

Pharmaceuticals in Asia: Regulatory and Safety Updates

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OVERVIEW OF ASIA AND ITS MEDICAL MARKETS

Demographics (2004)

Country	Population	Population Growth (2004 est.)	GDP (PPP)	Per Capita Income (PPP)	Life Expectancy (Years)
China	1,298,847,624	0.57%	6.449 trillion	5000	71.96
Hong Kong	6,855,125	0.65%	212.2 billion	28,700	81.39
Philippines	86,241,697	1.88%	390.7 billion	4,600	69.6
Indonesia	238,452,952	1.49%	758.1 billion	3,200	69.26
Japan	127,333,002	0.08%	3,567 trillion	28,000	81.04
Malaysia	23,522,482	1.83%	207.2 billion	9,000	71.95
Singapore	4,353,893	1.71%	109.1 billion	23,700	81.53
Korea	48,598,175	0.62%	855.3 billion	17,700	75.58
Taiwan	22,749,838	0.64%	528.6 billion	23,400	77.06
Thailand	64,865,523	0.91%	475.7 billion	7,400	71.41

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Healthcare Statistics (2003)

Country	Number of Hospitals	Doctors per 1000 Persons	Per Capita Spending on Healthcare (US\$)
China	330,348	1.69	30
Hong Kong	103	1.4	N/A
Philippines	1,652	N/A	33
Indonesia	1,089	0.14	19
Japan	169,556	1.91	2,908
Malaysia	360	0.7	101
Singapore	28	1.39	4,107
Korea	21,686	1.35	584
Taiwan	18,265	7.42	677
Thailand	1,392	0.32	71

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Size of Asian Pharmaceutical Markets

Country	Market Size (US\$)
China	US \$23 billion
Hong Kong	US \$1.5 billion
Philippines	US \$300 million
Indonesia	US \$350 million
Japan	US \$53 billion
Malaysia	US \$210 million
Singapore	US \$400 million
South Korea	US \$6.3 billion
Taiwan	US \$2.5 billion
Thailand	US \$1.5 billion

Source: Compiled from various sources by PBI

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Overview of Asian Pharmaceutical Market

- Over 30% of new expenditures on healthcare worldwide is attributable to Asia
- Spending is driven by:
 - Aging population
 - Increasing life expectancy
 - Increasing incidence of major diseases
 - Increasing health consciousness
 - Higher disposable income

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JAPAN

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Japan

Overview

- Economy
 - Basically, very little growth during the past 15 years
- Population: 130 million
- \$52 billion drug market; represents 11% of global sales

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Major Markets

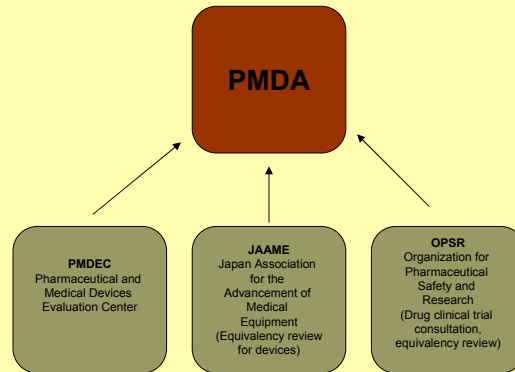
- Southern Kanto region
 - Tokyo, Chiba prefectures
- Kansai region
 - Osaka, Kyoto, Hyogo prefectures
- Tokai region
 - Aichi, Gifu prefectures

MHLW Overview

- Responsible for ensuring good living standards among Japanese people and promoting development of new programs to improve their lives
- Some of the areas regulated by MHLW:
 - Pharmaceutical, medical device and food regulations and safety (including PMDA and PAL)
 - Healthcare services
 - Employment and labor standards
 - Pension and health insurance

Structure of the PMDA

- Pharmaceutical and Medical Device Agency
- Established April 1, 2004



Recently Improved Measures Through the PMDA

- Creation of a system for consultation with the MHLW
 - Reduces time to submission
 - Improves quality of applications
- More medical specialists to review drug and device applications
 - Shorter review time by PMDA
- Products get to the marketplace faster
 - Better for companies
 - Better for patients

The New PAL

- Some of the changes taking place:
 - New MAH system
 - Risk-based classification system for medical devices
 - GMP similar to ISO 13845:2003
 - Class III medical devices require STED (Summary Technical Documentation)

