

Asia: Medical Device Regulatory Issues

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KEY ASIAN REGULATORY TRENDS

1. *In some countries, where there were no medical regulations for registration, new regulations are being put in place.*
 - There are currently very few regulations for imported medical equipment in Malaysia. The Ministry of Health (along with the Association of Malaysian Medical Industries), however, is drafting a more comprehensive regulatory framework for medical devices that should be implemented by 2001.
 - India, which has no regulatory body for medical devices will also formulate and implement new regulations by 2002.
2. *In some countries where medical registrations were lopsided (domestic and foreign rules differed), they are becoming fairer to the foreign party.*
 - Taiwan's Department of Health (DOH) is revising its registration requirements for both domestically manufactured and imported medical devices. In 2004, Taiwanese companies will be required to start meeting Taiwan's Good Manufacturing Practice (GMP) guidelines. The DOH has drafted what it believes to be comparable regulatory requirements for imported products to show GMP compliance
3. *In some countries where local rules only applied, global harmonization is becoming more prevalent.*
 - In January 1999, in an effort to harmonize its drug classification with international standards, the Thai government decided to reclassify drugs into three categories: over-the-counter drugs, drugs sold by pharmacists and prescription drugs.
4. *In some countries where current regulatory bodies have not been adequate or their mission unclear, new organizations with more specific focuses are being put in place.*
 - Formation of the State Drug Administration (SDA) in China last year.

- Japan's Ministry of Health and Welfare (MHW) has reorganized to meet new environment.
5. *In some countries, despite protests from industry, regulations have not improved or even become tougher.*
- In China new regulations will come into effect in March 2000. These regulations will require type testing locally for Class 2&3 medical devices.
 - In Korea, there has been little progress in the government's follow-through on its promised reforms. The government's pharmaceutical regulatory and pricing systems are still quite prohibitive and many discriminatory policies and barriers to market access remain for imported pharmaceuticals. Foreign companies recently lodged formal protest against the Ministry of Health and Welfare (MOHW) in March 1999, claiming among other things that clinical trial requirements for new drugs were too strict, and that there was no price transparency in the distribution of drugs. The Korean Food and Drug Administration (KFDA) has been responding slowly to these protests, and it remains to be seen whether the country's pharmaceutical industry will be easier for foreign companies to penetrate in the near future.
6. *The regulations in Asia will continue to evolve. While certain trends can be identified, one cannot make generalizations for the region without looking at the specific systems in each country.*

CHINA

I. DEMOGRAPHICS

Population: 1.25 billion (July 1999)

Ethnic Groups: Han Chinese 91.9%, Zhuang, Uygur, Hui, Yi, Tibetan, Miao, Manchu, Mongol, Buyi, Korean, and other nationalities 8.1%

Capital: Beijing

Economy: The next few years may witness increasing tensions between a highly centralized political system and an increasingly decentralized economic system. Economic growth probably will slow to more moderate levels (4-5%) in 2000.

GDP growth rate: 6.0% (1999)

Per capita income: \$3,600 (1998)

II. MEDICAL DEVICE MARKET

- With a rapidly aging population, a rising standard of living and the government's commitment to improving access to basic healthcare, China's \$1.5 billion medical device market is currently the second largest in Asia after Japan. It is expected that this market will grow a healthy 10% in 1999.
- Electromedical, diagnostic and imaging equipment are the medical device products in highest demand.
- Imports have grown and now account for more than 50% of China's medical device purchases. There are more than 200 foreign medical device companies operating in China, with the U.S. holding a 35% share of foreign imports, with sales totaling \$240 million in 1998.
- Local production is expanding, but Chinese domestic strengths will continue to be in the low to medium technology range, and therefore will not directly compete with many sophisticated imported products.

III. KEY REGULATORY ISSUES

A. Medical Device Registration Issues

- Medical devices were not required to be formally registered for sale in China until late 1994. In 1997, the State Pharmaceutical Administration's (SPAC)

“Provisions Governing the Registration of Medical Device Products” went into effect and unified the registration system throughout China.

- The SPAC was dismantled last year. The newly-established State Drug Administration (SDA) is in charge of registration and monitoring imported medical devices. The SDA’s responsibilities include:
 - Developing, revising and promulgating legal standards for medical devices
 - Establishing catalogs for the classified regulation of medical device products
 - Registration, testing and administration of all medical devices
 - Issuance of product registration certificates and production licenses
 - Quality system and safety certification of medical device products
- The SDA has imposed new requirements on importers. The key provisions include:
 - Type testing of Class II and Class III devices performed at one of 10 Chinese testing centers (test price to be determined by the lab).
 - Mandatory clinical trials in China for Class III implantables
 - Continued on-site inspection of implantables
 - A registration fee of \$2,500 per application to replace the former \$400 fee

B. Intellectual Property Protection

- Because China’s registration laws require companies to submit such materials as product manuals and technical specifications, piracy and counterfeiting are widespread in China. Since China still maintains a “first to register” system that requires no evidence of prior use or ownership, it is relatively easy to “beat” the rightful owner to registration.
- Some protection of registered products is offered under the 1993 Product Quality Law, which prohibits producers and sellers from counterfeiting products or using quality marks that are not their own (i.e. certification marks, famous brand marks or marks of excellence).

