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IMPACT OF CHINESE GOVERNMENT RESTRUCTURING ON THE LIFE SCIENCES INDUSTRY

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OVERVIEW OF THE STATE ADMINISTRATION FOR MARKET REGULATION

On March 17, 2018, China's National People's Congress (NPC) approved a general plan proposed by China's State Council to restructure certain Chinese government agencies. This restructuring plan affects a wide range of Chinese government institutions as well as life science companies, including those in the medical and food sectors.

Establishment and Leadership

The general restructuring plan established a new agency named the State Administration for Market Regulation (SAMR) on April 10, 2018. Its official website also was launched (http://samr.saic.gov.cn/).

On April 4, 2018, the State Council appointed Mr. Zhang Mao (张茅)—former director and Communist Party secretary of the State Administration for Industry and Commerce (SAIC)—as SAMR's director and deputy Communist Party secretary, and Mr. Bi Jingquan (毕井泉)—former director and Communist Party secretary of the China Food and Drug Administration (CFDA)—was appointed as SAMR's deputy director and Communist Party secretary.

Authority and Composition

According to the restructuring plan, the following agencies will cease to exist, and their functions will be transferred to the SAMR:

- State Administration for Industry and Commerce
- General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) (not including its export and import inspection and quarantine functions that will be combined with China Customs)
- China Food and Drug Administration
- Price Supervision and Antimonopoly Bureau of the National Development and Reform Commission
- Antimonopoly Bureau of the Ministry of Commerce
- Antimonopoly Commission of the State Council

After the restructuring, SAMR will become a super-regulatory agency under China's State Council. It will be responsible for a broad range of regulatory matters, including (1) market supervision and management, market entity registration, and maintenance of market order; (2) supervision of industrial product, equipment, and food safety; and (3) management of product examination issues, including those related to testing, certification, and accreditation.

Given that this restructuring will involve dozens of institutions at both the central and local level, it is being implemented incrementally. According to public sources, the central government is drafting detailed transfer plans, which are expected to be published by the end of June 2018. The deadline for the completion of the restructuring at the state level is the end of 2018, while the deadline for local agency restructuring is the end of March 2019.

POTENTIAL EFFECT ON LIFE SCIENCE COMPANY OPERATIONS IN CHINA

Under the current restructuring plan, the functions and staffing of the central and local CFDAs—the existing regulatory agencies responsible for medical- and food-related approvals and supervision—will be transferred to SAMR. We expect that this will not greatly affect the operations of life science companies in China, but post-approval supervision will likely be strengthened. Below are our reasons and comments:

CFDA's regulatory procedures will remain the same during transition period.

On April 10, 2018, the same day SAMR was established, it published a notice on its website stating that, during the transition period and before the detailed restructuring plans are published (expected by the end of June 2018), all applications, approvals, inspections, supervisions, and enforcements with respect to drugs; medical devices; food, including health food, infant and toddler formula milk powder, and food for special medical purposes; and cosmetics will remain subject to existing CFDA regulations and rules, and all applications and approval documentation will be applied to the form and substance of existing documentation.

Substance of major medical- and food-related laws and regulations might remain unchanged.

Unlike with import and export issues, Chinese laws and regulations for medical and food manufacturing and sales are relatively independent. Therefore, while the CFDA's functions and staff will be moved to the SAMR, we expect that, except for minor revisions like the name of the enforcement authority, the restructuring would not require significant substantive revisions to most existing laws and regulations issued by the NPC and the CFDA regarding the manufacture and sale of food and supplements.

SAMR leadership and staff responsible for medical- and food-related regulations would likely be the same as at the CFDA.

At the central level, on April 4, 2018, the State Council appointed Mr. Bi Jingquan (毕井泉) (former director and Communist Party secretary of the CFDA) as deputy director and Communist Party secretary of SAMR. In addition, in light of the special expertise required by the medical administration, the State Council also established a State Drug Administration Bureau (SDA) under the SAMR to specifically implement the registration and administration of drugs, medical devices, and cosmetics. Ms. Jiao Hong (焦红) (former deputy director of the CFDA) was appointed director of the new SDA. Also, according to unofficial sources, it appears that a majority of officials from the central CFDA would likely be responsible for the same or similar functions after they have moved to the SAMR.

With respect to the food sector, Ms. Sun Meijun was appointed SAMR's deputy director and is directly responsible for food-related work. Ms. Meijun is very familiar with food-related regulations, as she is the former deputy director and food safety director of the CFDA and former secretary of the Food Safety Commission of the State Council.

At the local level, previous government reforms implemented since 2013 have transferred the functions and staffing of local CFDAs in a majority of Chinese counties and districts to the local SAIC (the key predecessor of the SAMR). We therefore expect that the recent restructuring would not have a great effect on local CFDAs.

Announced CFDA restructuring would facilitate regulatory approvals for life science companies.

According to a public announcement on April 10, 2018 by Mr. Zhang Mao (张茅), director and deputy Communist Party secretary of the SAMR, the trend of medical- and food-related regulation restructuring is to simplify procedures, decentralize powers, enhance supervision, and optimize public services, as well as to further facilitate the administrative approval of drugs, medical devices, and food. As such, it is expected that the restructuring will make regulatory approvals more convenient for companies.

