Year in Review

International

2010

Pharmaceutical Regulatory and Compliance Congress

Ernst & Young

Quality In Everything We Do

Major regulatory bodies around the world are sharing non-public information

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

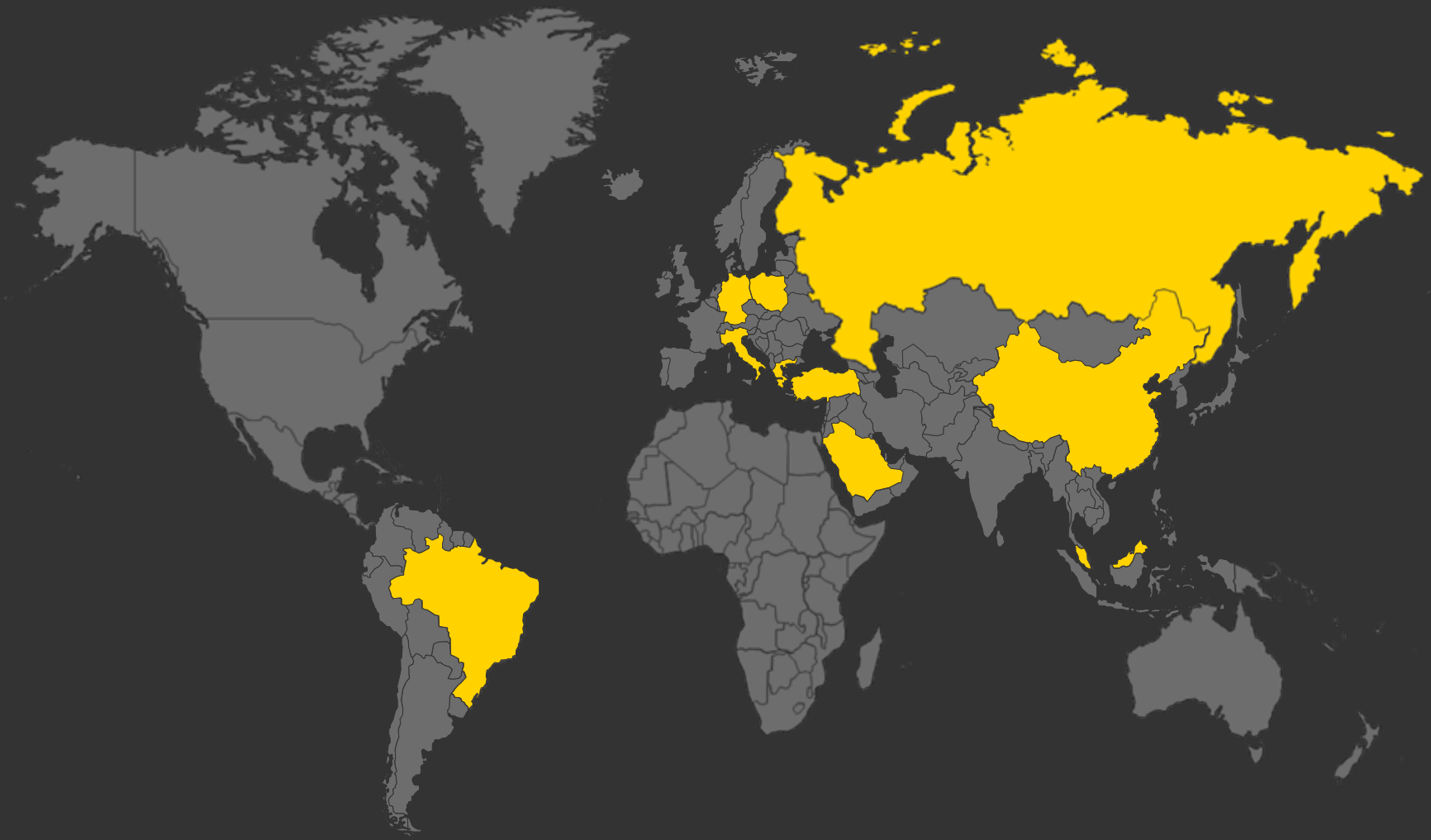
- UK Bribery Act — Guidance & Consultations begin ahead of implementation in 2011

