Year in Review
International
2010
Pharmaceutical Regulatory and Compliance Congress
Major regulatory bodies around the world are sharing non-public information

- European Agency for the Evaluation of Medicines (EMEA)
- US Food and Drug Administration (FDA)
- Health Canada
- Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS)
- Spanish Medicine Agency (AEM)
- Ministry of Health, Welfare & Social Affairs
- Italian Ministry of Health
- Ministry of Health, Labor and Waste
- Brazilian Sanitary Surveillance Service (ANVISA)
- Central Drug Standard Control (CDSCO)
- National Administration of Drugs, Foods and Medical Technology
- Medicines Control Council (MCC)
- Medicines and Medical Devices Safety Authority
- Federal Institute of Drugs and Medical Devices (BfArM)
- Ministry of Health (MoH) — Department of State Control over Quality, Efficiency and Safety of Drugs and Medical Equipment
- Japanese Agency for Healthcare and Medical Devices (MHLW)
- State Food and Drug Administration (SFDA)
- Australian Therapeutic Goods Administration (TGA)
- Swiss Federal Office for Public Health (FOPH)
- Medicines Inspectorate (MPI)
- Ministry of Health (SSA)
- Institute of Public Health (ISP)
- Health Canada
- US Food and Drug Administration (FDA)
Key 2010 international laws and other standards

► Bribery and Corruption/FCPA
  – UK Bribery Act received Royal Assent on 8 April 2010
  – OECD recommends banning all facilitation payments
  – EucoMed amends the Code of Ethics Enforcement Procedures
  – EucoMed and AdvaMed sign transatlantic statement on compliance

► Drug Trials outside of the US
  – HHS-OIG reports a huge shift to overseas clinical trials while questioning FDA’s ability to provide oversight
  – JAMA editorial recommends changes to reviews of company-sponsored clinical trials
Key developments in laws and other standards

► Newly created Enforcement Procedures for Code of Ethics ensure consistent interpretation of the EucoMed rules across Europe

► Clinical Trials/Safety
  – German Officials focus on transparency in clinical trials
  – EU withdraws marketing approval (Diabetes and Weight loss drugs)
  – JAMA Editors recommends more stringent review processes for industry sponsored trials

► Delay of Generic Competition
  – Supreme Court declined to hear the FTC’s appeal. FTC urges Congress to ban practice

► Antitrust Investigations
  – European Union regulators accused drugmakers of costing consumers in 17 countries as much as 3 billion euros ($3.9 billion) by using patent lawsuits and other tactics to keep cheaper generic medicines off the market.
Bribery and corruption highlights — Cross industry

► UK Bribery Act — Guidance & Consultations begin ahead of implementation in 2011

► China — Drafts amendments to Criminal Law — but keeps death penalty for crimes of graft

► After Supreme Court ruling, DOJ calls on Congress for new “Honest Service” legislation

► Worldwide — Implementation of OECD ban on foreign bribery improves but still weak
W.H.O. identifies common unethical practices in pharmaceutical supply chain

Key steps of the medicine supply chain and unethical practices in the pharmaceutical sector

Unethical practices common throughout the medicine chain

- Bribery
- Dispensing
- Promoting excessive use of medicine to increase profit

W.H.O.’s Good Governance for Medicines (GGM) Program

- Focus on fighting corruption in Public Governance
- Where the participating countries stand

Phase I
Transparency Assessment
7 countries

Phase II
Development of national GGM program
12 countries

Phase III
Implementation of national GGM program
7 countries

Source: World Health Organization
Europe

- **Regulation of medicinal products transferred to Directorate-General for Health and Consumers**: Consumer focused regulation. March 1, 2010
- **EU Parliament Takes Action Against Counterfeit Medicines**: Mandatory safety features — packaging. April 2010
- **Poland investigating profit trail in clinical Trials**: Stent procedures. September 6, 2010
- **Hungary investigates outsourcing high profit procedures to private companies**: Stent procedures. September 6, 2010
- **EFPIA – ‘EU Initiative does not go far enough’**: Response to EP initiative. Sept 2010

- **Turkey leads globe in addressing fraud with 1st implementation of serialization**: Counterfeit Medicines. April 2, 2010
- **EP Health Committee proposes new Pharmaceutical Initiative**: Counterfeit Medicines, Pharmacovigilance, Public access to Rx drug information. June 2010
- **MHRA Pursuing New Monetary and Statutory Sanctions for Non-compliance**: New Enforcement Strategy focused on prevention. Aug 6th, 2010
- **Russian changes in regulation of pharmaceutical circulation now in place**: Price pressures. Sept 2010
- **Italian authorities launch corruption probe into clinical trials**: 30 suspects, six arrests, 13 disqualifications. October 1, 2010
Year in Review — International 2010

