Vietnam’s Medical Device Market

November 3, 2011
Table of Contents

- Vietnam Market Overview
- Regulatory of Medical Equipment in Vietnam
- Do Business of Medical Equipment in Vietnam
- Conclusion
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

CPV

Government
  - Government Office
  - MOH
  - MOIT
  - MOF

Vietnam Fatherland fund
  - Local NGOs
  - International NGOs

National Assembly
  - Committee of Social affairs
    - Provincial People's Committee
      - Health Department
      - District People's Committee
        - Villages
        - Health Section
Structure of Health Delivery

MOH

Health Services

National hospitals

Public Hospitals

General Health Centers

Private Hospitals

Vietnam’s Health Indicators 2006-2012

<table>
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<tbody>
<tr>
<td>Hospital</td>
<td>867</td>
<td>871</td>
<td>876</td>
<td>881</td>
<td>886</td>
<td>891</td>
<td>895</td>
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<tr>
<td>Beds per '000 population</td>
<td>1.55</td>
<td>1.56</td>
<td>1.58</td>
<td>1.6</td>
<td>1.61</td>
<td>1.62</td>
<td>1.64</td>
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<tr>
<td>Doctors per '000 population</td>
<td>0.54</td>
<td>0.55</td>
<td>0.56</td>
<td>0.57</td>
<td>0.57</td>
<td>0.58</td>
<td>0.59</td>
</tr>
<tr>
<td>Births per '000 population</td>
<td>16.7</td>
<td>16.7</td>
<td>16.5</td>
<td>16.4</td>
<td>16.4</td>
<td>16.3</td>
<td>16.1</td>
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<td>Deaths per '000 population</td>
<td>5.46</td>
<td>5.44</td>
<td>5.43</td>
<td>5.41</td>
<td>5.38</td>
<td>5.35</td>
<td>5.3</td>
</tr>
</tbody>
</table>

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

Collection

Exclusive 5 M from private insurance companies

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

Expenditure

Patient flow

First registered hospitals/clinics

Higher level/specialized hospitals

Un-affordable insurance
Funded by government

14 M

Children under 6
Funded by government

10 M

Employees/officials
Deducted 3% of monthly base salary

10 M

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

Suppliers

Importers

Distributors

- Hospitals
- Pharmacies/wholesalers
- Private clinics

Patients

Medical Device Flow

Suppliers

Distributors

- Hospitals
- Pharmacies/wholesalers
- Private clinics

Patients

Operation: Rep. office in Vietnam or LLC
Activities: Marketing, may direct import. Not PHYSICAL DISTRIBUTION

Operation: Rep. office in Vietnam or LLC
Activities: Marketing, direct import, PHYSICAL DISTRIBUTION
Medical Device Market Overview

- 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

<table>
<thead>
<tr>
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<th></th>
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</thead>
<tbody>
<tr>
<td>Others</td>
<td>31</td>
<td>35</td>
<td>38</td>
<td>43</td>
<td>47</td>
<td>53</td>
<td>58</td>
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<tr>
<td>Surgical</td>
<td>11</td>
<td>12</td>
<td>14</td>
<td>15</td>
<td>16</td>
<td>17</td>
<td>19</td>
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<tr>
<td>Medical aids</td>
<td>17</td>
<td>19</td>
<td>20</td>
<td>22</td>
<td>25</td>
<td>27</td>
<td>30</td>
</tr>
<tr>
<td>Monitoring equipment</td>
<td>25</td>
<td>28</td>
<td>31</td>
<td>34</td>
<td>37</td>
<td>41</td>
<td>45</td>
</tr>
<tr>
<td>Disposables</td>
<td>28</td>
<td>31</td>
<td>34</td>
<td>37</td>
<td>41</td>
<td>45</td>
<td>50</td>
</tr>
<tr>
<td>Therapy &amp; rehabilitation equipment</td>
<td>32</td>
<td>35</td>
<td>39</td>
<td>43</td>
<td>47</td>
<td>52</td>
<td>57</td>
</tr>
<tr>
<td>Diagnostic equipment</td>
<td>36</td>
<td>40</td>
<td>45</td>
<td>50</td>
<td>55</td>
<td>61</td>
<td>68</td>
</tr>
</tbody>
</table>

Source: Vietnam Ministry of Health, International Trade Administration, US Commercial Service
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- Vietnam Market Overview
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Regulatory structure

**GOVERNMENT**
Issuing policy and decrees on medical devices

**The Ministry of Science and Technology**
Issuing regulation on management on quality of goods & import of used devices

**Directorate for Standards, Metrology, Quality STAMQED**
- State management on quality of goods
- Providing the product quality certification