- 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

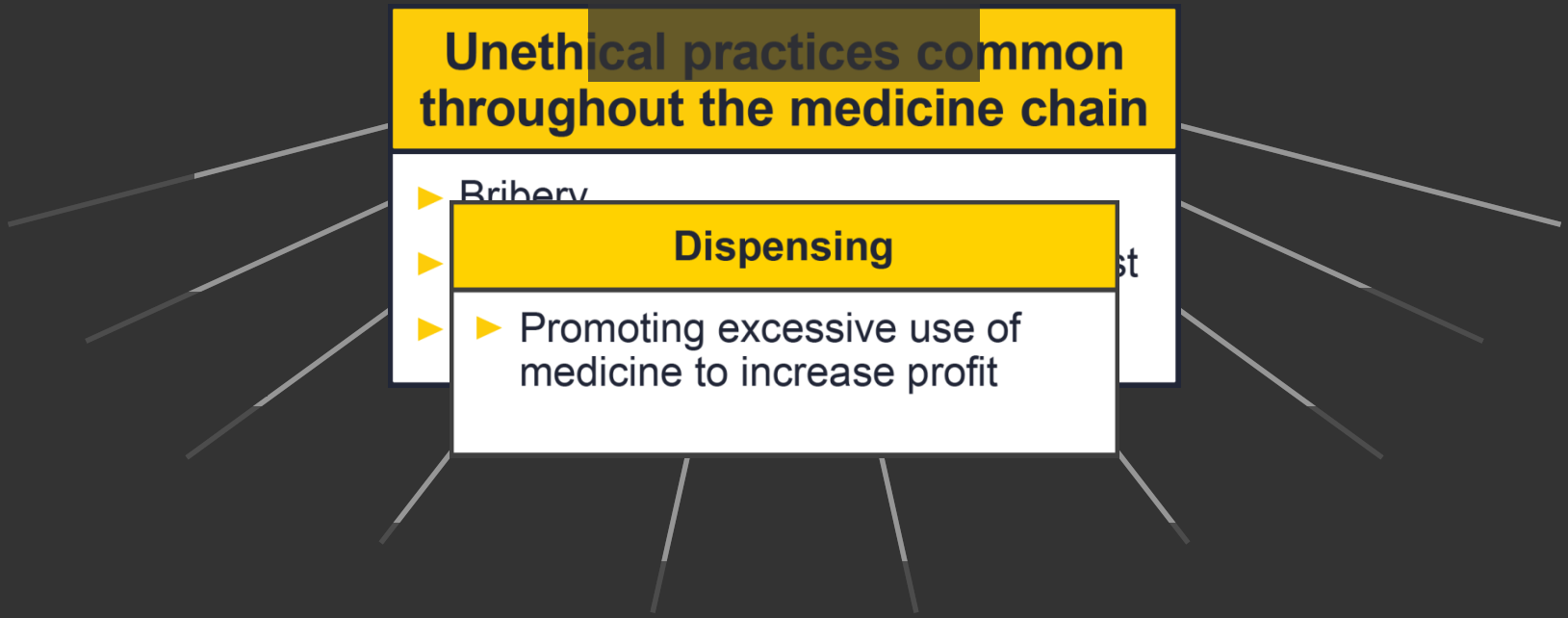
- Worldwide — Implementation of OECD ban on foreign bribery improves but still weak

US FCPA Probe of Pharma — reported locations



W.H.O. indentifies common unethical practices in pharmaceutical supply chain

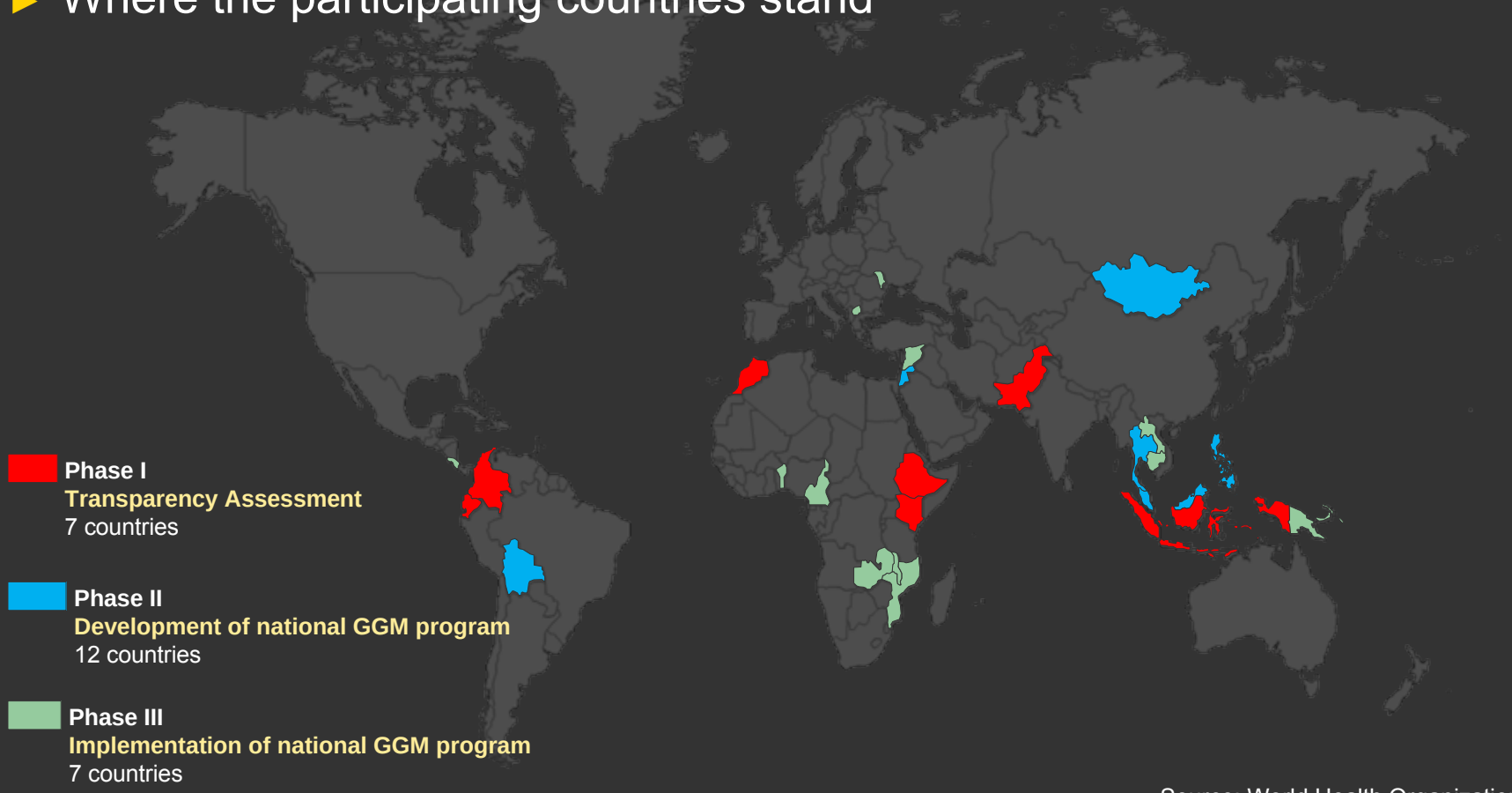
Key steps of the medicine supply chain and unethical practices in the pharmaceutical sector



