

Vietnam's Medical Device Market

November 3, 2011



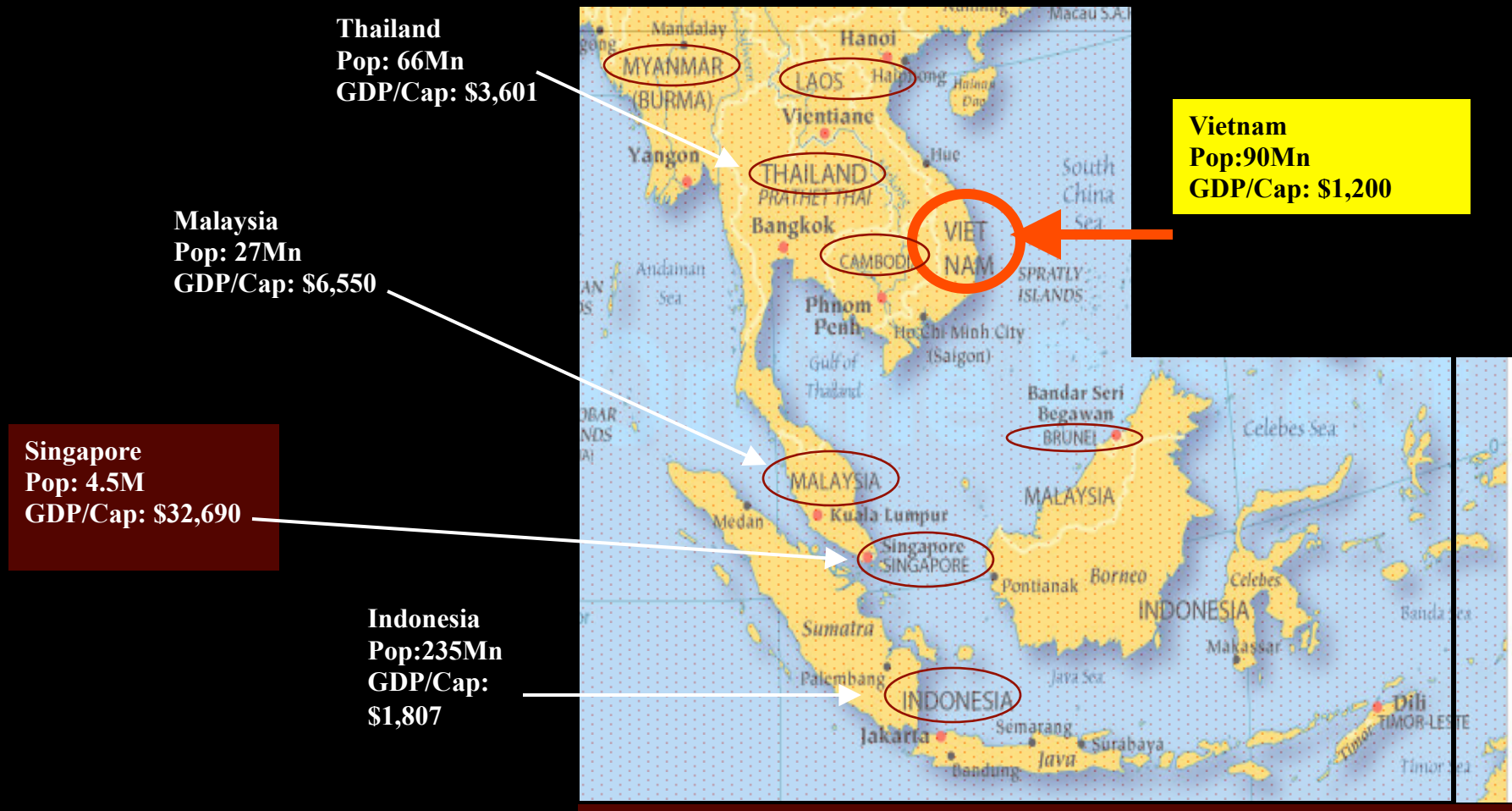
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- Regulatory of Medical Equipment in Vietnam
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- Conclusion

Where is Vietnam on the world map?



Vietnam is located in the South East Asia region.

GOVERNMENT

- Population: 90M, 2025 projection is 100M – increase of 0.9% per annum
- Young country:
 - 50% of the population is less than 25 years old
 - Working population: 45M (53%)
- Favoring FDI and local manufactured products

PEOPLE

- People and government are eager to learn, upgrade and accept the advanced products
- English speaking talent improved by young generation
- Literacy level: high (95%)



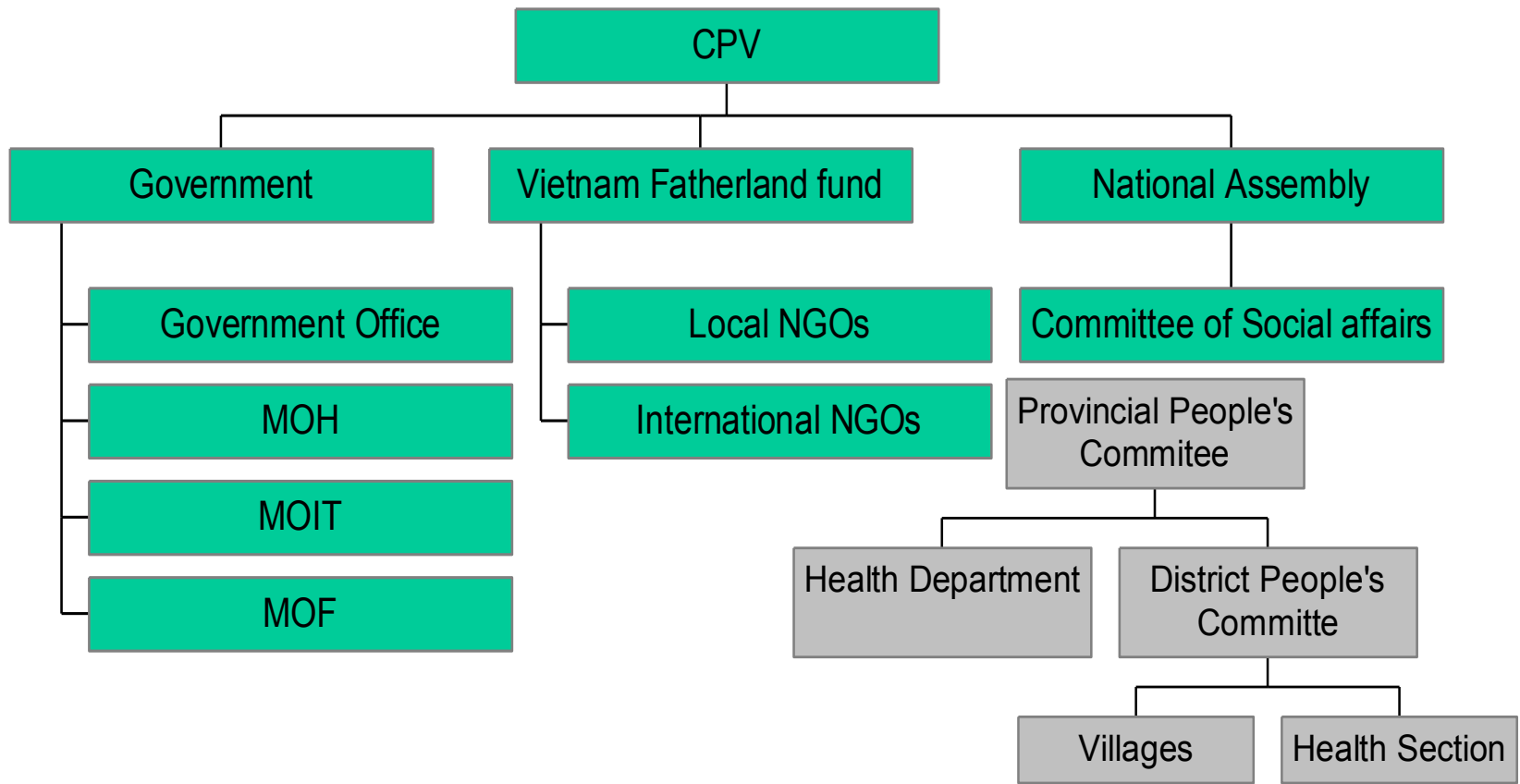
Economic

- Robust economic growth (GDP growing 6-8% each year)
- Fluctuating exchange rate of USD & VND to 19,500 from 21,000/ USD
- High inflation rate at 15%-17%
- Strong commitment from Government to open economy and create investment incentive policies
- Competitive advantages: Stability, low labor cost, large population, etc.

