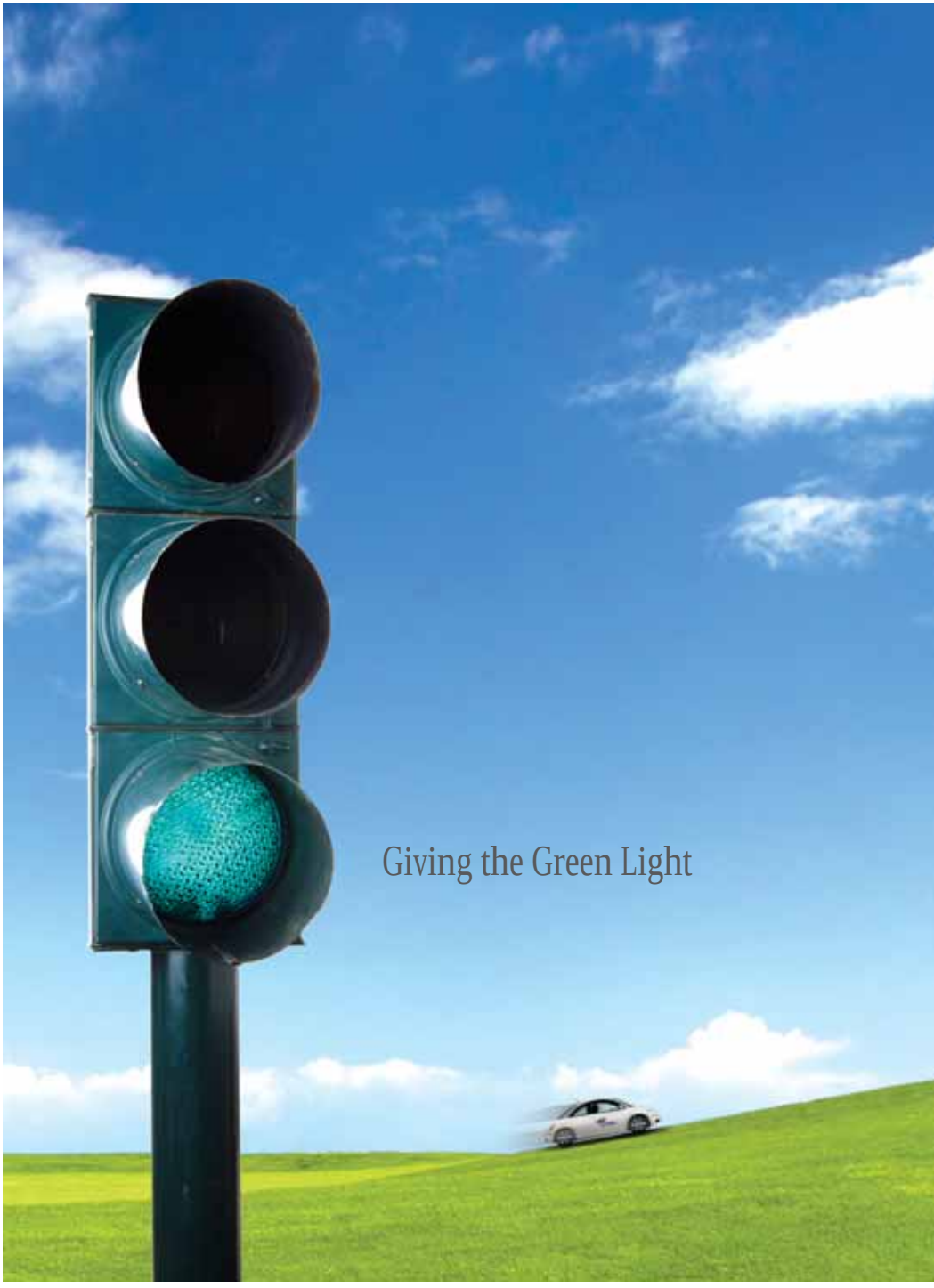

Giving the Green Light

We ensure that drugs, innovative therapeutics, medical devices, and health-related products in Singapore are wisely regulated to meet appropriate standards of safety, quality and efficacy.