IV. MEDICAL DEVICE REGISTRATION REQUIREMENTS

A. Medical device classification:

- Class I: devices whose safety and effectiveness are sufficiently provided through conventional management or general controls
- Class II: employ more sophisticated technologies and must have greater monitoring control to ensure safety and effectiveness
- Class III: includes implantable devices, life supporting or life sustaining equipment, and other complicated and high risk devices

B. The following documents must be submitted for imported medical devices:

- Certificate of Free Sale (CFS) qualifying the applicant and manufacturer for legal production and distribution
- Documentation showing that the product is approved to enter the market
- Documentation on product standards (safety, quality)
- Product manual (operation instructions)
- An additional “product quality guarantee” letter from the manufacturer
- Certificate and relevant documents from the designated service agency in China
- Product testing report (if required by the SDA)

C. Documents used to satisfy registration requirements are as follows:

- U.S. FDA Certificate to Foreign Government (CFG) as a quality standards
- Company Standards/Specifications and Tolerances for Key Attributes for “Product Standards” requirement
- Practitioner Fitting Guides in place of Product Manuals
- Copies of ISO 9000 Certificates and a Foreign Country Certification Statement for the “Quality Guarantee”

JAPAN

I. DEMOGRAPHICS

Population: 126 million (July 1999)

Ethnic groups: Japanese 99.4%, other 0.6% (mostly Korean)

Capital: Tokyo

Economy: For three decades overall real economic growth had been spectacular: a 10% average in the 1960s, a 5% average in the 1970s, and a 4% average in the 1980s. Growth slowed markedly in 1992-96 largely because of the after effects of over-investment during the late 1980s and contractionary domestic policies intended to eliminate speculative excesses from the stock and real estate markets. Growth picked up to 3.9% in 1996, largely a reflection of stimulative fiscal and monetary policies. But in 1997-98 Japan experienced a wrenching recession caused by financial difficulties in the banking system and real estate markets and by rigidities in corporate structures and labor markets. In 2000, there are signs that the economy is turning around with 1st quarter growth at 2.41% and 2000 growth projected at 2.0%.

GDP growth rate: approximately 1% (1999)

Per capita income: \$23,100 (1998)

II. MEDICAL DEVICE MARKET

- Japan's \$21 billion medical device market is currently the second largest in the world.
- Market demand grew approximately 13% annually from 1993 to 1995, but slowed to 5% between 1996 and 1998 during the recession. Japan's economy is now beginning to recover and the demand for medical devices is expected to grow by approximately 6% annually for the next few years.
- There are several forces driving this demand. For example, by the year 2000, nearly 20% of Japan's population will be older than 65, causing demand for cardiac pacemakers to increase by 30-40% during the next 10 years. Also, a growing number of Japanese are being diagnosed with cancer, heart disease, and other conditions that are common in industrialized countries. This is further driving the demand for advanced medical treatment.
- In an effort to be more cost effective, the country is looking to foreign medical companies that can supply innovative products at a much lower cost.

- In 1998, Japan also began to deregulate its medical industry to reduce burgeoning healthcare costs. Deregulation should be complete by the year 2000 and will remove numerous barriers to foreign companies by untangling some of the country's complicated product testing and registration regulations.

III. KEY REGULATORY ISSUES

A. Japan has yet to implement the Birmingham commitments from the Birmingham Summit of G-8 countries in 1998. They include:

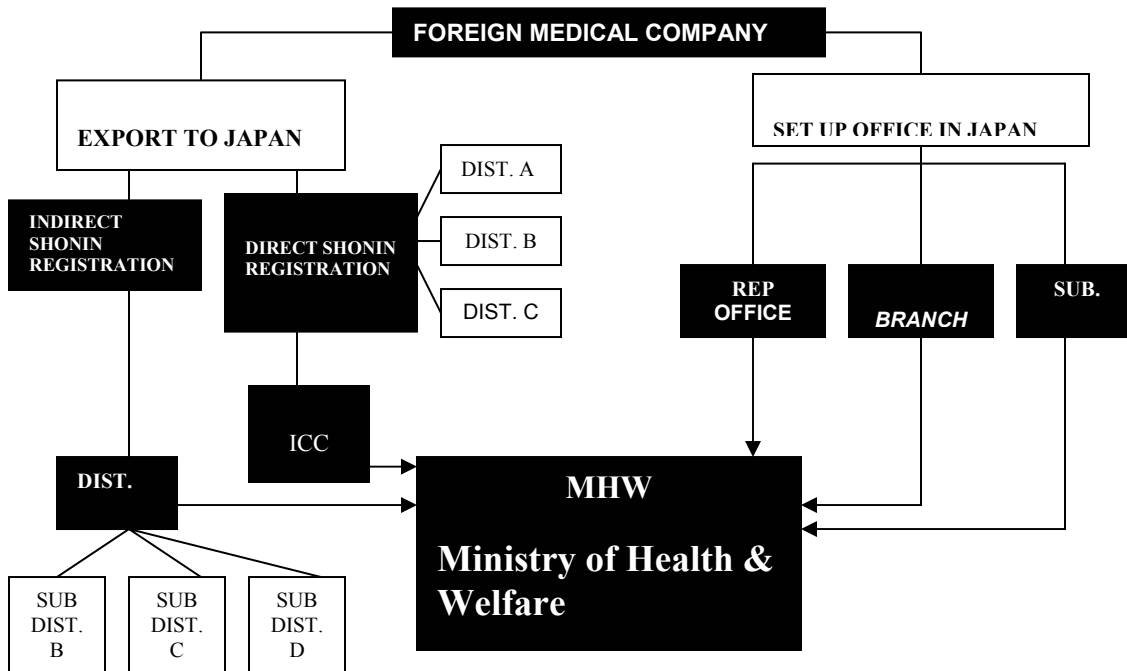
- Recognition of the value of innovation of pharmaceuticals and medical devices
- Ensuring transparency in the consideration of Japanese healthcare policy by allowing foreign manufacturers to exchange views with the Ministry of Health and Welfare
- Shortening the approval processing period to 12 months by April 2000
- An expansion in the acceptance of foreign clinical test data through the incorporation of International Conference guidelines into Japanese regulations by August 1998

