRP

CFM

CFS

CTM

CAS

WITH RESPONSIBILITY

FRONTIER - BOLDLY GOING

**making connections** ■ An organisation that can – keep up with the rapid changes in the industries that it regulates, continue to value-add to the essential services it provides to its stakeholders in the administration of justice, and apply the latest state-of-the-art technology to protect the national blood supply – requires a very special work culture to foster common goals and connectivity within its workforce, with its industry stakeholders, and with the public, the ultimate beneficiary of its work and mission.



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"We drive innovation through a simple mantra **"I Don't know"**. Innovation happens when we inspire our people to do more than they think they can and know. **Don't** fear failure - we never give up. We **know** our stakeholders and operating environment and are connected with one and all."

**Lim Peck Seah**  
Assistant Director  
Office for Innovation and Enterprise

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Creating Possibilities

**Managing Risk**

Developing Capabilities

**Exploiting Information  
Technology**

Serving with a Difference

**Caring for Our  
Community**



## CREATING POSSIBILITIES

In an operating environment that is becoming more sophisticated each day, one of our key success factors is to be able to develop a culture of innovation and enterprise to drive workforce behaviour and performance so that HSA can deliver its mission to protect public health and safety. Faced with the challenges of technology and biomedical innovation, globalisation, emerging diseases, threats of more advanced and large-scale criminal activities including technology for drug counterfeiting, it is imperative that our workforce, systems and processes have the capability and robustness to confront these critical challenges.

### Innovation Framework

We encourage a vibrant innovative and research culture through three guiding principles, *focus on vision, freedom with responsibility and frontier -boldly going forward* to create and promote growth of intellectual properties that are protected and optimised through our innovation management framework. Our innovation framework is built upon our vision, mission and core values to harness creativity through various strategies like risk management and value management, thereby generating a self-propagating and self-sustaining pool of innovation that will sustain our journey towards excellence.

## HSA Innovation Framework





### **FISH! Philosophy**

The year saw a tremendous evolution of our work culture in adopting the FISH! Philosophy. 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 the organisation. Bringing the culture across our organisation and to connect the officers, we held 23 half-day workshops reaching out to 90% of our officers.

### **Innovation In Action**

A core team of innovation activists spearheaded and drove various innovation initiatives within each centre and department, ensuring the reach to all staff throughout the organisation. A constant infusion of culture changing initiatives within an integrated framework provided a consistent drive based on our three guiding principles.

During the year, 5 of our Work Innovation Teams (WITs) were selected for presentation at the National QCC level. The teams returned with one gold, one silver and three bronze awards.

Our Staff Suggestion Scheme continued to tap on staff creativity and operational knowledge to refine the work systems, processes and environment. During the year, 509 out of 1,965 staff suggestions were accepted for implementation. In addition, the IDEAS Forum was organised to motivate and reward staff innovation and creativity.



### **Research and Development**

Our efforts in research and development, based on the guiding principles in our innovation framework, focused on projects that served to enhance the delivery of our mission.

From a number of research and development projects during the year, 39 papers were presented in international, regional and local professional conferences, 11 papers were published in key professional journals, and one patent was filed.

## making connections



The patent, the second filed by our organisation, involves the extraction of bioactive components from materials such as botanical samples and herbal preparations using pressurised hot water as a solvent at temperatures below 100 degrees Celsius. The method utilises less energy than sub-critical water extraction methods and may be used under dynamic flow conditions with or without an organic solvent.

In addition, a new research and development unit was set up within our CAS as a strategic move to advance the Centre's journey to be a world class laboratory for analytical testing.

We held our 1st Science@HSA Scientific Seminar in April 2002, focusing on "Health Sciences Research: Priorities and Opportunities". Our officers presented 24 papers and one poster covering a range of topics in biomedical science, forensic science and analytical and radiation science. The proceedings of the seminar were subsequently published.

### MANAGING RISK

Risks abound in the community and in the world of regulatory and scientific activities. Too much regulation stifles enterprise and progress but too little regulation exposes the community to unnecessary hazards. Too cautious a scientific approach is resource-

consuming without effectiveness but too little attention to scientific methodology undermines confidence and objectivity.

In managing risk within HSA, an enterprise-wide risk management study was carried out to assess and develop our capability for business continuity, emergency preparedness and crisis management.

The exercise was the first step in assessing external and internal risk exposure of our organisation, and would eventually lead to a balanced approach towards risk management. This exercise served to create a high level of awareness on the high-risk business our organisation dealt with on a day-to-day basis. It also established a common platform connecting the minds of our key managers in managing risks in their different areas of work.

Plans are being reviewed to increase business operational resilience arising from sudden disruptions to operational routines.

### Emergency Preparedness

We sent two representatives to attend the National Disaster Medical System Conference 2003 in the US for familiarisation with the strategies and current development in mass disaster management. Many of our centres updated their emergency preparedness plans during the year.



## DEVELOPING CAPABILITIES

Our continued progression as a world class organisation starts with our commitment to promote excellence among our people. In addition to fostering an innovative and enterprising culture, and one with our fingers on the pulse of the high-risk business we do, we nurture our people to ensure they have the skills, knowledge and motivation to advance our mission in the years to come.



## People Developer Standards

In December 2002, we were recognised with the award of the People Developer Standards. By applying this organisational excellence tool in a sustained and systematic approach, we ensure a continuous learning organisation and people.

## Training and Development

Through the year, we continued to place ongoing efforts and emphasis on building up our officers' capabilities, knowledge and professionalism. In August 2002, we introduced the Professional Development Programme to give our officers the opportunity to engage in distance learning. Upon attainment of the relevant qualifications, the officers could be emplaced to the respective schemes of service. The programme allowed for them to upgrade their knowledge and competencies and pursue a wider range of potential career paths. During the year, 6 officers signed up for the programme.

This programme was supplemented by regular lectures, workshops and seminars conducted by local and international specialists of the various disciplines relevant to our professional staff. Our professional staff also made presentations to their peers on scientific issues and development in their areas of work as part of knowledge management. Besides, promising officers were sent for overseas trainings, attachments and study visits to benchmark regulatory and scientific counterparts.

## making connections



### Scholarship Awards

To proactively recruit new talents who will be entering the job market, we offer scholarship awards to “A” level high achievers. During the year, one undergraduate scholarship was awarded for the pursuit of a science bachelor’s degree at the National University of Singapore.