Health Products Regulation Group

- CENTRE FOR DRUG ADMINISTRATION
- CENTRE FOR MEDICAL DEVICE REGULATION
- CENTRE FOR RADIATION PROTECTION*

CMDR CRP CDA

* With effect from 1 July 2007, the Centre for Radiation Protection has been transferred to the National Environment Agency and renamed as the Centre for Radiation Protection and Nuclear Science.

THE HSA Journey

To:

Front [Left to Right] :
Ms Chu Swee Seng
Yee Shen Kuan
Mrs Marie Tham

Back [Left to Right] :
Alfred Kwek
Seet Wing Gang
Chao Ye Peng
Kelvin Tan
Tham Lup Hong
R. Sivalingam

THE HSA Journey

To:

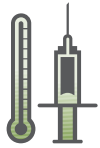
Front [Left to Right] :
Ms Lee Hui Keng
Mdm Suwarin Chaturapit
Sia Chong Hock
Ms Chan Cheng Leng

Back [Left to Right] :
Dr Lu Set
Dr Lai Weng Fai
Ms Hui Foong Mei
Boon Meow Hoe
Foo Yang Tong
Ho Yu Nam

New Drugs Registered
52

Chinese Proprietary Medicines Listed
1,340

Cosmetic Products Registered
7,983



Medical Devices Listed*
4,376

Irradiating Apparatus & Radioactive Materials Licensed
30,120

Clinical Trials Approved
217

Medical Advertisement Permits Issued
1,306

Site Audits Conducted for Good Manufacturing & Good Distribution Practices
468

Premises, Dealers, Importers & Exporters Licensed/Certified**
3,896

Tobacco Retail Outlets Licensed
916

Products Recalled
42

Adverse Drug Reaction Reports Received
11,984

* as at 31 March 2007
** includes new, renewal and amendment applications

Driving New Standards in Professional Excellence

Our Centre for Drug Administration [CDA] regulates medicinal products, complementary health products, cosmetics and tobacco products in Singapore. It administers and enforces the Medicines Act, Poisons Act, Sale of Drugs Act, Medicines [Advertisement and Sale] Act and Misuse of Drug Regulations and Smoking [Control of Advertisements and Sale of Tobacco] Act. A robust framework comprising pre- and post-marketing regulatory activities is applied. This comprises pre-market evaluation, licensing and certification activities, on-going post-marketing monitoring through inspections and surveillance, and Adverse Drug Reactions [ADRs] Reporting to track continued standards of products marketed in Singapore.

Our Centre for Medical Device Regulation [CMDR] has administered the interim Voluntary Product Registration Scheme [VPRS] for higher-risk medical devices since 2002. We are well on track to a legislated, regulated environment for medical devices in Singapore.

Our Centre for Radiation Protection [CRP], while with HSA, was the national regulatory authority for the safe use of ionising and non-ionising radiation of irradiating apparatus and radioactive materials in Singapore. It enforced the Radiation Protection Act and its subsidiary regulations through a system of licensing and inspection. Besides personalised monitoring services and radioactivity analyses, it also provided consultancy and training on radiation safety.

Innovative Regulation

On 12 February 2007, the Health Products Bill was passed by Parliament. The resulting Health Products Act was designed as an omnibus legislation that will consolidate, and eventually replace, the existing four separate Acts regulating medicines and other health-related products currently administered by HSA. The Health Products Act is notable in that it incorporates a legislative mechanism that allows the different controlling provisions in the Act to be effected on different categories of health products in a modular manner. This gives HSA more flexibility in tailoring different regulatory regimes for different categories of health products, and avoiding over- or under-regulating any particular category of product.

Medical devices is the first category of health products to be regulated under this new Health Products Act. Based on the principles endorsed by the Global Harmonisation Task Force [GHTF], which include licensing of medical device dealers as well as the products, the proposed framework underwent a two-month public consultation exercise between February and April 2007. In March 2007, as part of our continuing efforts to engage stakeholders in the formulation of the medical device regulations, we also conducted an industry briefing to representatives from over a hundred companies. The Phase I implementation of this new framework by 2007 will bring Singapore in line with international best practices on the regulation of medical devices.

