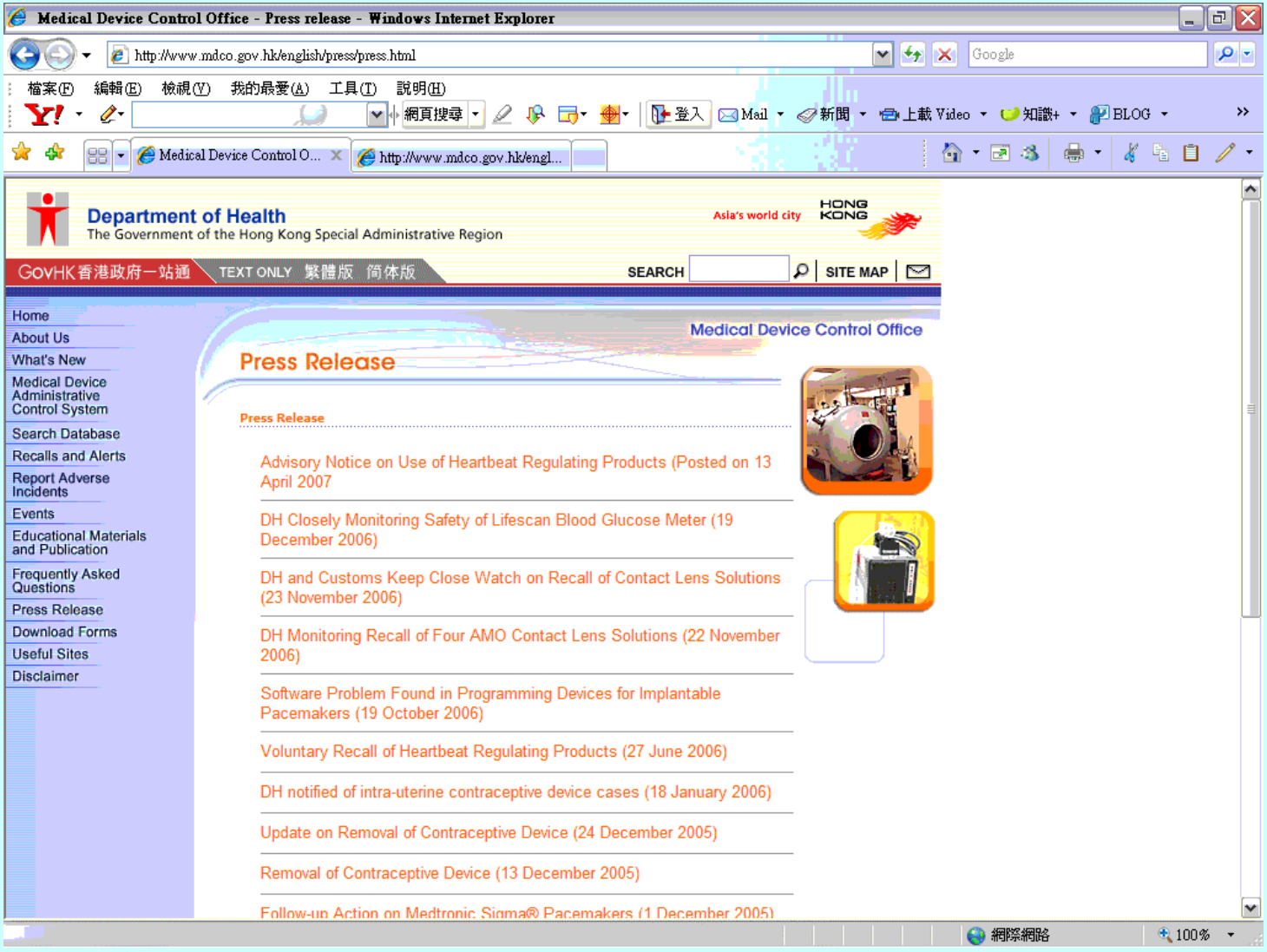
