Overview of Medical Device Regulatory Requirements in AHWP Member Economies

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Philippines

Philippines

- Country Profile
- Medical Device Market
- Pre-market Requirements
- Post-marketing Surveillance and Management of Medical Devices

Country Profile

Philippines

Capital : Manila

Population: 76.5M (2000)
88.7M (projected for 2007)

Official Languages: Filipino, English

Land Area : 300,000 km^2

Consists of 7,107 islands divided into three main groups of islands namely Luzon, Visayas, Mindanao

Sub-divided into 17 Regions

Philippines

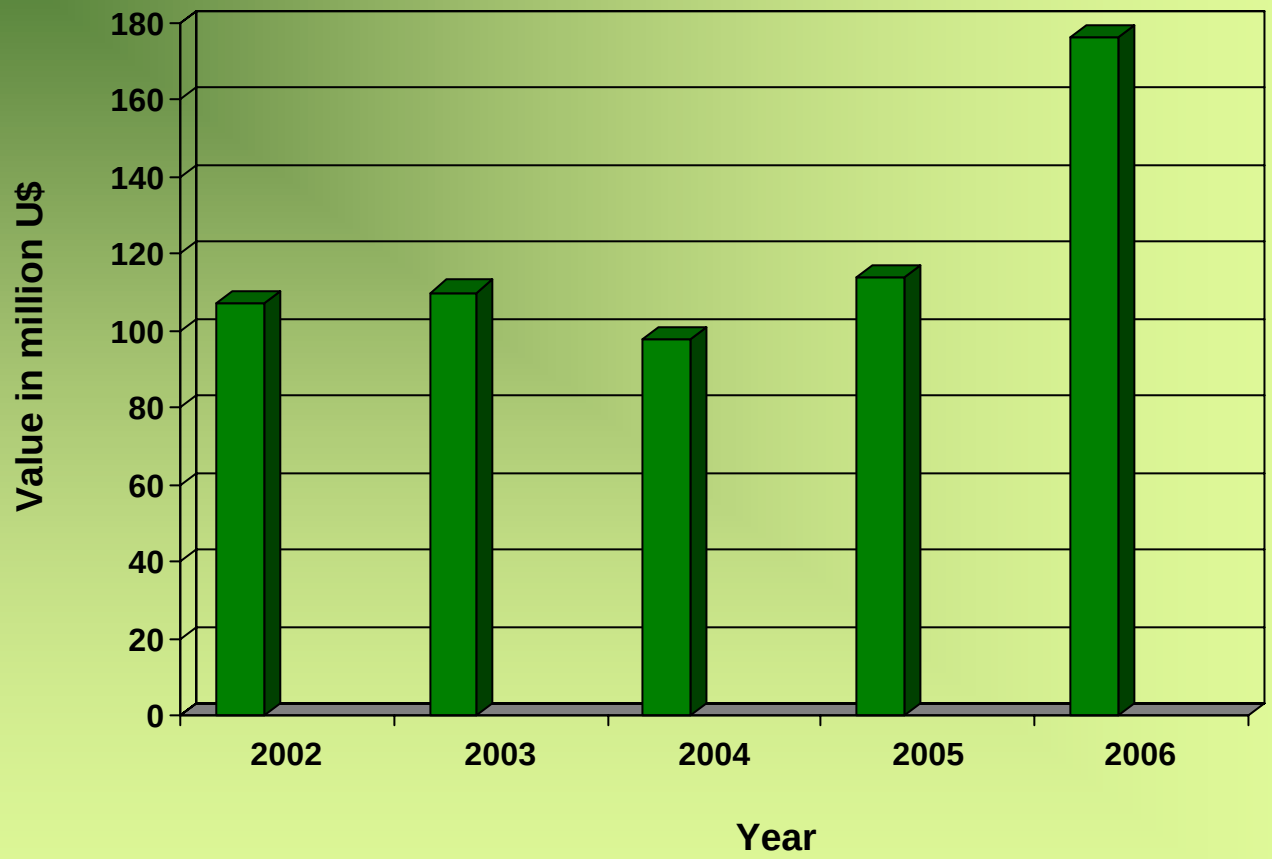
Medical Device Market Profile

MEDICAL DEVICE MARKET

Medical Devices for Import

Almost all medical devices, equipment and supplies

Philippine Imports of Medical Devices, Equipment and Supplies
CIF Value in U$
2002-2006