ICC System vs. MAH System

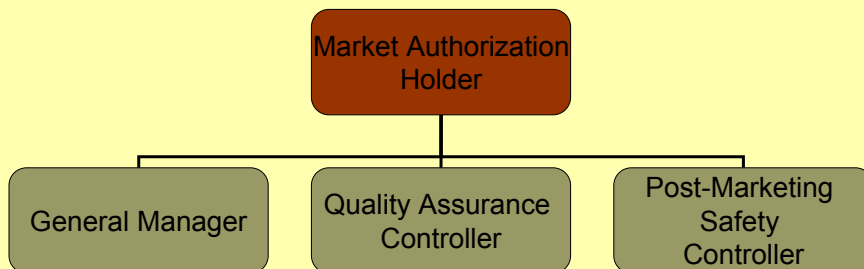
- ICC system:
 - License (kyoka) and approval (shonin) required
 - Manufacturer produced the products *and* released them into the market
- New MAH system:
 - Only production done by manufacturer
 - MAH is an enhanced regulatory control mechanism
 - Gives *final* permission for release of products into marketplace

Purpose of MAH System

- MAH system separates medical device manufacturing and product release
 - Increases quality and safety controls
 - Devices are more closely regulated like drugs
- MAH responsible for:
 - Purchasing or importing medical devices from a manufacturer
 - Ensuring compliance with GMP, GVP and GQP standards
 - Selling devices to sales groups
 - Temporarily storing devices in a MAH-licensed establishment



MAH Structure



Three Controllers

1. **General Manager**
 - Oversees all MAH duties, including GQP and GVP
2. **Quality Assurance Controller**
 - Responsible for GQP
 - Ensure that manufacturer follows proper methods for shipping and receiving
 - Notify MHLW of any changes in manufacturing or in-process controls
 - Develop release criteria for each product
 - Handle communication in the case of a recall
3. **Post-Marketing Safety Controller**
 - Responsible for GVP
 - Monitor safety of products released into the market
 - Provide reports to health authorities on adverse incidents, recalls, etc.

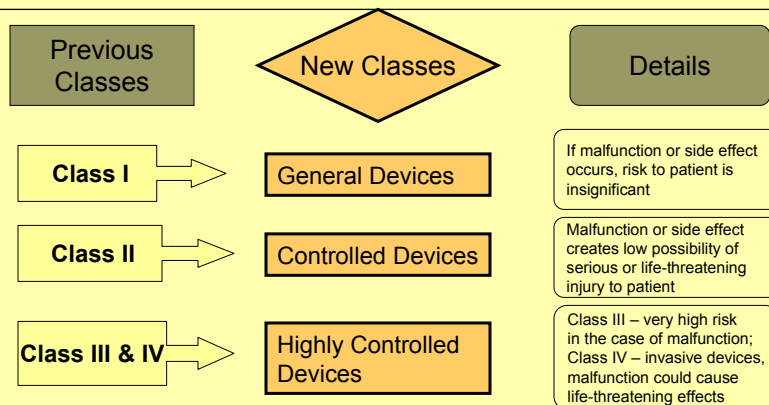
Good Vigilance Practice SOPs

- Post-marketing surveillance
- Collect and file product safety information
- Evaluate safety information
- Plan and implement counter measures to ensure safety
- Safety assurance training for personnel
- Sub-contracting
- Report to and from QA department
- Self check and audit

Good Quality Practice SOPs

- ❑ Release products into the market
- ❑ Ensure maintenance of QA documents and reports, including information on any device problems
- ❑ QA training for personnel
- ❑ Product storage control
- ❑ Handling of recalls
- ❑ Control of quality at local offices
- ❑ Self-check and audit

New Classification System



Generic Drug Market

- Lags behind that of the U.S. and Europe
 - Many Japanese have notion that generic drugs are inferior
 - High level of “brand consciousness” in Japan
 - Some Japanese doctors are unaware of generic drug names
 - Pharmacists can administer generic drug only if doctor prescribes it
 - Drug wholesalers often have close ties to patented drug makers; do not handle many generic drugs
- Slowly gaining more ground
 - Escalating medical costs
 - Number of cost-conscious patients on the rise
 - A few hospitals have begun issuing only generic drug prescriptions
 - Patients and hospitals can save up to 80% by choosing generic drugs rather than brand names

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Generic Drug Name Standardization