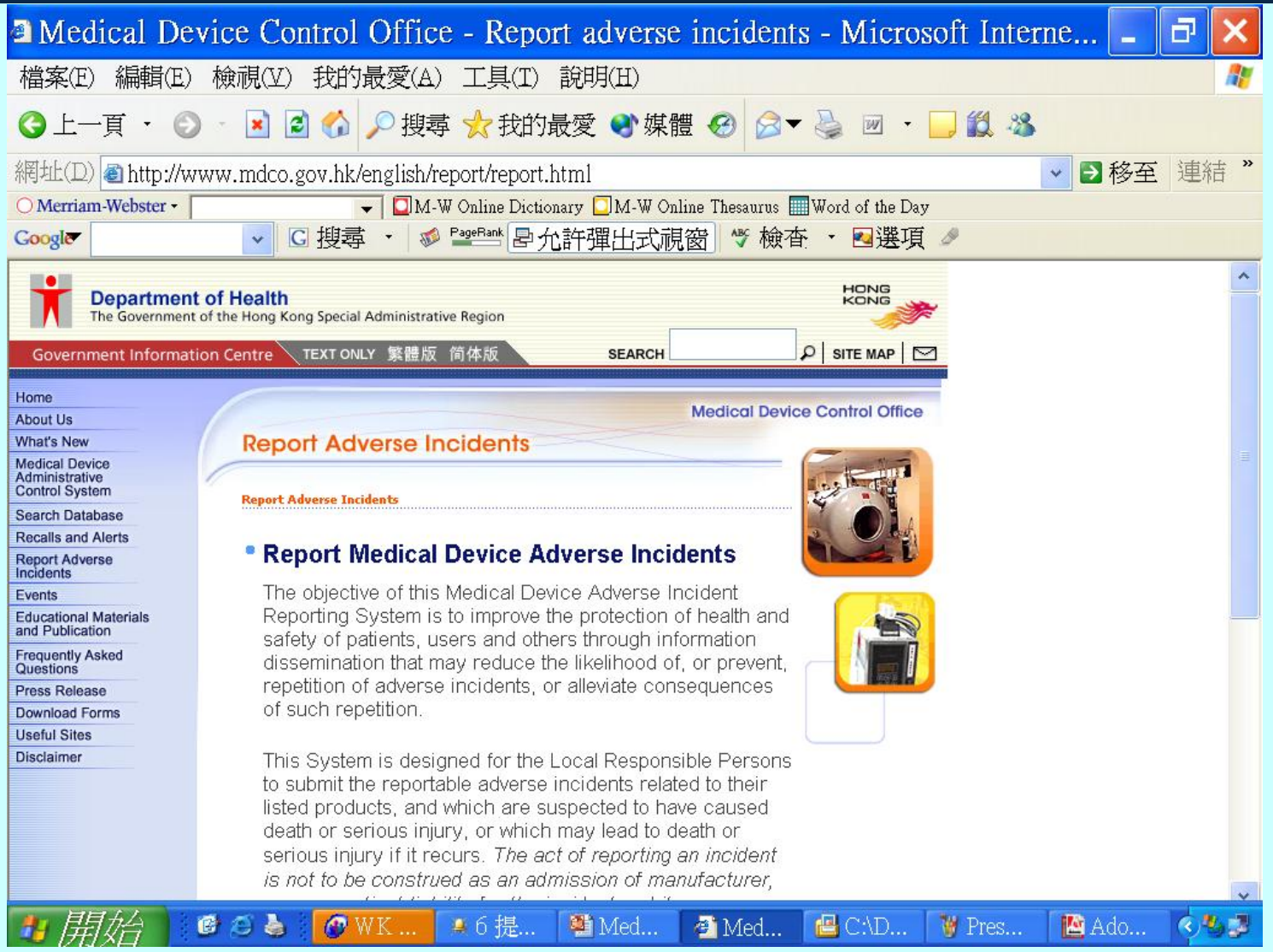