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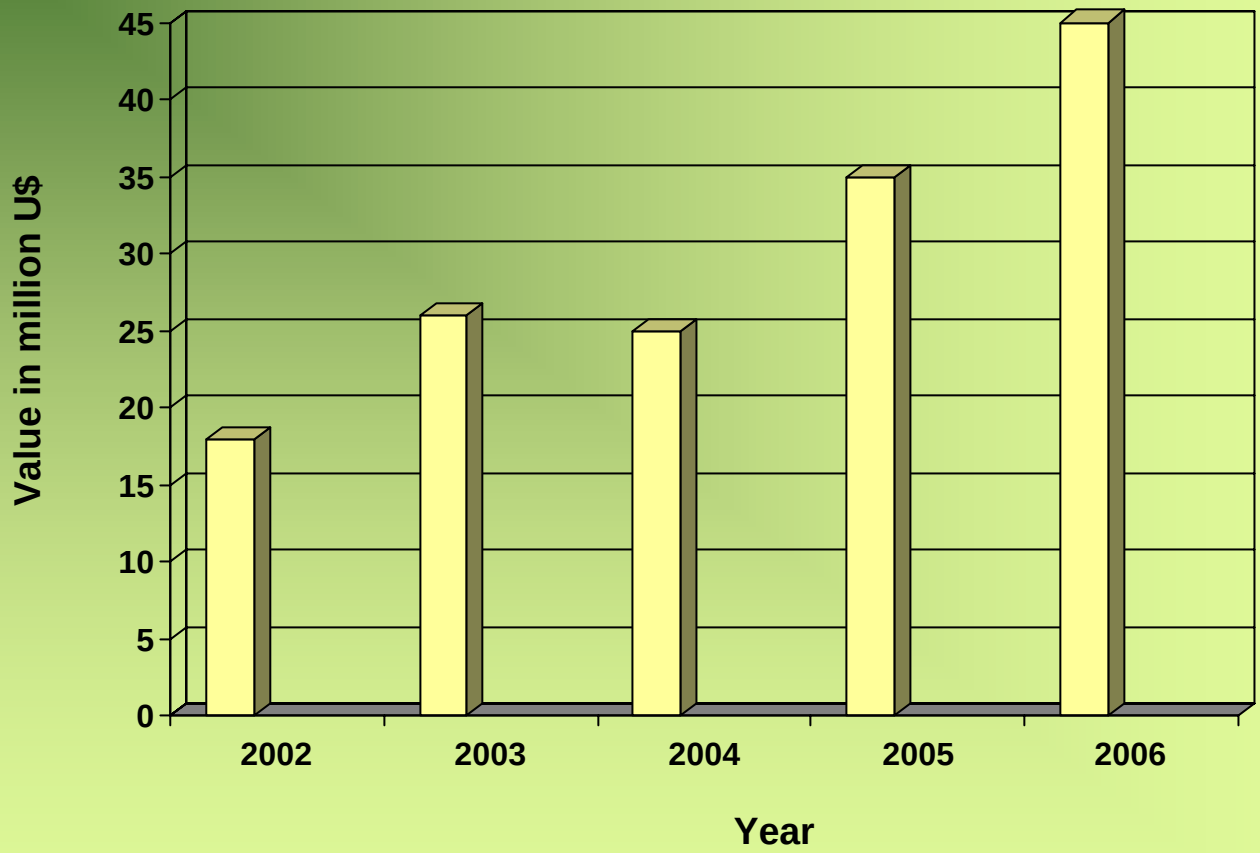
Medical Devices for Export

- Syringes
- Artificial dentures and fittings
- Catheters, cannulae
- Gas masks
- Gauze, bandages
- Dental instruments
- Adhesive dressings
- Orthopedic appliances
- Cotton
- Artificial parts of body
- Massage apparatus
- Diagnostic reagents

Philippine Exports of Medical Devices, Equipment and Supplies
FOB Value in U$
2002-2006



