



Updates on Asia's Medical Device Market

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Overview of Asia



Demographics (2006)

Country	Population (millions)	Population Growth	GDP (PPP)	Per Capita Income (PPP)	Life Expectancy (Years)
China	1,322	0.61%	\$10.21 trillion	\$7,800	72.88
Hong Kong	7.0	0.56%	\$259.1 billion	\$37,300	81.68
India	1,130	1.60%	\$2.965 trillion	\$2,700	68.59
Indonesia	235	1.21%	\$948.3 billion	\$3,900	70.16
Japan	127	-0.09%	\$4.218 trillion	\$33,100	82.02
Malaysia	24.8	1.76%	\$313.2 billion	\$12,800	72.76
Philippines	91	1.76%	\$449.8 billion	\$5,000	70.51
Singapore	4.55	1.28%	\$141.2 billion	\$31,400	81.8
South Korea	49	0.39%	\$1.196 trillion	\$24,500	77.23
Taiwan	23	0.61%	\$631.2 billion	\$22,600	77.43
Thailand	65	0.66%	\$596.5 billion	\$9,200	72.55

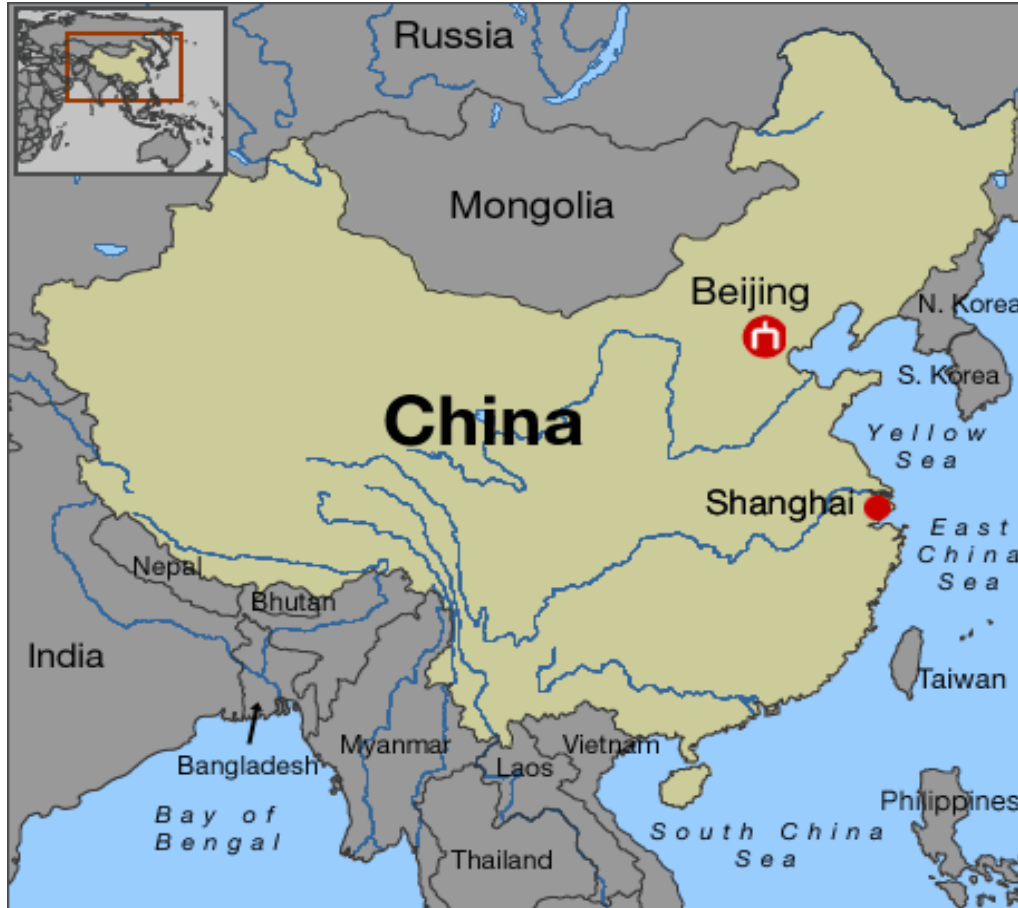
Asia Health Statistics

	Health expenditure per capita	Health expenditure as % of GDP	Physicians per 1,000 people	Hospital beds per 1,000 people
China	\$61	5.6%	1.6	2.5
India	\$27	4.8%	0.6	0.9
Indonesia	\$30	3.1%	0.1	6.0
Japan	\$2,662	7.9%	2.0	14.3
Korea	\$705	5.6%	1.6	7.1
Malaysia	\$163	3.8%	0.7	1.9
Philippines	\$31	3.2%	1.2	1.0
Singapore	\$964	4.5%	1.4	2.9
Thailand	\$76	3.3%	0.4	2.2
Taiwan	\$743	5.6%	7.4	5.7
Vietnam	\$26	5.4%	0.5	2.4