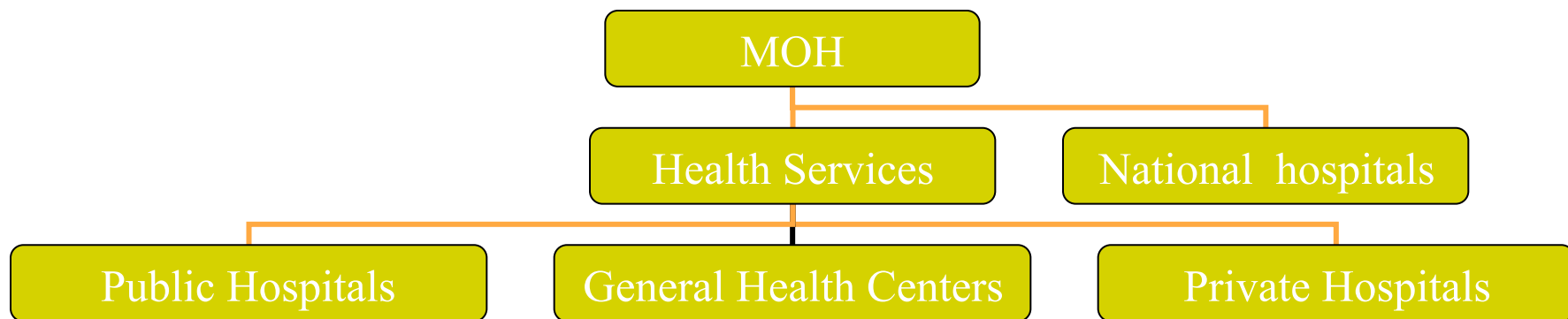
HEALTHCARE

- Insurance coverage: 65%. Target: 100% population to have compulsory health insurance by 2015
- Patient co-pay 20%, 5%
- Government support for private health sector development to overcome overloaded issue of hospitals
- individual tenders and centralized tender

State Management Functions for the Health Industry



Structure of Health Delivery



Vietnam's Health Indicators 2006-2012							
	2006	2007e	2008f	2009f	2010f	2011f	2012f
Hospital	867	871	876	881	886	891	895
Beds per '000 population	1.55	1.56	1.58	1.6	1.61	1.62	1.64
Doctors per '000 population	0.54	0.55	0.56	0.57	0.57	0.58	0.59
Births per '000 population	16.7	16.7	16.5	16.4	16.4	16.3	16.1
Deaths per '000 population	5.46	5.44	5.43	5.41	5.38	5.35	5.3

Source: UN, Ministry of Health, General statistics office of Vietnam

Insurance System

Exclusive 5 M from private insurance companies

Collection

24 M (41%)

Voluntary insurance
8-10 USD/ person

34 M (59%)

Compulsory Insurance

VN Government Social Insurance Association

30% - 80% reimbursement depended on hospital level

Voluntary

Compulsory

Un - affordable insurance
Funded by government 14M

Children under 6
Funded by government 10M

Employees/ officials
Deducted 3% of
monthly base salary 10M

Expenditure

Patient flow

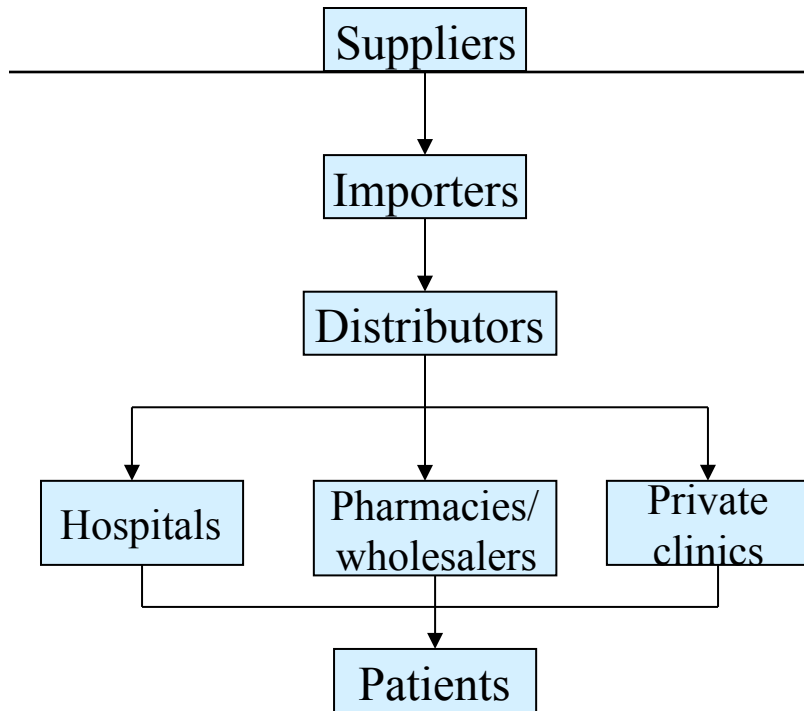
First registered
hospitals/ clinics



Higher level/ specialized
hospitals

• Insurance drug list is approved by DAV,
Therapy department, Insurance and Finance ministry
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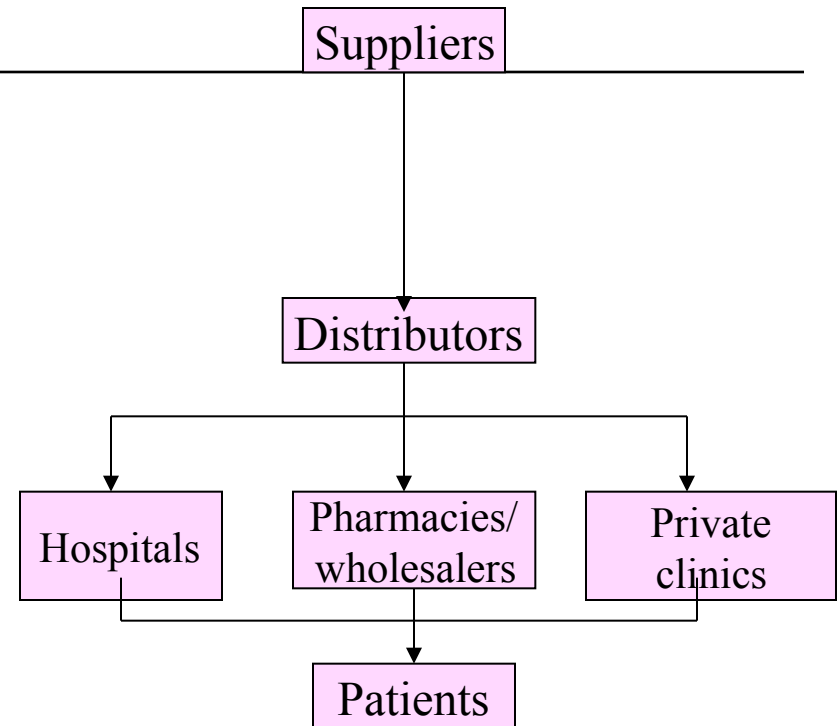
Pharmaceuticals Flow



Operation: Rep. office in Vietnam or LLC

Activities: Marketing, may direct import. Not PHYSICAL DISTRIBUTION

Medical Device Flow



Operation: Rep. office in Vietnam or LLC

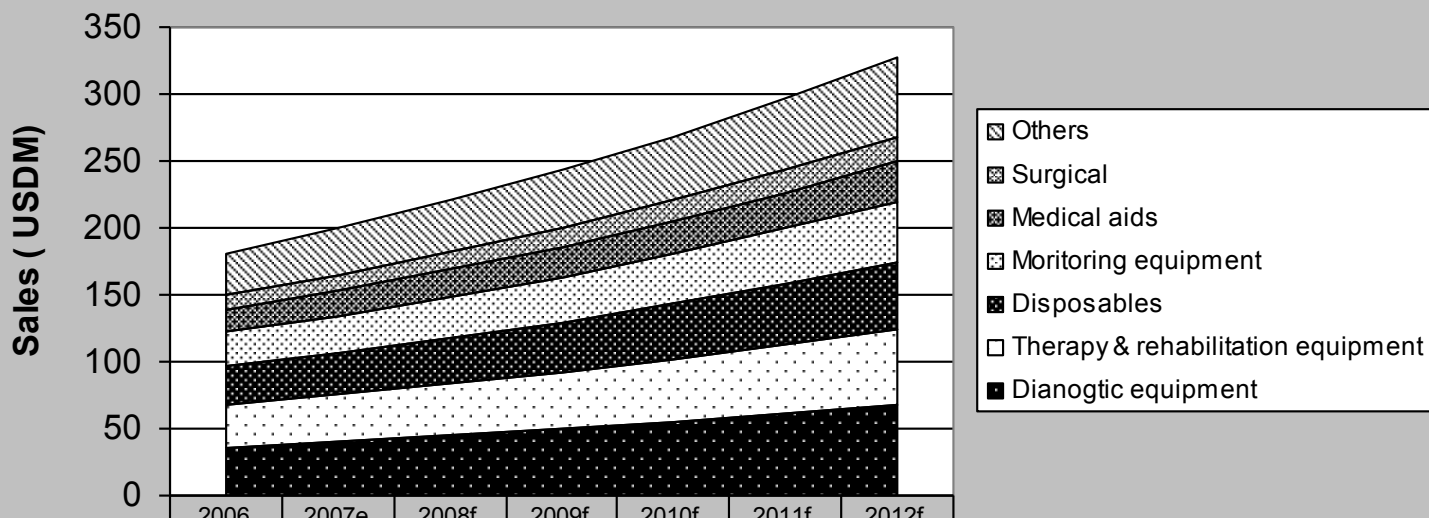
Activities: Marketing, direct import, PHYSICAL DISTRIBUTION