### EXPLOITING INFORMATION TECHNOLOGY

The appropriate deployment of technology is one means towards enhancing our service delivery. With the approval of our three-year Information Technology (IT) Master Plan in July 2002, we swiftly launched into streamlining the operations of our centres so as to achieve greater operational efficiencies. In the past, there were various manual processes that would be automated. Now, we not only leverage on IT as an enabler for fostering better connectivity with our stakeholders, but also exploit IT as a strategic tool for realising our public mission.



We are on track in the development of a one-stop centre with supporting new modern systems that service various target groups in the industries that we regulate and the population that we serve. These systems harness the power of the internet to allow us to better administer our regulatory frameworks and the integral processes, as well as offer a comprehensive suite of e-services to the public.

The organisation-wide network infrastructure was upgraded in November 2002 in areas like bandwidth, firewall, print and file servers so as to support the new complex IT systems. By March 2003, the infrastructure was able to support a virtual private network to improve officers’ mobility and connectivity as part of our business continuity plan and readiness in emergency and crisis planning. More modules in our human resource and financial information systems were also operational in the year.

Within the one-stop centre hosting platform are common services, such as client registration and identification service, secure electronic payment, short messaging services alerts and enquiries, which reduce duplications in the more complex systems that target the larger groups of different industry players. Less complex systems such as the Contact Lens Licensing System (collins) and the System for Transfusion Medicine Analysis and Management (stream) are also developed for greater operational efficiency and effectiveness.

## making connections



### **prism@hsa**

The Pharmaceutical Registration and Information System (prism@hsa) targets to provide an integrated licensing system to different industry players dealing in western drugs, Chinese proprietary medicines, health supplements, cosmetics and tobacco. With the system, the industry stakeholders can check and track their application status and make enquiry online. The first phase was rolled out in March 2003, allowing the stakeholders dealing with cosmetic products to apply for new import and product licenses online.

### **medics@hsa**

The Medical Device Licensing and Control System (medics@hsa) targets to facilitate electronic document submission for medical device registration, electronic billing and payment and information search and retrieval. Its first phase, which was successfully completed during the year, comprised product licensing portals to enable medical device companies to submit electronic applications for establishment registration and list medical device products with marketing clearance on the medical device register.

### **DonorCare@HSA**

The objective of DonorCare@HSA, a blood donor care management system, is to provide an easy, convenient, accessible and user-friendly interface with the altruistic and committed donors with a busy lifestyle. DonorCare@HSA includes an appointment management system for donors to book blood donation appointments online, and an e-service for blood donors to update

their particulars and receive the latest information from the Bloodbank@HSA. Its first phase was successfully rolled out in March 2003.

## **SERVING WITH A DIFFERENCE**

We serve the needs of a broad spectrum of people. Our customers also include members of the public who donate the gift of life at our Bloodbank@HSA and grief-stricken next-of-kin who undergo administrative procedures for their beloved at our Mortuary@HSA.

### **Apheresis Suite@HSA**

As part of our continuing efforts to excel in quality donor care and make blood donation a pleasant experience for the donors, we expanded our apheresis service via the new and fully dedicated Apheresis Suite@HSA, located within our Bloodbank@HSA.



## making connections



Unlike regular whole blood donation where it takes only 20 minutes to complete the donation process, apheresis donations can range from 45 minutes to two hours. Each apheresis donor can now enjoy his personal choice of the latest movies and full terrestrial networks via the individual TV monitor attached to each apheresis donation couch. In addition, the new Apheresis Suite provides a more comfortable and relaxed environment for its regular donors who make frequent donations of up to 6 times a year and sacrifice more time at each donation.

The expansion of the apheresis service via its fully dedicated service centre is part of our ongoing efforts to encourage voluntary blood donations through creating an environment that is consonant with the current expectations and lifestyle.

### **Mortuary@HSA**

The public waiting area at the reception of our Mortuary@HSA for the next-of-kin was extensively renovated to provide a clean, comfortable, well-lit and pleasant area, promoting an environmental sense of calmness and serenity at a time of distress. We have also created an interview room to allow for meetings with the next-of-kin in privacy. Counter officers were also sent for enhanced customer care training.

### **Customers First**

Customer satisfaction is our priority. A customer satisfaction survey was conducted in June 2002 to track our service performance against customer expectation and to identify service gaps for making improvements. A total of 1,558 customers participated



in the survey. The survey findings were encouraging, as we attained a mean score of 5.22 out of 7 for service quality, and 5.34 out of 7 for customer satisfaction of outcome.

Creating value for our customers is a continuous effort to improve our quality service to become a customer-focused organisation. During the year, our Quality Service Committee promoted quality service improvement efforts through three key areas:

- the development and implementation of customer satisfaction survey and the evaluation of staff quality awareness
- the improvement of customer service especially services at the various customer service counters
- the celebration of quality service acts, with awards like the Outstanding Service to Customers Awards and the Outstanding Quality Improvement Award which were presented at our annual dinner-and-dance function to deserving officers including those behind the quality improvement projects.



## CARING FOR OUR COMMUNITY

### Community Involvement

We encourage our staff to take an active personal interest in community involvement. A group of our officers, who attended the basic training and orientation course for volunteers conducted by the Ministry of Community Development and Sports, became befrienders to the Singapore Boys' Home and the Toa Payoh Girls' Home. A team also participated in the annual Great Walk for Humanity organised by the Singapore Red Cross Society.

### Charity

Our people are also active in fund raising and charity work. At the annual National Day Observance Ceremony, booths were set up by the Lions Befrienders, the Spastics Children Association and the Singapore Association for the Visually Handicapped to sell handicrafts to raise funds for their own respective charity. Further, a total donation of \$20,000 was made to the Community Chest at our annual dinner-and-dance function. This sum came from various sources including the profit made from the sale of fruits to staff at our annual Fruits Day, the registration fees collected from family members of staff at our annual Family Day, and the dollar-for-dollar matching by the organisation for the registration fees collected from the dinner-and-dance function.

### The Next Generation

We also played our part in moulding the future generation by hosting educational visits for students, especially for secondary schools and above. These visits were organised as part of the schools' science awareness programme. At each visit, the students were briefed on our public mission and national role in applying science to protect public health and safety. Tours of our forensic and analytical science laboratories were also facilitated.

### The Year Ahead

We exist to serve. We innovate our culture to make a difference in our workforce so that we can always be ready, responsive and relevant as we confront the new public health and safety challenges of the 21st century. We apply corporate and organisational excellence models to aid our progress and track our accountabilities.

Going forward, we will explore more opportunities in the newer technologies and best practices to deliver services that are not only congruent with the current state of development but also connect and meet the needs of our stakeholders.

