Republic of the Philippines
Department of Health
Food and Drug Administration

The State of Affairs of Pharmaceutical Products

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We cannot trust the regulatory processes at the moment.
10 STEPS
To Ensure Quality, Efficacy And Safety
Adoption of the ACTD and ACTR

• ASEAN Common Technical Dossier
  – An agreed arrangement of technical documents for systematic drug evaluation
  – Intended to cross language barriers and variation in document formats

• ASEAN Common Technical Requirements
  – An agreed list of documents to be required prior to grant of an authorization
Foreign CGMP Inspection

• The FDA can’t assure the quality or safety of most drugs available in the market
• Demand for cheap medicines compel Filipino companies to source from countries with less consistent regulations
• Conduct of GMP inspections of overseas sources are expected to identify high-risk establishments.
Demonstrating Bioavailability and Bioequivalence

• Drug efficacy is dependent on how much enters the blood.
  – Bioavailability - the relationship between solubility, permeability, and the available concentration in the blood of the drug
  – Bioequivalence - the bioavailability profile of one drug compared to another

• Only two local facilities are able to provide the BA and BE required by the FDA – unmet local demand
RMP and Product Stewardship

• PV4U
  – Pharmacovigilance for You aims to encourage patient participation in adverse event reporting

• Product Stewardship
  – Readiness and competence to address product recalls, consumer complaints, and audits

• Risk Management Protocols
  – Who is accountable for a company’s violations?
  – How does a company engage the regulators in a crisis?
  – What information is released to the public?
Adoption of Mexico City Principles

• APEC Declaration of Ethical Marketing of Biopharmaceuticals
• Implementation of ethical market communications to even out the playing field
Medicines Patent Pool

- Ensuring anti-HIV medicines are accessible in the Philippines and other emerging nations
- Allows patented agents to be produced by an independent low cost manufacturer

- Goals
  - Reduce cost
  - Facilitate fair market competition
Quality and Integrity of Evaluation

• **QPIRA (Qualified Person In Regulatory Affairs)**
  – Ensure that regulations are understood and followed by the parties engaging with the Agency
  – Elevating the level of interaction between the Agency and Industry

• **Electronic Dossiers**
  – Reducing handling of paper-based documents
  – In compliance with ASEAN directives and in preparation of harmonization
Clinical Trial Regulation

- Pharmaco-epidemiology
  - Post-Authorization Efficacy Studies (PAES)
  - Post-Authorization Safety Studies (PASS)
  - For registered products with problems of efficacy and safety.
  - Addressing the gap between proof and belief on the quality of generic medicines
Control of SSFFC Health Products

• SSFFC
  – Substandard/ Spurious/ Falsely-labelled/ Falsified/ Counterfeit

• Intellectual Property or Trademark clearance
  – Due diligence of applicant

• Unique Global Identifier
  – Enabling track and trace actions as part of risk management
  – Part of APEC harmonization under the Committee on Trade and Industry
Digital Cartography

- Intended to address patient asymmetry
- A map freely accessible through the Internet
  - A PPP project for general consumer information
  - Identifies licensed establishments and current prices
Mexico City Principles

• Ethical Marketing Practices for Biopharmaceuticals
  – a model to arrest corrupt practices in other industries where it is practice to receive commissions from suppliers to procurement personnel in business and trade
Survey of Promotional Practices in the Philippine Pharmaceutical Industry by the Medical Transparency Alliance

LANDSCAPE OF UNETHICAL PRACTICES
Methodology

• Face to face interviews
  – Anonymous interviewees
  – No formal questionnaire
  – Write-ups prepared within three days of interview
  – Each interview lasted about 90 minutes
Figures

- Largest field force: ~1,100 medical representatives for a local drug company
- Typical deployment cost for one medical representative: Php 1,000,000.00
- Number of calls for one medical representative: 15 to 20 doctors per day
Promotional Strategies

• “Cruises  Я  Us”
  – Baltic and Mediterranean luxury cruises

• Continuing Medical Education
  – a five-day trip to the Middle East with a one-hour lecture by one of the sponsored physicians

• Medical Society Sponsorships
  – Unsustainable, but there is no “plan B”
Regulatory Activity

• Post-Marketing Surveillance
  – The bar is not set high enough; 30 patients for one protocol was considered acceptable

• Internet Promotions
  – DoH has recognized that it is impossible to effectively monitor this medium.

• Enforcement (or Lack thereof)
  – “FDA/ DoH don’t impact my marketing decisions.”
Industry Self-Regulation

• Pharmaceutical and Healthcare Association of the Philippines
  – Clear ethical guidelines overseen by an independent ethics committee
  – More convoluted strategies for rule evasion

• Medical Societies
  – Most societies lack any code of conduct

• Local Companies
  – Do not provide training for Medical Directors outside of adverse event reporting
FDA Adopts Mexico City Principles

- Medical Directors and MDs in the Pharmaceutical Industry are expected to uphold ethical practices as agreed, based on a public hearing held on Friday 21 March 2014 at FDA.
Self-Regulation of Physicians

- Medical specialty organizations are called out to police their ranks
- Implement their own code of professional ethical practices
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