Asia Medical Device Markets

Country	Market Size (US\$)
China	\$ 6 billion
Hong Kong	\$ 550 million
Indonesia	\$ 165 million
Japan	\$ 25 billion
Malaysia	\$ 330 million
Philippines	\$ 82 million
Singapore	\$ 450 million
Korea	\$ 2.5 billion
Taiwan	\$ 1.5 billion
Thailand	\$ 550 million

China



Health Statistics and Comparisons

	China	US	United Kingdom	Japan
Hospital beds per 1,000 people (2005)	2.4	2.7	3.1	8.2
Physicians per 1,000 people (2005)	1.5	2.4	2.4	2.0 ¹
Total health expenditure per capita (2005)	\$79	\$6,400	\$3,064	\$2,803
Total health expenditure (% of GDP) (2005)	4.7%	15.3%	8.3%	7.7%

- ❑ Fifty percent of city dwellers in China have health insurance.
- ❑ Ninety-five percent of people living in the countryside ***do not*** have health insurance.

¹2004.

Overview of China's Medical Device Markets

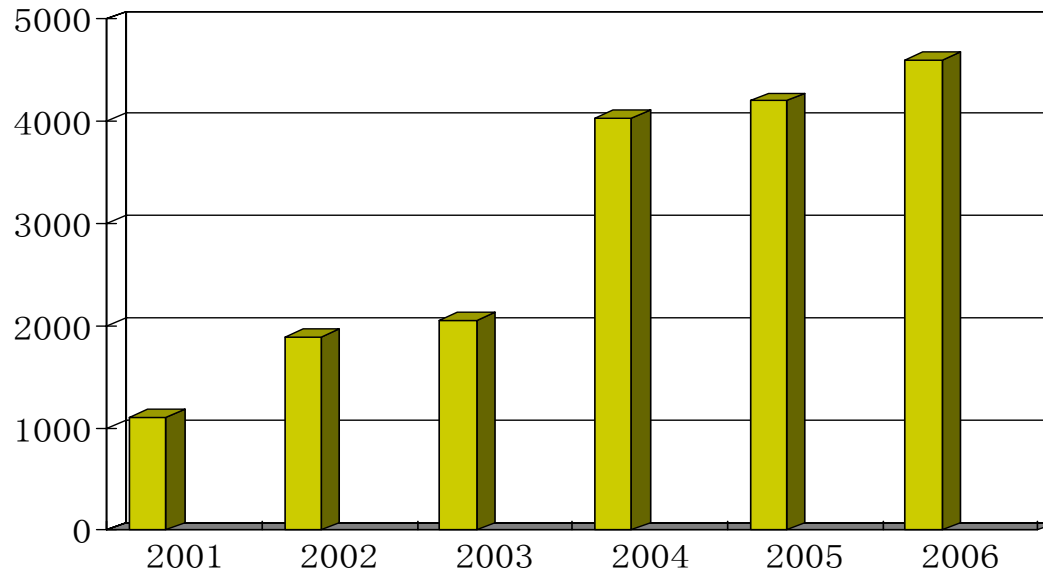
- In 2007, medical device sales were about \$6 billion
- Annual growth rate of 14 - 15%
- Market capacity of China's medical device industry has been growing year after year
- China has become one of the 10 emerging global medical device markets, Asia's largest market after Japan

* Source: Chinese version of *The Analysis and Investment Consultation Report of China Medical Device Industry – Year 2007-2008*

Medical Device Regulatory Environment Overview

- Number of foreign medical device registration applications has grown significantly between 2001 and 2006.