## OUR CUSTOMER SERVICE STANDARDS

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

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

*We are committed to*

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

*We will*

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

*We will*

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

*We will*

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

*We aim to*

***Attend to customers within 10 minutes of appointment time***

*We aim to*

***Answer all telephone calls within 10 seconds***

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



## research papers and projects

### REGULATING PHARMACEUTICALS AND HEALTHCARE PRODUCTS

TITLE OF RESEARCH PRESENTATION	AUTHOR(S)	PROFESSIONAL EVENT
Review Of New Drug Applications (NDAs) Received For Evaluation By The Centre For Drug Evaluation	Dr Vivian Chan & Tan Tek Seng	1st HSA Scientific Seminar, 12 April 2002
A Review Of Product Licences Issued By The Drug Registration Branch	Lee Hui Keng, Dr Kerwin Low & Marie Tham	1st HSA Scientific Seminar, 12 April 2002
An Analysis Of Regulatory Good Manufacturing Practice (GMP) Audit Findings Of Singapore	Sia Chong Hock, Lai Weng Fai, Boon Meow Hoe, Peh Eng Chin & Toh Lay Mui	1st HSA Scientific Seminar, 12 April 2002
Statistics On Chinese Proprietary Medicine Products And Dealers In Singapore	Victor Wong, Corina Tan, Xu Yimin	1st HSA Scientific Seminar, 12 April 2002
Adverse Drug Reactions (ADR) Reported In Singapore: A 5-year Trend Analysis	Chan Cheng Leng, Ang Pei San & Tan Bee Him	1st HSA Scientific Seminar, 12 April 2002
TITLE OF RESEARCH PROJECT	AUTHOR(S)	
A Mechanistic Prospective On The Specificity And Extent Of Cyclooxygenase-2 Inhibition In Pregnancy	Dr Vivian Chan	

### REGULATING MEDICAL DEVICES

TITLE OF RESEARCH PRESENTATION	AUTHOR(S)	PROFESSIONAL EVENT
Design And Development Of The Singapore Medical Device Register	Sree Lakshmi Garimella, Angelia Ng, Clement Ng, Ng Yin Mei, Wong Yew Sin & Nealda Leila M Yusof	1st HSA Scientific Seminar, 12 April 2002

### ENSURING RADIATION SAFETY

TITLE OF RESEARCH PROJECT	AUTHOR(S)
Radon Monitoring In Underground Tunnels	Stephen Chong & Annie Tan
Optimisation in Medical Radiation Exposures	Stephen Chong, Annie Tan & Tan Joo Thai
Investigation Of The Annual Variation Of Solar UVB In Singapore	Stephen Chong & Annie Tan



## PROVIDING FORENSIC PATHOLOGICAL AND INVESTIGATIVE SERVICES

TITLE OF RESEARCH PAPER	AUTHOR(S)	PROFESSIONAL PUBLICATION
Did He Drown, Or Was He Murdered?	Dr Gilbert Lau	Medicine, Science and the Law, 42: 172-80, 2002
Are Maternal Deaths On The Ascent In Singapore? A Review Of Maternal Mortality As Reflected By Coronial Casework From 1990 To 1999	Dr Gilbert Lau	Annals of the Academy of Medicine; 31: 261-275, 2002
Fatal Pulmonary Haemorrhage From A Perforated And Possibly Iatrogenic Thoracic Aortic Aneurysm	Dr Gilbert Lau	Forensic Science International; 126: 167-70, 2002
Fatalities From Enterovirus Infection During An Epidemic Of Hand, Foot And Mouth Disease In Singapore: Post-mortem Findings. In: Lin RVTP And Goh KT (eds). Enterovirus Infection In Singapore – With Particular Reference To The EV71 Outbreak In 2000.	Drs Lai Siang Hui, Gilbert Lau & Teo Eng Swee	Institute of Environmental Epidemiology, Ministry of the Environment (Singapore), 2002
A Case Of Massive Hepatocellular Necrosis: Was It Caused By Orlistat? A Case Report	Dr Gilbert Lau & Chan Cheng Leng	Medicine, Science and the Law, 42: 309-12, 2002
Falls From Heights. In: Payne-james J, Busuttill A (eds). Forensic Medicine: Clinical & Pathological Aspects	Drs Gilbert Lau, Teo Eng Swee & Prof Chao Tzee Cheng	Forensic Medicine: Clinical & Pathological Aspects, London: Greenwich Medical Media, 2002
Sudden Death Due To Granulomatous Myocarditis: A Case Of Sarcoidosis?	Drs Wee Keng Poh & Alwin Loh Hwai Liang (SGH)	Annals of the Academy of Medicine, Vol 31, No 6, Pg 805 – 7, 2002
TITLE OF RESEARCH PRESENTATION	AUTHOR(S)	PROFESSIONAL EVENT
Lessons In Trauma From The Mortuary	Dr Gilbert Lau	1st NGH Scientific Congress, August 2002
TITLE OF RESEARCH PROJECT	AUTHOR(S)	
Recent Homicide Trends In Singapore	Dr Gilbert Lau	
Suicide Trends In Singapore, Two Decades Down The Road	Dr Gilbert Lau & David Ng Wei Liang (NUS)	

research papers & projects



**PROVIDING FORENSIC SCIENTIFIC, INVESTIGATIVE AND ANALYTICAL SERVICES**

TITLE OF RESEARCH PAPER	AUTHOR(S)	PROFESSIONAL PUBLICATION
A New Lethal Blood Promethazine Level – A Neonatal Death	Leong Hsiao Tung, Drs Yao Yi Ju & Lo Siaw Teck	Bulletin of the International Association of Forensic Toxicologists, pg 17, Vol XXXII (No. 4), 2002
TITLE OF RESEARCH PRESENTATION	AUTHOR(S)	PROFESSIONAL EVENT
Analysis Of Ketamine In Drug Seizures	Mangudi Merula, Drs Chen Shao Xing & Lee Tong Kooi	16th International Symposium on Forensic Sciences, Canberra (Australia), 13-17 May 2002
Acetonitrile Related Death	Leong Hsiao Tung, Drs Yao Yi Ju & Lo Siaw Teck	40th Annual Meeting of The International Association of Forensic Toxicologists, Paris (France), 26-30 August 2002
Damages By An Excavator Bucket To A High-Tension Electric Cable	Dr Tay Ming Kiong, Chow Yuen San & Lim Thiam Bon	16th Meeting of the International Association of Forensic Sciences, Montpellier (France), 2-7 September 2002
Forensic Science, Management And Business	Dr Tay Ming Kiong & Lim Chin Chin	16th Meeting of the International Association of Forensic Sciences, Montpellier (France), 2-7 September 2002
Newspaper Sheets As Evidence At Crime Scenes	Lim Thiam Bon & Dr Tay Ming Kiong	16th Meeting of the International Association of Forensic Sciences, Montpellier (France), 2-7 September 2002
Cut Characteristics Of An Optical Fibre Cable By Different Tools	Dr Yap Tiong Whei, Lim Thiam Bon, Chong Pui Shan & Dr Tay Ming Kiong	16th Meeting of the International Association of Forensic Sciences, Montpellier (France), 2-7 September 2002
The Use Of Corrosive Substances In Crimes	Chia Poh Ling, Lim Thiam Bon, Chow Yuen San, Lim Chin Chin & Dr Tay Ming Kiong	16th Meeting of the International Association of Forensic Sciences, Montpellier (France), 2-7 September 2002
Anthrax Hoaxes In Singapore	Lee Lin Kiak & Dr Tay Ming Kiong	16th Meeting of the International Association of Forensic Sciences, Montpellier (France), 2-7 September 2002
Causes Of Damages To Leather Products	Lim Chin Chin & Dr Tay Ming Kiong	16th Meeting of the International Association of Forensic Sciences, Montpellier (France), 2-7 September 2002

