PRC Healthcare Sector 2013 Work Priorities

Overview

PRC healthcare regulators have stated they will expand reform of the pharmaceutical and healthcare system in 2013 by focusing on improving medical services, public health, and equitable access to affordable medicine, as well as increasing efficiency in the healthcare regulatory system. Major structural changes were made to agencies charged with regulating healthcare recently. The Ministry of Health (MOH) was consolidated into the new National Healthcare and Family Planning Commission, and the State Food and Drug Administration (SFDA) was elevated to a ministry-level agency directly under the State Council. Though the healthcare sector’s 2013 work priorities were released prior to the recent institutional reforms announced at the March 2013 National People’s Congress, the priority areas to guide key agencies’ work remain unchanged.

Work Priorities

- **Further healthcare reforms** Improve and expand coverage of the cooperative medical system in rural areas; ensure the quality and availability of essential drugs in hospitals; continue public hospital reform and develop relevant pilot projects; cultivate more medical talent, especially in underserved areas; and conduct large research and development (R&D) projects including new drug development and infectious disease treatment.

- **Ensure drug safety** Guarantee drug safety through effective enforcement of newly revised pharmaceutical good manufacturing practices (GMP) and good supply practices (GSP), including timely completion of inspection and certification processes.

- **Risk control and prevention** Establish a supervision system to better identify and pre-empt risks in healthcare, public health, and drug and food safety, an initiative that will require more inspection and risk screenings of essential drugs, high-risk drug categories, Chinese-patented drugs, and drug ingredients; enforce the 2013 National Food Safety Risk Supervision Plan.

- **Regulatory system reform** Improve review, approval, and inspection in food and drug regulations; ensure that drug product reviews are science-based and focused on data; and balance authority between national and local administrators to allow local authorities to play a more active role in pharmaceutical administration.

- **Anti-corruption** Fight corruption in pharmaceutical procurement and sales, and in entities that provide technical support for food and drug approval and inspection (this includes some drug testing institutes delegated by the government to test new drugs that are intended for sale in the market).

Comparison to 2012 Work Priorities

While many 2012 priorities are similar to last year, there are two new areas of focus for 2013.
Essential drug procurement  Centralize essential drug procurement at the provincial level to restrict sub-provincial level procurement; integrate the bidding, procurement, and payment procedures at the provincial level; and improve essential drugs list administrative measures and optimize the selection mechanism of essential drugs.

Public Hospital Reform  Make greater advances in public hospital reform in 2013 by delegating more management to public hospitals and have more than half of county-level hospitals participating in reform pilot projects.

Summary Highlights from Agency Plans

MOH’s work plan calls for the ministry to:

- **Expand healthcare system reform**  Improve the new rural area cooperative medical system; consolidate the essential drug administrative system; complete the essential drug catalogue administrative measures; and restrict essential drug procurement to be conducted online and centralized in the provincial level
- **Promote public hospital reform**
- **Improve work in dealing with health emergencies, disease control and prevention, and maternal and child healthcare**
- **Reinforce medical services administration and secure healthcare quality and safety**
- **Reinforce food safety and strengthen health inspection**  Focus on food safety and risk monitoring and evaluation, as well as standards-setting.
- **Boost development of Traditional Chinese Medicine (TCM)**
- **Cultivate more medical talent**
- **Encourage technology innovation and the use of healthcare sector information technology to support healthcare reform**

SFDA lays out key 2013 priorities that include calls for the agency to:

- **Ensure drug safety**  Discover and control risk; effectively enforce newly revised pharmaceutical drug good manufacturing practices (GMP) and good supply practices (GSP); and strictly meet criteria and timelines to establish a drug safety administration system.
- **Improve the regulatory system**  Conduct research on the pharmaceutical regulatory system; clarify drug safety responsibilities; push drug safety regulations throughout the supply chain; and explore risk management models to improve drug safety.
- **Strengthen regional risk controls of pharmaceuticals**  Focus on industry clusters of drug substances, excipients, Chinese herbal components, and traditional Chinese medicinal extracts.
- **Specific Projects**  By the end of 2013, conduct quality evaluations on 50 categories of generic drugs; launch 1,500 projects to improve drug standards; draft and revise 105 medical device industry standards; strengthen standards-setting for health food and cosmetics; and create ingredients requirements and testing methods for 35 types of food supplements.

Sources