China

Local Chinese Pharma Co., Ltd.
- Significant GMP deviations
- USA FDA Warning Letter
  January 28, 2010

SFDA official arrested in rabies vaccine scandal
- Deliberate substitution of materials, and bribery
  April 2010

Global Pharma Co. involved in bribery case in China
- Alleges bribes in exchange for help getting drug application numbers and certificate of registration of medical products.
  June 22, 2010

SFDA demands new health warning for sedative-hypnotic drugs
- Adverse Events
  September 19, 2010

SFDA Announces Illegal Drug Advertisements
- Domestic manufacturers and distributors “perfect,” peace benefit
  April 13, 2010

SFDA and the Ministry of Health jointly launch examination of vaccine supervision
- Response to bribery scandal
  June 2010

China establishes “blacklist” for bribes in the pharmaceutical industry
- Provinces required to list violators publically
  July 12, 2010

China rules out scrapping death penalty for graft
- “amendment to the Criminal Law was not intended to eliminate capital punishment”
  September 29, 2010
India

CDSCO 2009
“Report on Countrywide Survey for Spurious Drugs”
January 2010

Medical Council of India (MCI) issues new ethics code for doctors
February 19, 2010

Health ministry to inspect clinical trial sites
Rising death rate of study volunteers
July 24, 2010

Supreme Court rules directors of pharma companies can be prosecuted if company found responsible for manufacturing defective drugs
“Strict Liability” finding by court
September 2010

MOH authorizes Reward Scheme for whistleblowers
Spurious or fake drugs, cosmetics and medical devices
January 2010

Six months on, Maharashtra (State) government yet to hire FDA chief
Understaffed and over-burdened
March 2010

Government initiates independent study and may set policy to discipline pharmaceutical M&As
Impact of M&A activity on competition and pricing study to be done by year end
September 2010

July 24, 2010

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Latin America

Central and South America predicted to take market share from Asia-Pacific
CMO, CRO Outsourcing (IAOP)
January 2010

Brazil revised its GMP standards
- Computer-system validation
- Periodic product revision
- More...
April 19, 2010

Mercosur Establishes Customs Code, At Long Last
“free market” includes Pharmaceuticals
To be phased in by 2012
August 4, 2010

Brazil’s Law 11.093, implementing a national serialization system for medicines
Target of June 2010 for Manufacturers and Suppliers is slipping

FDA and ANVISA signed a confidentiality agreement that permits sharing of non-public information
September 24, 2010

Timing Uncertain
Russia

Russia passes Pharmaceutical Bill
- Drug registration procedures streamlined and fees reduced
- European Good Manufacturing Practice (GMP) standards will apply by 2014
- The most controversial elements of the bill—namely plans that additional clinical trials for innovative drugs be conducted in Russia—were scrapped.
- Adopts International standards of Good Clinical Practice (GCP) and raises qualification standards for lead researchers in clinical trials.
- Government price control limited to the essential drugs sector
- Hospitals may now buy direct from manufacturer (reduced distributor impact).

Passed March 29, 2010
Law in Effect September 1, 2010

Putin fires Health Official over disagreements on pending Pharma Bill
Official sided with Industry critics
February 10, 2010

Federal Anti-Monopoly Service accused Pharma company of violating anti-monopoly legislation
Company refused to sign supply contracts with some drug distributors “without cause”
Sept 27, 2010
Asia Pacific

Thai officials seize massive haul of fake and illegal drugs
January 2010

Thai FDA raids call center to seize illegal dietary supplement and drugs
May 31, 2010

Cambodia destroyed 19 tons of fake pharmaceuticals from city pharmacies and drug smugglers
August 9, 2010

Thai FDA arrests a counterfeit drug & cosmetics producer
September 10, 2010

Taiwan consolidates oversight into new “FDA”
January 1, 2010

Vietnam PM order inquiry into US drug-company kickbacks for doctors
March 30, 2010

Newly-created (2009) “FDA” in Philippines to tighten regulation of drugs and devices
August 2010
Africa

- **South Africa’s Medicines Control Council (MCC) not addressing alleged bribery and conflict of interest charges**
  - May 28, 2010

- **Nine tons of fake medicine seized in six East African nations**
  - August 26, 2010

- **Zanzibar Declaration against counterfeit medical products and pharmaceutical crimes**
  - September 3, 2010

- **INTERPOL anti-counterfeiting program to support operations across Western and Northern Africa**
  - May 25, 2010

- **Mozambican Health Ministry concern at the illegal sale of medicines which have been diverted from the National Health Service**
  - September 19, 2010

**Year in Review — International 2010**
Thank you and enjoy the rest of the conference