Source: World Health Organization, December 2009

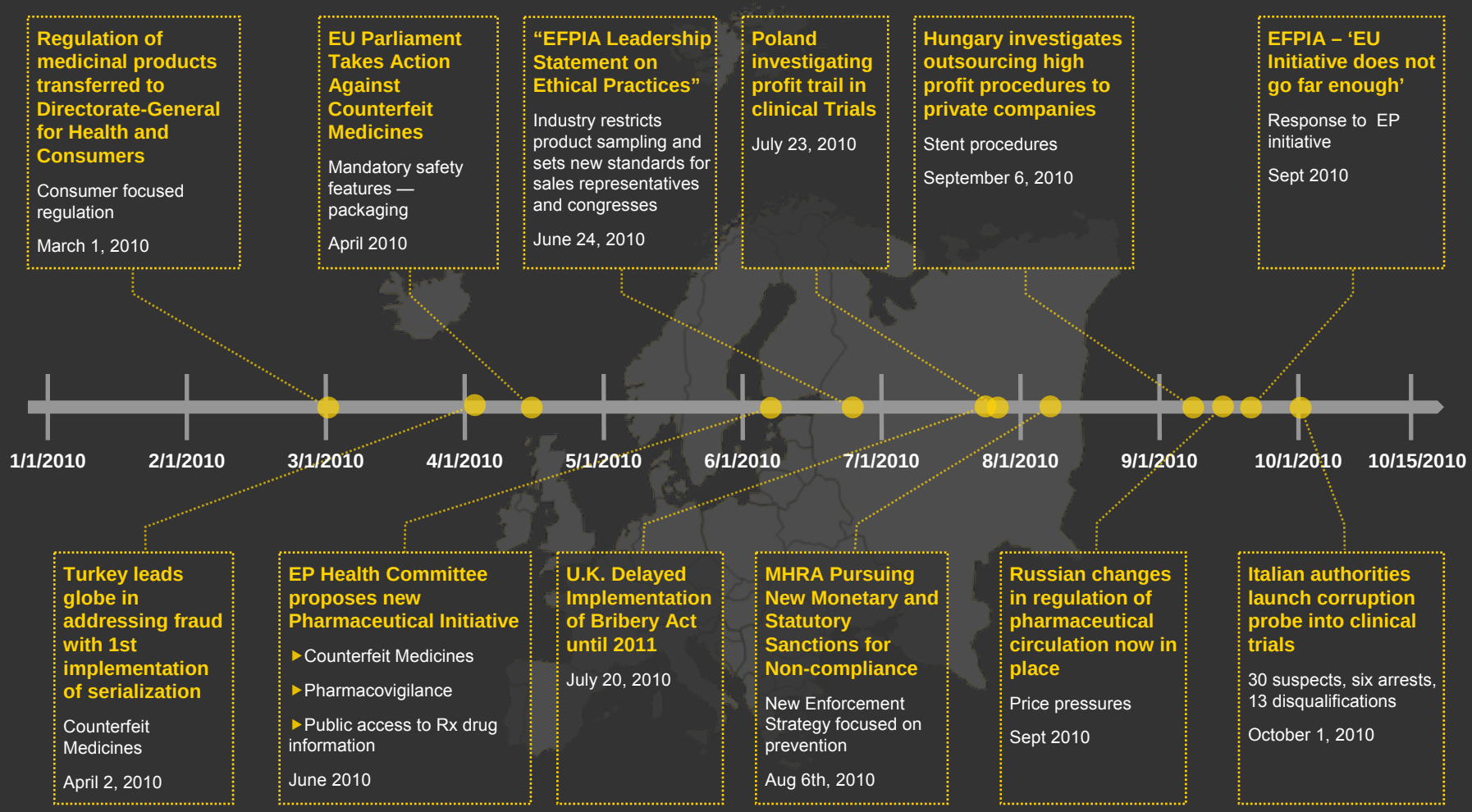
W.H.O.’s Good Governance for Medicines (GGM) Program