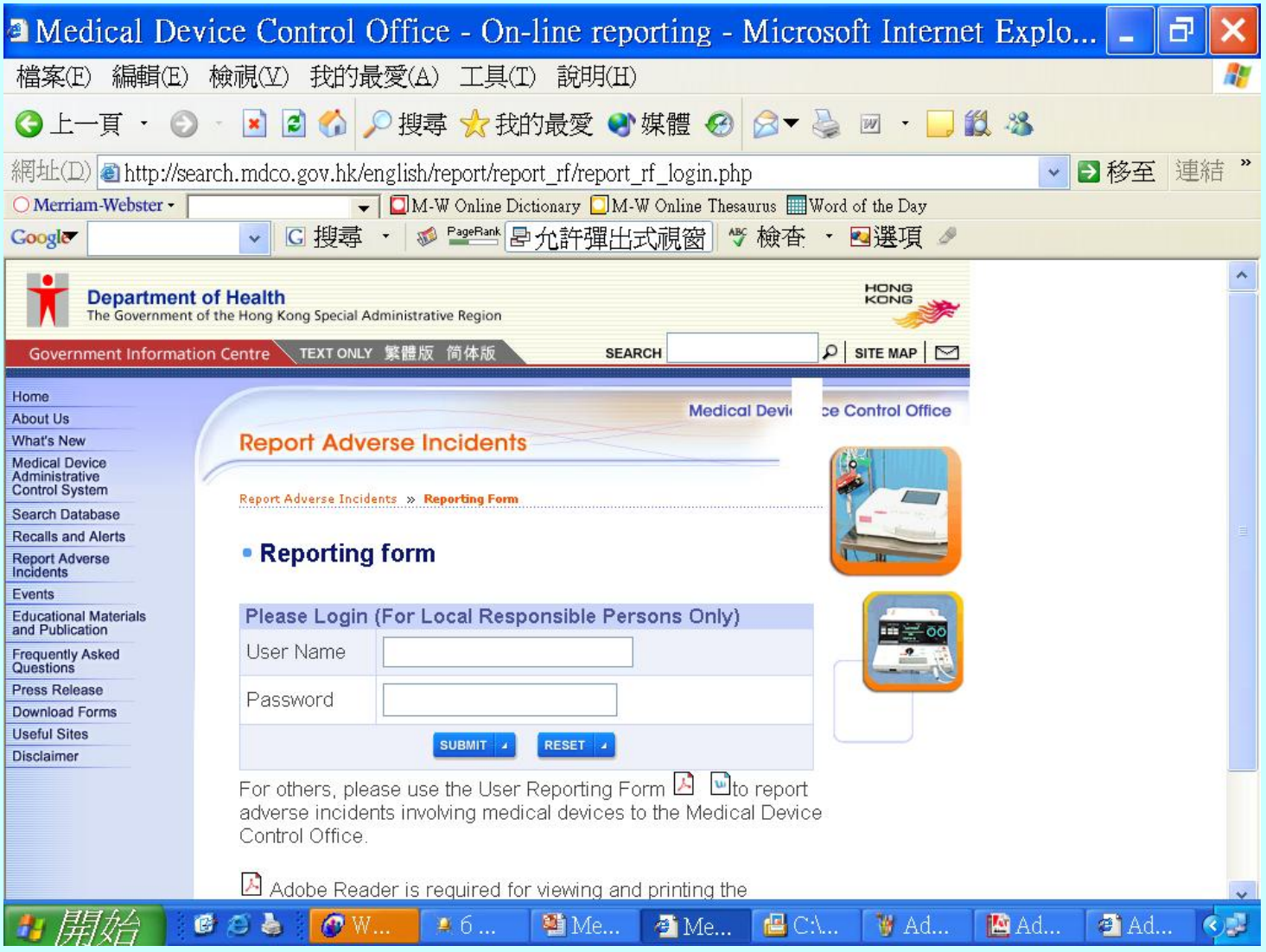
Press Releases



