physical examination, cervical screening and various appropriate investigations for clients, such as offering screening mammography to women who are aged 50 years or over. Clients with suspected abnormalities are referred to specialists for further management.

In 2007, a total of 19 531 women registered with three WHCs and ten MCHCs for Woman Health Service. Health problems detected included breast cancer, cervical cancer, raised blood cholesterol, hypertension, diabetes mellitus, and other gynaecological problems etc.

# **Health Administration and Planning Division**

#### **Medical Device Control Office**

The "Medical Device Control Office" was established in July 2004 for the implementation of the voluntary Medical Device Administrative Control System (MDACS) and development of a long-term regulatory framework for medical devices. The System has been implemented by phases from November 2004 and it covers the following scope:

- Listing of medical devices of Classes II, III and IV:
- Implementation of adverse incident reporting system;
- Screening of safety alerts;
- Recognition of Conformity Assessment Bodies;
- · Listing of Local Manufacturers; and
- Listing of Importers.

The Medical Device Control Office totally processed 228 device listing applications, screened 1 003 safety alerts, managed 11 adverse incidents and conducted eight workshops / seminars in 2007.

頸檢驗及各項適當的檢驗,如為50歲或以上的婦女提供乳房造影普查服務等。 懷疑有異常情況的婦女,會獲轉介至專 科醫生作進一步治理。

二零零七年,共有19 531名婦女在三間婦女健康中心及十間設有婦女健康服務的母嬰健康院登記,所發現的健康問題包括乳癌、子宮頸癌、血膽固醇過高、高血壓、糖尿病和其它婦科問題等。

# 衞生行政及策劃部

### 醫療儀器管制辦公室

「醫療儀器管制辦公室」於二零零四年 七月成立,以便推行自願的醫療儀器 行政管理制度和發展長遠的法例規管。 該制度由二零零四年十一月起分階段推 行,內容包括:

- 表列第□,□□及□V級醫療儀器;
- 推行醫療事故呈報系統;
- 甄別安全警報;
- 認可認證評核機構;
- 表列本地製造商;及
- 表列進口商。

醫療儀器管制辦公室於二零零七年度 共處理228宗醫療儀器表列申請,甄別 1 003宗安全警報,處理11宗醫療事故 報告及舉辦了八次工作坊/講座。 A consultant has been commissioned in July 2007 to conduct a regulatory impact assessment on statutory regulation of medical device and the study has been completed by early 2008.

# Office for Registration of Healthcare Institutions

Under the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Cap. 165), any person who intends to operate a private hospital, maternity home or nursing home must obtain registration from the Director of Health. The Medical Clinics Ordinance (Cap. 343) provides for the registration of clinics that are operated on a non-profit making basis. Legislations under Cap. 165 and Cap. 343 were promulgated in 1937 and 1964 respectively. The licensing authority was rested with the Director of Health.

Registration and monitoring of healthcare institutions is carried out with respect to accommodation, manpower and equipment. The Office for Registration of Healthcare Institutions is primarily responsible for enforcing statutory provisions under the relevant Ordinances and to ensure the institutions are fit for the services to be provided. Compliance of individual institutions to statutory requirements is monitored through field inspections; scrutiny of the institution activities and complaint statistics; issuing advice and warning; and direct handling of complaints lodged by public against the institutions. In 2007, 84 announced inspections and 57 surprise visits to a total of 12 private hospitals, 32 nursing homes and 9 maternity homes registered under Cap. 165 were conducted. There were 151 clinics registered under Cap. 343. We have also handled 60 complaints related to them in the same year.

To meet the advancement of medical technology and rising community aspirations for quality 醫療儀器管制辦公室已在二零零七年七 月聘請顧問公司為醫療儀器規管對各方 面的影響進行評估。該研究已於在二零 零八年初完成。

#### 醫護機構註冊辦事處

根據《醫院、護養院及留產院註冊條例》(第165章),任何人有意營辦私家醫院、留產院或護養院,須向衞生署署長申請註冊。非牟利診療所的註冊乃根據《診療所條例》(第343章)進行。香港法例第165章及343章分別在一九三七年和一九六四年實施,由衞生署署長執行。

衞生署會就處所、人手和設備方面的事 宜對醫護機構進行註冊及監察的工作。 醫護機構註冊辦事處主要是負責執行有 關條例的規定及確保有關機構適合法法 實來,會透過實地巡查、審閱機構都符合 要求,會透過實地巡查、審閱機構 要求,會透過實地巡查、審閱機構 要求,會透過實料。發出建議或警 是處理公眾對有關機構的投訴。 會對按香港法例第165章 一時12間私家醫院、32間護養院及九間 留產院,進行了84次例行巡查及57次 擊巡查。按香港法例第343章註冊的 電產院,按香港法例第343章註冊的診 察所則有151間。同年,我們共處理60 宗與該等機構有關的投訴。

為配合醫療技術的發展,以及社會對 優質醫療的殷切需求,衞生署於二零零 services, a "Code of Practice for Private Hospitals, Nursing Homes and Maternity Homes" was promulgated in 2003, and has been implemented since 2004. The Code sets out minimum standards for registration including general requirements on organisation and administration, policies and procedures, management of staff, equipment and accommodation, as well as specific types of clinical and support services. The Code enables healthcare institutions to understand the requirements and standards of good practice in a more explicit manner.

# 三年制定《私家醫院、護養院及留產院 實務守則》,並於二零零四年起開始推 行。該守則列明註冊的最低標準,當中 包括對有關架構及行政、政策及程序、 人手、儀器及處所管理,以及個別臨床 及支援服務的一般要求。此守則使各醫 療服務機構更明確了解優質服務的要求 及標準。

### **Special Health Services**

# Narcotics and Drug Administration Unit

The Department of Health operates an out-patient methadone maintenance as well as detoxification scheme for opiate drug abusers. There are 20 methadone clinics in Hong Kong operating daily including Sundays and public holidays. The total number of patients registered with the scheme was 8 202 as at 31 December 2007 and the average daily attendance in 2007 was 6 216.

Counselling services at methadone clinics are provided by social workers of the Society for the Aid and Rehabilitation of Drug Abusers. Methadone clinics are also the contact point for referring patients to other treatment and rehabilitation agencies when necessary.

As drug addicts constitutes a high risk group for AIDS and other blood borne diseases, health education and counselling for patients is always a priority. Concomitant activities include broadcasting of health educational video and cassette programmes in methadone clinics, free distribution of condoms, provision of blood testing and urine testing for HIV and blood testing for

### 特別衞生服務

#### 毒品管理部

衛生署為吸毒者提供美沙酮代用治療及 戒毒計劃的門診服務。全港共有20間 美沙酮診所,每天(包括星期日及公眾 假期)開放。截至二零零七年十二月三 十一日為止,登記參與計劃的總人數為 8 202人,而二零零七年的平均每日求 診人次則為6 216人次。

美沙酮診所內駐有香港戒毒會的社會工作者,提供輔導服務。這些診所亦為聯絡點,在有需要時將病人轉介往其他治療或康復機構。

由於吸毒者是感染愛滋病及其他透過血液傳播疾病的高危群,因此為病人提供健康教育及輔導工作是首要工作。有關的活動包括在美沙酮診所播放健康教育錄影帶及錄音帶、免費派發安全套,並為參與美沙酮治療計劃的人士提供愛滋病病毒血液和尿液測試,以及乙型及丙型肝炎血液測試服務。