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China's Ongoing Healthcare Reform and Compliance Changes to the Pharma Industry

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I. Overview of China's Healthcare Reform

Background

- January 1997: the Chinese Government launched the first round of health care reform
- February 2000: The Chinese Government published a plan on health care reform in urban areas
- July 2005: The Chinese Government acknowledged that the reform did not achieve its expected goals
- August 2006: A new round of reform started, a State Council Steering Committee for Coordination of Health Care Reform was set up
- April 2009: Health care reform was officially launched; a series of reform plans were announced
- 2010 to 2014: Annual Work Plans

Health Care Reform: 1997 vs. 2009

1997

- Designed to play down government's role and lessen its financial burden
- Market-oriented and profit-driven
- Insufficiently funded
- Unequal distribution of medical resources
- Focusing on treatment, not prevention
- Rural Cooperative Health Care System (RCMCS) became dysfunctional

2009

- To strengthen government's leading role in the reform
- Health care positioned as a "public service", i.e. *not-for-profit*
- To substantially increase government funding
- Equalization is a key objective
- To reduce health risks by prioritizing prevention
- To rebuild RCMCS

Framework

- **Mission**

To provide safe, effective, convenient and affordable health care services to all urban and rural residents

- **Five Priorities**

- ✓ Expand the basic health care coverage
- ✓ Build up the National Essential Drug System
- ✓ Upgrade the grassroots health care system
- ✓ Provide public health care services equally to all residents
- ✓ Reform the public hospital system

Timeline

- **2009**
 - ✓ Start-up
 - ✓ To implement five health care programs in priority
- **2011**
 - ✓ To set up the framework for each priority of the new health care system
- **2020**
 - ✓ To achieve the ultimate goal of the health care reform, i.e., everyone has access to basic health care services

Regulatory Regime (1)

Key Government Stakeholders

- **State Council Steering Committee**
 - ✓ Representatives from 16 agencies, most influential ones being:
 - National Health and Family Planning Commission (NHFPC)
 - National Development and Reform Commission (NDRC)
 - Ministry of Finance (MOF)
 - Ministry of Human Resources and Social Security (MOHRSS)
- **NHFPC**: medical institutions, medical practice, disease control
- **NDRC**: pricing
- **MOF**: government financing
- **MOHRSS**: social security and reimbursement

Regulatory Regime (2)

What has happened since 2009?

- Essential Drug List has been created and updated
- Reimbursable Drug List has been created and updated
- Public hospitals are required to purchase drugs through a centralized procurement process at the provincial level
- Certain high-value medical devices are subject to a similar centralized procurement process
- Pricing of drugs and high-value medical devices are being scrutinized
- Increasing preference over locally made drugs and medical equipment

2014 Work Plan

- To establish a proper compensation mechanism on public hospitals
 - ✓ To eliminate margins imposed by public hospitals on drugs
 - ✓ To increase government financing and control costs
- To adjust medical service prices
 - ✓ To reduce prices of drugs and high-value devices
 - ✓ To reduce treatment expenses of large medical equipment
- To improve the existing drug procurement system
 - ✓ Cross-province procurement and more information sharing
 - ✓ More involvement by the hospitals
 - ✓ Volume-based pricing mechanism in procurement
- To encourage private investments in non-profit healthcare sector

II. Compliance Challenges to the Pharma Industry

Compliance Challenges (1)

Issues that may give rise to compliance risks

- Financing of public hospitals
- Compensation of physicians
- Restriction on medical practice (physicians and nurses)
- Physicians/patients disputes
- Lacking of coordination among various agencies
- Lacking of clarification on regulations

Compliance Challenges (2)

❖ **Product Supply**

- ✓ Post-bidding rebates
- ✓ Preference over local products
- ✓ Hospital-controlled retail pharmacies
- ✓ Trusted management of hospital pharmacies

❖ **Interactions with physicians and hospitals**

- ✓ Sponsorships and grants
- ✓ Clinical studies

❖ **Practical dilemma**

Thank you !