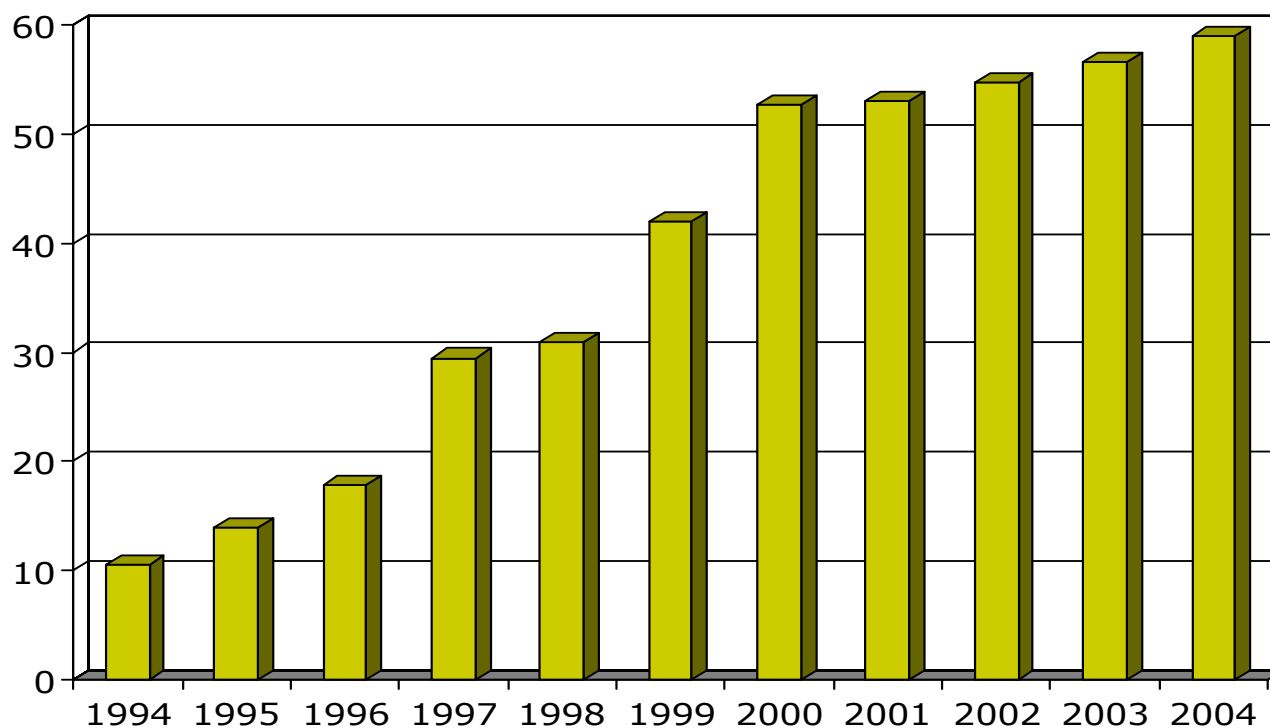
Import New Device Registration Applications



China Medical Device Sales 1994-2004

CAGR +20.6%

(billion RMB)



CHINA MEDICAL DEVICE REVIEW, SEPTEMBER 2004

China Medical Device Standards Regulatory Bodies

State Food & Drug Administration (SFDA)

- Equivalent to the U.S. FDA.
- Responsible for drugs, devices, and healthcare services.
- Headquarters is located in Beijing, with offices in each province also.

IVD Products in China

- ❑ Regulations for IVD products was unclear and incomplete for a long time.
- ❑ There was no clear classification regulations for IVD products before July 2004.
- ❑ Even with the classification regulations in 2004, there was no specific process on how to register IVD products.

IVD Regulations

- *Management Method of IVD Products Registration (Interim)* effective on June 1, 2007
- *Guidance on Clinical Trials and Package Insert Composition for IVD Products* effective on June 1, 2007
- *Dossier Format and Basic Requirements for IVD Product Registration* effective September 30, 2007

IVD Regulations (Cont'd)