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



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
"EFPIA Leadership Statement on Ethical Practices"
Industry restricts product sampling and sets new standards for sales representatives and congresses
June 24, 2010
Poland investigating profit trail in clinical Trials
July 23, 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
1/1/2010
2/1/2010
3/1/2010
4/1/2010
5/1/2010
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7/1/2010
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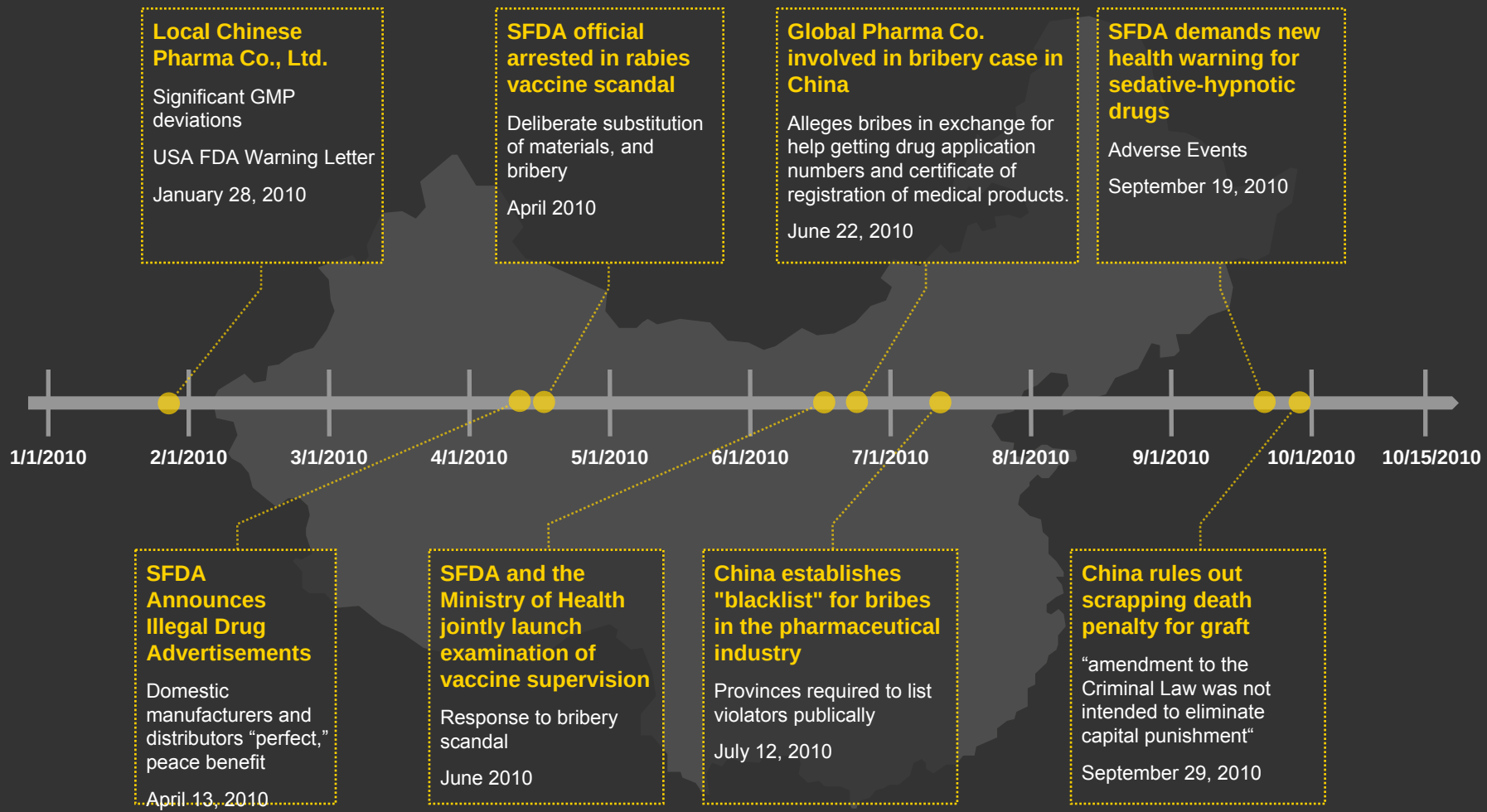
9/1/2010
10/1/2010
10/15/2010
Turkey leads globe in addressing fraud with 1st implementation of serialization
Counterfeit Medicines
April 2, 2010
EP Health Committee proposes new Pharmaceutical Initiative
▸Counterfeit Medicines
▸Pharmacovigilance
▸Public access to Rx drug information
June 2010
U.K. Delayed Implementation of Bribery Act until 2011
July 20, 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

