Facilitating the Access to Medicine: China’s Perspective and the Role of SFDA

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Key Messages

- SFDA, like other regulatory agencies in the world, recognizes its responsibility in ensuring that the safe and effective medicine is readily available to its citizens in a timely manner;

- However, Access to Medicine requires that the drug products are not only made available but also available on an affordable basis to meet health priority and/or unmet medical needs of the country.

- The strategies consist of:
  - Establishing a national essential drug system to address the affordability issues;
  - Initiating a national New Drug Development Plan, similar to that of US FDA’s Critical Path Initiative or EMEA’s Innovative Medicine Initiative, to promote drug innovation;
  - Building a science-based decision-making capacity to address both local demands and challenges and that of global drug development.
## Growth of Chinese Pharmaceutical Market Size

<table>
<thead>
<tr>
<th>Year</th>
<th>China</th>
<th>Global</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total Sales (Billion)</td>
<td>$9.5</td>
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<tr>
<td></td>
<td>Growth Rate (%)</td>
<td>28%</td>
</tr>
<tr>
<td>China</td>
<td>Total Sales (Billion)</td>
<td>$550</td>
</tr>
<tr>
<td>China</td>
<td>Growth Rate (%)</td>
<td>7%</td>
</tr>
</tbody>
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### Data Source:
China’s contributions to addressing the issues related to access to medicine

**From a global perspective:**
- More than 1,500 API’s are manufactured in China and many of them are exported to the rest of the world;
- The leading producer of Artermisinin that is widely used in treating Malaria in developing countries in the world;

**From a domestic perspective:**
- Expansion of medical insurance coverage in China;
- Free distribution and administration of preventive vaccines in China;
- Building a national essential drug system
Basic Principles in Building China Essential Drug System:

- To put people first
- To focus on the needs of China
- To find right balance between government and market force
- To address both short-term and long-term objectives

Building a national essential drug system (including policy, list and practice) addresses the issue of affordability and represents the government commitment in protecting and promoting the health of its citizen.

Data Source: Mr. MingLi Shao, the commissioner of Chinese SFDA, China Pharmaceutical News August 16, 2008
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The government plays an important role in promoting drug innovation and new drug development. We need new treatment options to meet the unmet medical needs of our citizens.

The Initiatives in Promoting New Drug Development:

- Critical Path Initiative (FDA 2002)
- The Innovative Medicine Initiative (EU 2007)
- New Drug Development Plan (China 2008)
Increased R&D Activities of China Pharmaceutical Industry

- Chinese pharmaceutical industry is transforming from a generic-dominated model to a one that promotes drug innovation.

- In the last five years ending 2005,
  - 45 drug products approved as new drugs
  - 41 new drug products currently under the NDA review
  - 109 entered into clinical development

- Between 1998 and 2007, a total of 78 new drugs were approved in China.
Increased R&D Activities by MNCs in China

- Global drug development, as part of globalization process, is coming to Asia, the emerging markets in particular. The regulatory bodies in emerging markets need to study it and understand it in order to better carrying out their public health mission to their citizens.
Ensuring a reasonable regulatory review timeline is important in enhancing patients’ access to medicine. However, the reasons behind a delay in regulatory application review timeline are often multifactorial, including that from both the industry and the agency.

Standard Clinical Trial Application Review and Approval Timeline in China:

- Technical Review (90 Days)
- Query to Sponsor
- Administrative Review (30 Days)
Our goal is to not just improve regulatory review timeline but to do it in a sustained manner, which requires an appropriate strategy for resource allocation, a transparent science-base decision-making process consisting of good review practice, and professional staff with a high level of technical competency.
Improving Resource Issue in the Regulatory Agency:
- SFDA/CDE Review Capacity vs. Workload

Improving Regulations and Process
- Newly Revised Provision of Drug Registration (October 1, 2007)

Key Guiding Principles
- To promote drug innovation;
- To focus on unmet medical needs;
- To build a transparent and consistent high quality system;

Process Improvement Related to Global Drug Development:
- 25% Reduction in CSA review time for new drugs
- ICH-CTD format is acceptable
- More flexible in cGMP document requirement
- Simplified sample testing requirement
Improving Regulations and Process
- A Special Review Procedure is Under Development

Issues under discussion to built a quality system

- Sponsor-Initiated Consultation Meeting
- Conditional Approval
- Submitting information during the review process
Conclusions

- Improving Patient’s Access to Medicine is of Public Health significance; SFDA is committed to this objective;

- Reasons behind the insufficient access to medicine are multifactorial. Improving the regulatory review timeline requires the combined efforts from both regulatory agency and the pharmaceutical industry

- A high quality review system will eventually lead to a sustained reduction in clinical trial application review time, therefore enhancing the patients assess to medicine.