MEDICAL DEVICE REGULATION

IN THE

PHILIPPINES

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BRIEF BACKGROUND

- **BFAD is mandated to regulate medical devices aside from foods, drugs and hazardous substances**

- **In year 2000, DOH implemented the re-engineered structure creating the Bureau of Health Devices and Technology (BHDT)**

- **BHDT is tasked to regulate all radiation emitting devices, medical devices and health related devices**

BRIEF BACKGROUND

- **At present, BHDT is drafting the law that will govern the regulation of these devices in the Philippines**

STATUS OF MEDICAL DEVICE REGULATION UNDER THE BHDT

- Finalized the guidelines on the notification and registration of medical devices in the Philippines and the guidelines on licensing of medical device establishments in the Philippines
- Passed the LPCC of the DOH
- Routed to WTO member countries through the BPS-DTI

STATUS OF MEDICAL DEVICE REGULATION UNDER THE BHDT

- **Target date of implementation is later part of year 2003**

- **In early part of 2003, the guidelines on notification and registration of in-vitro diagnostic medical devices and registration of refurbished active medical devices will be finalized for 2004 implementation**

CLASSIFICATION OF MEDICAL DEVICES

- Class I
- Class II
- Class III
- Class IV

Requirements for Notification (Class 1)

- Notarized Application Form
- Valid Licensed to Operate
- Proof of Payment
- Unattached labels or proposed labels and other labeling materials to be used

Requirements for Notification (Class 1)

- For imported medical devices, government certificate of clearance and free sale or product registration or product notification of device or export certificate or any equivalent certificate issued by the regulatory agency in the country of origin and duly authenticated by territorial Philippine Consulate

Requirements for Notification (Class 1)

- Government certificate attesting to the status of the manufacturer’s competency and reliability of the personnel and facilities or Quality Systems Certificate or compliance certificate with GMP or ISO 9000 series or the manufacturer’s of the particular device duly authenticated by the territorial consulate

Requirements for Registration (Class II)

- Same as requirements for Notification
- For distributors, authority of certificate of agreement between the manufacturer and the distributor duly authenticated by the territorial Philippine Consulate
- Composition and/or technical specification of all raw materials, if applicable

Requirements for Registration (Class II)

- Manufacturing flow chart / brief description of methods used, the facilities and control in the manufacture, processing, packaging of the device

- Complete quality control/assurance certificate/functional procedures for finished device issued by the manufacturer

Requirements for Registration (Class II)

- Declaration of product compliance with adopted standards, either ISO, IEC or other standards
- Technical specification and product description of the finished device
- Stability studies of the device to justify claimed of expiration date, where applicable

Requirements for Registration (Class II)

- Representative sample or commercial presentation of the product, when needed
- Clinical evidence, either foreign or local, to support the safety, quality and performance of a device using new technology (for newly introduced devices only)

Requirements for Registration (Class III and IV)

- Same requirements as Class II
- List of countries where the device has been sold
- Summary of all studies on which the manufacturer relies to ensure the safety and effectiveness requirements of the device

Requirements for Registration (Class II)

- **Bibliography of all published reports dealing with the use, safety and effectiveness of the device**

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Thank you ....