B. Medical Device Registration Issues

- Approval processes are long and complicated, sometimes doubling the MHW own 4 month standard. Problems slowing the process range anywhere from a lack of consistency in the inspection standards to a lack of international harmonization.
- The Highly Advanced Medical Technology (HAMT) program sometimes requires companies to give away their products without insurance-related reimbursement for an extended period of time, even after *shonin* has been issued. This slows the entry of new competing products into the marketplace.
- Japan normally does not accept foreign clinical data and will impose additional local clinical testing, even if the products are already available in the U.S. or Europe.
- The MHW treats in vitro diagnostic (IVD) products as pharmaceuticals rather than medical devices.

C. Direct / Indirect Registration

Distribution in Japan



Source: Pacific Bridge, Inc.

- **ICC Advantages:**
 - Increased control for the manufacturer over marketing strategy
 - Able to appoint multiple primary product distributors immediately
 - Easier to change distributors
- **ICC Disadvantages:**
 - Foreign medical device company bears large initial costs (i.e. registration fee, annual fees for ongoing responsibilities)

D. Reimbursement Issues

- In 1999, local governments were authorized to use the *overall greatest value methodology* (OGVM) to procure medical products on the basis of the best overall value for their performance and specification requirements. This replaced the practice of using the initial price as the primary factor when procuring medical devices.
- The reimbursement process is a lengthy and inefficient process. For example, despite the fact that a technical fee approval is needed before the insurance approval of the medical devices is granted, the committee approving technical

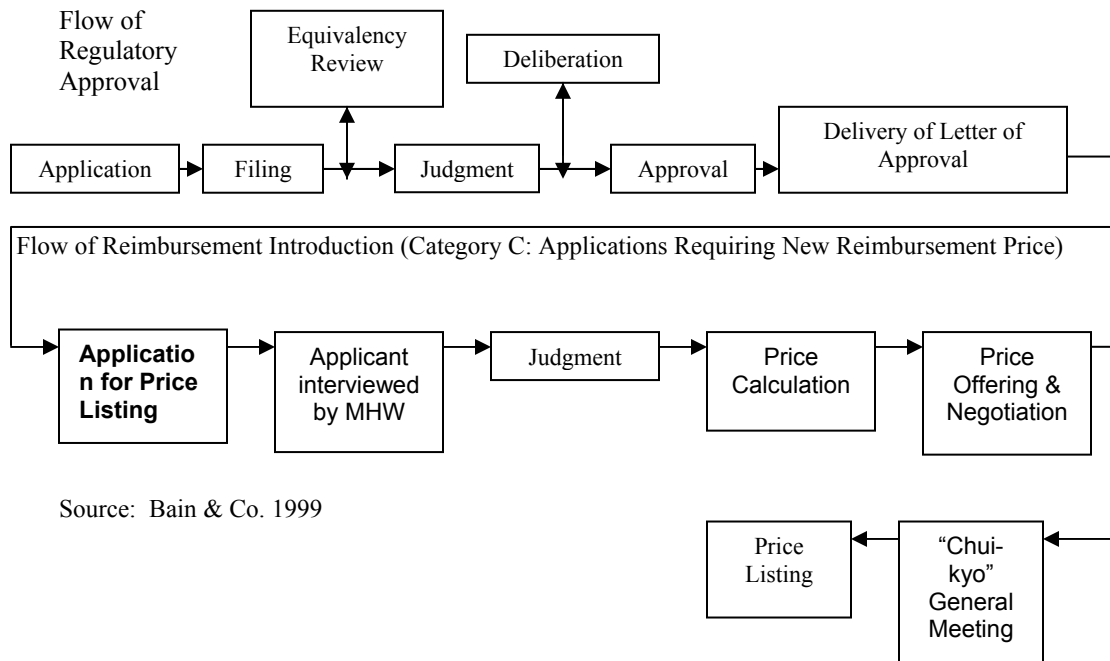
fees meets only once or twice a year. Thus, it can take 1-2 years from the time regulatory approval is granted to the time that insurance coverage is approved.