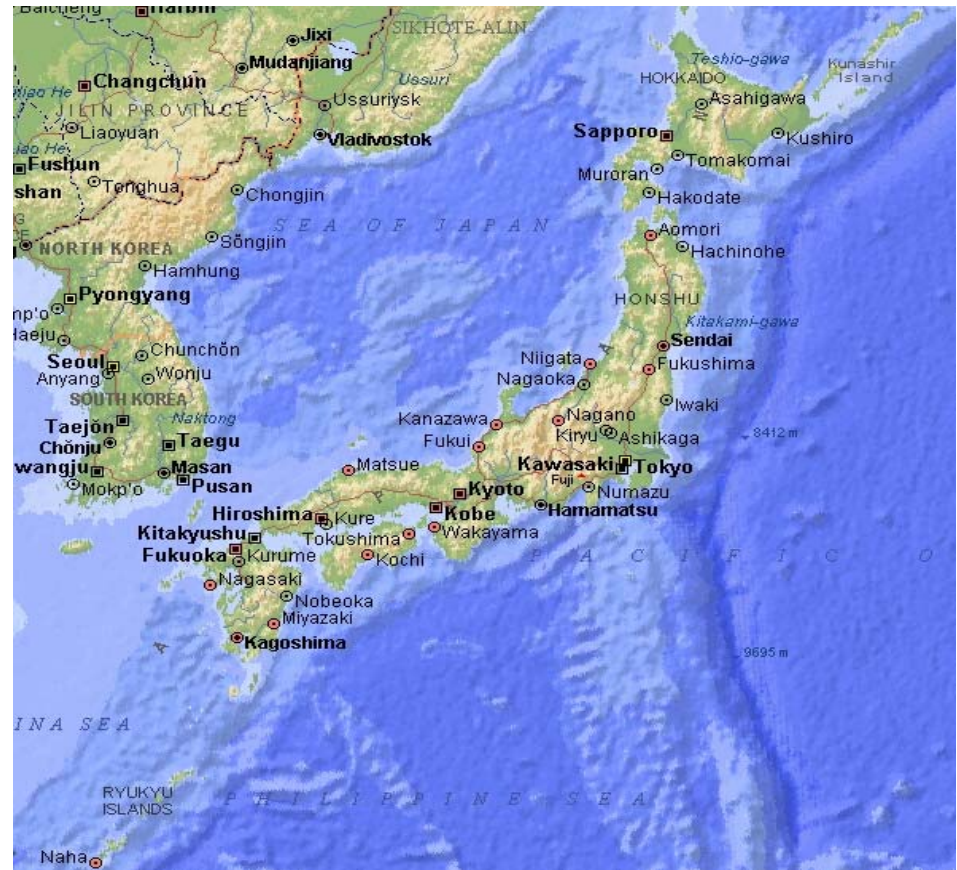
- *Guidance on Production Implementation Rules, Quality Management System Inspection and Assessment Standard for IVD Products (Interim)* effective on April 28, 2007
- *Management Method of IVD Products in Sales Procedures (Draft Version)* released on March 6, 2007 for discussion
- *Guidance on Sales Company Assessment and Opening Application Procedure* effective on May 3, 2007

JAPAN



Major Markets in Japan

- Southern Kanto region
 - Tokyo, Chiba prefectures
- Kansai region
 - Osaka, Kyoto, Hyogo prefectures
- Tokai region
 - Aichi, Gifu prefectures



Medical Institutions in Japan

□ By Category

Type	Hps
National Hp	336
Municipal Hp	1,377
Private Hp	5,533
Clinic	954
Others	987
Total	9,187

□ By Beds

No. of Beds	No of Hp
~99	3,558
100~299	3,865
300~499	1,118
500~799	384
800~	101
Total	9,026

(2005 MHLW Statistics)

Basic Structure of Medical Fees/Insurance

- 1 payer system – Japan government – no Aetna, Prudential, Travelers, etc.
- Medical fees are basically determined according to individual medical service (fee-for-service system).
 - Basic medical fees
 - Special medical fees
- In addition, there are fees to cover the cost of medical devices

Diagnosis Procedure Combination System

- The Diagnosis Procedure Combination (DPC) has been applied in special-function hospitals (82 university medical institutions and other institutions) since April 2003.
 - At present, daily comprehensive scores are applied to 1,726 groups of diagnoses.
- DPC follows a Fee-For-Comprehensive Service of Medical Care

Class III/IV Medical Device Approval Rates in Japan (domestic and imports)

Year	Product Approval		
	Approval	Partial Change	Total
2004	1,409	1,759	3,168
2005	1,156	1,348	2,504
2006	4,374	1,679	6,053

Japan Main Regulatory Bodies

- Ministry of Health, Labor, and Welfare (MHLW)
 - <http://www.mhlw.go.jp/english/index.html>
 - Overseas all health programs in Japan, including drugs, medical devices, and food.
- Pharmaceuticals and Medical Devices Agency (PMDA)
 - <http://www.pmda.go.jp/index-e.html>
 - Established in April 2004, overseas regulatory affairs for drugs and medical devices.
- The Central Social Insurance Medical Council (Chuikyo)
 - Responsible for medical service fees, such as setting points and reimbursement prices for medical devices and drugs.

IVD Products in Japan

- ❑ IVD products are usually classified as drugs or medical devices
- ❑ The application forms are very similar to regular drug and medical device applications
- ❑ Some additional attachments may be required depending on the classification of the IVD product.