Responsive Regulatory System

To ensure that rules and regulations are kept current and meet the needs of our stakeholders in the changing environment, HSA conducts ongoing reviews of its rules and regulations in consultation with its stakeholders. New initiatives arising from the regulatory reviews are developed together with our stakeholders and communicated to ensure clarity and transparency.

The drug registration system and requirements were reviewed. The major initiatives are:

- for safety labelling updates to be submitted through notification rather than the approval process, allowing predictability and better planning by the industry
- the waiver of Certificate of Pharmaceutical Product [CPP] for new product applications where other forms of approval documents can be used as appropriate substitutes
- for a major revision of the drug registration guidance document for the industry, to enhance clarity and transparency

To communicate these new drug registration initiatives, a two-day drug registration workshop for the industry was held in February 2007 and attended by over 200 industry representatives from Singapore, Malaysia, Indonesia, Australia, France and the USA.

The regulatory controls for Chinese Proprietary Medicines [CPM] were also reviewed and, in July 2006, the CPM product labelling requirements were revised to include an advisory on consumer discretion.

The licensing requirements for retail pharmacists were also reviewed and streamlined. Since 1 July 2006, pharmacists are no longer required to amend Form C poisons licences when they practise at pharmacy outlets under the same management.

To improve transparency in the product classification system for health products and food and to assist traders in carrying out preliminary self-classification of products, we have jointly developed a Food-Health Products Classification Tree with the Agri-Food and Veterinary Authority.

As part of our stepped-up efforts against retailers who illegally sell tobacco products to underage persons, the list of suspended tobacco retailers was made available on our website from April 2007.

Networked Risk Management

Networking and strategic alliances allow HSA to tap on knowledge and data beyond the agency and strengthen our regulatory decision-making and risk management processes. In FY 2006, we evaluated and approved several major new drugs, which included:

New Chemical Drugs

- Alvesco [ciclesonide] Mictonorm [Popiverine]
- Certican [everolimus]
- Protos [strontium ranelate]
- Faslodex [fulvestrant]
- Macugen [pegatanib]

New Biological Drugs

- Rabipur [rabies vaccine]
- Gardasil [HPV vaccine]
- ProQuad [MMR & varicella vaccine]
- Xolair [omalizumab]
- Neulastim [pegfilgrastim]

In January 2006, we introduced electronic reporting of ADRs, in addition to submissions through fax, mail or email. This was through the Critical Medical Information Store [CMIS]* of the Electronic Medical Record Exchange [EMRX]**.

We worked with the Ministry of Health [MOH] to implement the drug safety module of the Healthcare Professional Portal [HPP], to enhance our outreach to healthcare professionals, important partners in our risk management system. Since June 2006, healthcare professionals in Singapore receive important and urgent drug safety alerts almost immediately through SMS, e-mail and fax, and can make ADR report enquiries on-line.

* CMIS [Critical Medical Information Store] of the EMRX serves as a shared electronic repository of patients' medical alerts, ADR and drug allergy data. The CMIS online ADR reporting form is also available at the HPP to allow healthcare professionals from the private sector to submit ADR reports. The HPP is a one-stop portal for the healthcare professional community to access multiple e-services relating to professional practice and information repository using single-sign-on through a common interface.

** EMRX [Electronic Medical Record Exchange] is an electronic platform which enables hospitals and government clinics across the two public healthcare clusters, National Healthcare Group and Singapore Health Services, to share vital patient medical information such as inpatient discharge summaries, medical history and laboratory results.


HOME
HSA warns against
using toxic
remedy for

Risk communication is achieved through drug safety alerts to healthcare professionals and the public, and the *Adverse Drug Reaction News Bulletin*. In 2006, we published three issues of the Bulletin, which was disseminated to over 9,000 doctors, pharmacists and dentists in Singapore. We also worked closely with the pharmaceutical companies to issue six *Dear Healthcare Professional* letters, which updated healthcare professionals on emerging and potential drug safety problems.