Medical Device Market Overview

- ❑ Market Size : US\$300 million (2010)
- ❑ Average annual growth rate of medical device (MD) market : 20%
- ❑ Used and refurbished Medical devices are prohibited to import into Vietnam
- ❑ 98% of total MD market are imported
- ❑ Local producers: 15 facilities with un-sophisticated products such as: plastic gloves, bandages, compresses, clothes, masks, etc.
- ❑ Top foreign suppliers: Germany (30%), Japan (30%) and the United States (30%)
- ❑ **After sale service is the key concern for customers**

Vietnam Medical Device Market (US\$ million)

Vietnam Medical Device Market Forecast



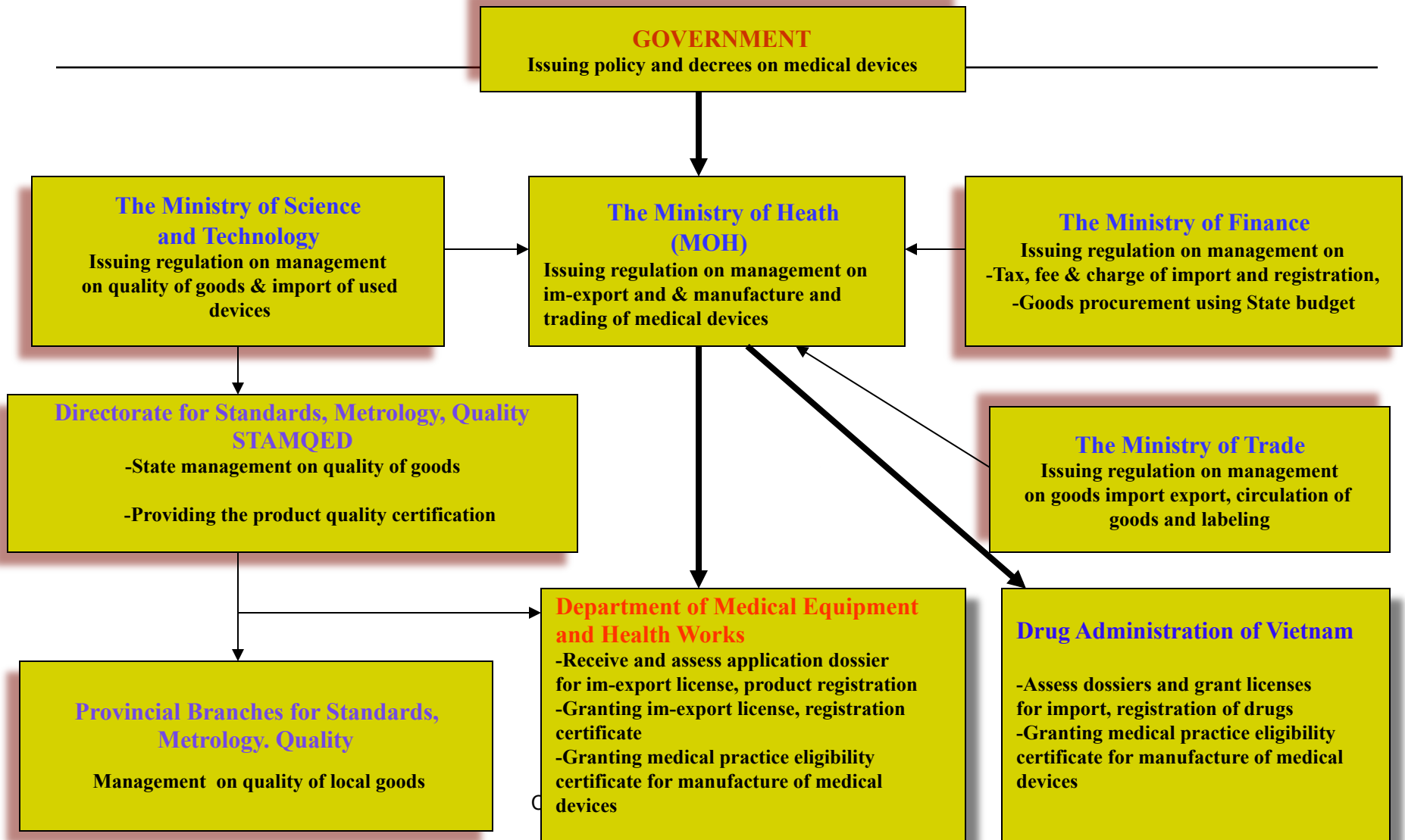
	2006	2007e	2008f	2009f	2010f	2011f	2012f
Others	31	35	38	43	47	53	58
Surgical	11	12	14	15	16	17	19
Medical aids	17	19	20	22	25	27	30
Monitoring equipment	25	28	31	34	37	41	45
Disposables	28	31	34	37	41	45	50
Therapy & rehabilitation equipment	32	35	39	43	47	52	57
Dianogtic equipment	36	40	45	50	55	61	68



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Regulatory structure



Administrative Bodies

- Principal agency: **Department of Medical Equipment and Health Works (DMEHW)**
- Responsibilities:
 - Planning public-sector purchases of medical devices
 - Management of purchase, utilization, maintenance and control of medical devices
 - Establishing and promulgating technical standards for medical devices
 - **Management of imported-exported medical devices**
 - Assessment of lists, specifications, standards of medical devices in projects of nationally-managed hospitals



**Circular 24/2011/TT - BYT DATED
JUNE 21, 2011**

**Guidance on Importation of Medical
Equipments to Vietnam**

- **PRODUCT**
- **ENTERPRISE TO IMPORT**
- **DOSSIER & PROCEDURE**

Definition of Medical Equipment

Medical equipment is the type of equipment, tools, materials and chemicals, consumables including necessary software used separately or together for human purposes:

- a) To prevent, test, diagnose, treat, mitigate or compensate for disease damage;
- b) Inspect, replace, modify, support operations during medical treatment;
- c) support or sustain life;
- d) control of conception;
- e) Sterilization of health care (not including chemicals, insecticidal preparations, disinfectants for home use and medical use);
- f) Transport service dedicated to health activities

Classification of Medical Devices

- **Group I: Medical devices likely to directly affect human health.**
 - **Consist of 50 items in appendix 1 of Circular 24-2011**
 - **Must apply for import-export license**
- **Group II: Medical devices which is not listed in appendix 1**
 - **Import without permit**
 - **But also need documents as same as registration dossier for clearing the goods from customs.**
- **Group III: New diagnosis and therapeutic methods and imported into Vietnam for the first time**
 - **Need results of clinical tests to be appraised and permitted for import by the Scientific and Technological Council of the Health Ministry**
 - **Must apply for import-export license**

APPENDIX 1

LIST OF MEDICAL EQUIPMENT (BRAND NEW) TO BE IMPORTED UNDER PERMITS OF THE HEALTH MINISTRY

(Promulgated together with the health ministry's circular No. 24/2011/TT-BYT of June 21, 2011)

Diagnostic equipment

1	The imaging device uses X-rays
2	MRI System
3	Ultrasound diagnosis
4	Endoscopic diagnostic system
5	Cyclotron System
6	Diagnostic equipment with radioactive isotopes (PET systems, PET / CT, SPECT, SPECT / CT equipment to measure the concentration of iodine I130)
7	Gauge refraction, corneal automatically
8	Gauge electrophysiological (EEG machines, ECG machines, electrical machines)
9	Power Meter retina
10	Gauge osteoporosis
11	Retinal scanners / cameras fluorescence of the eye
12	Fetal heart rate meter with ultrasound
13	Meter / analysis of respiratory function
14	Biochemical analyzer
15	Electrolyte analyzers, blood gas

16	Hematology analyzer
17	Coagulation meter
18	Blood sedimentation rate meter
19	Elisa test system
20	Blood analyzer
21	Machine extraction cells
22	Meter stop collection and analysis of platelet function
23	Machine identification of bacteria, viruses
24	Immune analyzer
Treatment Equipment	
25	The device uses X-ray treatment
26	Laparoscopic system
27	The radiotherapy equipment (cobalt machine for cancer treatment, a linear accelerator for cancer treatment, the type of gamma knife surgery, radiation therapy equipment close type)
28	Monitor patients
29	Infusion pump, injection pump power
30	Surgical (high-frequency electrical, laser, ultrasound)
31	Surgical Microscopes
32	Equipment system for prostate surgery