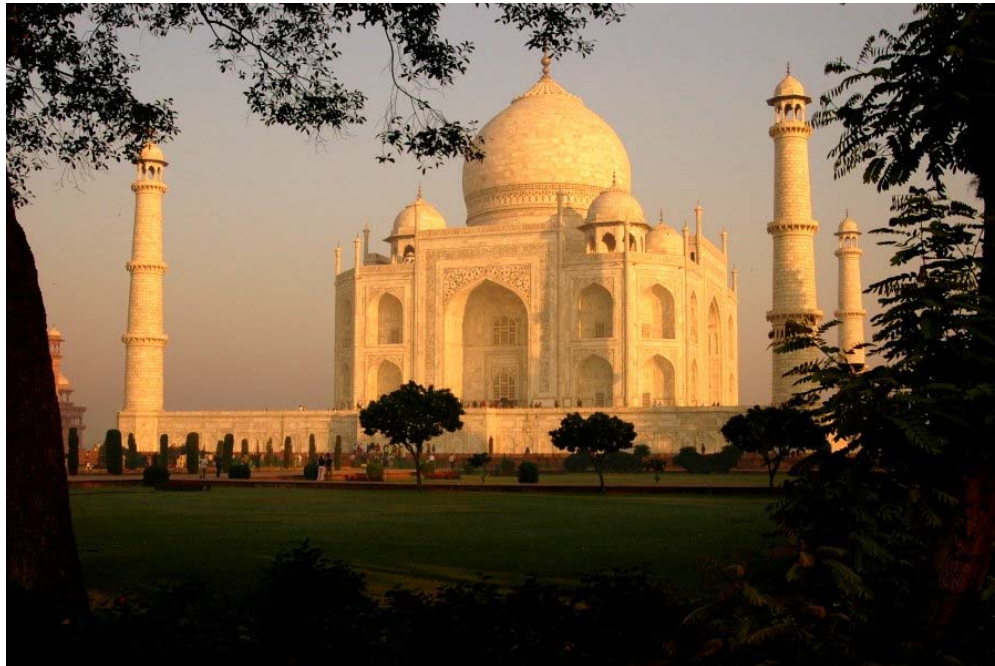
IVD Products in Japan (cont'd)

- The PMDA has issued specific checklists to help applicants provide appropriate information in the applications, as IVD applications require slightly different content.
- The PMDA tends to have more specific guidelines on IVD drugs.
- Applicants should make sure that they have the appropriate marketing (MAH) and manufacturing (GMP) licenses for both IVD device and drugs BEFORE product approval.

IVD Products in Japan (cont'd)

- Trends of de-regulation with IVD registration process
- Many hospitals and clinics in Japan incorporating IVD tests to allow more specific treatments catered to each individual patient.

INDIA



India – Healthcare

- ❑ Expenditure on healthcare including services, medical devices and pharmaceuticals is US \$30 billion.
- ❑ Public sector share is 70% and private sector is 30% of healthcare delivery.
- ❑ As of now only 25% of population has access to allopathic healthcare, as other systems of medicine also used.

India's Healthcare System

- ❑ Hospitals: 16,000 Beds, > 1,000,000
- ❑ Doctors: 625,000
- ❑ Nurses: 836,000
- ❑ Medical graduates: 15,000 per year
- ❑ There is no single national health insurance system.
- ❑ What exists is a number of schemes of free/ concessional treatments and insurance, mainly for hospitalization.
- ❑ Medicines, devices and services are provided/ reimbursed within the applicable cost limits.
- ❑ There is no system of pre-approval of drugs or devices for treatment / reimbursement.

Healthcare Comparative Costs (Medical Tourism)

Procedure	Cost in India (US \$)	Cost in USA (US \$)
Heart surgery	7,000	30,000
Bone marrow transplant	30,000	250,000
Liver transplant	40,000	500,000
Neurosurgery	8,000	29,000
Orthopedic surgery	6,000	20,000
Cosmetic surgery	2,000	20,000

India's Medical Device Market (1)

- ❑ Market size : US\$2.5 billion
- ❑ Per capita spending : US\$2.50
- ❑ Imports : 75%
- ❑ Recent annual growth rate : 8%
- ❑ Projected growth rate up to 2010 : 12 – 16%
- ❑ Import duty rate (maximum) : 36%
- ❑ VAT rate on sales : 4 – 12%
- ❑ Rate of excise duty on local manufacture: 16%
- ❑ Import category share:
 - ❑ Instruments, devices and disposables : 40%
 - ❑ Reagents and test kits : 20%
 - ❑ Radiology equipment : 15%

India Device Regulators (1)

❑ **Drug Controller General India (DCGI):**

- ❑ DCGI is the key official in the Central Drug Standards Control Organization (CDSCO)
- ❑ CDSCO is headquartered in New Delhi and has 4 regional offices – meant to help local governments.