research papers & projects



Forensic Survey Of Coloured Golds	Chow Yuen San, Lim Thiam Bon & Dr Tay Ming Kiong	16th Meeting of the International Association of Forensic Sciences, Montpellier (France), 2-7 September 2002
Quantitation Of Human DNA Using Real-Time PCR	Dr Syn Kiu-Choong, Sim Hwee Chze & Tan Wai Fun	16th Meeting of the International Association of Forensic Sciences, Montpellier (France), 2-7 September 2002
Extraction Of DNA From Bone Marrow Using FTA™ Paper	Sim Hwee Chze, Lim Wei Ling & Tan Wai Fun	16th Meeting of the International Association of Forensic Sciences, Montpellier (France), 2-7 September 2002
Evaluation And Modification Of The IsoCode® Card DNA Isolation Method	Lim Eng Seng & Tan Wai Fun	16th Meeting of the International Association of Forensic Sciences, Montpellier (France), 2-7 September 2002
Rapid STR Profiling Of Hair Samples	Dr Syn Kiu-Choong, Sim Hwee Chze & Tan Wai Fun	16th Meeting of the International Association of Forensic Sciences, Montpellier (France), 2-7 September 2002
Race Characteristics In English Handwriting In Singapore	Lee Gek Kwee, Cheng Nellie, Lee Lee Tiang & Tan Sock Kim	16th Meeting of the International Association of Forensic Sciences, Montpellier (France), 2-7 September 2002
The Forensic Comparison Of Cut Edges In Newspaper Sheets	Lim Thiam Bon & Dr Tay Ming Kiong	55th Annual Meeting of the American Academy of Forensic Sciences, Chicago (USA), 17-22 February 2003
Characterisation And Profiling Of Illicit Methamphetamine Tablets Abused In Singapore	Ng Khim Hui, Dr Chen Shao Xing, Dr Lee Tong Kooi, Mangudi Merula & Wong Yen Ling	55th Annual Meeting of the American Academy of Forensic Sciences, Chicago (USA), 17-22 February 2003
<b>TITLE OF RESEARCH PROJECT</b>	<b>AUTHOR(S)</b>	
Blood And Plasma Drugs Level - A Correlation Study	Dr Lo Siaw Teck, Prof Ng Tju Lik, Dr Yao Yi Ju, Goh Wee Sin & Leong Hsiao Tung	
To Establish A Genetic Analysis Method To Detect Genetically Modified (GM) Soybean Using PCR	Heng Jasmine, Dr Syn Kiu-Choong & Lim Eng Seng	
Study On The Level Of Difficulties In The Simulation Of Individual Characteristics In Signatures	Lee Gek Kwee & Tan Koon Puay	
Characterisation And Profiling Of Illicit Tablets Containing Methamphetamine	Dr Lee Tong Kooi, Ng Khim Hui, Dr Chen Shao Xing, Mangudi Merula, Wong Yen Ling	



## PROVIDING ESSENTIAL BLOODBANKING SERVICES

TITLE OF RESEARCH PRESENTATION	AUTHOR(S)	PROFESSIONAL EVENT
Prevalence Of HTLV In Singapore Blood Donors	Ng Weng Yik, Michael	1st HSA Scientific Seminar, 12 April 2002 Joint Annual Scientific Meeting of the Australian Society for Blood Transfusion and Australian Society of Haematology, Adelaide (Australia), 9-12 September 2003
Comparison For The Different Apheresis Machines For The Final Platelet Products In Centre For Transfusion Medicine	Dr Lai Hock Choong	1st HSA Scientific Seminar, 12 April 2002 55th AABB Annual Meeting, Orlando (USA), 26-29 October 2002
Increased Plasma Recovery With New Centrifugation Method	Leong Tong Seng, Dr Marieta Chan & Dr Diana Teo	1st HSA Scientific Seminar, 12 April 2002
Feasibility Of Malaria Testing In Selected Blood Donor Groups	Toh Chiew Yong & Lim Gek Yee	19th NRL Workshop on Serology, Melbourne (Australia), 20-22 August 2002
HCV-NAT Testing Of Singapore Blood Donors	Sally Lam	27th Congress of the International Society for Blood Transfusion, Vancouver (Canada), 24-29 September 2002
Anti-Jk <sup>a</sup> Autoimmune Hemolytic Anemia In A Singaporean Infant	Shu Pei Huey, Neo Theng Hee & Patrick Prakash	9th ASEAN Conference in Medical Laboratory Technology, 18-22 November 2002
Validation Of The Nageotte Chamber Quality Control Procedure For Leuko-reduced Components By Parallel Neubaur-Nageotte	Loke Mei Fong, Lim Sim Kuan Clara, Ng Kok Quan	9th ASEAN Conference in Medical Laboratory Technology, 18-22 November 2002
Performance Of Haemonetics ACP 215 Automated Blood Glycerolisation/ Deglycerolisation System	Liong Chong Wah	9th ASEAN Conference in Medical Laboratory Technology, 18-22 November 2002