IV. MEDICAL DEVICE REGISTRATION REQUIREMENTS

A. Before a medical device can be distributed in Japan, the most important registration requirements are:

- A *kyoka* ('license'), which essentially grants a medical device manufacturer or distributor permission to market its products in Japan and is required for each manufacturing plant and representative office in Japan
- *Shonin* ('approval'), which is granted for each separate product once the MHW is satisfied with the dependability and efficacy of a medical device

B. The Process of Regulatory Approval and Reimbursement Approval

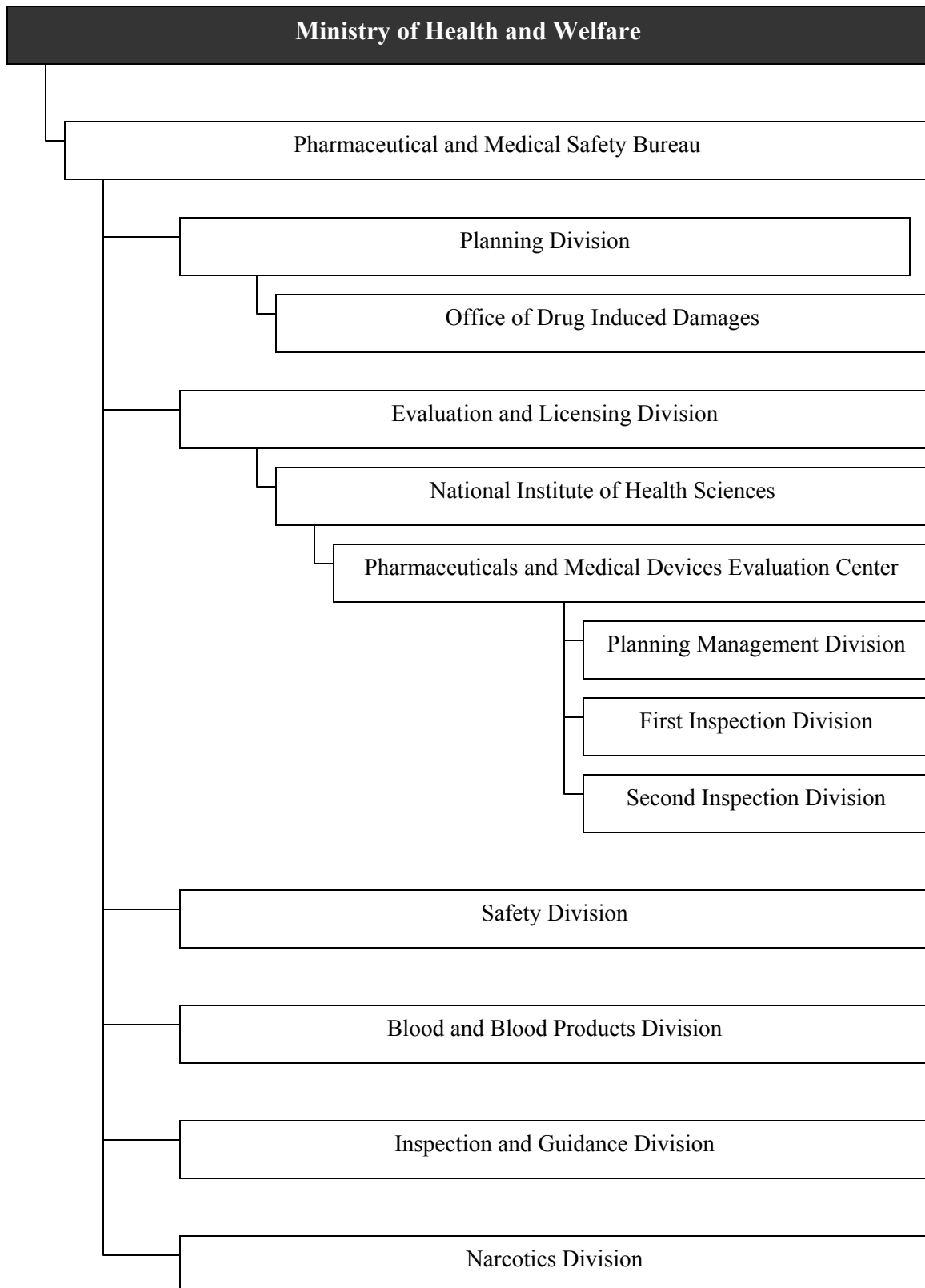


Source: Bain & Co. 1999

V. JAPAN'S MINISTRY OF HEALTH AND WELFARE STRUCTURE

See next page

Japanese Ministry of Health and Welfare Structure



SOUTH KOREA

I. DEMOGRAPHICS

Population: 46.9 million (July 1999)

Ethnic groups: homogeneous (except for about 20,000 Chinese)

Capital: Seoul

Economy: As one of the Four Dragons of East Asia, South Korea has achieved an incredible growth record in the 1970s, 1980s and up until 1997. The Asian financial crisis of 1997-98 exposed certain longstanding weaknesses in South Korea's development model. By the beginning of 1999 Korea had improved its financial stability and rebuilt foreign exchange reserves to record levels by running a current account surplus of \$40 billion.