September 2004

- Previously, companies in Japan could name generic drugs after brand patents expired
 - Led to barrage of similar names
 - Caused confusion, dispensing errors by pharmacists, doctors and hospitals
- New regulation requires specific labeling information on the packaging or drug itself

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CHINA

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China

Overview

- Economy:
 - GDP (at PPP) - \$6.499 trillion (2003 est.)
 - GDP growth rate – 9.1% (2003 est.)
- Population: 1,298,847,624
- \$7 billion in drug sales in 2001 – world's 9th largest market
- Pharmaceutical market has grown 10-15% per year for the last 15 years
- Domestic pharmaceuticals occupy approximately 70% of the market
- Retail drug outlets expected to grow, but hospitals are still main distributors of pharmaceuticals

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China's Pharmaceutical Market

- China's pharmaceutical market continues to grow by about 15% per year
- 9th largest pharmaceutical market in the world
- Currently about 1,800 China-foreign pharmaceutical joint ventures
- Over 5,000 domestic drug companies in China



State Food and Drug Administration (SFDA)

- State Drug Administration (SDA) established by the Chinese government in 1998 to consolidate China's healthcare regulatory bodies
- SDA became the SFDA in 2003
- Responsibilities of the SFDA include:
 - Provide regulations on drug registration, management, distribution, etc.
 - Establish and ensure quality and safety standards for drugs
 - Issue product licenses for drugs
 - Monitor clinical trials, adverse reactions, advertisements

Chinese Pharmaceutical Regulations

China

- Three types of drug registration:
 - New drug registration
 - Divided into 5 categories
 - Abbreviated registration
 - Drugs that already have China drug specifications established
 - Registration supplement
 - For a change to an application

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Chinese Pharmaceutical Regulations

China

- Some of the required documents for the dossier:
 - Name of drug in English and Chinese
 - GMP certificate, product registration from country of origin, Free Sale certificate, patent certificate
 - Package and label design sample
 - Package insert
 - Certificate of analysis
 - Stability data
 - Information on animal pharmacokinetic studies
 - Data from multinational clinical trials may be acceptable

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Chinese Pharmaceutical Regulations: Imported Drugs

China

- Imported products receive a 5-year import drug license
- Renewal applications must be submitted 6 months before the license expiration date

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Clinical Trials

China

- Increasing number of foreign companies are conducting clinical trials in China
 - Lower costs
 - Large patient base
 - Many people have never received medication to treat their conditions
- Some foreign contract research organizations (CROs) have been established in China
- Most of their clients are foreign companies due to high costs of service

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Drug Safety Evaluation Center

China

- National Center for Safety Evaluation of Drugs (NCSED) launched in 2002
- Funded by Chinese government; some equipment provided by Japanese government and Japan International Cooperation Agency
- Started trial operations in December 2001
- Conducts drug safety evaluations in compliance with international standards

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Update: Prescription Required for Antibiotics July 2004

China

- Previously:
 - No prescription needed to purchase antibiotics
 - No limit on the quantity of antibiotics that could be purchased by an individual
- Under SFDA's new regulation:
 - Purchase of antibiotics limited to *only* patients with a doctor's prescription
- Purpose:
 - Due to high healthcare costs, many citizens relied on self-diagnosis; tended to purchase antibiotics for all minor illnesses
 - Major drugstores in China carry up to 200 different types of antibiotics
 - Almost 2.5 million people per year are hospitalized for adverse reactions to antibiotics due to misuse
- Hospitals have prepared by designating specific codes for antibiotics
 - Will be inscribed on prescription pads and electronic prescriptions at major hospitals
 - Allow doctors and pharmacists to verify authenticity of prescriptions

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Update: New GMP Regulations 2004 - 2008

China

- July 1, 2004
 - GMP required for all drug manufacturers
- January 1, 2006
 - GMP required for IVD reagents (administered as drugs)
- January 1, 2007
 - GMP required for medicinal gas manufacturers
- January 1, 2008
 - GMP required for cut crude drugs for Chinese medicine
 - How manufacturer processes and contains prepared slices of drugs, including the cleaning, cutting and steaming processes

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Update: Credit Levels for Drug Companies September 2004