research papers & projects



**PROVIDING SCIENTIFIC ANALYTICAL AND CONSULTING SERVICES**

TITLE OF RESEARCH PAPER	AUTHOR(S)	PROFESSIONAL PUBLICATION
Chemical Assay Of Glycyrrhizin In Medicinal Plants By Pressurised Liquid Extraction (PLE) With Capillary Zone Electrophoresis (CZE)	Ong Eng Shi	Journal of Separation Science, 25, 825-83, 2002
Determination Of Ginsenosides In Medicinal Plants And Health Supplements By Pressurised Liquid Extraction (PLE) With Reverse Phase High Performance Liquid Chromatography	Lee Hwei Khien, Ong Eng Shi & Woo Soo On	Journal of Separation Science, 25, 160-166, 2002
Pressurised Hot Water Extraction Of Berberine, Baicalein And Glycyrrhizin In Medicinal Plants	Ong Eng Shi & Len Shea Mei	Analytica Chimica Acta 482 81-89, 2003
TITLE OF RESEARCH PRESENTATION	AUTHOR(S)	PROFESSIONAL EVENT
Colourants In Perfume	Wong-Neo Geok Eng, See Phek Hah & Tang Kwai Fong	1st HSA Scientific Seminar, 12 April 2002
Determination Of Carbon Monoxide In Tuna Flesh	Anne Bruneau, Philip Barlow, Department of Chemistry (NUS) & Joanne Chan Sheot Harn	1st HSA Scientific Seminar, 12 April 2002
Determination Of Deoxynivalenol In Grain/Cereal	Grace Chua, Loke Swee Leng, Teo Sumin & Yap Wee Kim	1st HSA Scientific Seminar, 12 April 2002
Uncertainty Of Measurement Of Analysis Of Nitrate By Capillary Electrophoresis	Joanne Chan Sheot Harn & Lee Lin Min	Workshop of Measurement Traceability and Uncertainty in Analytical Chemistry, Switzerland, 16-18 June 2002
Chemical Standardisation Of Medicinal Plants And Herbal Preparations By Pressurised Liquid Extraction With HPLC/CE	Ong Eng Shi	Interact 2002, Sydney (Australia), 21-25 July 2002
Methods For Characterising Herbal Medicine	Ong Eng Shi	Seminar on Evidence Based Herbal Medicines, Kuala Lumpur (Malaysia), 19 February 2003
TITLE OF RESEARCH PROJECT	AUTHOR(S)	
Determination Of Ethyl Carbamate In Sauces	Joanne Chan Sheot Harn	
Chromatographic Determination Of Acrylamide In Carbohydrate-Rich Food	Joanne Chan Sheot Harn	
Developing Analytical Procedures For Identification And Assay Of Hydroquinone In Cosmetic Creams	Wong-Neo Geok Eng	

senior management



**Dr Clarence Tan**  
Chief Executive Officer



**Dr John Lim**  
Director, Centre for Pharmaceutical Administration  
Acting Director, Centre for Drug Evaluation



**Mr Wong Yew Sin**  
Director, Centre for Medical Device Regulation



**Mr Stephen Chong**  
Director, Centre for Radiation Protection



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

senior management



**Dr Paul Chui**

Director, Centre for Forensic Medicine  
Director, Office for Innovation and Enterprise



**Dr Chow Shui Tse**

Director, Centre for Forensic Science



**Mr Chua Teck Hock**

Director, Centre for Analytical Science



**Mr Vincent Fong**

Director, Corporate Management Group



**A/Prof Ng Tju Lik**

Senior Scientific Advisor  
Quality Service Manager

# principal officers

(as at July 2003)

## Chief Executive Officer

Dr Clarence Tan

## Deputy Director, Legal

Peter Lim

## Senior Scientific Advisor

Quality Service Manager

A/Prof Ng Tju Lik

## OFFICE FOR INNOVATION & ENTERPRISE

### Director

Dr Paul Chui

### Assistant Director

Ms Lim Peck Seah

## CORPORATE MANAGEMENT GROUP

### Director, Corporate Management

Vincent Fong

### Deputy Director, Corporate Communications

Ms Jeannie Thng

### Deputy Director, Corporate Services

Chua Hong Tong

### Deputy Director, Finance

Philip Ngiam

### Deputy Director, Human Resource

Mrs Sarojini Padmanathan

### Deputy Director, Information Management

Dr Bosco Chen Bloodworth

## CENTRE FOR PHARMACEUTICAL ADMINISTRATION

### Director

Dr John Lim

### *Compliance & Complementary Medicines Division*

### Senior Deputy Director

Yee Shen Kuan

### Head, Prosecution

Yee Shen Kuan

### Head, Investigation & Surveillance

R Sivalingam

### Head, Chinese Proprietary Medicine

Ms Chu Swee Seng

### Head, Health Supplements

Chao Ye Peng

### Head, Tobacco Regulation

Tham Lup Hong

### Head, Regulatory Support

Ho Yu Nam

### *Product Evaluation & Registration Division*

### Deputy Director

Mrs Marie Tham

### Head, Drug Registration

Dr Kerwin Low

### Head, Clinical Trials

Dr Kerwin Low

### Head, Cosmetic Control

Mrs Marie Tham

## principal officers

### *Manufacturing & Quality Audit Division*

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Sia Chong Hock

**Head, Good Manufacturing Practice**  
Sia Chong Hock

**Head, Good Distribution Practice**  
Sia Chong Hock

**Head, Certification**  
Dr Lai Weng Fai

**Head, International Operations**  
Boon Meow Hoe

### *Pharmacovigilance, Communications & Research Division*

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Mdm Suwarin Chaturapit

**Head, Pharmacovigilance**  
Ms Chan Cheng Leng

**Head, Information & Research**  
Ms Chan Cheng Leng

**Head, Communications & International Liaison**  
Mdm Suwarin Chaturapit

### **CENTRE FOR DRUG EVALUATION**

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**Deputy Director & Clinical Pharmacology Advisor**  
Prof Vernon Oh

**Assistant Director & Senior Medical Reviewer**  
Dr Gerard Wong

**Training Coordinator & Senior Regulatory Scientist**  
Dr Vivian Chan

**Regulatory Scientist & Corporate Management Coordinator**  
Tan Tek Seng

### **CENTRE FOR MEDICAL DEVICE REGULATION**

**Director**  
Wong Yew Sin

**Manager**  
Dr Nealda Leila Muhammad Yusof

### **CENTRE FOR RADIATION PROTECTION**

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Stephen Chong

**Head, Environmental Radiation & Waste Management**  
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**  
Tay Yong Heng

**Head, Services & Consultancy**  
Tay Yong Heng

### **CENTRE FOR TRANSFUSION MEDICINE**

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**Head, Blood Resources**  
Dr Tan Hwee Huang