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
1/1/2010
2/1/2010
3/1/2010
4/1/2010
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6/1/2010
7/1/2010
8/1/2010
9/1/2010
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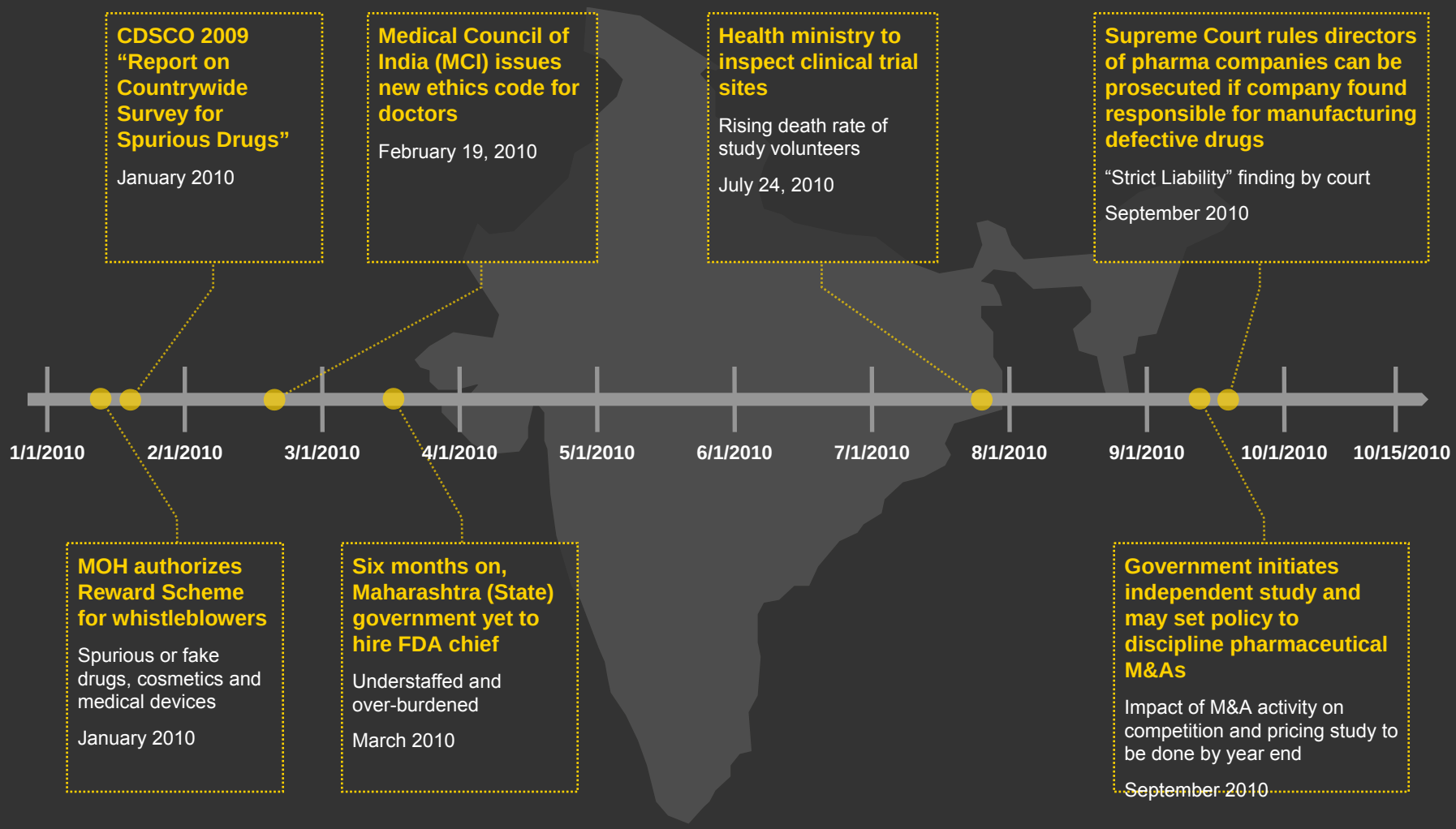
10/15/2010
SFDA Announces Illegal Drug Advertisements
Domestic manufacturers and distributors “perfect,” peace benefit
April 13, 2010
SFDA and the Ministry of Health jointly launch examination of vaccine supervision
Response to bribery scandal
June 2010