■ **Functions of DCGI/CDSCO:**

- ❑ Approval of manufacturing certain drugs (vaccines, large volume parenterals, blood products, r-DNA derived), specific devices and new drugs.
- ❑ Standards and quality.

India Device Regulators (2)

❑ **Drug Controllers of the State Food and Drug Administration:**

❑ There are 35 officials and departments – one in each state, under the respective State Governments (Drug testing laboratories in each State).

■ **Functions:**

- ❑ Issues licenses to manufacture pharmaceuticals and specified devices (with prior approval of DCGI for specified products).
- ❑ Standards and quality monitoring.

Unclear Regulation of Devices

- ❑ Devices are not properly defined; all regulation is of “drugs.”
- ❑ Different regulations applicable to different items.
- ❑ Procedures are not uniformly specified.
- ❑ No single list of devices or categorization of devices into classes exists.

Devices Regulated in India (1)

- ❑ Disposable hypodermic syringes
- ❑ Disposable hypodermic needles
- ❑ Disposable perfusion sets
- ❑ Copper T IUD
- ❑ Tubal ring
- ❑ Condoms
- ❑ Sterile disposable devices for single use
- ❑ Metered dose inhaler

Devices Regulated in India (3)

- Since March 1, 2006 the following items have been declared as drugs for regulation of import, manufacture and sale:
 - **Cardiac stents**
 - **Drug eluting stents**
 - **Catheters**
 - **Intra-ocular lenses**
 - **IV cannulae**
 - **Bone cement**
 - **Heart valves**
 - **Scalp vein sets**
 - **Orthopaedic implants**
 - **Internal prosthetic replacements (includes cardiac patches and occluders)**

Proposed New Regulations

- ❑ Create a **Central Drugs Authority of India “CDA”** (similar to the US FDA), with the Drug Controller of India (DCI) as CEO, in place of the CDSCO—with a regulatory mechanism and responsible for all manufacturing, import, export, registration, approval, quality / QA, certification, clinical trials, post-marketing surveillance.
- ❑ Define Medical Devices specifically under the DCA and provide rules and guidelines for their regulation.
- ❑ Legislation to create CDAI, definition of medical devices is pending in the Parliament (Drugs & Cosmetics Amendment Bill 2007 or DCAB).
- ❑ New standalone legislation covering drugs and therapeutics for price control instead of using the DPCO (no such legislation proposed so far).

Proposed Medical Device Regulations

- ❑ At the same time under the Ministry of Science and Technology there is a proposed legislation (not yet placed before Parliament) called The Medical Devices Regulation Bill 2006 (MDRB) which has been drafted and posted for public comment.
- ❑ It envisages the creation of a **Medical Device Regulatory Authority of India “MDRA”** with a CEO – and a regulatory mechanism responsible for all manufacturing, import, export, registration, approval, quality / QA, certification, post-marketing surveillance of medical devices.
- ❑ All manufacturing and import licensing with MDRA.
- ❑ MDRB defines Medical Devices and later will provide rules and guidelines for their regulation.

IVD Products in India

- As mentioned previously, medical products are regulated as “drugs.”
- IVD products are classified as either critical or non-critical kits.
 - Critical kits: HIV, HBsAg, HCV and Blood Grouping Reagents
 - Non-critical: everything else

Export: IVD Product Registration

- ❑ All imported regulated devices must be registered by the manufacturer; i.e. registration of both the product and each facility that produces the product.
- ❑ “Manufacturer” is a company, unit or facility that manufactures drugs in a facility outside India
- ❑ Manufacturer must either have a license to manufacture or sell drugs in India **OR** have an agent or importer who has a license.
- ❑ Application for registration must be submitted by agent/importer duly authorized to do so by power of attorney.

Agent/Importer for IVD Registration

- ❑ If you do NOT have your own subsidiary, branch office or joint venture, it is critical to appoint a local agent and/or importer.
- ❑ Who can be an agent? Importer or another person.
- ❑ Agent represents the manufacturer for business in India.
- ❑ Importer is the holder of the import license and must have license to stock and sell drugs, as well as a license to manufacture if there is any re-processing or pre-packing involved.
- ❑ Agent and importer can be the same, or separate, if importer is not to have access to confidential material.
- ❑ The agent and/or importer is responsible for the manufacturer's business in India.

