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CFDA Unveils New Details Of Drug Safety Plan To Give Provinces More Power

In his first major speech since SFDA's reorganization, newly appointed China FDA Deputy Commissioner Yin Li laid out the agency's plans to delegate drug safety oversight to provincial regulators but place responsibility on manufacturers.

BEIJING – China set a lofty goal of reaching international standards of drug safety by 2015, which will require more effort from regulators, CFDA Deputy Commissioner Yin Li said during the annual Drug Information Association China conference in Beijing May 13.

The reorganized CFDA – elevated to the role of a ministerial agency – received a mandate from China's State Council to streamline regulatory resources and enhance overall food and drug safety supervision, Yin said.

"We will reform and improve pharmaceutical safety monitoring, scientifically allocate power between the central and local regulators … ensuring a regulatory system that is accountable, protected by law and reasonably delegated," Yin said.

According to an ambitious plan released March 31, provincial regulators will hold more authority than they have in the past. Provinces will handle pharmaceutical contract manufacturing applications and change applications for some domestic Category 3 medical devices (*"CFDA Aims For Bigger Staff, More Power For Provinces As Cabinet-Level Agency" — PharmAsia News, Apr. 17, 2013 8:06 AM GMT*).

China's State Council mandated that oversight of product manufacturing done by the General Administration of Quality Supervision, Inspection and Quarantine (GAGIQ), and drug distribution and sales oversight by the Ministry of Commerce be consolidated into the new CFDA. Since April, the agency has made appointments for several high-profile positions (*"Asia On The Move: China FDA Reorganizes, Appoints Deputy Commissioners" — PharmAsia News, May 3, 2013 3:08 PM GMT*).

The new CFDA appears to be stepping up its efforts to tackle drug safety issues. Yin identified drug safety as a top priority at the DIA China Conference in 2012, three months after he assumed the commissioner position at State FDA (*"Meet Yin Li: China's New SFDA Chief Has A Public Health Background, And International Ties" — PharmAsia News, Feb. 29, 2012 3:42 PM GMT*). The focus since then has mainly been on information technology such as digital surveillance (*"China's State FDA Lays Out Plans To Spur Innovation – DIA China Conference" — PharmAsia News, May 23, 2012 4:40 PM GMT*).

Patient safety is also the theme of this year's DIA China meeting, the fifth since it started in 2009.

Tightening Clinical Trial Oversight

As the world's largest active ingredient supplier, China has vowed to promote new drug innovation as the economy shifts to new growth areas.

CFDA plans to accelerate drug review reform, push for the establishment of drug research platforms, and increase oversight over testing institutes and clinical trial facilities.

The lack of qualified testing facilities and clinical study sites has been cited as a major stumbling block for new drug R&D in China. The government expressed its intent to prepare sites for first-in-human studies, but progress remains to be seen (*"China Prepares Site For First-In-Human Studies But Safety Concerns Remain" — PharmAsia News, Nov. 9, 2012 8:26 PM GMT*).

Drug approval efficiency needs to be improved through streamlining review resources, Yin said. Meanwhile, the agency also intends to implement bioequivalence testing for generics, starting with essential and commonly used drugs, he added.

CFDA issued draft guidelines in November stating bioequivalence testing would start in 2013, beginning with oral tablets listed on China's Essential Drug List that is expected to take

three years to complete (*"Bioequivalence Testing Is First Step In China's Pharma Industry Upgrade – RDPAC" — PharmAsia News, Dec. 12, 2012 6:38 PM GMT*).

China is also upgrading drug standards to improve drug safety, including adding 288 new drugs to the China Pharmacopeia, according to an April 27 CFDA announcement.

Meanwhile, Yin said CFDA intends to strictly enforce regulations for the rollout of good manufacturing practices (GMP) and good supply practices (GSP) guidelines.

All drug manufacturers in China are required to be in compliance with GMP regulations by 2015, and manufacturers of sterile and injectable drugs are required to complete GMP certification by the end of 2013.

The implementation of the GMP and GSP regulations will push manufacturers to the front seat in ensuring product safety, Yin said.

"Through gradually changing the industry chain into a responsibility chain, we will make enterprises the ultimate entity responsible for drug safety."

State, provincial and city-level regulators need to upgrade testing capabilities and better coordinate among themselves to improve enforcement, Yin said.

Better Adverse Event Reporting And Risk Management

Medical facilities report the majority of adverse reactions in China. In 2012, 1.2 million adverse reactions were reported, 74.8% of which came from hospitals and 25% from manufacturers and distributors.

That constitutes a stark contrast to the U.S., where drug manufacturers report 80% of adverse events. Even in China, multinational firms reported most of the cases from industry, according to **Pfizer Inc.** VP of Worldwide Development Operations Tan Lingshi, who spoke at DIA.

To ensure drug safety, domestic manufacturers need to ramp up their adverse drug reaction reporting responsibility, Tan said.

Meanwhile, the government is using digital tools to better track drug use and prevent counterfeits. CFDA requires manufacturers of drugs imported to China to attach 20-digit barcodes, issued by the agency, to wholesalers and individual packages. Imported drugs without such codes will be rejected after April 30, 2014 (*"China's State FDA Proposes Digital Monitoring For All Imported Drugs" — PharmAsia News, Oct. 23, 2012 5:46 PM GMT*).

CFDA has also stepped up efforts to crack down on illegal drug and medical device advertisements. In the first quarter, the agency investigated 36,747 drug ads and 3,828 medical device ads, resulting in 37 advertising approval codes being revoked and 76 sales suspensions.

By Brian Yang