China establishes "blacklist" for bribes in the 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
1/1/2010
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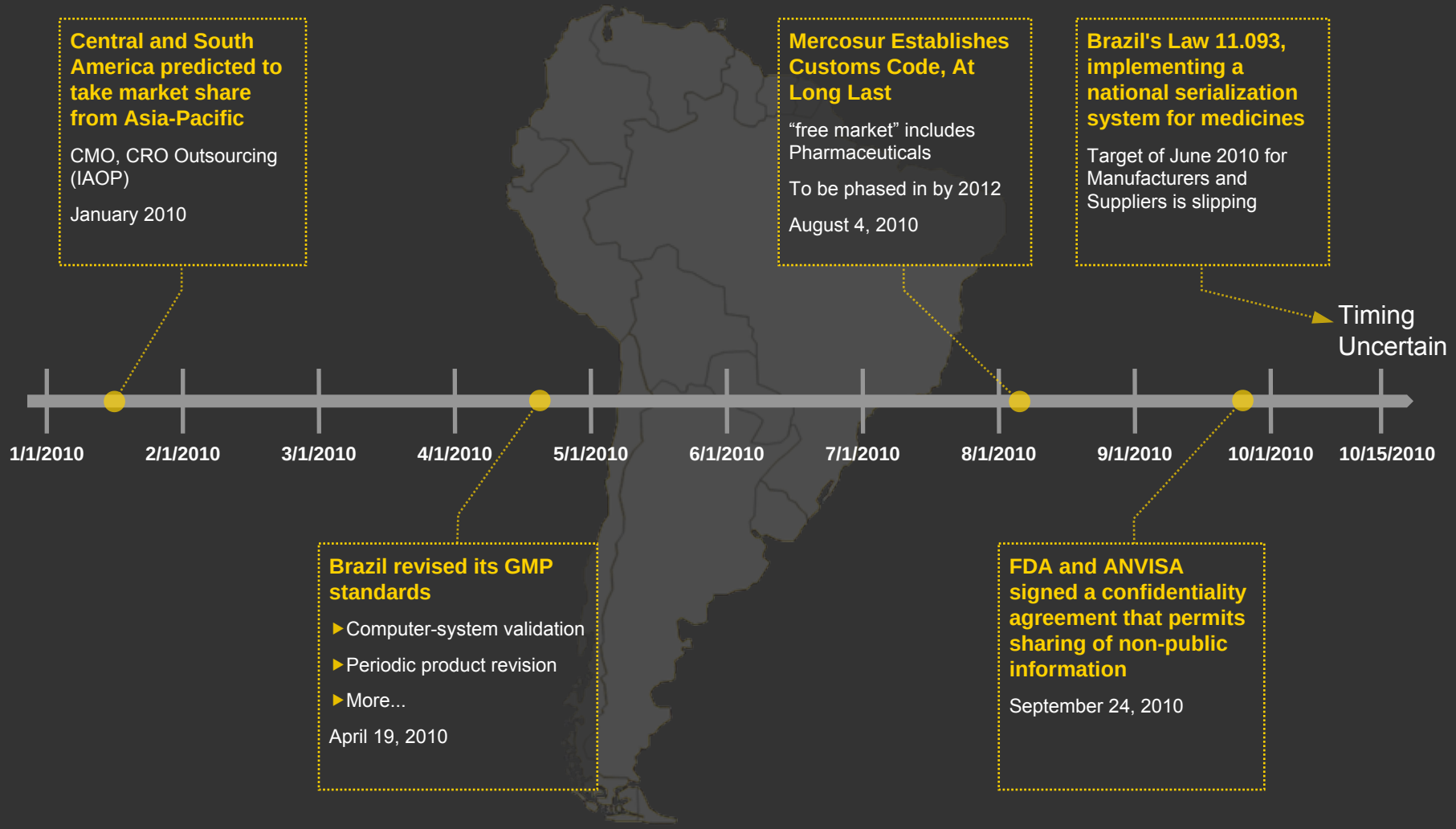
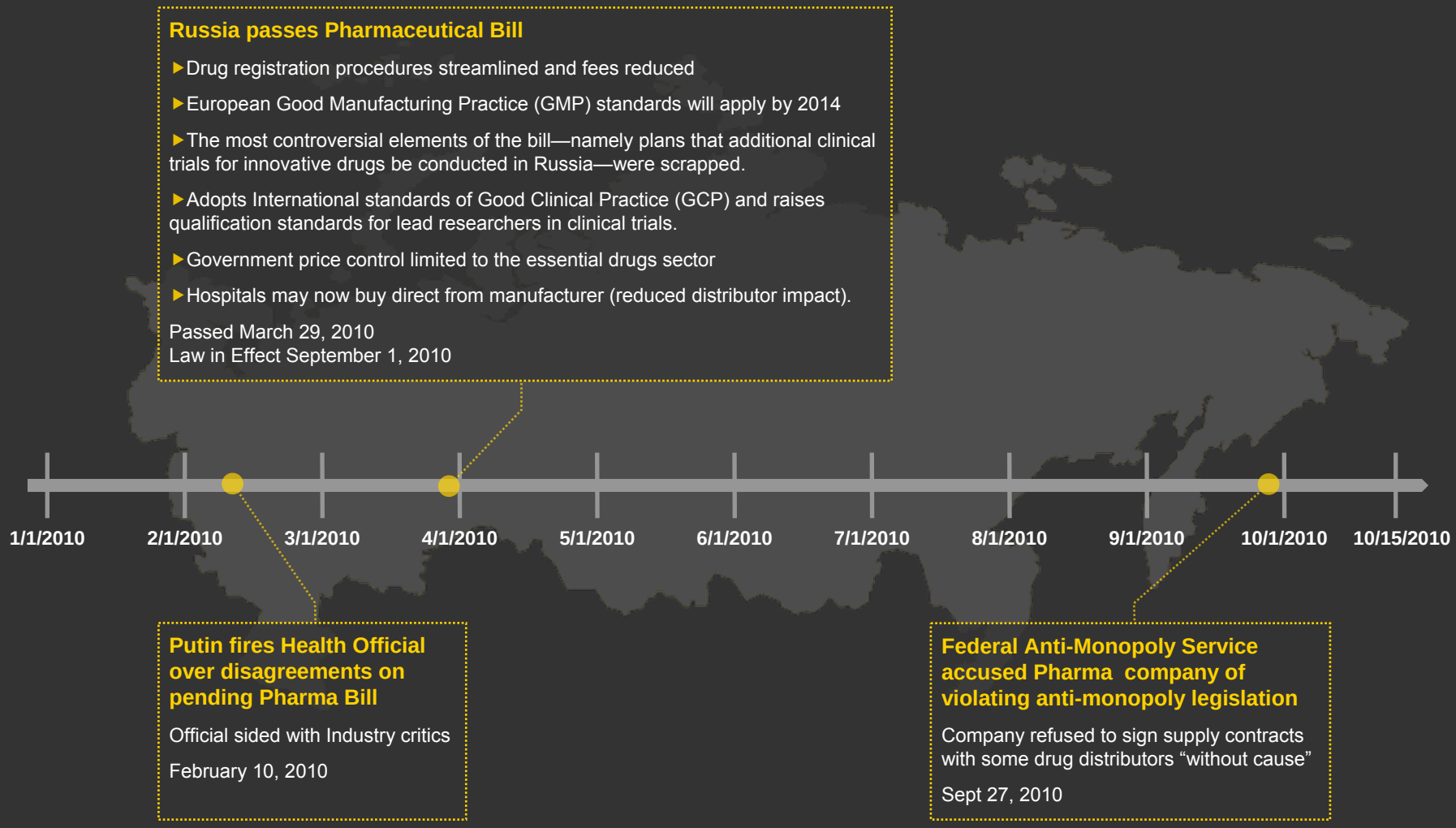
6/1/2010
7/1/2010
8/1/2010
9/1/2010
10/1/2010
10/15/2010
MOH authorizes Reward Scheme for whistleblowers
Spurious or fake drugs, cosmetics and medical devices
January 2010
Six months on, Maharashtra (State) government yet to hire FDA chief
Understaffed and over-burdened
March 2010
Government initiates 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

