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Overview of Recent Chinese Laws and Regulations: Update and Forward-looking

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Overview

- In 2013 and 2014, there have been more enforcements in China than legislations
  - On-going criminal investigation against a multinational pharmaceutical company
  - Increasingly aggressive AIC investigations against multinational pharmaceutical and device companies on promotional activities
  - Aggressive NDRC antitrust investigations against, among others, pharmaceutical companies, with medical device companies potentially to be the next targets
  - Ongoing investigations on drug prices by NDRC (costs & margin)
  - State audit on major medical academic associations
- Other than legislations, there have been significant "change of practice"

Update on Recent Regulations

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Blacklist System for Commercial Bribery

- Initially created in January 2007, "enhanced" by National Health and Family Planning Commission (NHFPC) in December 2013, effective from March 1, 2014
  - If a drug manufacturer/distributor is penalized for "commercial bribery", it (including its agents) may be black-listed by the provincial health authority
  - Report to NHFPC
  - Consequence
  - Legal basis?

Publication of Penalty Decisions

- The recent regulations by the State Council and SAIC on publication of enterprise information could significantly change the risk profile of companies under the blacklist system.
  - Companies are required to self disclose any administrative penalties they receive on the Enterprise Credit Information Publication System, (http://gsxt.saic.gov.cn), a website established by SAIC.
  - ECPIS information should include date, case number, facts, legal basis and results of each penalty decision as well as the agency issuing such decision.
  - Other government agencies should also publish their penalty decisions either on ECIPS or other public websites.
  - ECIPS information will remain publicly availably for 5 years

Nine Prohibitions on Healthcare Providers

- An internal NHFPC notice on December 26, 2013, regulating hospitals and HCPs.
  - No sponsorships or donations directly to hospital departments or HCPs
  - No disguised sponsorships (e.g., site-seeing tours)
  - No entertainment activities paid or arranged by drug or device companies at "for-profit entertainment sites"
  - No collection of prescription data at individual physician level
  - No kick-backs
  - No attendance on drug and device product "*promotional*" activities
- Reiteration of existing, scattered anti-corruption requirements, with ambiguities to be clarified

Patient Data Protection

- **Interim Measures for Administration of Population Health Information**
  - Issued by NHFPC on May 13, 2014
  - Regulating healthcare institutions in managing patient information
    - ✓ "Basic personal information and specific medical service information generated in the course of medical services"
    - ✓ No storage on servers located outside the PRC
- **Impact on the industry?**
  - Clinical studies
  - Pharmacovigilance
  - Cloud services

Recent Change of Practice

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CFDA's Review Practice

- Use of data generated from Multiregional Clinical Trial (MRCT) to support drug registration in China
  - ✓ One step approval v. two-step approval v. three-step approval
- Is this truly a violation of CFDA regulations?
- Change of CFDA's position would significantly delay the product launch to the China market

Collection of Biological Samples in Clinical Studies

- Regulations on Use of Chinese Human Genetic Resources
  - Sino-foreign collaboration *involving* HGRs
    - ✓ Approval by China HGA Administration Office before any agreement is signed
    - ✓ Joint IP ownership
    - ✓ Biological samples owned by the Chinese partner
    - ✓ Review and approval is processed every 3 months
  - No definition of Sino-foreign collaboration, recent informal interpretation expands to clinical trials sponsored by foreign companies in China
  - An extra layer of approval will further delay clinical trials
- Companies have to understand what they are complying with
  - a written law or an informal interpretation?

Forward Looking

What's Next?

- In the coming months, it would be critical to watch
  - ✓ Whether the business model of multinational pharmaceutical companies would be criminally convicted
    - Academic promotion v. per se bribery
  - ✓ NDRC pricing regulations on drugs and high-value devices
  - ✓ New drug/device procurement rules
  - ✓ CFDA regulation on drug registration (e.g., patent linkage)

What's Next?

- China is in the process of revising certain laws and regulations affecting R&D and commercial operations of pharmaceutical companies in China
  - ✓ Drug Administration Law
  - ✓ PRC Anti Unfair Competition Law
  - ✓ PRC Patent Law
  - ✓ PRC Regulations for Administration on Human Genetic Resources

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Thank You!

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