33	Cardiopulmonary bypass machine
34	Positioning devices in surgery
35	Cryosurgery equipment
36	Infant incubator, infant heating machine
37	Anesthesia Machine / Anesthesia breathing
38	A breathing machine
39	Breakers fibrillation, pacemaker
40	High-pressure oxygen chamber
41	Lithotripsy system outside the body / endoscopic lithotripsy
42	The system of high-intensity ultrasound tumor therapy
43	Dialysis equipment
44	The system of specialized ophthalmologic surgery (Excimer Laser, Laser Phemtosecond, Phaco, glass cutting services, cutting the corneal flap)
45	Contact lenses (access, telecommunications, astigmatism) and preservative solutions lenses
46	Laser treatment used in ophthalmology
47	The type of device, implant material long-term (over 30 days) on body
48	The type of equipment, materials interfere with the body of the cardiologist, cranial nerve
Other Devices	
49	Medical Gas System Center
50	Ambulance / vehicle and other specialized medical use

Conditions of Enterprise Allowed to Import Medical Devices

□ **Legal**

Certificate of business registration or certificate of investment which includes the range of import and doing business for medical equipment

□ **Personnel**

Dedicated technical Personnel has specialized certificate
Technical personnel for installment, warranty and maintenance services

□ **Facilities:**

warehouse, fire system and environment hygien

□ **Label of medical Equipment**

Dossier Assembly (1 set) new

- 1. Application form**
2. Certificate of business registration or certificate of investment (certified copy).
3. Certificate of quality: ISO 13485 or ISO 9001 (original or notarized copy)
4. Certificate of Free Sale in production country OR FDA Certificate OR CE Mark Certificate (original or certified in Vietnam or notarized and legalized by Vietnam Embassy in production country)
5. Attorney letter for import and distribution from manufacturer (original or certified in Vietnam or notarized and legalized by Vietnam Embassy in production country)
6. Product Catalogue (original or copies certified by the importer)
- 7. Technical description form**

Dossier Assembly (1 set) Renewal

1. **Application form**
2. Certificate of business registration and certificate of investment (certified copy).
3. Certificate of quality: ISO 13485 or ISO 9001(original or notarized copy)
4. Certificate of Free Sale in production country OR FDA Certificate OR CE Mark Certificate (original or certified in Vietnam or notarized and legalized by Vietnam Embassy in production country)
5. Attorney letter for import and distribution from manufacturer (original or certified in Vietnam or notarized and legalized by Vietnam Embassy in production country)
6. Product Catalogue (original or certified by the importer)
7. **Technical specifications**
8. **Copy of the expired import permit**



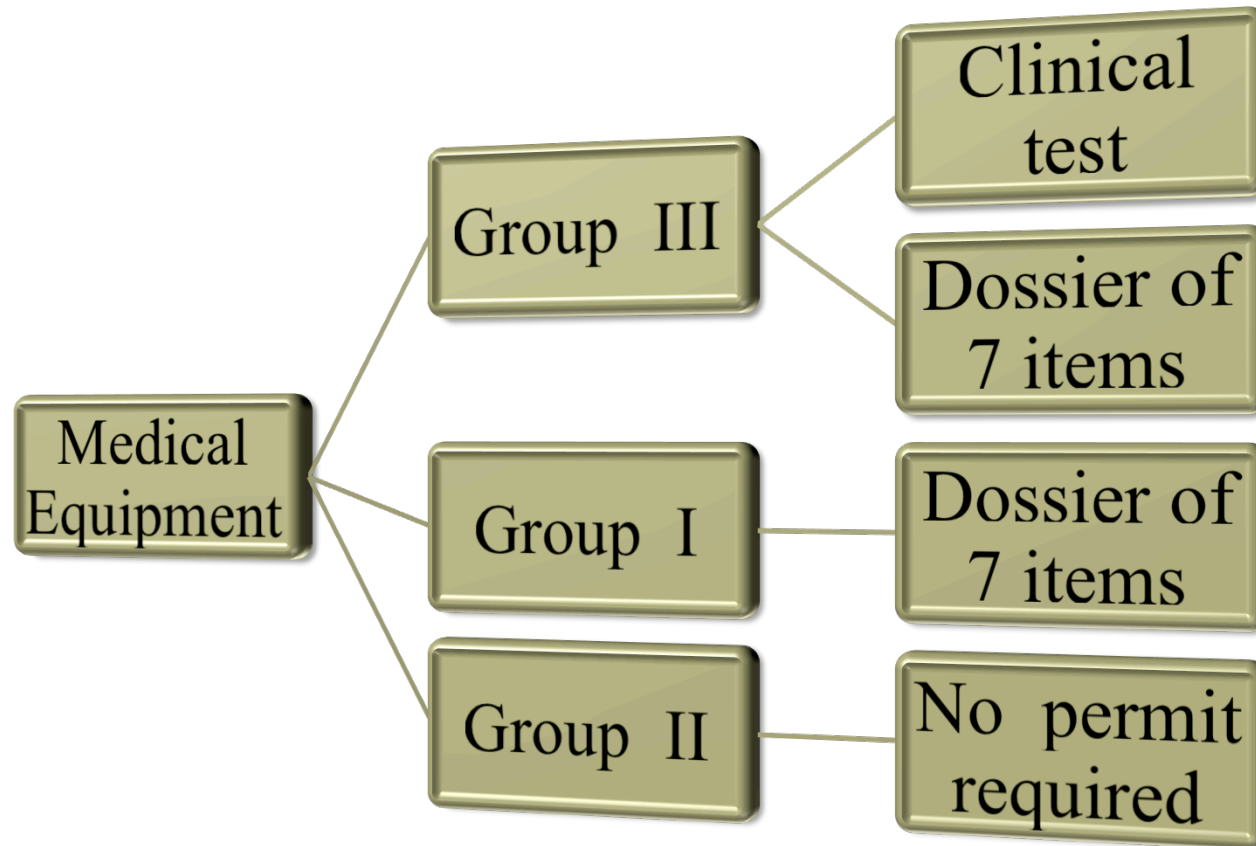
Special Requirement for Group III

- In addition to the conditions, dossiers and procedures of application for import permits must be accompanied with results of clinical tests, and be appraised and permitted for import by the Scientific and Technological Council of the Health Ministry

Clinical Testing

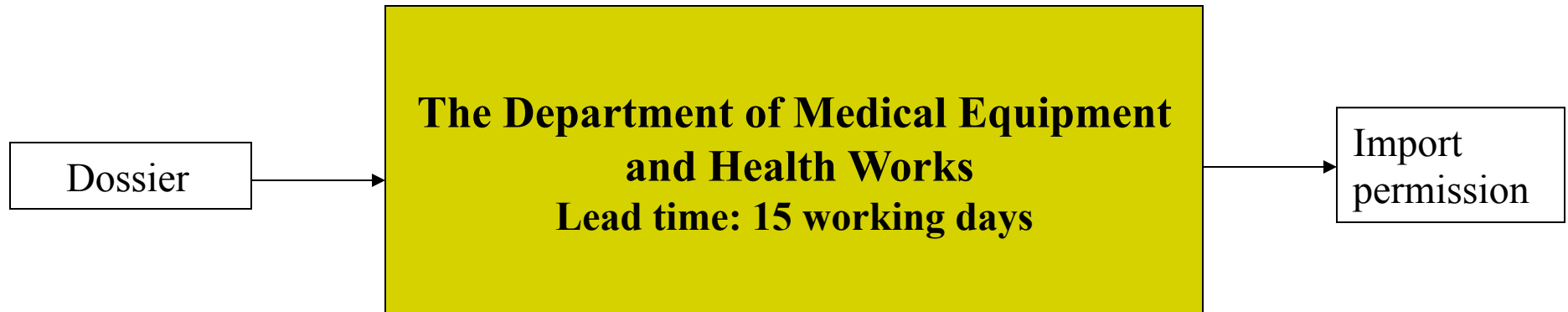
- ❑ Medical equipment that has new diagnosis and therapeutic methods and imported into Vietnam for the first time shall require clinical testing
- ❑ The MOH will specify at least 3 hospitals for testing under its own supervision
- ❑ Application for clinical testing is done before application for import permit
- ❑ Clinical tests of some special items may be exempted if those are accepted and used by other countries' MOH and appraisal result of the Scientific and Technological Council of the Health Ministry