In 2006, HSA participated in investigations initiated from alerts by the Singapore National Eye Centre [SNEC] on an increased incidence of Fusarium Keratitis seen in contact lens users at the centre. We worked closely with MOH, SNEC and other local institutions, as well as the US Communicable Disease Center and US Food and Drug Administration. This eventually resulted in a voluntary withdrawal of Bausch & Lomb's ReNu products in Singapore on 17 February 2006 and a global voluntary withdrawal of ReNu MoistureLoc Contact Lens Solution on 15 April 2006.

Gaining Momentum through Strategic Alliances

Our Local Role

HSA works closely with local and overseas agencies to prevent illegal and unsafe drugs from entering our market. In 2006, we conducted several joint seizures on illegal codeine cough mixtures with other enforcement agencies, including the Central Narcotics Bureau [CNB], the Immigration & Checkpoints Authority [ICA] and the Singapore Police Force [SPF]. In one such operation, eight barrels of 200 litres of codeine mixture were seized, the largest seizure of such mixtures by HSA.

In August 2006, two individuals were arrested by CNB for illegally dealing in Dormicum. One of them, a foreign doctor, was sentenced to 15 months' imprisonment. The case involved 15,000 tablets and was one of the largest seizures of smuggled Dormicum tablets to date.

Working closely with ICA, we foiled several attempts to bring consignments of counterfeit and illegal medicinal products into Singapore. In one case, about 30 different types of illegal medicinal products, amounting to 100,000 tablets and capsules with an estimated street value of over S$500,000, were intercepted and seized.

In January 2007, we provided assistance to the Malaysian Health Ministry in their investigations on a case which involved the importation of an adulterated product, 'Miagra', worth RM14 million.

During the year, we made presentations at various local radiological security and safety seminars, including the SIN/US "Radiological Dispersal Device [RDD] Threat Reduction Workshop" organised by Defence Science and Technology Agency, and Ministry of Defence's Chemical, Biological, Radiological and Explosives seminar on Safety & Security.

Forging Closer Ties within the Region

ASEAN Consultative Committee for Standards and Quality [ACCSQ] Product Working Groups [PWGs]

In support of an integrated ASEAN healthcare vision led by the Ministry of Trade and Industry, the regulatory group continued to be actively engaged in numerous activities through PWGs established under the ACCSQ:

- Pharmaceutical PWG
- Traditional Medicines & Health Supplements PWG
- ASEAN Cosmetics Committee
- Medical Device PWG

Together with its ASEAN counterparts, the PWGs worked towards harmonising regulatory measures in product and labelling standards, Good Manufacturing Practices [GMP] standards, registration dossiers, the post-marketing alert system and negotiations on a Mutual Recognition Arrangement [MRA] for GMP Inspections for Medicinal Products.

Pharmaceuticals Product Working Group [PPWG]

The PPWG held its 12th Meeting in October 2006. HSA chaired the Implementation Working Group [IWG] and the MRA GMP Inspection Taskforce, which are responsible for coordinating the implementation of the ASEAN Common Technical Dossier [ACTD] and development of an MRA for GMP Inspection respectively. At the 12th Meeting, an agreement was reached to allow the ACTD developed by the International Conference for Harmonisation [ICH] for innovative products.

Traditional Medicines and Health Supplements Product Working Group [TMHS PWG]

With the support from the local traditional medicines and health supplements associations, we successfully hosted the 5th ACCSQ TMHS PWG meeting on 27 and 28 July 2006 and a seminar which preceded the meeting. The meeting attracted 178 regulatory and industry representatives from Asia, Europe and the USA and featured eminent experts from the World Health Organisation [WHO], Europe, USA and China. The 6th TMHS PWG Meeting was held in December 2006 and continued to focus on working out the definitions of traditional medicines and health supplements, the studies and surveys on technical requirements, GMP standards, quality control testing, labelling requirements and the regulatory infrastructure and product placement system.

ASEAN Cosmetics Committee [ACC]

The 7th ACC meeting was held in December 2006. At the meeting, the ASEAN Guidelines for the Safety Assessment of Cosmetic Products were formally adopted and Singapore was appointed to lead in its development.