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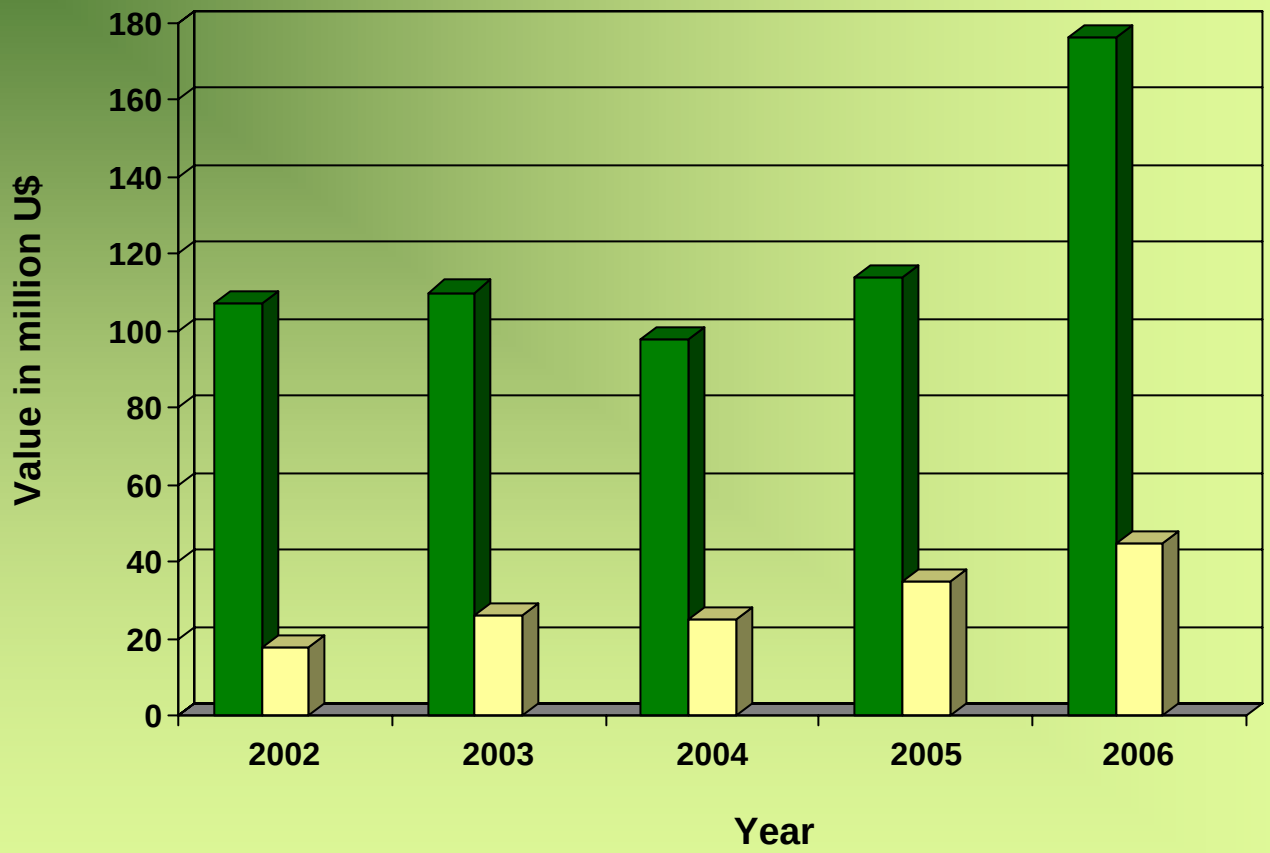
Comparative Presentation
Import vs Export



Different Types of Health Facilities

Health Facility	
Government Hospital	359
Private Hospital	595
Birthing Homes	77
Dialysis Clinics	39
Blood Bank Center	199
Ambulatory Surgical Clinic	35
OFW Medical Clinic	136
Occupational Establishments, Dental Clinics	11

data as of December 2005

Different Types of Health Facilities

Health Facility	
Dental Laboratory	398
Drug Abuse Treatment and Rehabilitation Center	45
Private School Dental Clinics	88
Infirmary	801
Acute Chronic Psychiatric Care Facility	4
Custodial Psychiatric Care Facility	2

data as of December 2005

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Infirmary – a health facility that provides emergency treatment and care to the sick and injured, as well as clinical care and management to mothers and newborn babies

Birthing Home – a health facility that provides maternity service on pre-natal and post-natal care, normal spontaneous delivery, and care of newborn babies

Acute Chronic Psychiatric Care Facility – a health facility that provides medical service, nursing care, pharmacological treatment, psychosocial intervention for mentally ill patients

Custodial Psychiatric Care Facility – a health facility that provides long term care, including basic human services such as food and shelter, to chronic mentally ill patients

Radiation-Emitting Facilities for Medical Use

(as of August 2007)

Facility	
General Radiography	3594
Transportable	200
Computed Tomography	215
Gamma Camera	27
Magnetic Resonance Imaging	32
Mammography	149
Cobalt	14
Brachytherapy	15
Medical Linac	11

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Registered Health Professionals