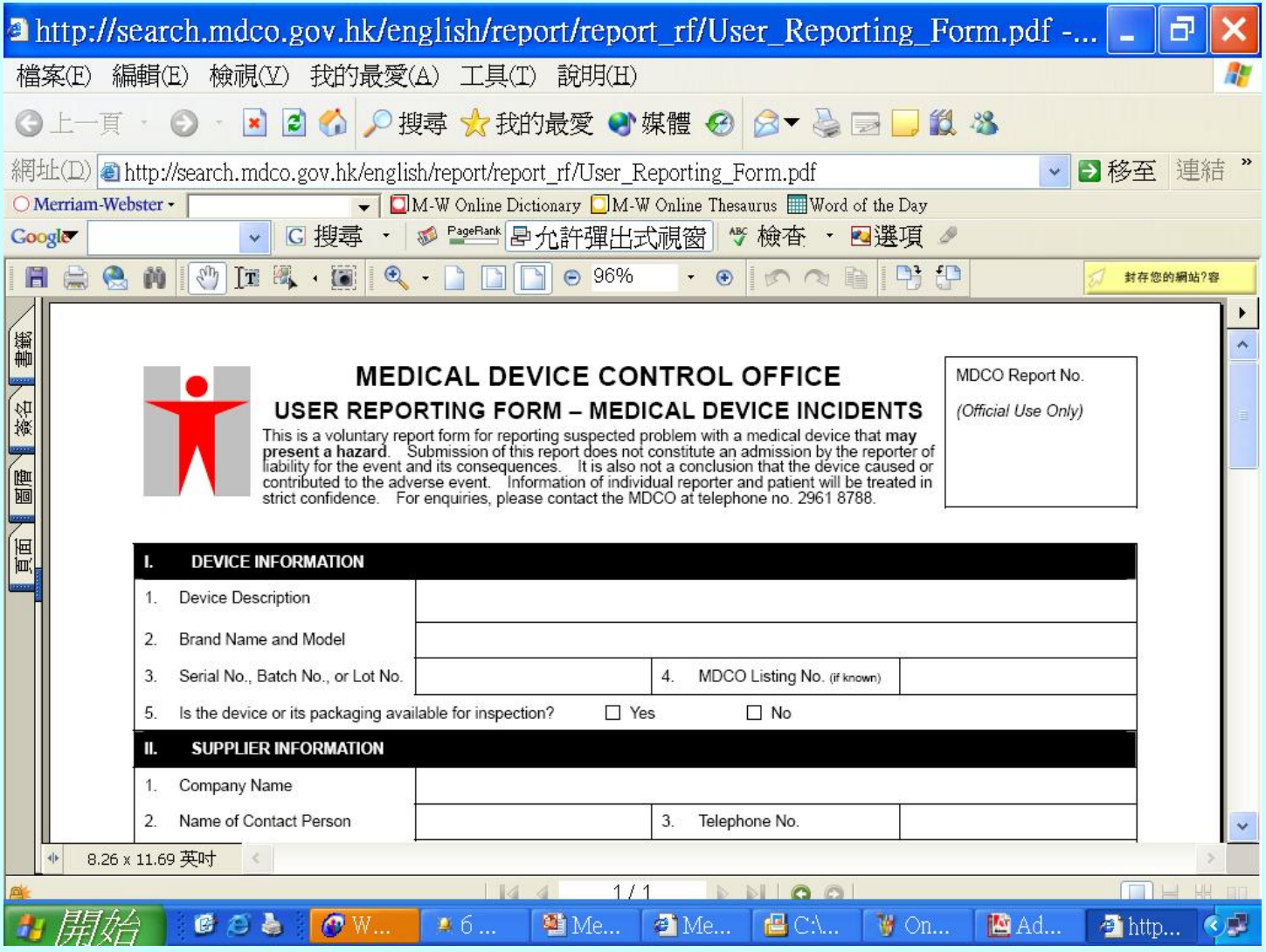
Adverse Incident Reporting System



On-line Reporting

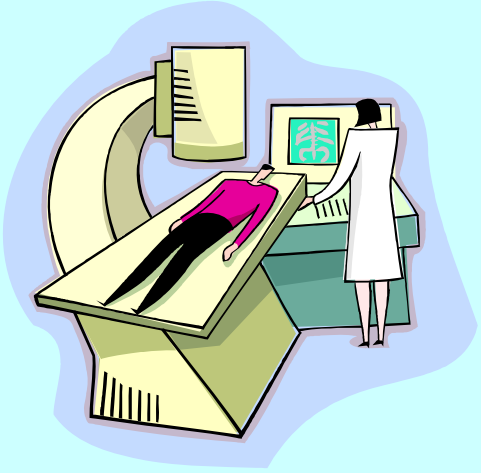


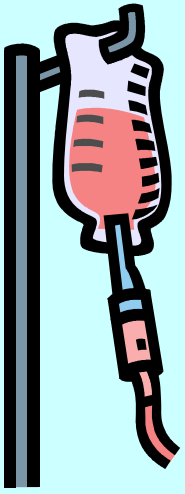
Reporting Form

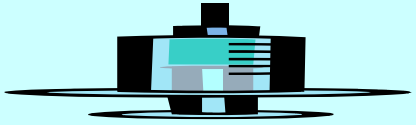


Adverse Incidents (2 Aug 2005~23 Apr 2007)