IVD Products in India (cont'd)

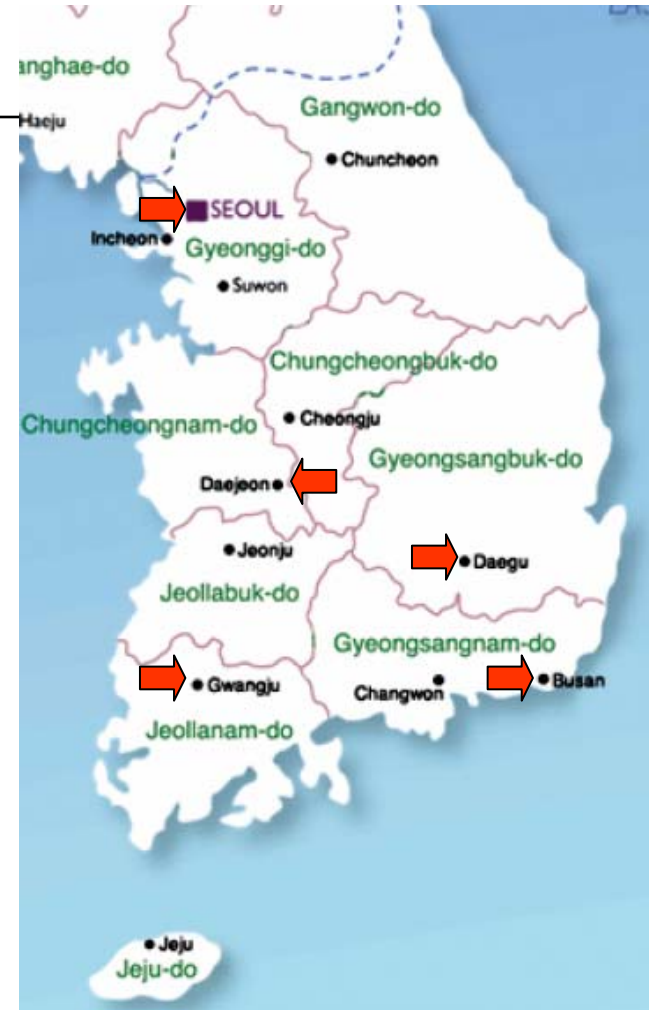
- ❑ Only critical kits require a formal product registration and usually testing
- ❑ Non-critical kits only require a simple Form 10 License (import license)
- ❑ Critical Kits require submitting Form 40 (an application form) and product dossier which complies with Schedule D(I) and (II) of the DCA.
- ❑ Sample testing for critical kits will also take place at National Institute of Biologicals-Appellate Authority.

KOREA



Major Markets

- Korea – size of the state of Virginia with 8x as many people
- The five largest cities represent about 60% of the total hospital beds of the country
 - Seoul and Kyonggi (37%)
 - Pusan (10%)
 - Daegu (5%)
 - Kwangju (4%)
 - Daijeon (3%)
- The Seoul and Kyonggi area (called ‘Seoul Metropolitan Area’) represent about 60% of the imported high technology medical device market.





Healthcare in Korea

- Healthcare expenditure/capita \$705 in 2006
- 1.6 doctors per 1,000 in 2005
- 6.5 hospital beds per 1,000 in 2005