Latin America



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
1/1/2010
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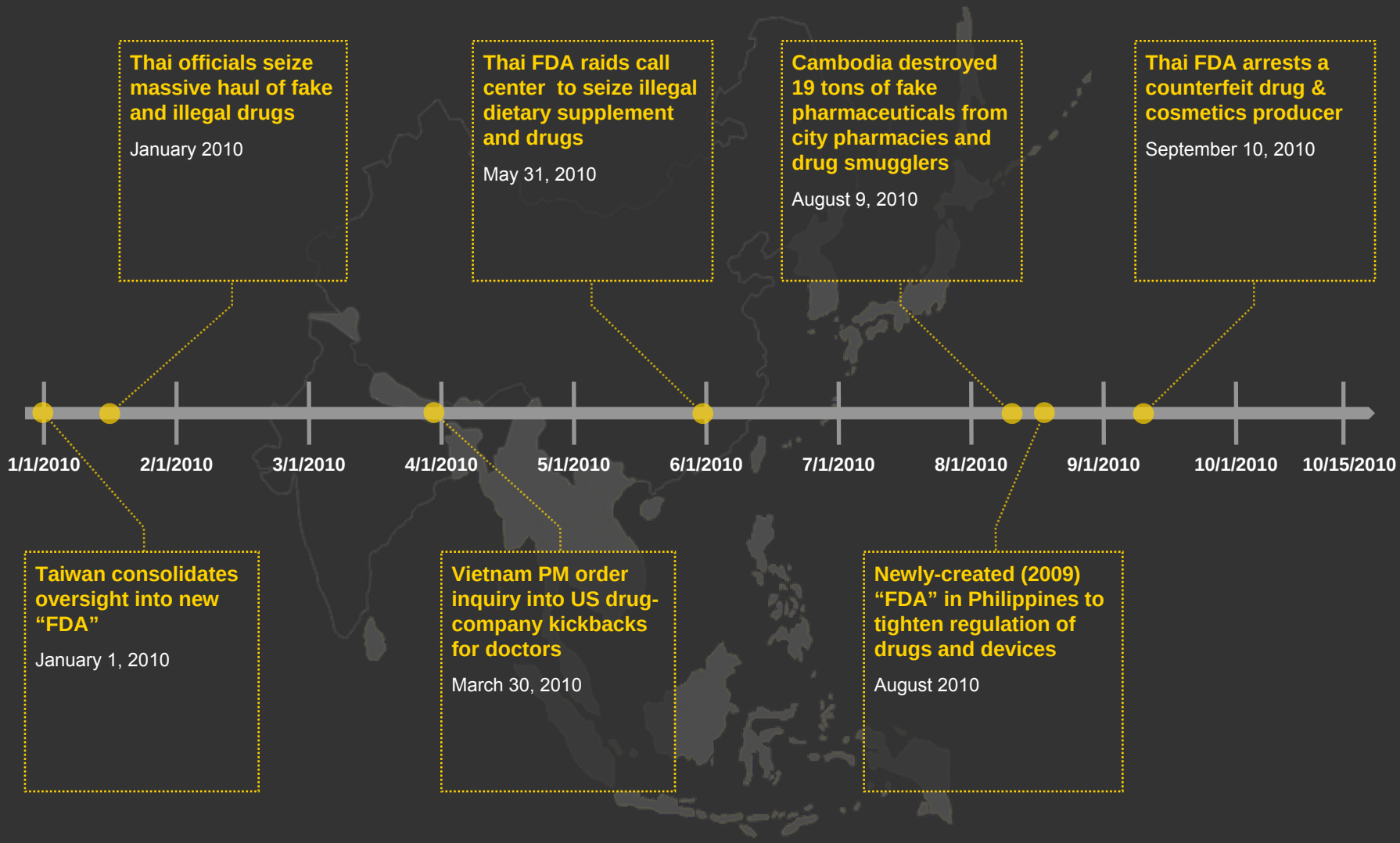
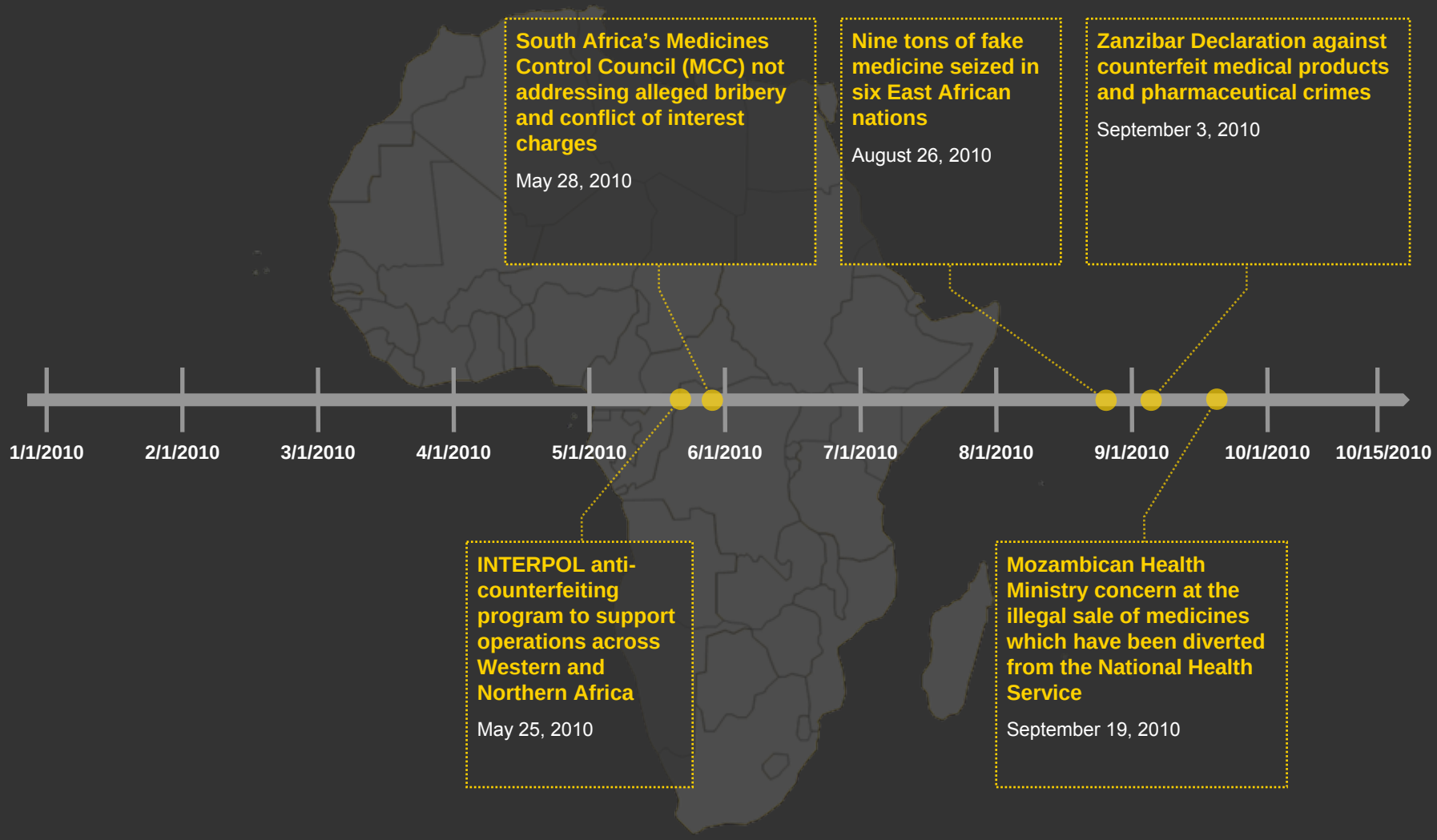
5/1/2010
6/1/2010
7/1/2010
8/1/2010
9/1/2010
10/1/2010
10/15/2010
Putin fires Health Official over disagreements on pending Pharma Bill
Official sided with Industry critics
February 10, 2010
Federal Anti-Monopoly Service accused Pharma company of violating anti-monopoly legislation
Company refused to sign supply contracts with some drug distributors “without cause”
Sept 27, 2010

Asia Pacific



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
1/1/2010
2/1/2010
3/1/2010
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6/1/2010
7/1/2010
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10/1/2010
10/15/2010
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

Thank you and enjoy the rest of the conference