- Cases reported 14
- Cases completed : 6

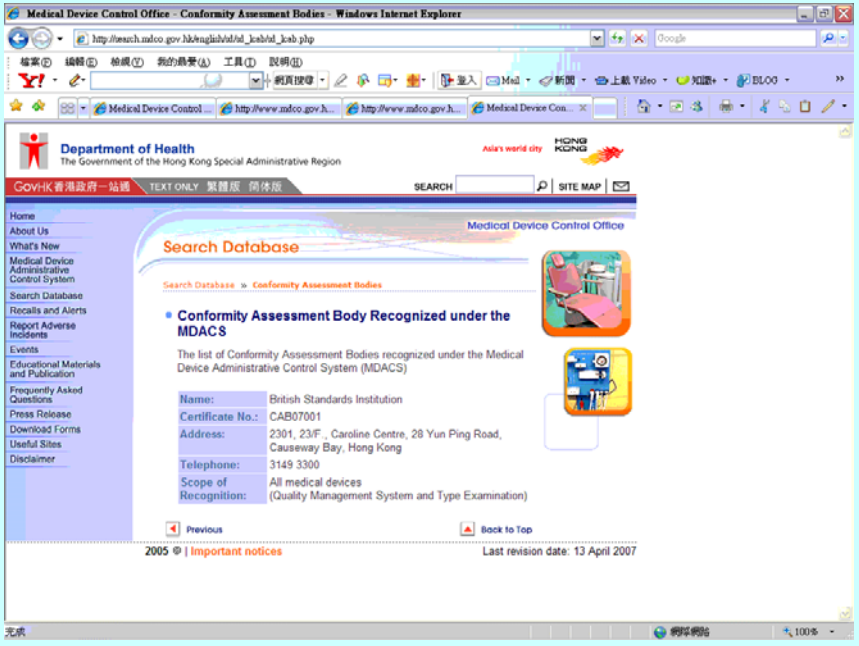




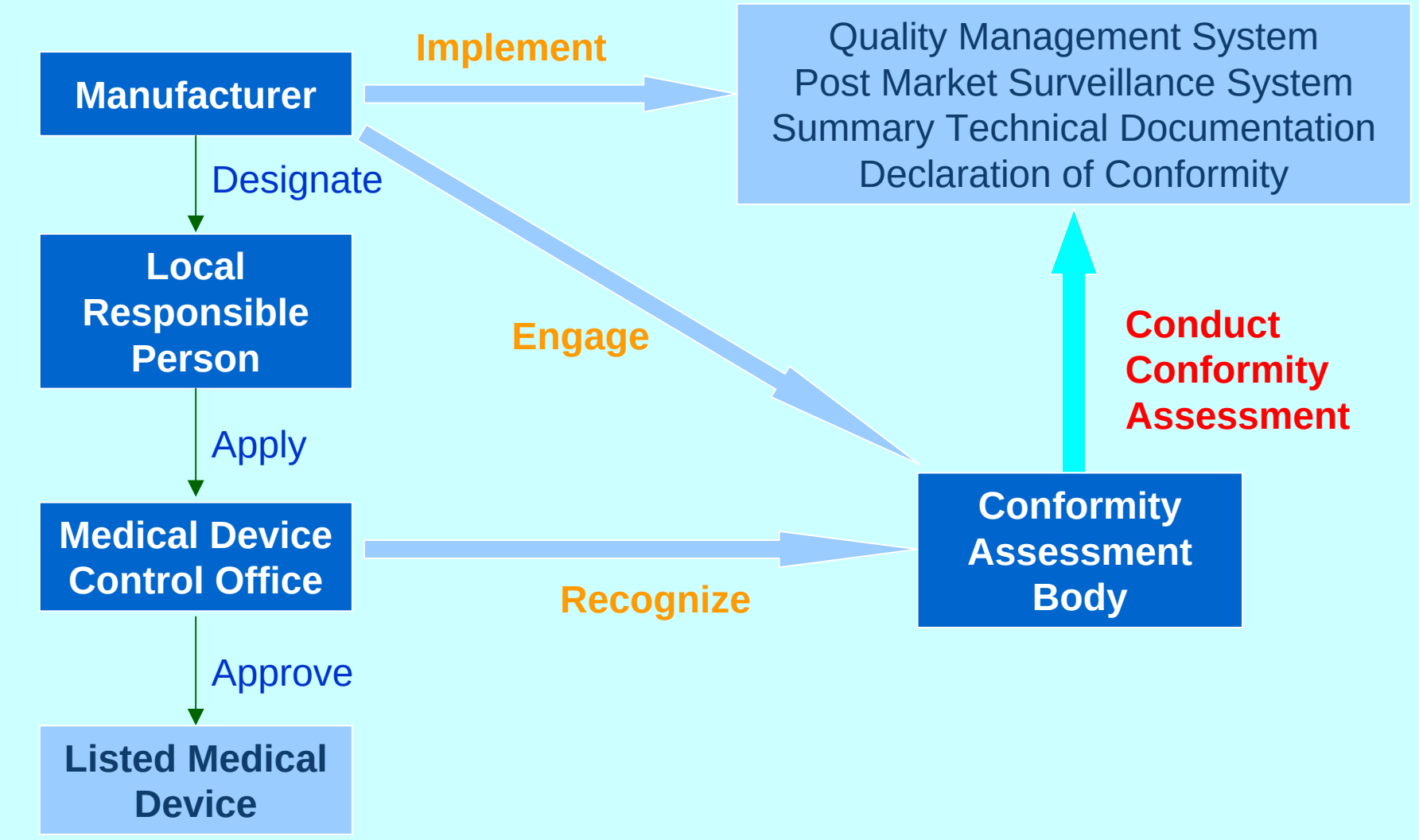


Conformity Assessment Body (CAB)

- **CAB is a body recognized by the MDCO to engage in the performance of procedures for determining whether the relevant MDACS requirements are fulfilled.**



Conformity Assessment Process



Alternate Route of Conformity Assessment

- Marketing approval from GHTF founding members
  - Australia
  - Canada
  - European Union (countries have implemented European Council Directives)
  - Japan
  - USA