Korea Medical Device Market

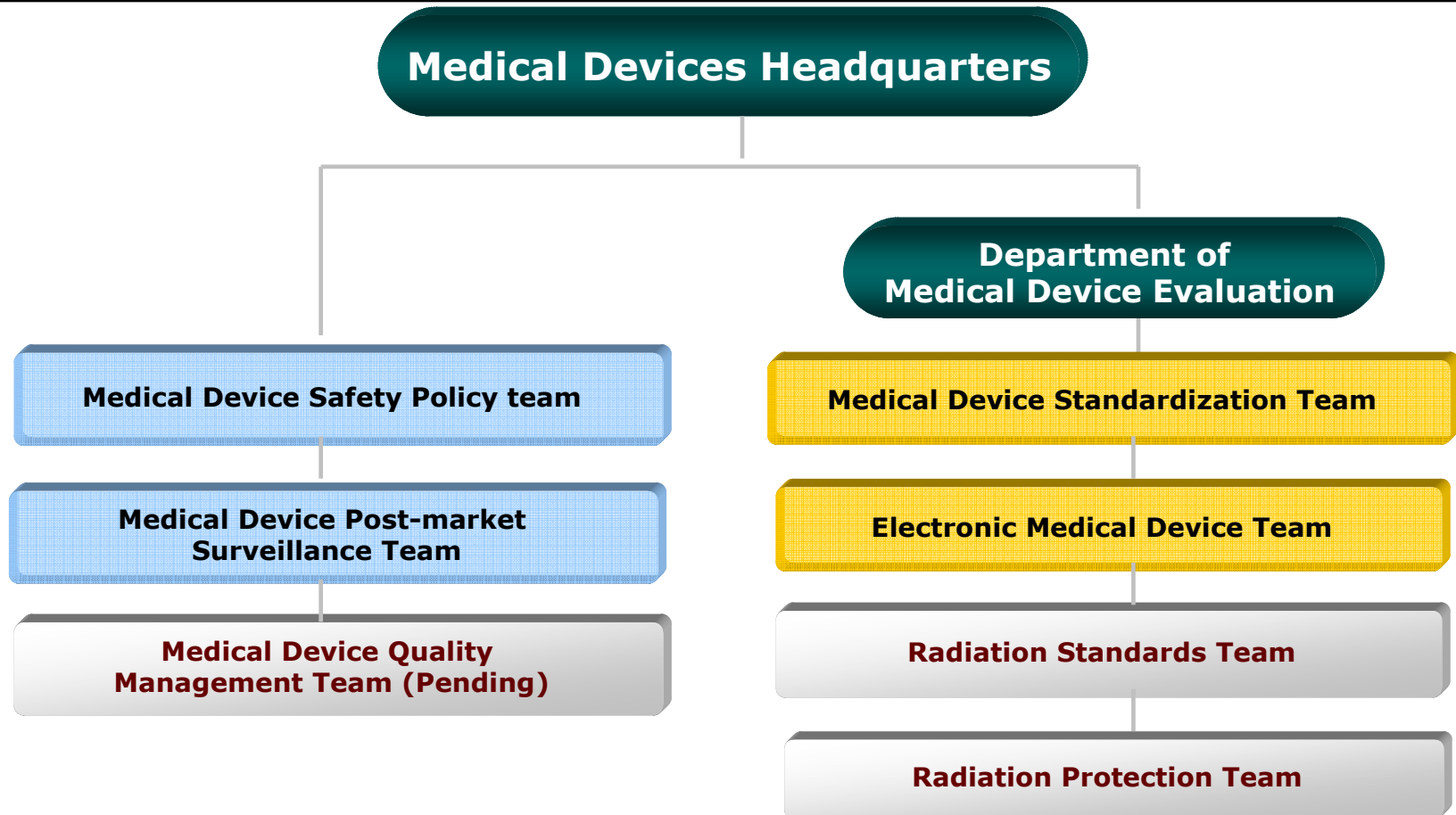
- Almost 60% of medical device market consists of imported products
- Top imported devices: stents, MRI equipment, dental implants, kidney dialysis equipment, CT equipment, etc.
- Top importers are from US, Japan, and Germany



Medical Device Regulatory Agency: Korea Food & Drug Administration (KFDA)

- Main regulatory body responsible for the safety and efficacy of medical devices, pharmaceuticals, foods, and cosmetics
- 952 employees in 2006
- About 100 employees in the Medical Devices Headquarters

Offices Responsible for Medical Device Regulation



The Medical Device Act (MDA)

- History
 - Enacted in May 29, 2003
 - Implementation beginning in May 29, 2004
 - Full enforcement in May 29, 2007
- Major Goals
 - Separate regulation for medical devices from pharmaceutical regulation
 - Previously, medical devices regulated under the Pharmaceutical Affairs Act
 - International harmonization of medical device regulation
- Change the previous three-class system into a four-class system
- Introduce new post-market surveillance requirements

Product Registration in General

- Only manufacturers or importers can submit applications
 - Applicant must have business entities inside of Korea
 - Foreign manufacturers cannot submit applications to KFDA directly
- Applications must be written in Korean
- Direct communication with responsible officials in English is not feasible



IVD Products in Korea

- IVD equipment are regulated as medical devices under the Medical Device Act (MDA).
- IVD reagents are regulated as drugs under the Pharmaceutical Affairs Act (PAA).

IVD Products in Korea

- IVDs for research purposes only (not for patient use) usually do not require pre-market approval.
- For approval, KFDA generally requires safety and efficacy review in addition to the dossier.
- Applicants will need to also submit a CFG, descriptions of manufacturing process, performance and stability tests, quality control records, product information, etc.

IVD Equipment in Korea (medical device)

- Usually, will need the following licenses for importing and manufacturing IVD equipment in Korea:
 - Medical Device Importer License
 - Korean Good Import Practice (GIP) Certification
 - Medical Device Distributor License
 - Medical Device Repair License
 - Medical Device Manufacturer License
 - Korean Good Manufacturing Practice (GMP) Certification

IVD Reagents in Korea (drug)

- Usually, will need the following licenses for importing and manufacturing IVD reagents in Korea:
 - Pharmaceutical Importer License
 - Pharmaceutical Wholesaler License
 - Good Supply Practice (GSP) Certification



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