**Nursing Administrator**  
Mrs Chua-Ong Chye Leng

**Head, Blood Processing & Inventory**  
Ng Kok Quan

## principal officers

**Head, Quality Control**  
Ms Sally Lam

**Head, Hospital Services**  
Dr Marieta Chan

**Head, Blood Programme Support**  
Ms Koh Geok Tin

**Quality Manager**  
Patrick Prakash

### **CENTRE FOR FORENSIC MEDICINE**

**Director**  
Dr Paul Chui

**Deputy Director**  
Dr Gilbert Lau

**Principal Forensic Consultant**  
Dr Wee Keng Poh

**Head, Professional Training & Education**  
Dr George Paul

### **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**  
Chua Teck Hock

**Deputy Director**  
Wong Yew Sin

**Head, Food Laboratory**  
Ms Joanne Chan

**Head, Pharmaceutical Laboratory**  
Dr Bosco Chen Bloodworth

**Head, Industrial Health Laboratory**  
Dr Woo Soo On

**Head, Cosmetics Laboratory**  
Mrs Wong Geok Eng

**Head, Cigarette Testing Laboratory**  
Dr Chow Yue Thong

**Head, Environment Laboratory**  
Ng Soon

**Head, Research & Development**  
Ong Eng Shi

## **financial statements**

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**107** notes to the financial statements

## 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 2003, as set out on pages 102 to 118. 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 Statements of Accounting Standard so as to give a true and fair view of the state of affairs of the Authority as at 31 March 2003, 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

10 July 2003

## STATEMENT BY THE HEALTH SCIENCES AUTHORITY

In our opinion, the accompanying financial statements of Health Sciences Authority (the "Authority") as set out on pages 102 to 118 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 2003 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

*Singapore*

*10 July 2003*



**Dr Clarence Tan Tiong Tee**

Chief Executive Officer

*Singapore*

*10 July 2003*

## BALANCE SHEET

As at 31 March 2003

	Note	2003 \$'000	2002 \$'000 (Restated)
<b>ACCUMULATED SURPLUS</b>	4	2,528	2,097
<b>PRE-RESTRUCTURING FUNDS</b>	5	246	390
<b>DEFERRED CAPITAL GRANTS</b>	6	3,708	232
		<u>6,482</u>	<u>2,719</u>
<b>REPRESENTED BY:</b>			
<b>CURRENT ASSETS</b>			
Cash and cash equivalents	7	19,744	14,568
Trade receivables		5,067	5,886
Other receivables, deposits and prepayments	8	744	14,336
Inventories	9	1,678	1,216
Total current assets		<u>27,233</u>	<u>36,006</u>
<b>NON-CURRENT ASSET</b>			
Plant and equipment	10	14,426	8,023
<b>CURRENT LIABILITIES</b>			
Trade payables		(4,310)	(7,086)
Other payables and accruals (Note below *)	11	(27,013)	(31,952)
Grants received in advance:			
Government	12	(917)	(62)
Non-government	13	(227)	(20)
Contribution to Consolidated Fund		(122)	(680)
Total current liabilities		<u>(32,589)</u>	<u>(39,800)</u>
<b>NON-CURRENT LIABILITY</b>			
Other payables and accruals	11	(2,588)	(1,510)
<b>NET ASSETS</b>		<u>6,482</u>	<u>2,719</u>

\*Note:

This included an amount payable for the net assets of \$18,610,000 transferred from the Ministry of Health when the Authority was established on 1 April 2001. Pending the completion and finalisation of the mode of transfer (loan or 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.

## INCOME AND EXPENDITURE STATEMENT

Financial year ended 31 March 2003

	Note	2003 \$'000	2002 \$'000 (Restated)
<b>OPERATING INCOME</b>			
Laboratory analysis fees		18,808	20,107
Blood processing fees		11,737	9,520
Patient laboratory testing fees		1,447	1,236
Forensic investigation fees		5,749	5,884
Licensing fees		5,300	4,990
Professional service fees		704	597
Miscellaneous income		137	131
		43,882	42,465
<b>OPERATING EXPENDITURE</b>			
Staff costs	14	30,777	30,339
Supplies and services		9,856	8,771
Rental of premises and equipment		5,768	5,540
Blood donor expenses		3,478	2,537
Repairs and maintenance		3,096	2,990
Depreciation of plant and equipment	10	3,060	5,657
Staff welfare and development		2,767	1,603
Professional services		1,722	1,008
Utilities		1,193	1,118
Transport, postages and communications	15	1,037	753
Publicity and public relations	15	522	234
Audit fees	16	70	55
Board members' allowances		38	63
Other expenses		855	748
		64,239	61,416
<b>OPERATING DEFICIT</b>		(20,357)	(18,951)
<b>NON-OPERATING SURPLUS</b>	17	398	328
<b>DEFICIT BEFORE GRANTS</b>		(19,959)	(18,623)
<b>GRANTS</b>			
Government grants	12	19,083	19,790
Non-government grants	13	1,382	757
Pre-restructuring funds	5	14	834
Deferred capital grants amortised	6	33	19
		20,512	21,400
<b>SURPLUS BEFORE CONTRIBUTION TO CONSOLIDATED FUND</b>		553	2,777
<b>CONTRIBUTION TO CONSOLIDATED FUND</b>	18	(122)	(680)
<b>NET SURPLUS FOR THE YEAR</b>		431	2,097

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

## STATEMENT OF CHANGES IN RESERVES AND FUNDS

Financial year ended 31 March 2003

	Accumulated surplus \$'000	Pre- restructuring funds \$'000	Deferred capital grants \$'000	Total \$'000
Balance as at 1 April 2001	-	-	-	-
Amount received from Ministry of Health during the year	-	1,475	-	1,475
Surplus for the year	2,097	-	-	2,097
Transfer to deferred capital grants (Note 5)	-	(251)	251	-
Transfer to income and expenditure statement	-	(834)	(19)	(853)
Balance as at 31 March 2002	2,097	390	232	2,719
Surplus for the year	431	-	-	431
Transferred to deferred capital grants	-	(130)	3,509	3,379
Transfer to income and expenditure statement (Notes 5 and 6)	-	(14)	(33)	(47)
Balance as at 31 March 2003	2,528	246	3,708	6,482