China

- SFDA issued *Interim Provisions for Drug Safety Credit Classification*
- Applies to foreign and domestic drug companies, including manufacturers, distributors, R&D units
- Officials will conduct inspections of facilities and assign one of four categories based on compliance with drug regulations:
 - 1) Initial compliance or made improvement and is now in compliance
 - 2) Received one warning due to non-compliance
 - 3) Received second warning due to non-compliance
 - 4) Received multiple warnings; no effort to comply
- Companies with low credit ratings →
 - Subject to higher level of supervision; more frequent inspections
- Companies with high credit ratings →
 - Less inspections; priority in administrative approval processes

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INDIA

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India

India Overview

- Economy:
 - GDP (at PPP) - \$3.033 trillion (2003 est.)
 - GDP growth rate - 8.3% (2003 est.)
- Population: Nearly 1.2 billion
- \$6 billion pharmaceutical industry
- About 20,000 foreign and domestic drug makers accounting for nearly 3% of GDP
- Over 60% of India's bulk drug production is exported
- India is home to the largest number of USFDA approved pharmaceutical plants outside of the U.S.

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Pharmaceutical Regulations

- Pharmaceuticals regulated under the Drugs and Cosmetics Act 1940 (DCA)
- Applies to imported and domestic products made in India
- Enforced by Central Government (Department of Chemicals and Fertilizers, Ministry of Chemicals and Petrochemicals) in New Delhi
- Office of the Drug Controller of India (DCI) has prime responsibility
- Enforcement also done by individual State governments through their Food and Drug Administrations
- DCA regulates:
 - Product approval and standards
 - Clinical trials
 - Introduction of new drugs
 - Import licenses
- State governments regulate:
 - Approvals for setting up manufacturing facilities
 - Obtaining licenses to sell and stock drugs

Clinical Trials

- Good place for clinical trials - large, diverse population and varied gene pool
- Patient recruitment often easier and faster than in the West
- Companies can save as much as 50% in clinical trial costs

Outsourcing Clinical Trials: A Company Example

India

- Germany's Mucos Pharma GmbH
 - Hired Indian company to find 650 out of 750 volunteers needed for a clinical trial
 - Indian company found the patients within 18 months visiting only 5 hospitals
 - Mucos Pharma spent nearly twice as long visiting 22 hospitals to find the remaining 100 patients in Europe

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Update: Clinical Trials Announced October 2004

India

- MOH plans to amend Drugs and Cosmetics Act to allow foreign and domestic companies to conduct clinical trials in India and other countries simultaneously
 - Applies to Phase II and III trials only
 - Phase I trials not included, since Phase I trials test drug safety
 - > Protects Indian citizens from being subject to untested and unproven drugs
 - Clearances to conduct trials will be granted on a case-by-case basis
 - Foreign companies will not be permitted to conduct clinical trials solely in India
- MOH will set up special group to monitor clinical trials
 - Ensures that companies comply with GCP; trials that do not comply will immediately be stopped
- > Currently, a drug has to undergo clinical trial one phase higher in another country first, before the previous trial phase can be conducted in India

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Update: Patent Protection

- Previously:
 - India granted “process patents”
 - Another drug inventor could patent the same product as long as it was created by a “new” process
 - A tiny modification in the synthesis of a molecule would justify a new patent
- Passed a new patent law March 23, 2005
 - Sellers of already-approved generic drugs in India will now have to pay licensing fees
 - Generic drug producers can apply to copy a patented drug, but only after it has been on the market for 3 years
 - Generic producer may have to pay “royalty fees”
 - The patent owner can object to the copying

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Update: Generic Drugs in India

- Increased generic drug use by US and Europe due to rising costs of healthcare
- During the next 4 years, \$45 billion worth of drugs to go off-patent
 - Indian generic drug firms will benefit
 - Have the capabilities to manufacture many of these drugs
- Many US/European drug firms now looking for partnerships, mergers or acquisitions in India

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SINGAPORE

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Singapore

Singapore Overview

- Economy
 - GDP (PPP): about \$110 billion (2003)
 - GDP 1.1% growth rate (2003)
- Population: 4.3 million

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Regulatory Bodies

- Health Sciences Authority (HSA) was formed April 2001
 - Monitors healthcare services and establishes new medical regulations
 - Responsible for quality, safety and efficacy of drugs and devices
- Center for Drug Administration (CDA) under the HSA established January 2004
 - Center was formed by merging the Center for Pharmaceutical Administration (CPA) and the Center for Drug Evaluation (CDE)
 - These two centers were responsible for the regulation and evaluation of medicinal products in Singapore
 - The CDA's mission is to further rationalize and streamline the evaluation and registration processes of western drugs in Singapore

