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

<table>
<thead>
<tr>
<th>1997</th>
<th>2009</th>
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<td>• Designed to play down government’s role and lessen its financial burden</td>
<td>• To strengthen government’s leading role in the reform</td>
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<td>• Market-oriented and profit-driven</td>
<td>• Health care positioned as a “public service”, i.e. <em>not-for-profit</em></td>
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<td>• Insufficiently funded</td>
<td>• To substantially increase government funding</td>
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<td>• Unequal distribution of medical resources</td>
<td>• Equalization is a key objective</td>
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<td>• Focusing on treatment, not prevention</td>
<td>• To reduce health risks by prioritizing prevention</td>
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<td>• Rural Cooperative Health Care System (RCMCS) became dysfunctional</td>
<td>• To rebuild RCMCS</td>
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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!