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

## CASH FLOW STATEMENT

Financial year ended 31 March 2003

	Note	2003 \$'000	2002 \$'000 (Restated)
<b>CASH FLOWS FROM GRANTS:</b>			
Pre-restructuring funds received	5	–	1,475
Government grants received	12	37,266	5,903
Non-government grants received	13	1,589	777
Total cash from grants		38,855	8,155
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Deficit before grants		(19,959)	(18,623)
Adjustments for:			
Depreciation of plant and equipment	10	3,060	5,657
Loss on disposal of plant and equipment	17	–	11
Interest income	17	(72)	(76)
Deficit before working capital changes		(16,971)	(13,031)
Changes in working capital excluding cash and cash equivalents:			
Trade receivables		819	4,135
Other receivables and prepayments		(357)	(387)
Inventories		(462)	70
Trade payables		(2,776)	6,357
Other payables and accruals		(3,861)	10,927
Cash (used in) generated from operations		(23,608)	8,071
Contribution to Consolidated Fund paid during the year		(680)	–
Net cash (used in) generated from operating activities		(24,288)	8,071
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Purchase of plant and equipment	10	(9,498)	(1,750)
Interest received		72	76
Proceeds from disposal of plant and equipment		35	16
Net cash used in investing activities		(9,391)	(1,658)
Net increase in cash and cash equivalents		5,176	14,568
Cash and cash equivalents at beginning of year		14,568	–
<b>Cash and cash equivalents at end of year</b>		<b>19,744</b>	<b>14,568</b>

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

## CASH FLOW STATEMENT

Financial year ended 31 March 2003

**Note: The following assets and liabilities transferred to the Authority from the Ministry of Health (“MOH”) on 1 April 2001 (date of establishment) did not result in any cashflow impact for 2002 :**

	2003 \$'000	2002 \$'000
Plant and equipment	–	11,957
Trade receivables	–	10,021
Inventories	–	1,286
Trade payables	–	(729)
Other payables	–	(3,925)
Financed by: Amount owing to MOH for net assets transferred (Note 11)	–	18,610

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

## NOTES TO THE FINANCIAL STATEMENTS

Financial year ended 31 March 2003

### 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 2003 were authorised for issue by the members of its Board on 10 July 2003.

### 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) and Singapore Statements of Accounting Standard.

#### *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.

## NOTES TO THE FINANCIAL STATEMENTS

Financial year ended 31 March 2003

### 2 SIGNIFICANT ACCOUNTING POLICIES *(continued)*

#### *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 8 years
Motor vehicles	10 years
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.

#### *f) Impairment of assets*

At the balance sheet date, the Authority reviews the carrying amount 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). If the recoverable amount of the asset is estimated to be less than its carrying amount, the carrying amount of the asset is reduced to its recoverable amount. Impairment losses are recognised as an expense immediately.

#### *g) Leases*

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

#### *h) Foreign currency transactions*

Transactions in foreign currencies are recorded in Singapore dollars at 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 gains and losses are dealt with in the income and expenditure statement.

## NOTES TO THE FINANCIAL STATEMENTS

Financial year ended 31 March 2003

### 2 SIGNIFICANT ACCOUNTING POLICIES *(continued)*

#### *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 off.

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 are charged as an expense when incurred.

Prior to 1 April 2002, 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. With effect from 1 April 2002, defined benefit retirement obligations are recognised in the balance sheet based on management estimates. This has the effect of increasing the charge to income and expenditure statement for the year by approximately \$373,000.

#### *l) 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.

## NOTES TO THE FINANCIAL STATEMENTS

Financial year ended 31 March 2003

### 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 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 internal funds and 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 ACCUMULATED SURPLUS

The accumulated surplus is to be utilised for future capital and operating expenditures of the Authority.

## NOTES TO THE FINANCIAL STATEMENTS

Financial year ended 31 March 2003

### 5 PRE-RESTRUCTURING FUNDS

	<b>2003</b>	<b>2002</b>
	<b>\$'000</b>	<b>\$'000</b>
Balance at beginning of year	390	–
Receipt during the year	–	1,475
Transferred to deferred capital grants (Note 6)	(130)	(251)
Transferred to income and expenditure statement	(14)	(834)
Balance at end of year	246	390

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

### 6 DEFERRED CAPITAL GRANTS

	<b>2003</b>	<b>2002</b>
	<b>\$'000</b>	<b>\$'000</b>
Balance at beginning of year	232	–
Transferred from pre-restructuring funds (Note 5)	130	251
Transferred from grants received in advance – IT Master Plan (Note 12)	3,379	–
Transferred to income and expenditure statement to match depreciation of related assets	(33)	(19)
Balance at end of year	3,708	232

### 7 CASH AND CASH EQUIVALENTS

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

	<b>2003</b>	<b>2002</b>
	<b>\$'000</b>	<b>\$'000</b>
Bank and cash balances	11,729	8,554
Fixed deposits	2,006	–
Short-term bank note [quoted, market value of \$6,009,000 (2002 : \$6,014,000)]	6,009	6,014
	19,744	14,568

The short-term bank note is a fixed-rate secured note which bears interest at the rate of 1.08% (2002 : 1.4%) per annum and matures on 14 May 2003.

## NOTES TO THE FINANCIAL STATEMENTS

Financial year ended 31 March 2003

### 8 OTHER RECEIVABLES, DEPOSITS AND PREPAYMENTS

	2003 \$'000	2002 \$'000 (Restated)
Government grants receivable from MOH	–	13,949
Other receivables from MOH <sup>(a)</sup>	–	313
Other receivables	237	–
Deposits	421	–
Advances to staff <sup>(b)</sup>	21	17
Prepayments	65	57
	<u>744</u>	<u>14,336</u>

(a) This pertained to a deposit account maintained with MOH which was set up for the purpose of the disbursement of salaries to the employees of the Authority during the initial 9 months after the establishment of the Authority. The account was closed in 2003.

(b) 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.

### 9 INVENTORIES

	2003 \$'000	2002 \$'000
Gases, laboratory and medical supplies, at cost	<u>1,678</u>	<u>1,216</u>

## NOTES TO THE FINANCIAL STATEMENTS

Financial year ended 31 March 2003

### 10 PLANT AND EQUIPMENT

	Building improvements \$'000	Computers \$'000	Motor vehicles \$'000	Equipment, furniture and fittings \$'000	Work- in-progress \$'000	Total \$'000
Cost:						
At beginning of year	624	3,260	186	9,610	-	13,680
Additions	1,376	474	-	4,196	3,452	9,498
Disposals	-	(367)	-	(1,268)	-	(1,635)
At end of year	2,000	3,367	186	12,538	3,452	21,543
Accumulated depreciation:						
At beginning of year	13	2,227	24	3,393	-	5,657
Depreciation for the year	67	788	13	2,192	-	3,060
Disposals	-	(353)	-	(1,247)	-	(1,600)
At end of year	80	2,662	37	4,338	-	7,117
Depreciation for the year 2002	13	2,227	24	3,393	-	5,657
Net book value:						
At end of year	1,920	705	149	8,200	3,452	14,426
At beginning of year	611	1,033	162	6,217	-	8,023

