China continuous improvements to more efficient regulatory agencies

By Ana Ladino, Director Regulatory Affairs

On March 13, 2018, Chinese State Councilor Wang Yong delivers an institutional restructuring plan of the State Council at the fourth plenary meeting of the first session of the 13th National People's Congress (NPC) at the Great Hall of the People in Beijing.

The draft restructuring plan is intended to make the government better-structured, more efficient, and service-oriented.

The integration of three administrations will strengthen the government's functions on supervision of the food, drug and medical device markets. The registration and approval process is intended to be streamlined. More timely and standardized inspection and post-market surveillance could be expected under the consolidation of power.

The proposed plan will establish the following three new regulatory agencies:[1]

- State Market Regulatory Administration (SMRA)
- National Health Commission (NHC)
- Ministry of Agriculture and Rural Affairs (MARA)

The stated goal of this organizational restructuring by the Chinese government is to consolidate decentralized market regulatory forces and optimize regulatory resource allocation. Industry may benefit from more regulatory consistency following this consolidation, though it remains to be seen how these changes will play out at both the central and local levels. A general overview of the restructuring plan is provided below.

State Market Regulatory Administration (SMRA)

The new SMRA administration is affiliated with the State Council, and will undertake various responsibilities, including food safety, business registration, anti-trust enforcement, industrial product safety, etc. It will consist of the following agencies:

- General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ)
- China Food and Drug Administration (New name National Medical Products Administration (NMPA)
- State Administration for Industry & Commerce (SAIC)
- Certification and Accreditation Administration (CNCA)
- Standardization Administration of China (SAC),
- Food Safety Commission of the State Council (FSC)

New NMPA name:

The new name NMPA shall be adapted from 1st September 2018, it has been changed from 'CFDA' to 'NMPA' in the medical device registration and approval system. Any registrants need to use the new name and its abbreviation of the China medical device authorities during the medical device registration in China.

The Certification and Accreditation Administration (CNCA) and Standardization Administration of China (SAC), which were affiliated with AQSIQ, are now transferred to SMRA. However, the names of both CNCA and SAC will be retained. In this regard, CNCA is perhaps best known as an Agency approving overseas manufacturing facilities for foods exported to China (e.g., dairy products, meat products) as well as product certification (e.g., organic). Meanwhile, SAC is the agency formulating various Chinese Standards.

National Health Commission (NHC)

The National Health and Family Planning Commission (NHFPC) is being restructured to form the newly established National Health Commission (NHC), which will also incorporate certain health-related functions from other administrations. In recent years, NHFPC has been responsible for developing Food Safety Standards and conducting food safety assessment. There is no indication that NHC will be relieved of these responsibilities.

Ministry of Agriculture and Rural Affairs (MARA)

The new Ministry of Agriculture and Rural Affairs (MARA) will replace the Ministry of Agriculture (MOA). The new Ministry will continue to carry out the responsibilities of the former MOA; these include the supervision of agricultural product safety and approval of agricultural genetically modified organisms. While the institutional reshuffle may not lead to immediate and significant changes in food regulatory policies, its impact on many regulatory matters (e.g., potential delays in the promulgation of the Food Safety Law Implementing Regulation, approvals of food petitions and Food Safety Standards, etc.) should not be overlooked. Although it may be several months - or even years - before the reshuffle is completed, we will continue to monitor these developments and provide relevant updates.

Potential Impact Evaluation[2]

Grace Fu Palma, CEO of China Med Device, a Boston- and Beijing-based consulting company focused on regulatory and market access for China, explained to Focus that the changes will mean CFDA is no longer a standalone department but will be part of a larger unit, and though the changes may not impact device or pharmaceutical approval timelines, she said changes will allow CFDA to focus more on the lifecycle of products.

Leon Lei of China Med Device added: "Previously, the registration of medical device and pharmaceuticals had to go through the Administration for Industry & Commerce, which was also partly conducting administrative penalties; Administration of Quality Supervision, Inspection and Quarantine, which was responsible for inspection and quality issues. Now they are supposed to be integrated as a whole."

Palma also said she spoke with CFDA section heads recently and that they do not think these high-level changes will affect their day-to-day work, but previously announced efforts to increase transparency around regulatory decision making will.

[1]https://www.natlawreview.com/article/china-s-national-people-s-congress-passes-reshuffle-plan-to-establish-new-food-and

[2]https://www.raps.org/news-and-articles/news-articles/2018/3/china-plans-cfda-changes,-reshuffling-of-ministrie