GDP growth rate: 2% (1999)

Per capita income: \$12,600 (1998)

II. MEDICAL DEVICE MARKET

- South Korea's medical device market was growing rapidly at an annual rate of about 14% in 1997. In fact, the market was approaching \$1 billion before the crisis struck in 1997. The crisis caused the market to lose about \$300 million on a short-term basis.
- While the market suffered huge losses in 1997 and 1998, this was due more to the decline in sales of expensive medical equipment (MRIs, CT scanners, etc.) than the decline in sales of lower costing hospital staples. With South Korea's economic recovery, its medical device market should pick up quickly.
- Due to a rising per capita income prior to the crisis, many doctors and facilities developed a strong preference for sophisticated medical technology. About 70-80% of medical devices are currently imported and due to the lack of local production this share should remain stable over the next few years

III. KEY REGULATORY ISSUES

A. Medical Device Registration Issues

- The new regulatory approval system for medical devices implemented by the Ministry of Health and Welfare (MHW) in 1997 ended its transitional period on

September 1, 1999. In addition with the new approval system, the MHW delegated approval authority for medical devices to the Korean Food and Drug Administration (KFDA).

- Even though Korean regulations sometimes allow imported medical devices exemptions from local type tests when equivalent foreign test data is submitted, very few U.S. firms have been exempted from these expensive local tests.
- The requirements for submitting testing standards are full of inconsistencies. For example, the KFDA will not accept a U.S. manufacturer's own standards and testing methods over the new ISO (GMP) documentation, even though they are often more stringent than international requirements. Furthermore, the KFDA has consistently required U.S. manufacturers to produce a certificate of U.S. Quality System Regulation compliance by the U.S. FDA even though the U.S. FDA does not issue such a "certificate of compliance."

B. Reimbursement

- Korea's monopolistic National Health System is closed to private healthcare insurance providers, resulting in artificially low reimbursement rates, inconsistency and a lack of transparency.
- R&D expenses incurred by foreign companies to develop or improve a medical device are lost under current regulations because the National Federation of Medical Insurance only lists improved, enhanced or upgraded medical devices on the National Reimbursement List when their prices are *lower* than those of the existing product.

C. Biocompatibility (Safety) Data Requirement

- The KFDA's requirement that there be data to prove that the materials used in medical devices are safe is troublesome because some materials have been deemed so safe that data is no longer being generated and while exemption for some materials is being considered, there is little being done.

IV. MEDICAL DEVICE REGISTRATION REQUIREMENTS

- A. The medical device importer must obtain a Medical Device Importer's License through the city government.
- B. All medical device importers must obtain a Quality System Approval from the Korean Academy of Industrial Technology (KAITECH) based on the following requirements using its "Quality Management Standards for Imported Medical Devices Regulations":

- Accurate maintenance of all records regarding imported devices
 - Testing facilities and personnel training and review to assure quality.
 - The quality of “help lines” for those using the medical device.
- C. Medical device importers must undergo a compliance inspection at least every two years by KAITECH. U.S. manufacturers can be technically exempted from these compliance inspections if updated GMP documents are presented.
- D. Class I devices: A “Technical Specification Notification” covering name, type, efficacy, technical specs and instruction is the only major item required, but importers must now notify the KFDA (which replaced the KMIIC).
- E. Class II and III devices: Approval by the KFDA is contingent on:
- (1) A Review of Standards and Testing Methods (STM) covering the same requirements as the Technical Specification Notification for Class I devices
 - (2) A local Type Test prior to importation that covers physical tests by a test agency and identification of products with the approved STM.
 - Foreign manufacturers are now required to test their products *themselves* in local test labs that they maintain in S. Korea; certain exemptions technically exist.
 - Final import approval after the STM and type test results are submitted and approved by the Ministry of Health and Welfare.

TAIWAN

I. DEMOGRAPHICS

Population: 22 million (July 1999)

Ethnic groups: Taiwanese 84%, mainland Chinese 14%, aborigine 2%

Capital: Taipei

Economy: Taiwan has a dynamic capitalist economy. Real growth in GDP has averaged about 8.5% a year during the past three decades. Export growth has been even faster and has provided the impetus for industrialization. Inflation and unemployment are low, and foreign reserves are the world's third largest. Because of its conservative financial approach and its entrepreneurial strengths, Taiwan suffered little compared with many of its neighbors from the Asian crisis.