Update: Patent Regulation for Drugs June 2004

- Improved three key areas:
 - Patent term flexibility
 - Patent term starts once product is approved for market
 - Previously: patent term started once patent approved; company still had to wait for market approval → wasted patent term time
 - Parallel importation of products
 - Patent owner can stop parallel importer from importing a product that is a generic equivalent or similar to the patented product, *if the product has not been previously sold or distributed in Singapore*
 - Once the patent owner imports the product into Singapore, this right will be voided – the patent owner may be subject to competition from parallel importer
 - If product needed for treatment of specific patient in Singapore, product may be parallel imported with HSA's approval, regardless of whether the patent owner has brought the product into Singapore
 - Treatment will not be denied due to lack of certain drugs in the country
 - Application and approval process: creation of two-track system
 - Track 1: "fast track;" enables patent applicant to expedite application process and obtain a patent asap
 - Track 2: "slow track;" allows patent applicant to spend more time working on a marketing plan and patent strategy before entering patent term

Update: New Guidelines on Disease Awareness Campaigns

Singapore

November 2004

- Disease Awareness Campaigns (DACs) are a convenient way for companies selling drugs for rare diseases to educate the public about the disease and its various treatment options
- A company can only provide non-biased information - cannot emphasize a particular medication or treatment
- DACs do not require pre-approval or advertisement licenses from the HSA
- DAC advertisements should meet the following requirements:
 - Make no mention of any brand of medication
 - Does not promote any particular medicinal product or recommend consumers to ask their health professionals for any particular product
 - Can provide only factual, up-to-date and substantiated information
- Companies can also indirectly advertise a prescription only medicine (POM), though *this type of advertising cannot be done in the form of a DAC* and requires approval from the HSA

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Update: New Guidelines on Good Distribution Practices

Singapore

January 2005

- Issued to improve reliability and quality of drugs during distribution
- GDP documentation system
 - Must establish procedures for developing, controlling, and maintaining documentation related to the distribution process
 - Documents should be kept up-to-date and be readily available upon request
- Electronic records
 - If records are also maintained by electronic data systems, a detailed description and explanation of system should be created
 - Any changes made to the data should be electronically recorded and can be used as reference information in the case of an audit
- EEFO (Earliest-Expiry-First-Out) and FIFO (First-In-First-Out)
 - Must develop EEFO/FIFO system to help avoid distributing products with approaching expiration dates
- Handling of active pharmaceutical ingredients (APIs) and intermediates
 - Anyone who distributes, trades, or stores APIs or intermediates in Singapore will need to maintain documents for tracing these products
 - Name and address of the original manufacturer, purchase orders, batch numbers, transportation information and Certificates of Analysis

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Update: New Guidance for Minor Variation (MIV) Applications

Singapore

January 2005

- Singapore allows MIV applications for small changes
 - Eliminates need for re-registration
- New guidance divides MIV applications into 2 categories
 - MIV-1 (Requires regulatory approval)
 - For changes in: manufacturing site, shelf-life, storage conditions, packager, testing procedures, pack size, and product labeling, etc.
 - Require specific documents be submitted to HSA along with MIV-1 for approval before changes can be made
 - MIV-2 (Regulatory approval not required)
 - For changes in: product owner, manufacturer's name or address, name or address of the product license holder, excipient, composition of packaging material, batch size, etc.
 - Requires statement be submitted to the HSA *only specifying the effective date of change*, not requesting approval.
 - Must be submitted 2 months prior to implementing changes

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Update: New Safety Reporting Requirements

Singapore

February 2005

- New requirements apply to license holders responsible for bringing western medicinal products into Singapore
- Covers 3 types of safety reports
 - Spontaneous suspected adverse drug reaction reports
 - Refers to clinical observation of ADR outside of formal study
 - If possible causal relationship found, must file report to CDA within 15 days
 - Periodic safety update reports (PSUR)
 - May be requested by CDA for certain products
 - Must be submitted bi-annually for first 2 years, annually for next 3
 - Reports regarding actions taken due to safety issues
 - If safety concerns cause regulatory actions to be taken, CDA must be notified within 7 days
 - Significant safety concerns include: product withdrawal/recall, failure to obtain product license renewal, removal of regulatory approval, etc.