POTENTIAL EFFECT ON IMPORT AND EXPORT BUSINESSES OF LIFE SCIENCE COMPANIES IN CHINA

CIQ Institutional Restructuring

In addition to the establishment of the SAMR, China Inspection and Quarantine (CIQ), a department under the AQSIQ responsible for export and import inspections and quarantine, will cease to exist at both the central and local level. CIQ's functions will be transferred to China Customs rather than to the newly established SAMR.

According to public announcements published by China General Customs, since April 20, 2018, (1) the CIQ has carried out its work in the name of China Customs, (2) a united service window has been opened at each local Customs to receive applications for matters including passenger inspection, Customs clearance, and registration of qualified importers and exporters; and (3) officials responsible for passenger inspection, goods inspection, and over-the-counter public services must wear Customs uniforms and badges.

We also note that beginning on the morning of April 20, 2018, the domain names and agency names published on CIQ's official central and local websites have been changed to "China Customs."

However, other detailed transfer plans regarding CIQ restructuring have not yet been issued. According to our informal inquiries with several officials at local CIQs in Shanghai and Jiangsu Province, they do not know how the transfer and restructuring will proceed, where they will be assigned, or how their functions will be divided between themselves and Customs.

Potential Effects of CIQ Restructuring

Compared with CFDA reform, we anticipate that the CIQ reform will more significantly affect the import and export businesses of life science companies. We expect that the effects will include the following:

- **Applicable regulations and regulatory rules may be amended**. CIQ and Customs separately issued numerous overlapping regulations and rules regarding imports and exports. We expect that these rules and regulations will be streamlined after the CIQ-Customs merger.
- **Regulatory procedures may be simplified**. The overlapping authority of CIQ and Customs regarding imports and exports subjected importers to two levels of supervision. For example, in the past, importers and exporters were required to submit two separate filings before becoming qualified: (1) CIQ's inspection declaration filing and (2) Customs' importer/exporter filing. But the restructured General Customs issued a decision on April 16, 2018 stating that after April 20, these two filings would be merged into a single filing, and the applicant need only submit one application to the united public service window at the applicable local Customs office. Once the application has been approved, the applicant will be registered as a qualified declarer and importer/exporter.

- **Regulatory functions may be streamlined**. Under existing rules, importers must separately apply to the CIQ for inspection clearance approval before they apply to Customs to release imported goods. The restructuring will streamline these functions. We expect that these two applications will most likely be simplified into a single application. Also, according to our informal discussions with some local officials from Customs and CIQ, it is expected that the complicated import/export declarations, inspections, and clearance approvals that were implemented by the CIQ and Customs separately will be combined and simplified. If these restructuring measures are implemented, we believe that the time and cost companies spend on import and export requirements will be significantly reduced.
- **Post-importation supervision may be stricter**. Compared with the practices of CIQ, Customs is more focused on post-import supervision and investigation to ensure that importers do not violate Chinese law and their import declaration commitments. In addition, Customs has specialized departments that focus on investigations and enforcement matters, including the Department of Customs Control and Inspection, Department of Anti-smuggling, as well as a team of anti-smuggling police jointly led by General Customs and the Ministry of Public Security. Also, after the institutional merger, it is possible that CIQ and Customs would share their expertise and relevant data. For example, officials from CIQ who have expertise on special foods, drugs, or medical devices might help Customs officials determine the appropriate Harmonized System (HS) codes for imported goods that are difficult to categorize. If a company has negative import/export records at either CIQ or Customs, this information might be shared between Customs and CIQ. Although it is still unknown if Customs' investigatory departments and employees will participate in the inspection and quarantine of imported goods after the institutional merger, or how officials from CIQ and Customs would cooperate, it is advisable that companies enhance their import and export compliance procedures and fully comply with Chinese laws and regulations.
- **The regulatory procedures used to upgrade a company's import and export credits are uncertain and might be amended**. We understand that many companies in the life sciences intend to apply to the local competent CIQ to update their import and export credit from grade A to grade AA in order to improve their reputation in China and to facilitate import and export procedures. However, under the current restructuring, there are many uncertainties regarding CIQ's credit upgrade policy. According to our informal telephone inquiries with several officials at local CIQs in Shanghai and Jiangsu Province, it is unclear how the upgrade would be done; it is unknown whether the departments responsible for the CIQ credit upgrade would continue to exist, or whether the current CIQ credit upgrade policy would remain or be significantly changed. Some officials speculated that significant changes might be made to the current CIQ credit upgrade policy; it is even possible that the CIQ policy could be revoked or combined with Customs' existing Customs Credit Management Policy, because both policies are related to import and export matters. According to unofficial sources, the central authority might issue official guidance on this issue before September or October of 2018.

CONCLUSION

China's government restructuring project is a major undertaking. Although detailed restructuring plans have not yet been issued—causing many uncertainties for market participants—it is clear that simplifying regulatory approval procedures and enhancing post-approval supervision are two key purposes of the restructuring. On the one hand, it may facilitate business in China, but on the other hand, it could impose stricter compliance requirements upon companies. Therefore, it is advisable that companies with operations in China be vigilant regarding their regulatory compliance and keep a close eye on the proposed restructuring.

Contacts

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