GDP growth rate: 5.1% (1999)

Per capita income: \$16,500 (1998)

II. MEDICAL DEVICE MARKET

- With net incomes remaining high in Taiwan, there is money available to spend on quality healthcare.
- Taiwan's currency depreciation from the crisis has also been small compared with other countries, and medical device imports continued to grow at 3-5% between 1997 and 1999. Total market demand in Taiwan for medical devices is currently around \$700 million, with imports accounting for nearly 80% of this figure.
- The demand for sophisticated medical services and technology has also increased rapidly. The market for cancer diagnostic and therapy equipment, for example has been growing at approximately 8-10% per year since 1995.
- The most frequently imported instruments in Taiwan today include CAT scanners, ultrasonic diagnostic machines and electronic diagnostic devices.
- Local clinics and hospitals continue to prefer U.S. medical equipment for its quality and innovation. U.S. medical manufacturers have about a 42% market share in the Taiwanese market.

III. KEY REGULATORY ISSUES

A. Medical Device Registration Issues

- There has been a lot of confusion and inconsistency regarding the new requirement of submitting a plant master file (PMF) with medical devices. The DOH clarified its requirements by:
 - (1) Making it clear that U.S. manufacturers do not have to include the PMF in the registration package and that the absence of PMF material would not adversely affect the registration application
 - (2) For manufacturing facilities in the U.S., manufacturers may be exempted from submitting PMFs and submit a FDA's Establishment Inspection Reports (EIRs), a FDA's Certificate to Foreign Government and an ISO 13485 Certificate instead.
- The DOH requires three published clinical documents in order to register a "First Introduced Device" even though many devices in this category do not have such requirements for marketing in the U.S. or E.U. Furthermore, because these products may no longer be considered innovative products in developed countries, related clinical papers may not be published in well-known medical magazines.
- Due to the outdated and complicated medical device registration process, license transfer is difficult. The American Chamber of Commerce recommends that the DOH amend the license transfer process with the following changes: (1) that there be no notarization requirements for the declaration of letters of ownership change needed from the manufacturer, (2) no export certificate requirement for specific products (have a "blanket transfer" and (3) allow the manufacturer to revise the labels, data sheets and packaging after the Department of Health (DOH) approves the transfer process.

B. Medical Device Reimbursement Price Issues

- The Diagnosis Related Groups (DRG) system implemented by the Taiwan government pays a single, flat rate for similar functioning medical devices, encouraging hospitals to make decisions on price rather than quality. There is pressure for the Bureau of National Health Insurance (BNHI) to differentiate products based on functionality, consistent with the 1996 U.S.-Taiwan pricing agreement.

C. GMP Compliance

- Even though quality system documentation (QSD) is intended primarily for internal use, the DOH requires that non-U.S. companies and factories submit QSD even though they are also certified with ISO. Taiwan is the only country among the Asia Pacific countries that operates in accordance with international standards *and* requires QSD as well.

D. Intellectual Property Protection

- The Taiwanese government does not guarantee that the information submitted by U.S. medical companies will be kept confidential. The only course of action is to submit a request for confidentiality to the AIT who will then submit it to the DOH.

IV. MEDICAL DEVICE REGISTRATION REQUIREMENTS

A. In order to obtain a pre-marketing registration license approval, foreign manufacturers must have a local agent in Taiwan that is a qualified importer of medical devices or a registered seller of medical devices.

B. If the foreign manufacturer has a branch office in Taiwan, it may fill out the application forms and submit them to the DOH.

C. The DOH requires the following documents to accompany the application:

- Letter of authorization
- Free sales certificate issued by the highest health authority in your home country
- Leaflet – Company profile (a brief history)
- Quality control records
- Information on form, structure, dimension, raw materials or ingredient and quantity, performance, purpose of use, indication or effort
- Sample
- Clinical reports
- Misc. equipment specific indications and operating procedures

D. The DOH asks that a plant master file (PMF) be submitted, containing:

- Company general information
- Organization and personnel
- Buildings and facilities
- Production equipment
- Control of components, drug product containers and closures, packing and labeling
- Production and process controls
- Responsibilities of quality control
- Stability testing
- Documenting sterilization process validation
- Contract manufacture and analysis