Import Permit Chart

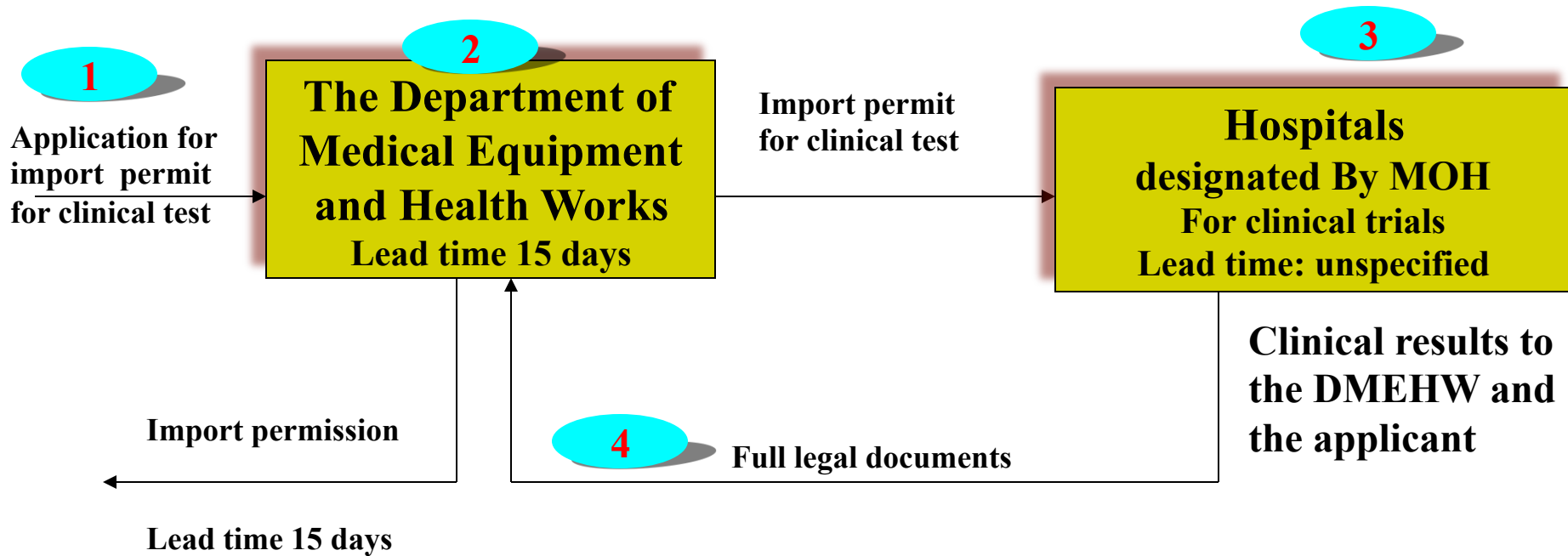


Import permit application flow chart

Clinical trials not required



Import Permit Application Flow Chart Clinical Trials Required



List of Hospitals Designated for Clinical Trials

Hanoi:

- Huu Nghi Hospital**
- Hospital E**
- Bach Mai Hospital**
- Viet Duc Hospital**
- Hospital K**
- Central Ophthalmology Hospital**
Central Pediatric Hospital
- Central Gyneco-Obstetric Hospital**
- Acupuncture Hospital**
- Central Tuberculosis and Lung Disease Hospital**
- Endocrinology Hospital**

Ho Chi Minh City:

- Cho Ray Hospital**
- Thong Nhat Hospital**
- Central Otorhinolaryngology Hospital**

Others:

- Central Psychiatric Hospital 1 (Ha Tay province)**
- Central Psychiatric Hospital 2 (Dong Nai province)**
- Central Convalescence and Functional Rehabilitation Hospital (Thanh Hoa province)**

Fees for Granting Export/Import Permits

- ❑ VND 500,000/ US\$23.9

- ❑ If more than 1 item is listed in an import permit application form, a separate fee is assessed for each item
 - i.e., different types of the same device

Taxes Assessed

Two kinds of tax

- ❑ Value added tax: 5% (mostly), 10%(some items)
- ❑ Import tax: 0% for medical devices, except:
 - Disposable syringes: 5%
 - Chairs: up to 25%
 - Spare parts: up to 28%
 - Aesthetic: up to 25%



Registration of Medical Devices

- ❑ Medical devices manufactured in Vietnam do need product registration with the Ministry of Health for circulation.

Legal Documents for Product Registration of Domestically Produced Devices

1. Registration application form
2. Notarized copy of business registration certificate
3. Clinical trial reports by at least 3 health establishments as designated by MOH, **if needed**
4. **Announcement of quality standards or announcement of standard conformity**
5. **Analytical results of chemical and physical characteristics and safety verification report (depending on category)**
6. Technical documents and user instructions

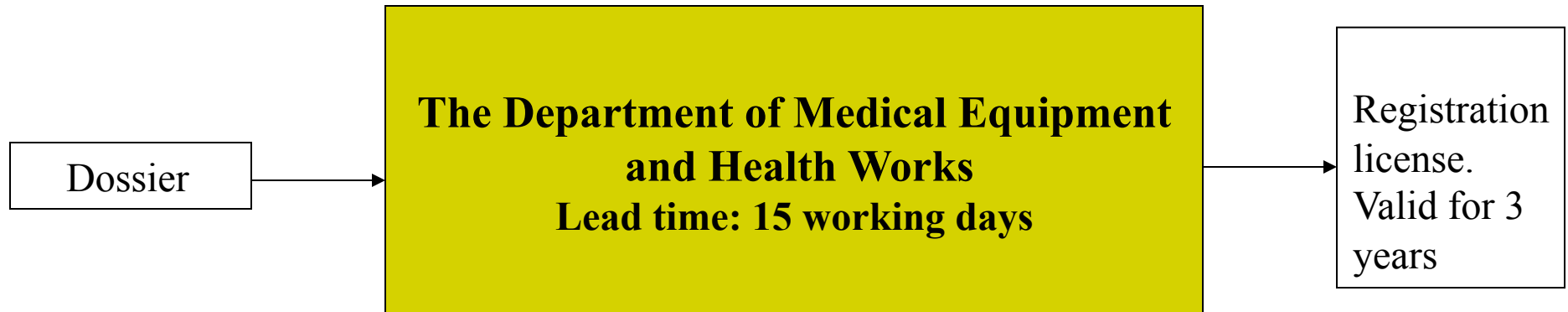
Quality Announcements for Domestic Medical Devices

- ❑ Quality announcements required as preliminary to product registration
- ❑ Selected higher-risk devices: Announcement of standard conformity (ASC)
 - **Assessment by Institute of Medical Equipment and Works Design and by Directorate for Standards, Metrology, and Quality**
 - **Takes about 60 days**
- ❑ Other, lower-risk devices: Announcement of quality standards (AQS)
 - **Simpler announcement to Provincial Branch of Standards and Quality**
 - **Takes about 15 days**

Quality Announcements Compared

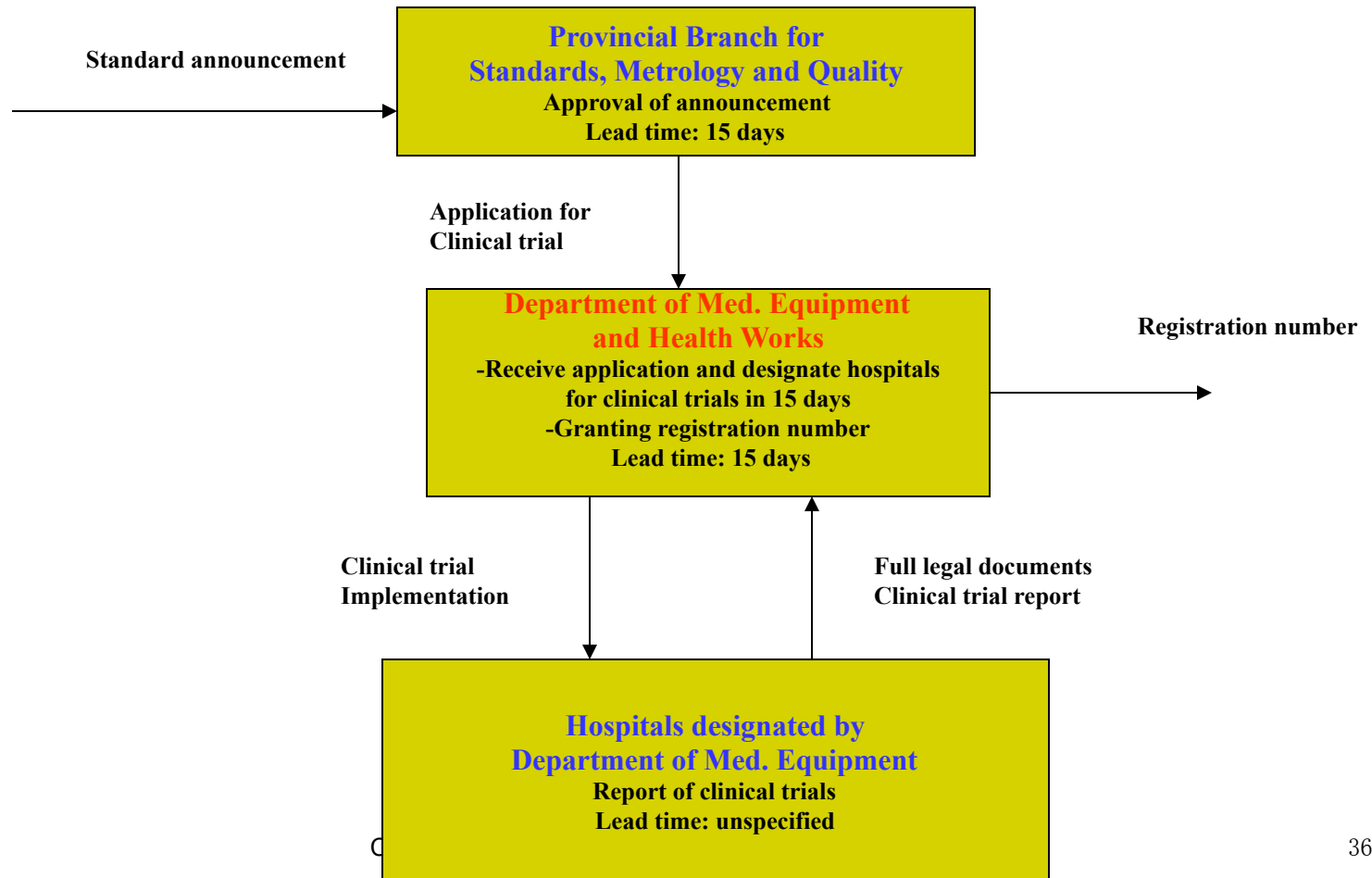
- ASC:
 - Assessment of quality compliance under ISO/IEC systems
- AQS:
 - Name and code of standards used
 - Any set of standards may be used (Vietnamese, foreign, international, in-house)
 - Product (name, model, category and code)
 - Standards in quality system relevant to product (if any)
 - Technical requirements
 - Testing methods
 - Packing, labeling, transport and preservation methods