Medical Device Product Working Group [MDPWG]

We successfully hosted the 5th ACCSQ MDPWG meeting in January 2007, which was attended by 95 government delegates and representatives from the ASEAN Secretariat and the medical device industry. At the meeting, the member countries formally adopted the "Dear Doctor Letter" Guideline, which allows a manufacturer or competent authority to inform healthcare professionals of any product safety issues. In addition, Singapore's proposed framework on "Post-Marketing Alert System" [PMAS] that aims to facilitate inter-ASEAN adverse event and product recall reporting was also accepted.

Asian Harmonisation Working Party [AHWP]*

As the co-chair of the AHWP Technical Committee, we have been working with other member countries to fine-tune the post-market alert system and common submission dossier template. In February 2007, we also represented AHWP to participate in the GHTF Study Group 1 [SG1]** meeting in Japan.

* The Asian Harmonisation Working Party [AHWP] studies and recommends ways to harmonise medical device regulations in the region and coordinates with the Global Harmonisation Task Force [GHTF] and Asia-Pacific Economic Cooperation [APEC].

** The SG1 compares operational medical device regulatory systems around the world and is responsible for developing a standardised format for pre-market submissions and harmonised product labelling requirements.

The International Arena

Memoranda of Understanding [MOU]

In 2006, HSA signed MOU with Health Canada's Health Products and Food Branch and the United States Pharmacopoeia. The MOU with the two international organisations aim to enhance mutual communication and scientific collaboration, encourage collaborative efforts in health products regulation, analysis and research, and increase the awareness of the importance of the quality and safety of medicinal products between agencies.

Relationships with the US Food and Drug Administration [FDA] and the Australian Therapeutics Goods Administration continue to be strengthened.

International Atomic Energy Agency [IAEA]

During the year, we participated in several IAEA events, which included delivering the Singapore Statement during the IAEA General in Vienna, and two regional co-ordination meetings on Public Exposure Control and Radioactive Waste Management in Myanmar and Indonesia respectively.

In July 2006, we hosted a week-long training course organised under IAEA/Regional Co-operative Agreement on the Organisation and Implementation of a National Regulatory Programme for the Control of Radiation Sources, including the Code of Conduct on the Safety and Security of Radiation Sources. During the month, a study visit was also organised for an IAEA fellow from the Iran Nuclear Regulatory Authority to study Singapore's system of radiation control.

WHO International Electromagnetic Field Project Advisory Committee

As a member of the WHO International Electromagnetic Field Project Advisory Committee, we participated in the Geneva meeting in June 2007. The focused research knowledge shared during the meeting has enhanced the EMF control programmes locally.

In addition, to strengthen international preparedness and regional response system for Nuclear and Radiological Emergencies, we also participated in a National Competent Authority Workshop in Melbourne, Australia in November.

International Medicinal Products Anti-Counterfeiting Taskforce [IMPACT]
Initiated by the WHO, the IMPACT is a voluntary grouping of governments, organisations, institutions, agencies and associations from developing and developed countries aimed at sharing expertise, identifying problems, seeking solutions, co-ordinating activities and working towards the common goal of fighting counterfeit medical products. To accomplish this mandate, IMPACT will focus on five key areas, namely: Legislative and Regulatory Infrastructure, Enforcement, Technology, and Risk Communication. Singapore, represented by HSA, was nominated as one of the Vice-Chairs of the IMPACT taskforce and thus became a member of the IMPACT Planning Group. Five Working Groups were established to address the five key areas of concern, and have been working independently to present their proposals at the Second General Meeting in December 2007.

WHO-sponsored GMP Audit
During the year, we participated in GMP audits in China and India sponsored by the WHO as part of its pre-qualification programme to ensure medicinal products of acceptable standards of quality, safety and efficacy are available for United Nation agencies' procurement.

