BAKER & MCKENZIE

Country Compliance Update: Japan

MINI-SUMMIT XIII

Chia-Feng Lu JD, Baker & McKenzie, Tokyo

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Understanding the market structure

The leading impacts of Abenomics

A noticeable decrease in hospital visits and pharmaceutical sales is unlikely.

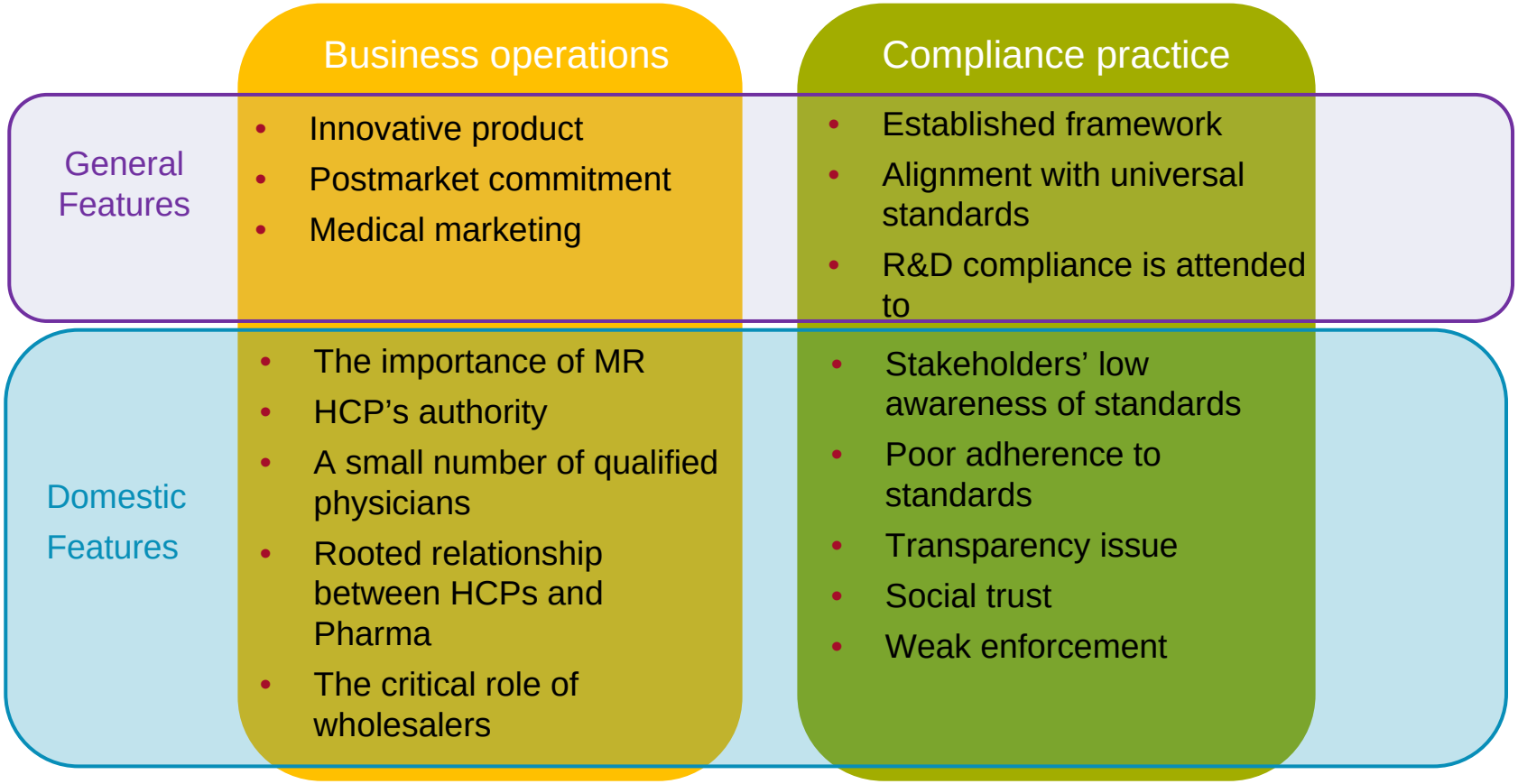
Too early to evaluate the real contributions of Abenomics at the current stage because the so-called “third arrow” of structural reforms, most relevant to pharma companies, is still on its way.

The aging population and longer life expectancy are important factors. Innovation is key to success in Japan, and these efforts may be valued under the current regulatory environment and reimbursement system.

Competition in scientific innovation, such as regenerative medicine, and growths in the generics and biosimilars markets are in the spotlight.