## NOTES TO THE FINANCIAL STATEMENTS

Financial year ended 31 March 2003

### 11 OTHER PAYABLES AND ACCRUALS

	2003 \$'000	2002 \$'000 (Restated)
Licence fees collected in advance	4,316	4,391
Amount payable to MOH for net assets transferred <sup>(a)</sup>	18,610	18,610
Amount payable to MOH for operating leases (Note 21)	–	5,139
Accrual for staff costs	5,367	4,278
GST payable	163	111
Refundable security deposits	205	211
Accrual for purchase of plant and equipment	–	93
Other payables and accruals	940	629
	29,601	33,462
Non-current portion:		
Licence fees collected in advance	(1,036)	(820)
Obligations in respect of defined benefit retirement plan as included in accrual for staff costs <sup>(b)</sup>	(1,552)	(690)
	(2,588)	(1,510)
Current portion:	27,013	31,952
Movements in obligations in respect of defined benefit retirement plan:		
	2003 \$'000	2002 \$'000
Balance at beginning of year	690	–
Charge to income and expenditure statement (Note 14)	989	740
Payment during the year	(127)	(50)
Balance at end of year	1,552	690

<sup>(a)</sup> This represents 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.

<sup>(b)</sup> This represents 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 plans 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. Prior to 1 April 2002, defined benefit retirement obligations are recognised in the balance sheet as advised by the Accountant-General's Department in their circular No. 14/2000 (AG(S) 37/95 Vol 2) dated 11 April 2000. With effect from 1 April 2002, defined benefit retirement obligations are recognised in the balance sheet based on management estimates. This has the effect of increasing the charge to income and expenditure statement for the year by approximately \$373,000.

## NOTES TO THE FINANCIAL STATEMENTS

Financial year ended 31 March 2003

### 12 GRANTS RECEIVED IN ADVANCE - GOVERNMENT

	IT Master Plan <sup>(a)</sup>		Operating Grants		HMDP <sup>(b)</sup>		Total	
	2003 \$'000	2002 \$'000	2003 \$'000	2002 \$'000	2003 \$'000	2002 \$'000	2003 \$'000	2002 \$'000
Balance at beginning of year	-	-	-	-	62	-	62	-
Receipts during the year	3,704	-	33,312	5,700	250	203	37,266	5,903
Receivable at year end (Note 8)	-	-	(13,949)	13,949	-	-	(13,949)	13,949
Transfer to deferred capital grants (Note 6)	(3,379)	-	-	-	-	-	(3,379)	-
Transfer to income and expenditure statement	-	-	(18,951)	(19,649)	(132)	(141)	(19,083)	(19,790)
Balance at end of year	325	-	412	-	180	62	917	62
Total grants received since establishment	3,704	-	39,012	5,700	453	203	43,169	5,903

(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 has been formulated to align the Authority's computerisation blueprint. This blueprint outlines the information system required over a 3-year period. The IT Master Plan is scheduled to commence in 2003 and 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 Health Manpower Development Programme ("HMDP") relates to funds received from MOH for sponsoring professional staff for overseas training.

### 13 GRANTS RECEIVED IN ADVANCE - NON-GOVERNMENT

	2003 \$'000	2002 \$'000
Balance at beginning of year	20	-
Receipts during the year	1,589	777
Transfer to income and expenditure statement	(1,382)	(757)
Balance at end of year	227	20

## NOTES TO THE FINANCIAL STATEMENTS

Financial year ended 31 March 2003

### 14 STAFF COSTS

	2003 \$'000	2002 \$'000
Staff costs	30,777	30,339
Cost of defined contribution retirement plans included in staff costs	3,276	3,199
Cost of obligations in respect of defined benefit retirement plan included in staff costs	989	740

The Authority has 494 (2002 : 464) employees as at the end of the year.

### 15 TRANSPORT, POSTAGES AND COMMUNICATIONS, PUBLICITY AND PUBLIC RELATIONS

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

	2003 \$'000	2002 \$'000
Overseas travelling	65	92
Entertainment	19	33

### 16 AUDIT FEES

	2003 \$'000	2002 \$'000
Current	60	55
Underprovision in prior year	10	-
	70	55

### 17 NON-OPERATING SURPLUS

	2003 \$'000	2002 \$'000
Interest income	72	76
Fines and forfeitures	258	226
Miscellaneous income	189	38
	519	340
Foreign currency exchange loss	(121)	(1)
Loss on disposal of plant and equipment	-	(11)
	(121)	(12)
Non-operating surplus	398	328

## NOTES TO THE FINANCIAL STATEMENTS

Financial year ended 31 March 2003

### 18 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). This contribution is based on the net surplus for the respective financial years ended 31 March 2003 and 31 March 2002, at the prevailing corporate tax rates for the Year of Assessment 2003 at 22% (2002 : 24.5%).

### 19 CAPITAL EXPENDITURE COMMITMENTS

	2003 \$'000	2002 \$'000
Estimated amounts committed for future capital expenditure but not provided for in the financial statements	18,477	689

### 20 OPERATING LEASE COMMITMENTS

	2003 \$'000	2002 \$'000 (Restated)
Minimum lease payments paid under operating leases	5,768	5,540

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

	2003 \$'000	2002 \$'000 (Restated)
Within one year	5,758	5,379
In the second to fifth years inclusive	315	5,723

## NOTES TO THE FINANCIAL STATEMENTS

Financial year ended 31 March 2003

### 21 RECLASSIFICATIONS AND COMPARATIVE FIGURES

In the previous financial year, the Authority occupied premises at 11 Outram Road and 2 Jalan Bukit Merah, Singapore, owned by the MOH, on a rent-free basis while liaising with MOH on the arrangements with regards to the transfer or lease of these premises.

During the current financial year, formal lease agreements for the rental of the abovementioned premises were drawn up between the MOH and the Authority for the period from 1 April 2001 to 31 March 2004. Accordingly, \$5,139,120 should have been charged as rental expense for the financial year ended 31 March 2002. The Authority also received additional operating grants of \$5,139,120 from MOH during the year to match the rental expense for the previous financial year.

Prior year adjustments have been passed to effect the above as follows:

	Balance as previously reported \$'000	Prior year adjustments \$'000	Balance as restated \$'000
<b>Balance sheet as at 31 March 2002</b>			
Other payables and accruals	26,813	5,139	31,952
Other receivables and prepayments	9,197	5,139	14,336
<b>Income and expenditure statement for the financial year ended 31 March 2002</b>			
Rental of premises and equipment	401	5,139	5,540
Government grants	14,651	5,139	19,790

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