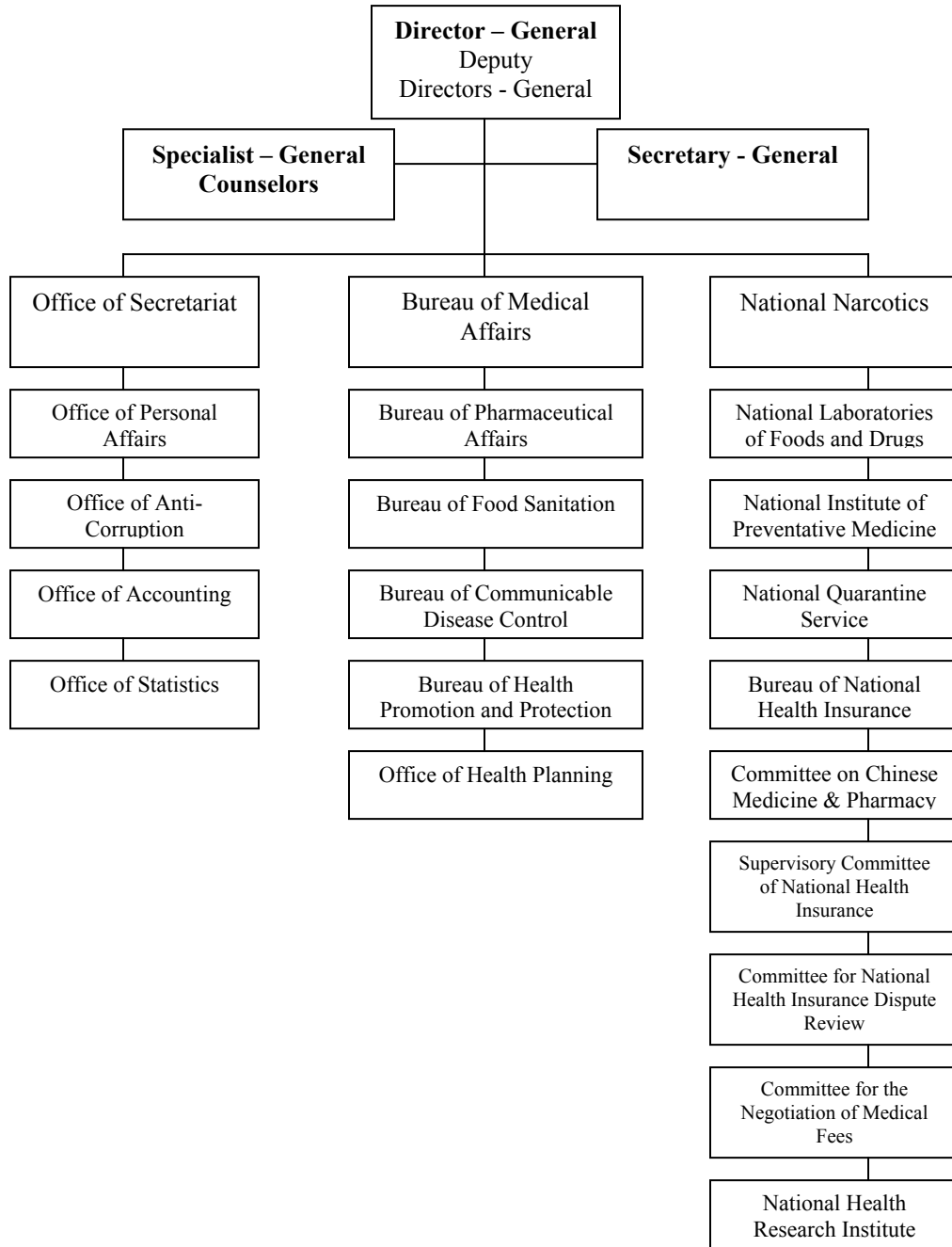
E. Other issues in pre-marketing registration

- The product can be imported (by your agent) after the product license is available. This license is valid for 5 years.
- The license holder (the agent who files the pre-registration license application) can transfer the license to another agent with the permission of the manufacturer.
- The manufacturer may also authorize other agents to register the same product concurrently.
- Manufacturers with different locations but the same company name (i.e. branches) must file separate applications.

V. ORGANIZATION OF THE DEPARTMENT OF HEALTH

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Taiwanese Department of Health Organization



MALAYSIA

I. DEMOGRAPHICS

Population: 21 million (July 1999)

Ethnic groups: Malay and other indigenous 58%, Chinese 26%, Indian 7%, others 9%

Capital: Kuala Lumpur

Economy: After a decade of 8% average GDP growth, the Malaysian economy—severely hit by the regional financial crisis—declined 7% in 1998. Malaysia was still in a recession for the first half of 1999. Currently, however, the Malaysian economy is beginning to turn around and is expected to grow by approximately 1% by the end of 1999.

GDP growth rate: 1.7% (1999)

Per capita income: \$10,300 (1998)

II. MEDICAL DEVICE MARKET

- Since the early 1990s, Malaysia's medical device market has been growing at 15-20% annually. With the rejuvenation of the Malaysian economy after the crisis of 1997-98, the country's medical device market is currently worth about \$300 million, with imports accounting for more than 90% of this total.
- Best sales prospects for medical devices in Malaysia are high-tech equipment such as anesthesiology equipment, diagnostic equipment, home healthcare products, life support equipment, ultrasound equipment, MRIs and radiology equipment.
- There are currently very few trade barriers or regulations for imported medical equipment in Malaysia. Only latex rubber products (such as condoms or surgical gloves) require certification by the Ministry of Health. The government also maintains some safety related regulations on medical devices. For instance, it is government policy not to buy used/refurbished medical equipment, or allow new, experimental products into the country without FDA or other international standard approval. Also, any x-ray equipment must be specially examined and approved by the Ministry of Health before being used by doctors and radiologists.