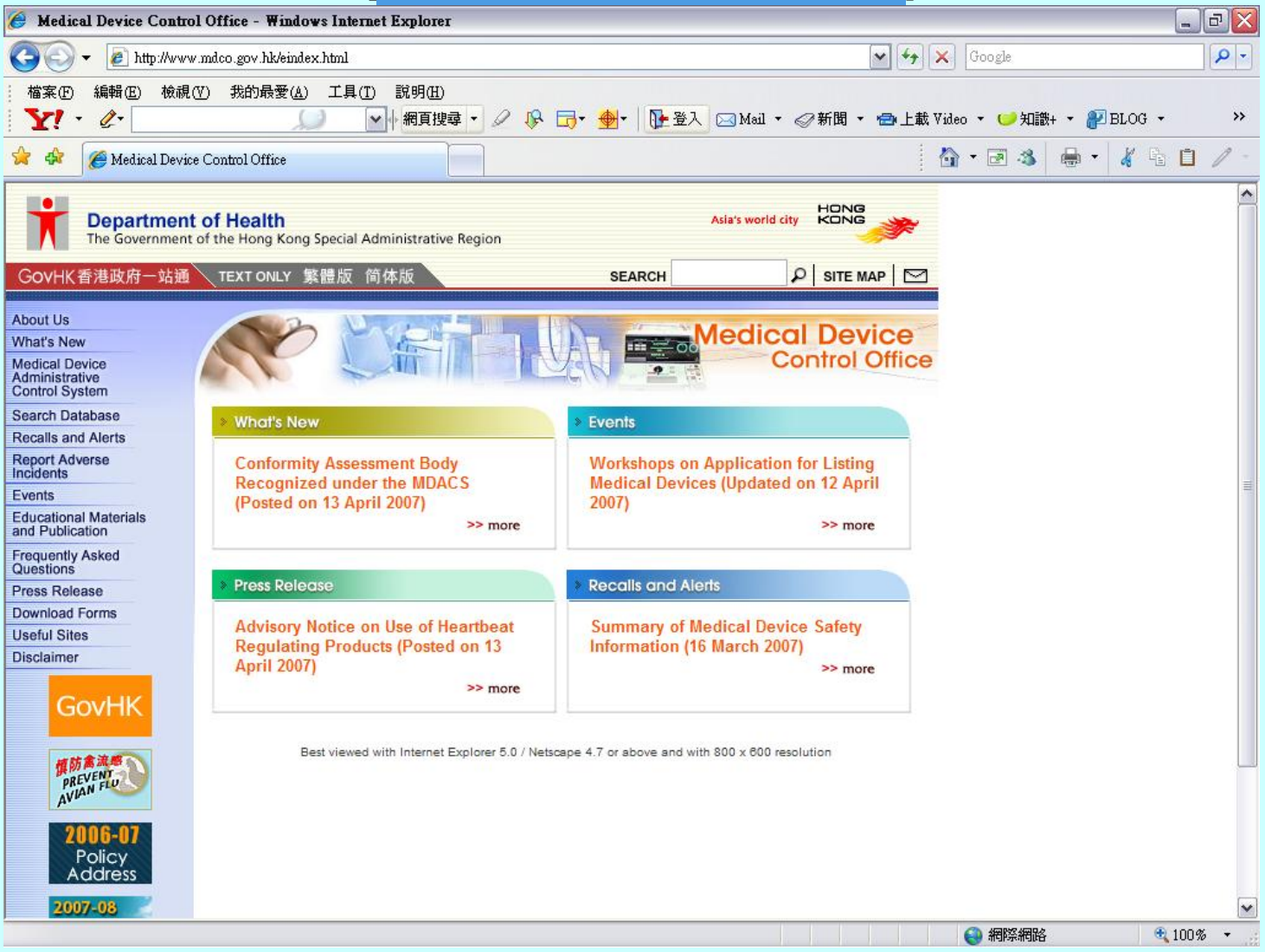
Listing of Local Manufacturers

- A local manufacturer is a manufacturer whose business as a manufacturer of medical devices has either been registered in Hong Kong pursuant to the Business Registration Ordinance (Cap. 310) or is part of a business which has been so registered.
- QMS requirements: ISO 13485
- Commencement: Mar 2007

Listing of Importers

- An importer is a legal or natural person who brings or entrusts others to bring medical devices that fall within the scope of the MDACS into Hong Kong.
- Proposed document: GN-07
- Comments: before 30 Apr 2007

MDCO Website
( )



Workshops & Seminars

- **Workshops: 23**
- **Educational Seminars: 6**

Publicity & Education

Way Forward

- Full scope of MDACS:
  - Mid 2007
- Regulatory Impact Assessment:
  - May ~ Nov 2007
  - Includes public consultation
- Report to Legislative Council: end 2007

Thank You!