Registration Procedures

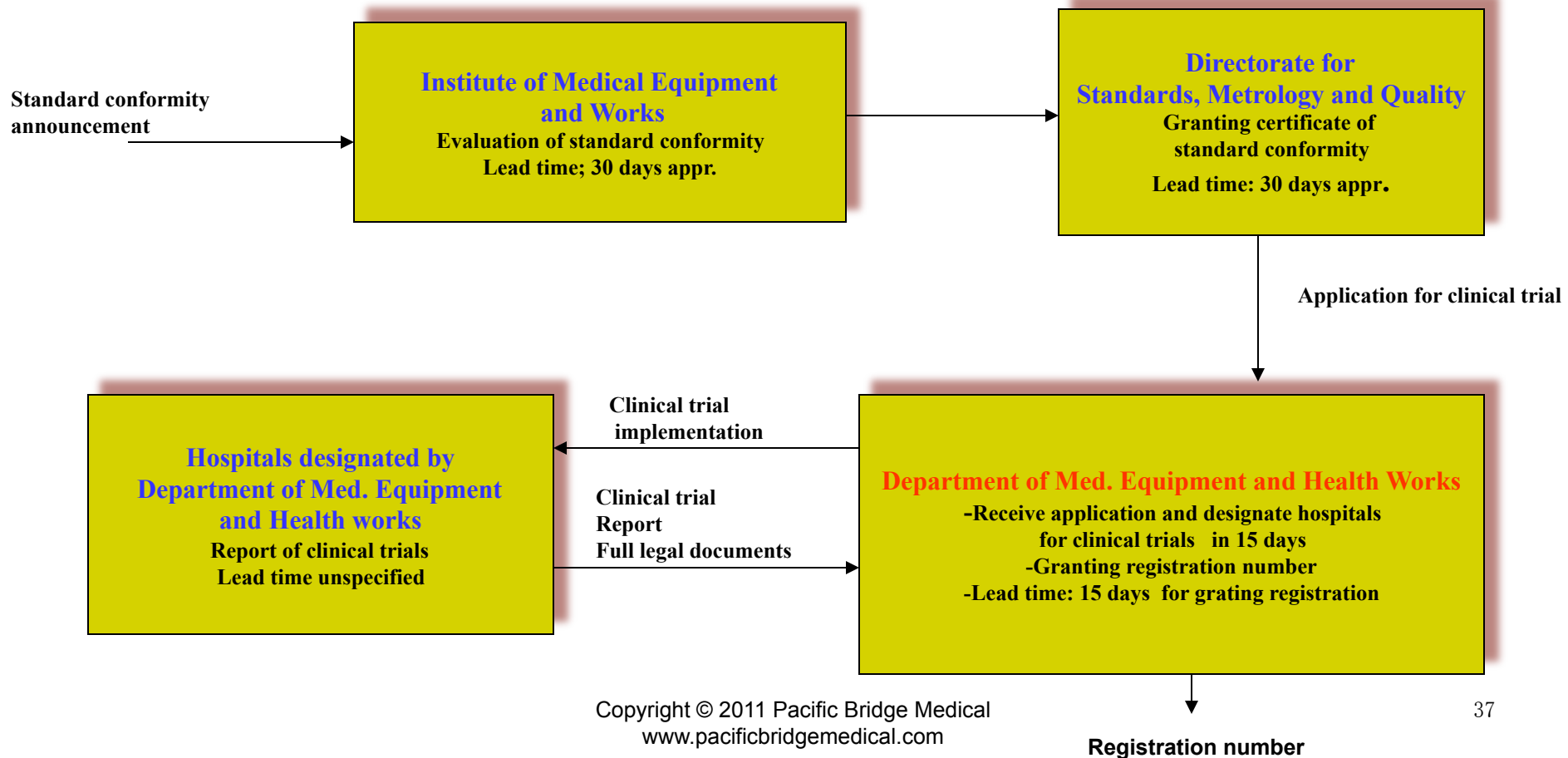


- ❑ Must renew registration with DMEHW no less than 30 days before expiration
- ❑ Renewal dossier and process is comparable to making a new application

Registration Flow Chart (with AQS)



Registration Flow Chart (with ASC)



Registration charge and fee

- Registration fee: VND 1,000,000 per dossier (~US\$47.6)
- Fee is same for all devices



Post-Market Surveillance Requirements

- There is no guideline from MoH

Post-Market Surveillance Requirements (2)

- **Manufacturers and distributors are liable for the quality of the products they produce or trade in**
- **They must also handle complaints, recall substandard products, and reimburse any damage caused to customers**
- **Hospitals conduct supervision of product utilization and safety with these procedures:**
 - **Regular workplace checks**
 - **Annual evaluations**

Intellectual Property Protection

- Vietnam has recently overhauled IP law in response to international pressure
 - Law on International Property came into effect July 1, 2006
 - Legal structure now mostly harmonized with international principles (TRIPs)
 - Structure for bringing suit against infringers has become more robust
- But great care is necessary to protect IP
 - Government's enforcement ability remains weak
 - Taking out patents in Vietnam will still strengthen future claims
 - IP administered by National Office of Intellectual Property (NOIP)

Good Manufacturing Practice (GMP) in Vietnam

- For drug:
 - local manufacturer MUST obtain GMP-WHO
 - Submit application dossier to Drug Administration of Vietnam
 - The DVA will set up the inspection team or reasons for refusal in 60 working days of receipt of dossier
 - Registration number is valid for 2 years from date of issue
- For Medical device: GMP is not required so far



Tips to Register Your Medical Device Quickly

- ❑ Use service agent for registration
- ❑ Register in advance because the permit is effective for 01 year, NOT wait until last minute rush
- ❑ Should register for all medical devices even those are NOT listed in appendix 1

Tips to Register Your Medical Device Quickly (2)

- ❑ To save cost: combine more items in one registration application
- ❑ Matching the name of products among documents(ISO, Catalog), name in registration forms and product category of tax codes



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Market Drivers

MARKET ENVIRONMENT

- Government support for private health sector development
- Insurance coverage is increasing to 100%
- Circular 43: socialization of hospital
- Service after sale

POLITICAL

- **Vietnam – New Cabinet with strong economic-management credentials.** Favoring FDI and local manufactured products.