III. KEY REGULATORY ISSUES

- A. There are very few trade barriers or regulations for imported medical equipment in Malaysia. The few existing regulations are general and fairly broad – for example, it is government policy not to buy used/refurbished medical equipment or allow experimental products into the country without U.S. FDA or other international standard approvals.
- B. The Ministry of Health, along with the Association of Malaysian Medical Industries, is drafting a more comprehensive regulatory framework for medical devices that should be implemented by 2002.
- C. The Malaysian government plans to implement new measures in the enforcement of intellectual property rights in order to conform to the Trade Related Aspects of Intellectual Property Rights Agreement implemented by the WTO. Current measures include (but are not limited to):
 - Reviewing section 42 of the Copyright Act 1987 in an effort to establish a more practical method for proving copyright ownership, as well as making it easier to initiate legal action against copyright pirates.
 - Amending the Trademarks Act 1976 and Patents Act 1983.
 - Implementation of the Technology Action Plan for industrial development programs: installing a document imaging system (DIP) to increase the efficiency of search and examination functions.

IV. PROPOSED MEDICAL DEVICE REGULATORY FRAMEWORK

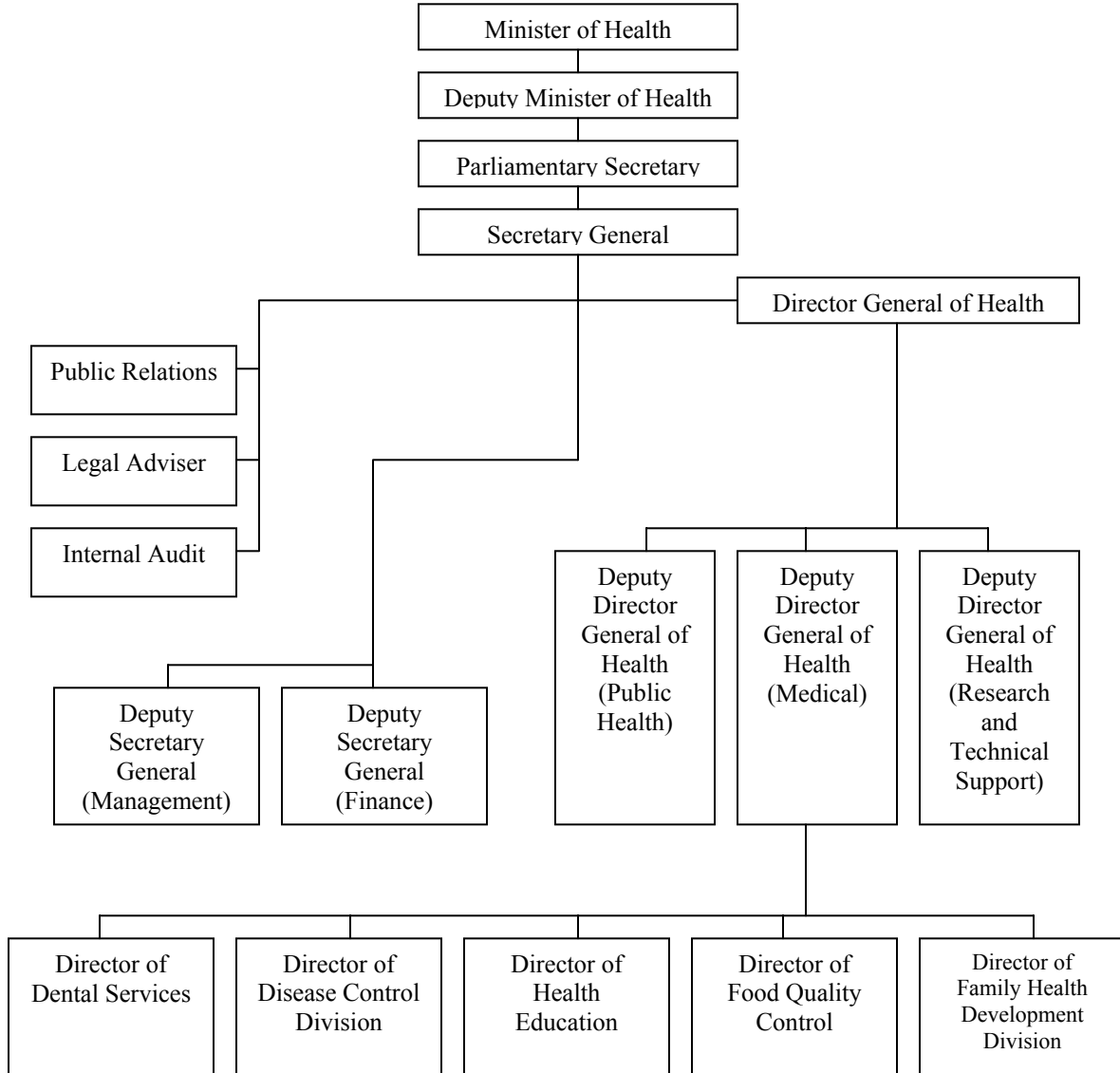
- A. Will cover the registration of medical devices
- B. Regulate compliance of Good Manufacturing Practice (GMP) for local and imported medical devices
- C. Regulate the importation of medical devices and the use of certain types of medical devices in terms of their usage, maintenance, and personnel
- D. Regulate the sale of medical devices, as well as monitor and implement an effective system for customers to file complaints

V. MALAYSIA'S MINISTRY OF HEALTH STRUCTURE

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Malaysian Ministry of Health

Source: Department of Public Health, Malaysia 1999



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