We continued our obligations and commitments in several regional and international agreements and forums. Some of the major involvements include:

- US-Singapore Free Trade Agreement
- MRA on GMP Inspections with Australia
- MOU with the US FDA
- Singapore-Japan Joint Statement on Medicinal Product GMP Inspection under the Japan-Singapore Economic Partnership Agreement
- Pharmaceutical Inspection Convention/ Pharmaceutical Cooperation Scheme [PIC/S]
- Permanent Forum on International Pharmaceutical Crime [PFIPC]
- WHO-supported Western Pacific Regional Forum for the Harmonisation of Herbal Medicines [FHH]
- WHO-supported International Regulatory Cooperation for Herbal Medicines [IRCH]
- ASEAN Working Group on Technical Cooperation in Pharmaceuticals [AWGTCP]
- Brunei-Malaysia-Indonesia-Singapore-Thailand [BMIST] Public Health Conference

The Next Leg of Our Journey

With the rapidly evolving landscape of biomedical and life sciences, the emergence of novel technologies and their application in health products development and Singapore's ongoing biomedical sciences initiatives, HSA is facing new challenges in regulating novel health products with our limited resources. At the same time, this opens up new opportunities for the regulatory group to tap on HSA's other professional groups' expertise and external expertise in Singapore and abroad. As HSA moves forward, it is increasingly important for us to be innovative in our regulatory approaches and capabilities development.

We will enhance our capabilities in the following four key areas:

1. Conduct risk assessments of new health products, including medical devices, novel biologics and other innovative health products. HSA is building up our capability through expansion of our in-house scientific capabilities as well as by leveraging on expertise in our partner agencies and research institutes. By improving our risk assessment capability, we aim to enhance our professional evaluation capabilities and marketing approval timelines.

2. Manage the evolving risks of products through systematic surveillance, enforcement and a risk communication programme. HSA will review and target implementation of effective risk-based programmes to monitor the safety and regulatory compliance of health products throughout product lifecycles. Our legislative framework will also be enhanced to enable HSA to more effectively enforce post-marketing studies from the pharmaceutical industry that will allow us to further characterise the safety profiles of selected drugs. We will also explore tapping the promising tools of pharmacogenetics to innovatively detect ADRs in our local population, which in the future may facilitate approvals of certain drugs tracked under this scheme.

   In the area of risk communication, we will continue to step up efforts to provide early warnings to our healthcare professionals of emerging or potential drug safety problems to enable them to make discerning choices on the safer use of drugs and health products.

3. Develop smart regulation and policies for health products that protect public safety while facilitating the growth of the biomedical industry. HSA is refining its regulatory philosophy in line with our mission to wisely regulate health products by applying a risk-based rather than a "one-size-fits-all" regulatory approach. The recently passed Health Products Act will be instrumental in helping us achieve these objectives. HSA intends to actively engage our stakeholders in the implementation of the Health Products Act, so as to better meet their needs and expectations in transparency, clarity, responsiveness and robustness in our regulation of health products.

4. Enhance our strategic alliances, connectedness and influence in the regional and international regulatory arena. This will position Singapore as a thought leader in the field and facilitate our participation in decisions shaping the future of the regulation of health products. Moving ahead, we will focus on efforts to strengthen relationships and develop closer co-operation with our key reference agencies and our regional partners in ASEAN. In the coming year, we will also actively participate and lead in regional and global initiatives, especially in ASEAN health products harmonisation, GMP inspections and anti-counterfeiting and enforcement initiatives. HSA will be organising the following major regional and global events in the coming year:

   - PIC/S Meeting in Singapore
   - PFIPC Meeting in Singapore
   - ASEAN-China IMPACT Conference in Indonesia
   - APEC Life Sciences Anti-counterfeiting Seminar in Singapore

CRP Transfer to NEA

After six years as one of HSA's professional centres since its formation in 2001, the Centre for Radiation Protection [CRP] was transferred to the National Environment Agency and became the Centre for Radiation Protection and Nuclear Science [CRPNS] on 1 July 2007.

CRP has built up a reputation over the years for having a sound capability in radiation protection in health and safety during the years under the guidance of HSA and CRP's predecessor departments.

Faced with an ever-changing landscape, there are increasing demands for expertise in the areas of nuclear science, security and emergency response. This move has brought together experts from both health and environmental radiation science as they discuss how to better meet the challenges ahead at a national, regional and global level.

We wish our colleagues a fulfilling journey ahead.