IMPLICATIONS TO US Medical Devices

- Investment plan for machines placement is recommended for long term growth
- Right presence for long term growth
- Good plan to prepare for full insurance coverage

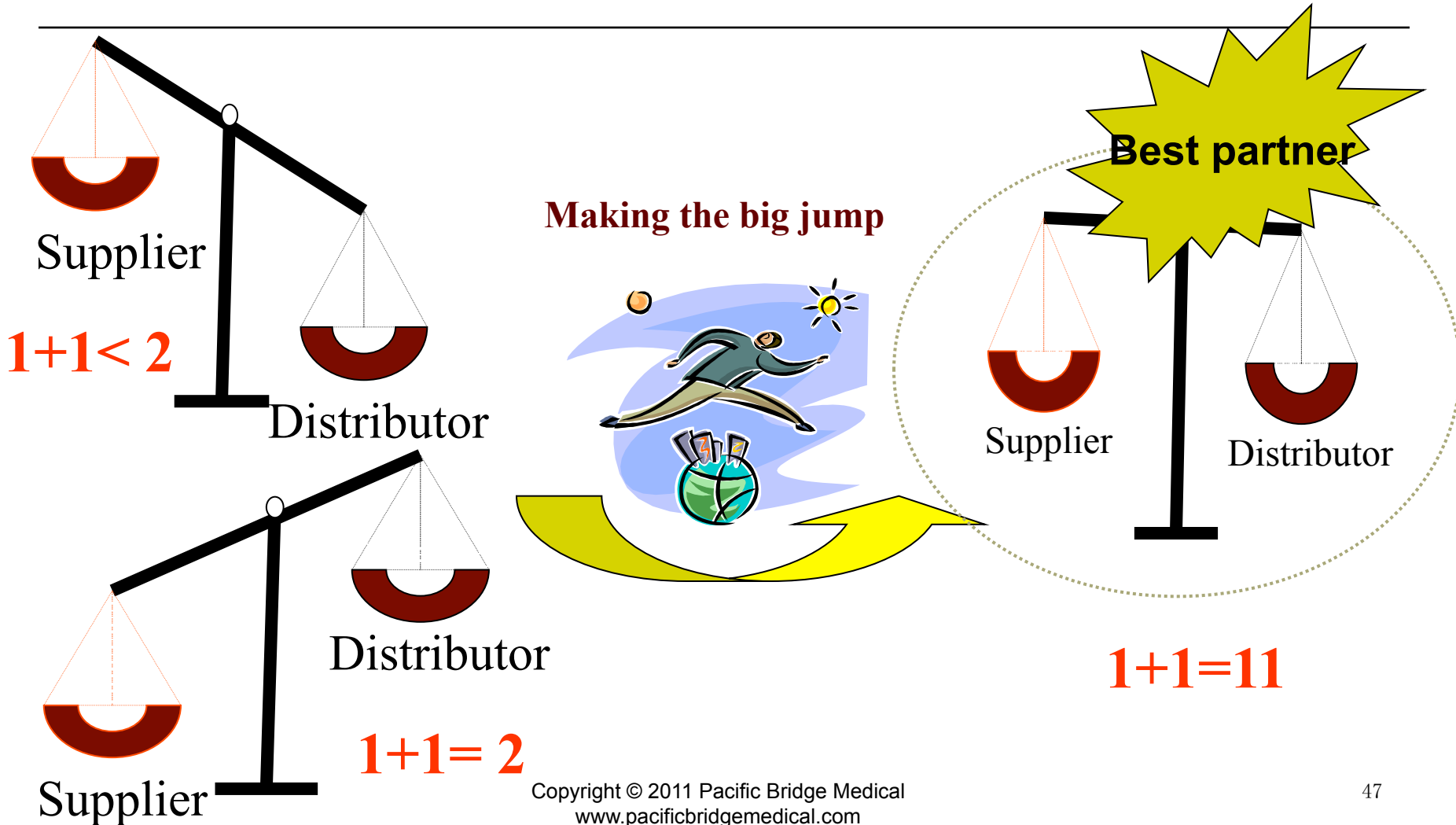
COMPETITION

- Germany
- Japan

ECONOMIC ENVIRONMENT

- Vietnam is the 2nd fastest growth country in the region
- Fluctuated exchange rate of USD & VND to 21,000 from 19,500/USD
- High inflation rate at 15%-17%
- Strong commitment from Government to open economy and create investment incentive policies
- Competitive advantages: Stability, Low labor cost, large population, etc.

Business Model



End-User Analysis

Government funded
Hospitals

Private
Hospitals

Self tender
organizing

Regional
tender
organizing

National
tender
organizing

Sponsor
company
organizing

Domestic
hospital

Foreign
investment
hospital

Reimbursement for medical devices

- ❑ Almost medical consumables are reimbursed by Vietnam Social Insurance
- ❑ The government's insurance system determines the reimbursement level with ceiling prices or package treatment reimbursement

Types of Procurement

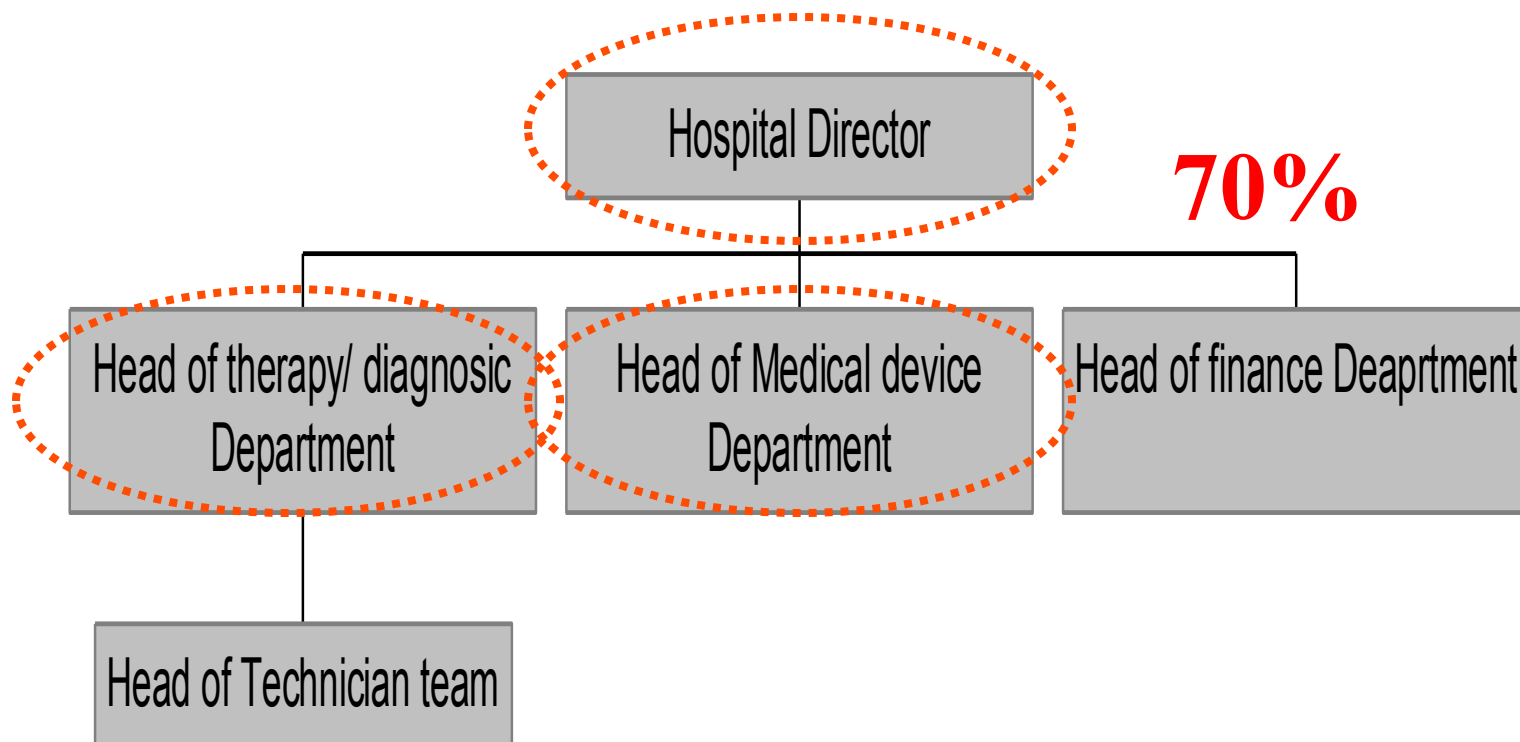
- Purchases of under VND 100 million (about US\$4,762): hospital can purchase without bids
- Up to VND2B (about US\$95,000): bidding must be organized but hospital can nominate the bidding supplier.
- Over VND2B (Over US\$95,000): results of bidding must also be approved by Health Service or Ministry of health