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MALAYSIA

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Malaysia

Malaysia Overview

- Economy:
 - GDP (PPP): about \$210 billion (2003)
 - GDP growth rate: 5.2%
- Population: 23.5 million (2004)

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Regulatory Authority

- National Pharmaceutical Control Bureau, through its Drug Control Authority, oversees pharmaceutical regulations in Malaysia
- Created to ensure the safety, quality and efficacy of pharmaceuticals in Malaysia
- Responsibilities include:
 - Registration of pharmaceutical products and cosmetics
 - Licensing of drug importers, manufacturers and wholesalers
 - Adverse Drug Reaction Monitoring

Pharmaceutical Registration Overview

- Registration process takes 12-18 months
- Only locally-incorporated companies can apply for product registration
 - Foreign companies can use a Market Authorization Holder as their local company
- Some of the required documents:
 - Letter from product owner stating that the local Market Authorization Holder is authorized to submit the application on behalf of the owner
 - Free Sale Certificate from country where product is made and GMP certificate
 - Samples of finished product for testing with Certificate of Analysis

Adverse Effect Reporting

- Local Reporting:
 - Life-threatening or fatal: No later than 1 week after first knowledge of incident
 - Serious, unexpected, but not life-threatening or fatal: No later than 15 days after first knowledge of incident
 - Non-serious : Within 15 days
- Foreign Reporting:
 - Not required on a regular basis
- Local and Foreign Reporting:
 - For notification of changes in nature, severity, frequency or risk factors for local and foreign reporting: Within 15 days
 - New information impacting risk-benefit profile: Within 3 days
 - Withdrawal of registration in any country: 24 hours
- Periodic Safety Update Reviews for NCEs:
 - Every 6 months for first 2 years
 - Annually for following 3 years

Malaysia Regulations: Promotion

- Promotional material should be checked by a senior official (preferably a doctor or pharmacist) of the company prior to distribution
- Any medical claims promoted must be supported with clinical evidence
- Promotional material for prescription drugs can only be provided to medical professionals
- Direct consumer advertising is not permitted for prescription drugs, but is allowed for OTC products

Malaysia Regulations: Samples

- Pharmaceutical Association of Malaysia (PhAMA) regulates the distribution of pharmaceutical samples
- Samples can only be given to a doctor or someone authorized by a doctor to receive samples on the doctor's behalf
- Cannot be used as an incentive to encourage doctors to purchase a particular product
- Companies generally use standard sales packs with the words "sample not for sale"
- Companies should keep good records of which doctors have received samples
- International companies may request that doctors sign an official receipt

Update: New Hologram Security Device

- Ministry of Health issued *Directive on the Use of the Hologram Security Device*
- All pharmaceuticals must bear a hologram security label, called a Meditag
- Phase one:
 - Begins January 1, 2005
 - For non-parenteral products (non-injections)
- Phase 2:
 - Injectable pharmaceuticals
 - Begins July 1, 2005
- Local manufacturer, repacker or the importer responsible for affixing Meditag
- Meditag can be affixed overseas by overseas manufacturer and imported pre-labeled
- Meditag should be placed on front panel of product label on outer packaging
- Meditag will have a unique serial number; can be traced to manufacturer/importer
- Each label costs RM0.056 (US 1.5 cents)
- Recall not necessary if products without hologram remain on the shelves after January 1 or July 1 2005; customers choose whether they feel comfortable purchasing products without a hologram

Update: New Marketing Authorization Holder Transfer Procedures (2005)

- Only local companies can submit a pharmaceutical product registration application
 - Foreign companies must use a MAH as their local representative
 - MAH responsible for the product application & quality, safety and efficacy of the product
- Conditions to be met for MAH transfer:
 - (1) No other changes included in MAH transfer (e.g. change in labeling or technical data). Only the MAH name and address can be changed
 - (2) Current product registration must be valid for at least six months
 - (3) The new MAH should submit the transfer application
- If application approved by the DCA, the new MAH license will be valid for the time remaining on previous MAH license
- Product registration number will remain unchanged

VIETNAM

Vietnam Overview

- Economy
- Population
- Foreign-invested enterprises contribute over 60% of the total drugs available in Vietnam
- Vietnamese pharmaceutical regulations tend to be unclear and are implemented on case-by-case basis
- 9% increase in drug prices from 2003 to 2004