**The Ministry of Heath (MOH)**
Issuing regulation on management on im-export and & manufacture and trading of medical devices

**The Ministry of Finance**
- Issuing regulation on management on Tax, fee & charge of import and registration,
- Goods procurement using State budget

**The Ministry of Trade**
Issuing regulation on management on goods import export, circulation of goods and labeling

**Drug Administration of Vietnam**
- Assess dossiers and grant licenses for import, registration of drugs
- Granting medical practice eligibility certificate for manufacture of medical devices

** Provincial Branches for Standards, Metrology. Quality**
Management on quality of local goods

**Department of Medical Equipment and Health Works**
- Receive and assess application dossier for im-export license, product registration
- Granting im-export license, registration certificate
- Granting medical practice eligibility certificate for manufacture of medical devices
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
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, consummables 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)

<table>
<thead>
<tr>
<th>No.</th>
<th>Equipment Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The imaging device uses X-rays</td>
</tr>
<tr>
<td>2</td>
<td>MRI System</td>
</tr>
<tr>
<td>3</td>
<td>Ultrasound diagnosis</td>
</tr>
<tr>
<td>4</td>
<td>Endoscopic diagnostic system</td>
</tr>
<tr>
<td>5</td>
<td>Cyclotron System</td>
</tr>
<tr>
<td>6</td>
<td>Diagnostic equipment with radioactive isotopes (PET systems, PET / CT, SPECT, SPECT / CT equipment to measure the concentration of iodine 1130)</td>
</tr>
<tr>
<td>7</td>
<td>Gauge refraction, corneal automatically</td>
</tr>
<tr>
<td>8</td>
<td>Gauge electrophysiological (EEG machines, ECG machines, electrical machines)</td>
</tr>
<tr>
<td>9</td>
<td>Power Meter retina</td>
</tr>
<tr>
<td>10</td>
<td>Gauge osteoporosis</td>
</tr>
<tr>
<td>11</td>
<td>Retinal scanners / cameras fluorescence of the eye</td>
</tr>
<tr>
<td>12</td>
<td>Fetal heart rate meter with ultrasound</td>
</tr>
<tr>
<td>13</td>
<td>Meter / analysis of respiratory function</td>
</tr>
<tr>
<td>14</td>
<td>Biochemical analyzer</td>
</tr>
<tr>
<td>15</td>
<td>Electrolyte analyzers, blood gas</td>
</tr>
<tr>
<td></td>
<td>Hematology analyzer</td>
</tr>
<tr>
<td>---</td>
<td>---------------------</td>
</tr>
<tr>
<td>17</td>
<td>Coagulation meter</td>
</tr>
<tr>
<td>18</td>
<td>Blood sedimentation rate meter</td>
</tr>
<tr>
<td>19</td>
<td>Elisa test system</td>
</tr>
<tr>
<td>20</td>
<td>Blood analyzer</td>
</tr>
<tr>
<td>21</td>
<td>Machine extraction cells</td>
</tr>
<tr>
<td>22</td>
<td>Meter stop collection and analysis of platelet function</td>
</tr>
<tr>
<td>23</td>
<td>Machine identification of bacteria, viruses</td>
</tr>
<tr>
<td>24</td>
<td>Immune analyzer</td>
</tr>
</tbody>
</table>