Bidding suppliers can be limited for more expensive or specialized devices

Type of Tender

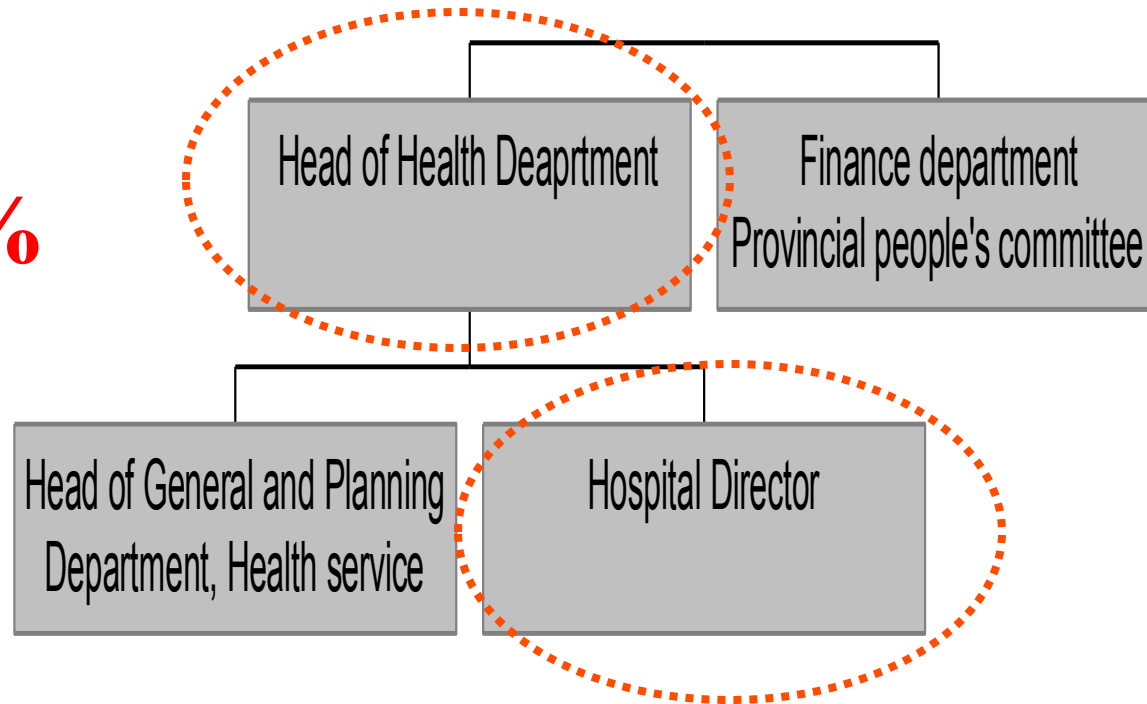
- ❑ Individual tender: the hospital open tender for its-self. Normally: Hospitals located in HCMC, Hanoi and National hospitals
- ❑ Regional tender: normally for provincial hospitals. Provincial health department shall be the sponsor
- ❑ National tender: sponsor be MoH, WB or others for big national projects
- ❑ Special tender: Army hospital system, SPONSOR

Decision Makers of Individual Tender

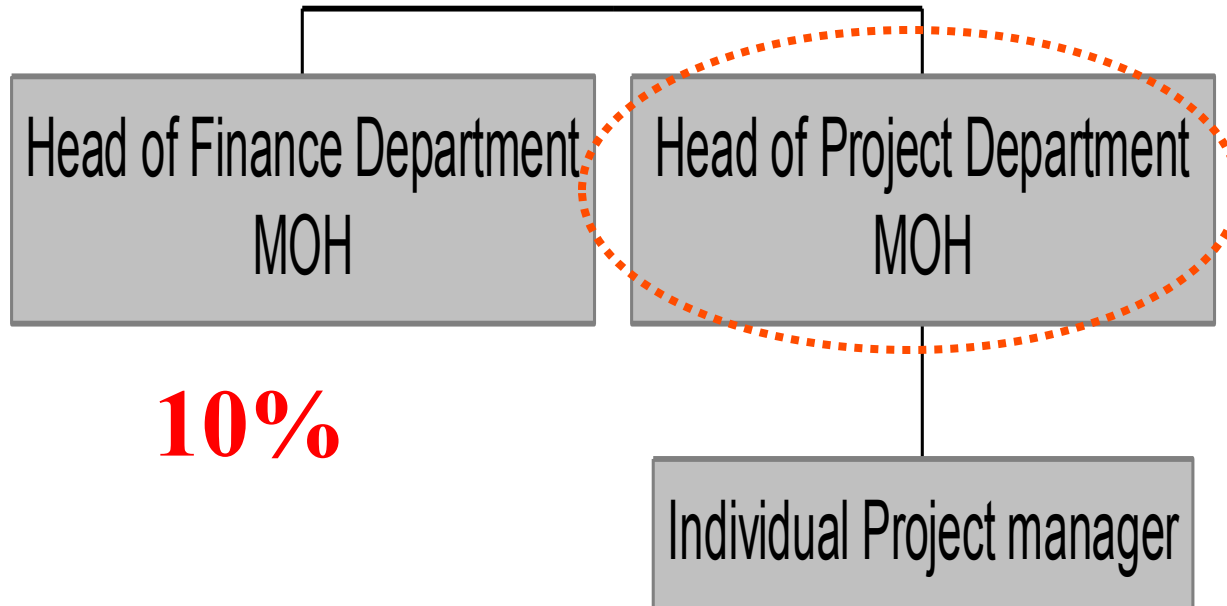


Decision Makers of Regional Tender

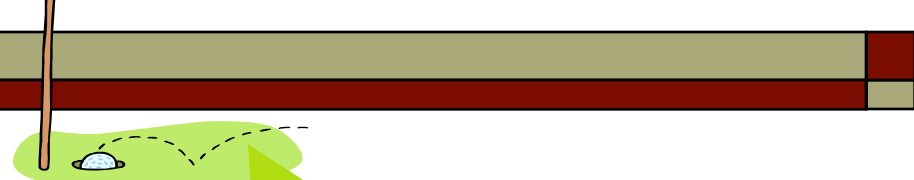
20%



Decision Makers of National Tender



Road Map for Tender Success



6. Buying

5. Submit the result to its supervised department, finance department of city

3. Call for tendering

- Companies must meet some major features in order to attend tender:
 1. Has at least two similar business contracts over the past 2 years

4. Assessment and result from hospital

- Decision makers are different based on each type of tender

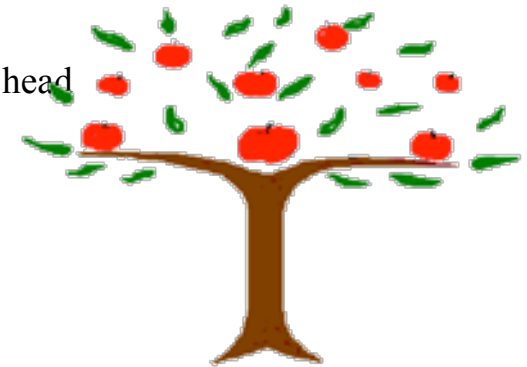
2. Develop Specification

- Technical specification
- Hospital requirement standards
- Influencers: head of therapy department, head of medical device, head of engineer



1. Approval for proposal

- Hospital get approval from its supervised department
- then get approval from Finance department of planning & investment department . Influencer: director, head of therapy department



Principles for Procurement Decisions

- ❑ Standard list of medical devices
- ❑ Should be upgradeable
- ❑ Supplier must be reputable, have legal distributor in Vietnam, commit to supplying spare parts or consumables for at least 5 years
- ❑ Products should be adapted for use in tropical climate
- ❑ Facility should be prepared to install device and have trained staff to use and maintain it
- ❑ After sale –service

Advertising

- All medical advertisements in Vietnam must be approved by the government in advance
- Illegal to advertise for unregistered drugs/devices
- Ads for devices are examined by DMEHW; ads for drugs are examined by DAV
 - Examination fee: VND 1,000,000 (about US\$62)
- An ad can be considered approved if there is no rejection or request for amendment in 10 days from submission
 - Registration is valid for 1 year
- Some ads in public spaces (like billboards) may also need separate permit from Ministry of Culture and Information

Advertising (2)

- An advertisement must be included the following contents:
 - Name of medical device, manufacturing country, registration number
 - Main features, effects and use instruction
 - Name, address of manufacturer, distributor and warranty-maintenance place
- Registration dossier for advertising consists of
 - Advertisement application form
 - Document proves the content of advertisement: technical document of the manufacturer that certified and qualified by competent authorities
 - power of attorney from manufacturer if distributor does advertisement
 - Marquette of advertisement

Legal Base

- ❑ Circular 024/2011/TT-BYT dated 21 June 2011: Guidance on the importation of medical devices, vaccine, Biological products from Vietnam MoH
- ❑ Circular 131/2008/TT-BYT dated 26 Dec, 2008: Guidance on implementation of VAT for the product list with import tax incentive
- ❑ Decision 21/2008/QĐ-BYT dated 09 June, 2008: promulgation of medical device list
- ❑ Document 4652/BHXH-CSYT dated 31Dec, 2008: insurance reimbursement for medical devices
- ❑ Circular 01/2004/TTLT-BVHTT-BYT: Guidance on Advertisement in healthcare industry
- ❑ Decision 3886/2004/QĐ-BYT: implementation of GMP-WHO in Vietnam

Conclusion

- ❑ Large market for medical device for the next 5 years
- ❑ Registration of medical device is much simpler document preparation, less time consumed and less spending
- ❑ Should use service agent for registration for being faster
- ❑ Plan for the year of 2015: 100% health reimbursement
- ❑ Should not attend tender if you have not done any activities before



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