Drug Registration

- Drugs regulated by the Ministry of Health
- The following entities can apply for drug registration:
 - Drug manufacturers established in Vietnam
 - Domestic entities registered to trade pharmaceuticals (includes foreign invested companies licensed to manufacture in Vietnam)
 - Foreign entities holding a Vietnamese trading license

Vietnam Regulations: Promotion

- Some forms of promotional activities:
 - Giving free samples to customers for trial use
 - Selling goods/providing services at prices lower than normal prices
- Who can promote?
 - Vietnamese enterprises
 - Foreign-invested enterprises
 - Branches of Vietnamese and foreign enterprises
- Promotional material must be approved by Drug Administration of Vietnam (DAV) prior to distribution
- Approved material can be distributed to medical professionals
- All promotional material must be in Vietnamese (and can also be in other languages)

Vietnam Regulations: Samples

- Law states that, “Free samples given to customers must be goods which are currently sold or will be sold in the market”
- Ministry of Health states that giving samples to doctors is not permitted → no law exists that supports their statement
- Non-prescription drugs *can* be distributed as samples to the public, but is not common practice

Update: Drug Price Control Measures

- Effective April 2004
 - MOH established weekly panel to review license applications for approval of drugs not yet registered for distribution in Vietnam
 - Should speed up the license application review process
- Effective June 2004
 - Foreign drug companies with operating licenses in Vietnam could begin supplying pharmaceuticals to any local import-export company in Vietnam
 - → So long as local distributors or manufacturers could not supply the drug, or could only supply it at a very high price
 - *Previously:*
 - Foreign firms only permitted to sell their products to local Vietnamese companies holding registered drug trademarks
- Effective January 2005
 - Foreign drug companies cannot raise drug prices without prior permission from MOH
 - Even in urgent cases, companies will still be required obtain permission from MOH and provide specific details of their planned price increase

Update: New GMP Requirements

- Based on WHO standards
- November 2004
 - Pharmaceutical manufacturing sites built after Nov. 2004 must meet WHO GMP in order to obtain manufacturing operator's license
- 2006
 - All existing pharmaceutical manufacturing sites must meet WHO GMP
- 2010
 - Pharmaceutical material companies must meet WHO GMP
- Department of Pharmaceutical Management (DPM) will be in charge of GMP inspections and granting GMP certificates
- GMP licenses valid for two years
- Pharmaceutical manufacturing sites that currently have ASEAN GMP certification can continue production
 - Once ASEAN GMP expires, the factory must obtain WHO GMP certification

SOME IMPORTANT CULTURAL ISSUES

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Cultural Issues

- It is important to understand the cultural and business norms that are unique to a specific country or ethnic group

Western Approach

- *Do a deal
- *Maximize short-term profits
- *Assess competitive capabilities
- *Be frank
- *Make changes fast

Eastern Approach

- *Build relationships
- *Establish long-term foundations
- *Assess integrity
- *Don't deliver bad news
- *Move when ready

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Understanding the Japanese

- Use and View of Time
 - Americans – minute/hour
 - Japanese – event/season
 - Events move forward when *group* is ready
- Relationships
 - Company to company
 - Person to person (how business relationships develop)
 - Family relationship
 - Most successful Japanese companies keep records of client information (birthdays, anniversaries, etc.) and sent cards
- Japanese Logic
 - Often based on emotion rather than reason
- “Group” and “Individual”
 - Group consensus – no single person should be targeted
 - Emphasis on company spirit
- When Things Go Wrong
 - Apology is very important

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Understanding the Chinese

- Chinese mentality
 - Importance of family
 - Concept of “face”
- Conducting effective business
 - Introductions
 - Negotiating
- Little things that mean a lot
 - Gifts
 - Body language
 - Conversation

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Understanding People in India

- Hierarchy (caste system) plays a large role in Indian society
- Relationships and trust are key to successful business
- Language
 - Different regions have different dialects
 - English commonly used for international business
- Meetings
 - Should be arranged well in advance
 - Greet the most senior person first with a handshake
 - Exchange business cards
 - Use formal titles, Dr., Mrs., etc.
 - Start with informal conversation – small talk
- Negotiations
 - Can be slow; Middle East mentality
 - Can be very confrontational

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Understanding Southeast Asians

- Intercultural communication – differentiate Chinese from locals
- Conducting effective business
 - Personal connections
 - Negotiating with locals – more harmonious
 - Do not point – seen as a threatening gesture
 - Dress conservatively
 - Do not touch anyone's head
 - Do not point feet towards another person

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