**Treatment Equipment**

<table>
<thead>
<tr>
<th></th>
<th>The device uses X-ray treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>25</td>
<td>Laparoscopic system</td>
</tr>
<tr>
<td>26</td>
<td>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)</td>
</tr>
<tr>
<td>27</td>
<td>Monitor patients</td>
</tr>
<tr>
<td>28</td>
<td>Infusion pump, injection pump power</td>
</tr>
<tr>
<td>29</td>
<td>Surgical (high-frequency electrical, laser, ultrasound)</td>
</tr>
<tr>
<td>30</td>
<td>Surgical Microscopes</td>
</tr>
<tr>
<td>31</td>
<td>Equipment system for prostate surgery</td>
</tr>
<tr>
<td>32</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cardiopulmonary bypass machine</td>
</tr>
<tr>
<td>---</td>
<td>----------------------------------------------------------------</td>
</tr>
<tr>
<td>33</td>
<td>Positioning devices in surgery</td>
</tr>
<tr>
<td>34</td>
<td>Cryosurgery equipment</td>
</tr>
<tr>
<td>35</td>
<td>Infant incubator, infant heating machine</td>
</tr>
<tr>
<td>36</td>
<td>Anesthesia Machine / Anesthesia breathing</td>
</tr>
<tr>
<td>37</td>
<td>A breathing machine</td>
</tr>
<tr>
<td>38</td>
<td>Breakers fibrillation, pacemaker</td>
</tr>
<tr>
<td>39</td>
<td>High-pressure oxygen chamber</td>
</tr>
<tr>
<td>40</td>
<td>Lithotripsy system outside the body / endoscopic lithotripsy</td>
</tr>
<tr>
<td>41</td>
<td>The system of high-intensity ultrasound tumor therapy</td>
</tr>
<tr>
<td>42</td>
<td>Dialysis equipment</td>
</tr>
<tr>
<td>43</td>
<td>The system of specialized ophthalmologic surgery (Excimer Laser Phemtosecond, Phaco, glass cutting services, cutting the corneal flap)</td>
</tr>
<tr>
<td>44</td>
<td>Contact lenses (access, telecommunications, astigmatism) and preservative solutions lenses</td>
</tr>
<tr>
<td>45</td>
<td>Laser treatment used in ophthalmology</td>
</tr>
<tr>
<td>46</td>
<td>The type of device, implant material long-term (over 30 days) on body</td>
</tr>
<tr>
<td>47</td>
<td>The type of equipment, materials interfere with the body of the cardiologist, cranial nerve</td>
</tr>
<tr>
<td>48</td>
<td><strong>Other Devices</strong></td>
</tr>
<tr>
<td>49</td>
<td>Medical Gas System Center</td>
</tr>
<tr>
<td>50</td>
<td>Ambulance / vehicle and other specialized medical use</td>
</tr>
</tbody>
</table>
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 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
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

- Medical Equipment
  - Group I
  - Group II
  - Group III
    - Clinical test
    - Dossier of 7 items
    - No permit required
Import permit application flow chart
Clinical trials not required

The Department of Medical Equipment and Health Works
Lead time: 15 working days

Dossier

Import permission

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www.pacificbridgemedical.com
Import Permit Application Flow Chart
Clinical Trials Required

1. Application for import permit for clinical test

2. The Department of Medical Equipment and Health Works
   Lead time 15 days
   Import permit for clinical test
   Full legal documents
   Lead time 15 days

3. Hospitals designated by MOH
   For clinical trials
   Lead time: unspecified
   Clinical results to the DMEHW and the applicant

4. Import permission
   Hospitals designated By MOH
   For clinical trials
   Lead time: unspecified
   Clinical results to the DMEHW and the applicant
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

The Department of Medical Equipment and Health Works
Lead time: 15 working days

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

Registration license. Valid for 3 years
Registration Flow Chart (with AQS)

- **Provincial Branch for Standards, Metrology and Quality**
  - Approval of announcement
  - Lead time: 15 days

- **Department of Med. Equipment and Health Works**
  - Receive application and designate hospitals for clinical trials in 15 days
  - Granting registration number
  - Lead time: 15 days

- **Hospitals designated by Department of Med. Equipment**
  - Report of clinical trials
  - Lead time: unspecified

- Standard announcement
- Application for Clinical trial
- Clinical trial Implementation
- Full legal documents
- Clinical trial report
- Registration number
Registration Flow Chart (with ASC)

Institute of Medical Equipment and Works
Evaluation of standard conformity
Lead time; 30 days appr.

Directorate for Standards, Metrology and Quality
Granting certificate of standard conformity
Lead time: 30 days appr.

Hospitals designated by Department of Med. Equipment and Health works
Report of clinical trials
Lead time unspecified

Clinical trial implementation
Clinical trial Report
Full legal documents

Department of Med. Equipment and Health Works
-Receive application and designate hospitals for clinical trials in 15 days
-Granting registration number
-Lead time: 15 days for grating registration

Registration number
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.

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.

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
Business Model

1+1<2

Supplier

1+1=2

Distributor

1+1=11

Supplier

Distributor

Making the big jump

Best partner
### End-User Analysis

#### Government funded Hospitals
- Self tender organizing
- Regional tender organizing
- National tender organizing
- Sponsor company organizing

#### Private Hospitals
- 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 itself. 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

- Hospital Director
- Head of therapy/diagnostic Department
- Head of Medical device Department
- Head of finance Department
- Head of Technician team

70%
Decision Makers of Regional Tender

- Head of Health Department
- Head of General and Planning Department, Health service
- Hospital Director
- Finance department
- Provincial people's committee

20%
Decision Makers of National Tender

- Head of Finance Department, MOH
- Head of Project Department, MOH
- Individual Project manager

10%
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

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

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

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

6. Buying

Road Map for Tender Success
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
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 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 31 Dec, 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
Thank you for your consideration!

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