Compliance practice features

The market landscape vs. compliance practice



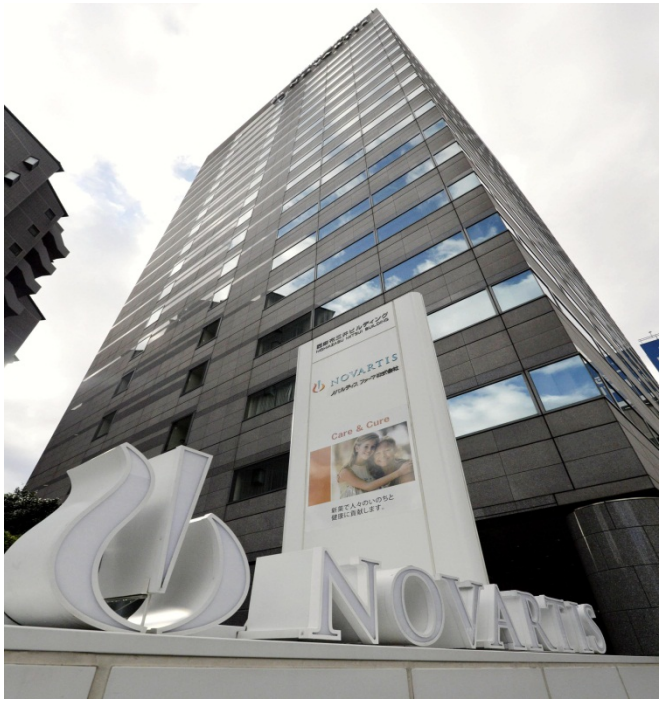
Case study

Novartis KK

- From late 1990 to early 2010
- Investigator initiated trial

- Issues:
  - Fabrication/falsification of data
  - Illegal promotional activities
  - Conflict of interest
    - Labor
  - Failure to report safety event in time
  - Violation of Personal Information Protection Law
  - Breach of confidentiality

- Criminal prosecution
- Third party investigation vs. internal investigation



Takeda

- From late 1990 to mid 2000
- Investigator initiated trial

- Issues:
  - Conflict of interest
    - Monetary
    - Labor
  - Illegal promotional activities

- Third party investigation vs. internal investigation

Kyowa Hakko Kirin

- 2012 and 2013
- Issues:
  - Conflict of interest
    - Monetary
    - Labor
  - Disclosure of patient information
- Internal investigation

Preventive and corrective measures

Framework of governance

Name	Nature	Oversight or enforcement agency	Action
Pharmaceutical Affairs Act and associated regulations	Mandatory	Ministry of Health and Labor Welfare	Criminal sanctions and/or monetary penalties; but insufficient authorities to discover the evidence
Penal Code		Ministry of Justice	
Antitrust Law, Act against Unjustifiable Premiums and Misleading Representations		Fair Trade Commission	
Fair Competition Code of the Ethical Drug Manufacturing Industry	Semi-legal binding	Self-regulation authorized by Fair Trade Commission	Written warning if failure to cooperate; remedial actions if violation is found
JPMA Code of Practice	Voluntary	JPMA	Membership suspension; potential reputation harm
Fair Competition Code of the Ethical Drug Manufacturing Industry	Voluntary	JPMA	
JPMA Transparency Guideline	Voluntary	JPMA	

Examples of local consideration - JPMA's CoP

Stakeholders

- Researchers
- Wholesalers

R&D

- Disclosure of payments for R&D academic research fees, etc.
- Appropriate self-control from the standpoint of animal welfare for laboratory animals

Information dissemination

- Press releases, disease awareness ads, IR information
- Digital communications such as social media

Collaboration with Patient Organization

- Disclosure of payment made by companies

Relationship with Wholesalers

- Establish company standards for provision of money, goods, food and drinks.

JPMA transparency guideline

Scope of disclosure

- R&D expenses
- Payments related to academic research grants
- Honoraria
- Payments related to provision of information
- Other payments (e.g., hospitality, social courtesy)

Payor

- JPMA member companies
- Member companies' affiliates based in Japan

Recipient

- Medical institutions, medical related organizations, HCPs, etc.
- Include payments through third parties

Excluded payment

- Samples
- Payment made by overseas affiliates
- Payments made to recipients whose primary place of practice is outside of Japan
- Payments to patient organizations

Feature

- No threshold for the amount of the payment to be disclosed
- No disclosure of the payments to individual HCPs
- Disclosure made on the company's website
- Disclosure of the preceding fiscal year

Enforcement

- Voluntary and non-binding
- Approved by agreement of all member companies
- Start of disclosure in fiscal year 2013

Patient-centered approach vs. Accountability

Regulatory oversight

- Proactive stance
- Whistle blower
- Transparency
- Joint ethical guidelines regarding people involved in medical research

Joint ethical guidelines regarding people involved in medical research

- Integrate clinical research and epidemiological studies
- Mandating of audits and monitoring of work by the principal investigator by third parties
- Ethical Review Board members could also investigate and comment on research to ensure its reliability.

Current practice

- Conduct an independent investigation
- Appoint a proper Monitor in oversight of the performance of compliance structure or relevant programs

- Reshuffle the company management
- Set up Compliance Advisory Board
- Establish dedicated department or task force team

- Review the current program
- Introduce specific guidelines or SOPs
- Devise new controlling procedures

- Perform internal E-learning
- Provide training to service providers
- Cultivate new compliance culture

- Build up the screening and evaluation of donations system
- Acquire appropriate talents

Thank you very much

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Chia-Feng is a member of the Pharmaceuticals, Healthcare and Life Sciences Industry Group. He assists clients in developing strategies for research and development, regulatory compliance, market access, and business development and licensing. He has extensive experience in formulating compliance strategies and devising compliance programs, and has overseen the implementation of the global compliance structure in more than 70 jurisdictions during his secondment with a multinational pharmaceutical company. In his current capacity, he serves as a leading compliance counsel to a flagship biotech company in Asia, and to one of the largest specialty pharmas in the world.

Prior to joining the Firm, he worked at a multinational pharmaceutical company and a consulting firm, handling market entry, product life-cycle management, and R&D portfolio assessment. Chia-Feng also holds appointments as an adjunct academic of the Faculty of Medicine at Kyoto University, and the School of Pharmacy at Kitasato University in Japan.