Dentist	47,335
Medical technologist	49,465
Medical laboratory technician	3,736
Midwife	145,256
Nurse	381,411
Nutritionist/Dietitian	12,338
Optometrist	9,435
Pharmacist	52,171
Physician	98,210
Physical Therapist	19,433
Occupational Therapist	2,280
Radiologic Technologist	5,845
X-ray technologist	8,444

as of October 2005

Source: Philippine in Figures 2006, National Statistics Office

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Leading Cause of Mortality

Disease of the Heart	70,223
Cerebrovascular diseases	40,515
Malignant neoplasm	38,821
Pneumonia	34,218
Tuberculosis	28,507
Chronic Lower respiratory disease	19,320
Accidents	14,218
Certain conditions originating from pre-natal period	14,209
Diabetes mellitus	13,922
Assault	13,267

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Leading Cause of Morbidity

Pneumonia	509,274
Diarrheal diseases	615,692
Bronchitis	604,107
Influenza	431,216
Hypertension	325,390
Tuberculosis	92,079
Disease of the Heart	30,398
Malaria	28,549
Chickenpox	26,137
Measles	24,876
Acute lower respiratory track infection	169,069

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Medical Device Regulation

Legal Mandate

Republic Act No. 3720 as amended by Executive Order No. 175
Known as the Foods, Drugs, Devices and Cosmetics Act

Executive Order No. 102
Redirecting the functions and operations of the Department of Health

Administrative Order No. 2007-0003
Policies and Guidelines Governing the Registration and Licensing of Establishments dealing with Medical Devices

Joint Bureau Memorandum No. 2007-1
Process flow for the implementation of AO No. 2007-0003

Classification of Medical Devices

Bureau Memorandum Circular No. 7 s. 1992

List of Registrable and Non-Registrable Devices

Registrable	**74 devices**
Non-Registrable	**30 devices**
Exempted	**Not included in the above lists**

REGULATION OF MEDICAL DEVICES

1. License to Operate (LTO) as medical device establishment (manufacturer, importer, wholesaler)

2. Certificate of Product Registration (CPR)

Requirements for Registration of Medical Devices Initial

1. **Valid License to Operate (LTO) in the Philippines**

2. **For imported medical devices, government certificate of clearance and free sale / registration approval of the product from the country of origin issued by Health Authority and duly authenticated by the territorial Philippine Consulate**

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3. Government certificate attesting to the status of the manufacturer's competency and reliability of the personnel and facilities duly authenticated by the territorial Philippine Consulate and/or valid ISO certification

4. Certificate of agreement between the manufacturer and trader/distributor/importer regarding the device

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5. Specific use and directions for use

6. List of amount and technical specification of raw materials

7. Brief description of the methods used, the facilities and control in the manufacture, processing, and packaging of the device. For sterile products, include sterilization procedure

8. Technical specification and physical description of the finished devices.

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9. **Stability studies of the products**

10. **Labeling materials to be used for the Product: immediate label, box label and package insert/bochures**

11. **Representative sample in the market or Commercial representation (at least one of size)**

For complete list of registrable products and other policies and guidelines, please visit this website www.bfad.gov.ph

Validity of Certification

Initial	**1 year**
Renewal	**2 to 5 years (choice of the company)**

Clinical Trials

(Proposed procedure)

The Company needs to:

- **Develop protocol in accordance with ISO: 14155: Clinical Investigation of Medical Devices using human subject**
- **Select their choice of hospital**
- **Submit report regularly on the status of the study**