PRE-MARKET ACTIVITIES
Evaluation, Licensing & Certification

Drugs and Biologics

New Product Licences Issued		52
• Chemicals	[32]	
• Biologics	[9]	
• Generic [Chemicals]	[11]	
Variations in Product Licences		1,779
Registered Medicinal Products [as at 31 March 2007]		6,020
• Prescription-Only Medicines	[69%]	
• Pharmacy Medicines	[14%]	
• General Sale List Medicines	[17%]	
Import of Medicinal Products for Re-Export		2,224
Import of Unregistered Medicinal Products		3,818
• by doctor for named patient	[3, 801]	
• by tourists for personal use	[217]	

Chinese Proprietary Medicines [CPM]

CPM Listed [as at 31 March 2007]	10,111
CPM Rejected [as at 31 March 2007]	467

Cosmetic Products

Cosmetic Products Registered [as at 31 March 2007]	26, 074
New Importers Licensed	99
Cosmetic Products Rejected	14
Letters of Free Sales for Export	327

Health Supplements

Enquires on Classification, Import and Sales Requirements	5,076

Premises, Dealers, Importers & Exporters — 3,896

Manufacturers/Assemblers Licences Issued*	[141]
Wholesale Dealer's Licences Issued*	[517]
Import Licences Issued*	[945]
Export Licences Issued*	[233]
Pharmacy Certificates Issued*	[354]
Form A Poisons Licences Issued*	[461]
Form C Poisons Licences Issued*	[853]
Certificate of Pharmaceutical Products	[296]
Good Manufacturing Practice [GMP] Certificates Issued	[26]
Good Distribution Practice [GDP] Certificates Issued	[5]
Free Sale Certificates	[26]
Statement of Licensing Status Issued	[14]
GMP Clearance for Overseas Manufacturers	[25]

* includes new, renewal and amendment applications

Clinical Trials [January to December 2006]

Clinical Trials Approved:		217
• Phase I	[48]	
• Phase II	[35]	
• Phase III	[116]	
• Phase IV	[18]	
Clinical Trials by Therapeutic Areas:		
• Oncology	[26%]	
• Clinical Pharmacology	[21%]	
• Cardiology	[9%]	
• Gastroenterology/Hepatology	[8%]	
• Neurology	[7%]	
• Endocrinology	[4%]	
• Ophthalmology	[3%]	
• Renal Medicine	[3%]	
• Psychiatry	[3%]	
• Urology	[3%]	
• Others	[13%]	
Initial Reports of ADRs		3,364
Follow-up Reports of ADRs		4,131

NB: More than one suspected drug may be implicated in an ADR report.

POST-MARKET ACTIVITIES

Investigation, Surveillance and Prosecution

Complaints Received	799
Prosecution Cases Completed	131
Offenders Sentenced to Imprisonment	40

ADR Monitoring

ADR Reports from Public Hospitals, Government Clinics and National Specialty Centres	89.9%*
ADR Reports Associated with Pharmaceutical Products	96.6%

* Based on 1,523 ADR reports analysed

Top 10 Drugs Suspected of Serious ADRs

	Active ingredient	No.
1.	Atenolol	28
2.	Cotrimoxazole	28
3.	Diclofenac	28
4.	Phenytoin	25
5.	Allopurinol	21
6.	Aspirin	21
7.	Carbamazepine	21
8.	Amoxicillin	20
9.	Ceftriaxone	20
10.	Paracetamol	20

Radiation Control

Inspections on Facilities Using Ionising Radiation	573
Inspections on Facilities Using Non-ionising Radiation	63
Import and Export of Irradiating Apparatus Components	3,877
Endorsements of Nuclear Consignments on Ships	147
Thermoluminescent Dosimeters Processed [monthly]	8000
Wipe Test for Sealed Radiative Sources	212
Radioactivity Analysis on Food Samples	1,541
Investigations of Suspected Industrial Radiation Overdose	29
Tests for Applicants of Ionising Safety Licences	354
Tests for Applicants of Laser Safety Course	869

Tobacco Regulation

Tobacco Retail Outlets Licensed [as at 31 March 2007]	6,000
Illegal Sale of Tobacco to Under 18 Years	66
Youths Compounded	5,999
Youths Prosecuted in Court	292