Registration Procedure

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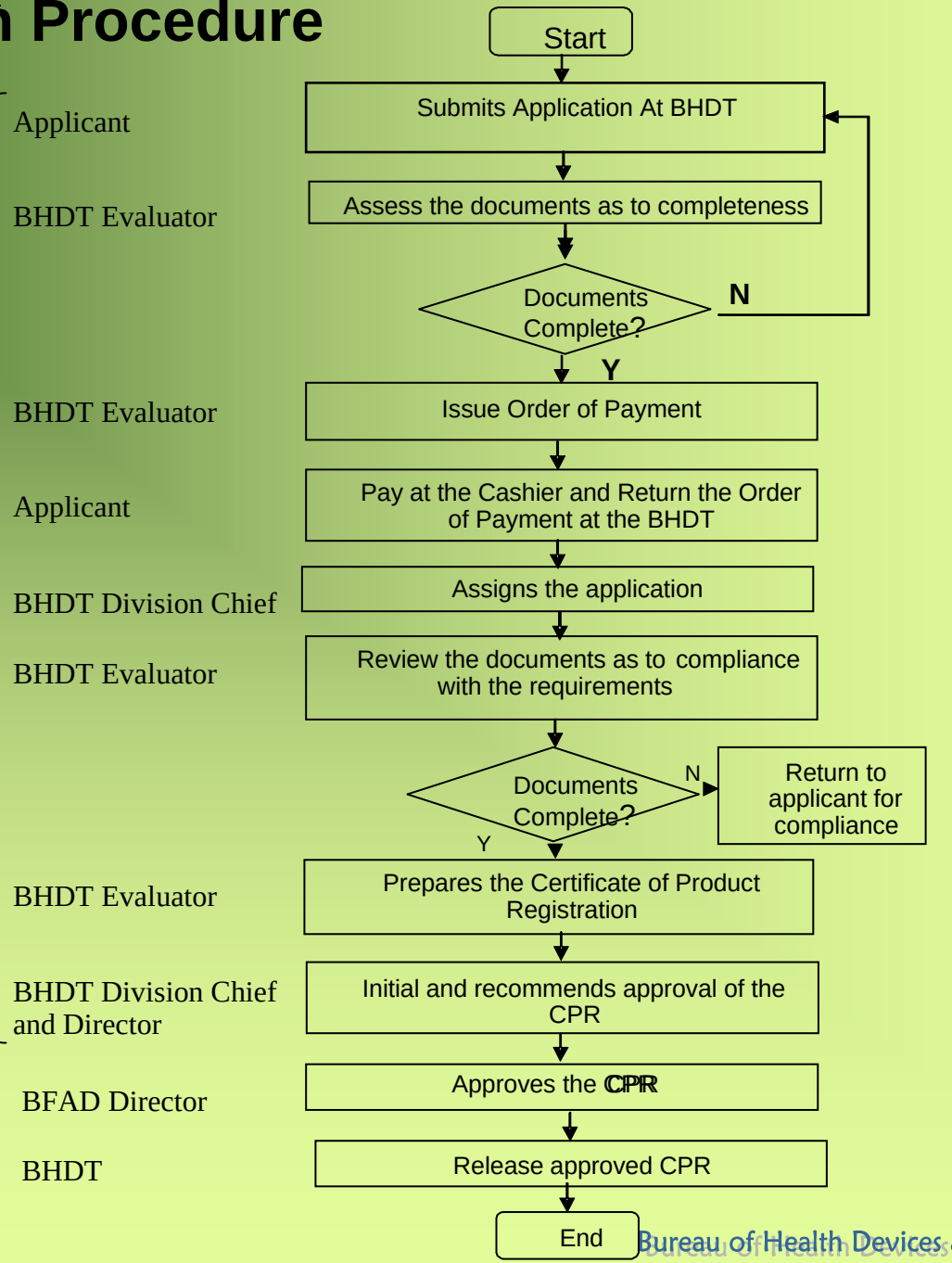
90 days



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Post Market Surveillance

Post-Market Activities

Monitors device alerts and product recalls issued by other health regulatory agencies

Inform the local distributor of the alert

Make necessary advisory when needed

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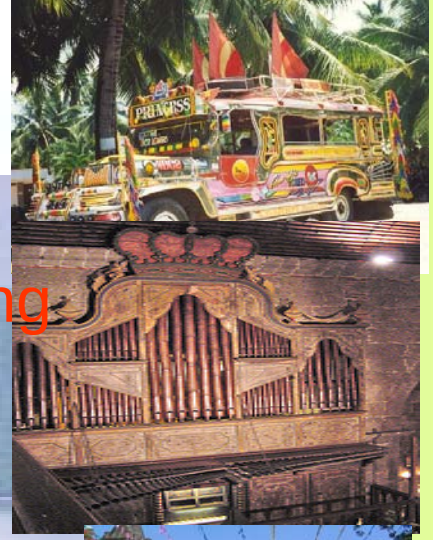
WOWPINOY

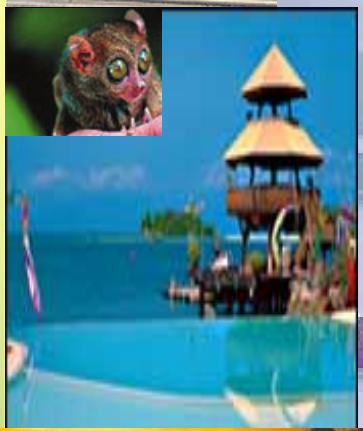
Experience 7,107 Islands!



See you in the Philippines

7th ACCSQ-MDPWG Meeting

January 2008



Thank you…