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ALERT

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# China's New State Market Regulatory Administration: What to Know and What to Expect

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On March 17, China's highest legislative body, the National People's Congress, approved a sweeping government restructuring plan.[1] This is generally considered to be the most comprehensive government restructuring that China has undertaken since the country implemented its "Open Door" policy in the late 1970s. As part of the new plan, China has established a State Market Regulatory Administration (SMRA),[2] which will merge and undertake the responsibilities previously held by the State Administration for Industry and Commerce (SAIC),[3] General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ),[4] the Certification and Accreditation Administration (CAC),[5] the Standardization Administration of China (SAC)[6] and the China Food and Drug Administration (CFDA).[7]

The restructuring will also assimilate the antitrust and price supervision functions of certain regulators, including the Anti-monopoly and Anti-unfair Competition Enforcement Bureau of the SAIC[8] (as part of the aforementioned broader absorption of the SAIC into the SMRA), Price Supervision and Anti-monopoly Bureau of the National Development and Reform Commission,[9] the Anti-monopoly Bureau of the Ministry of Commerce (MOFCOM),[10] and the Anti-monopoly Commission of the State Council.[11] Finally, it will govern a newly formed State Intellectual Property Office (SIPO)[12] to regulate intellectual property rights.

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[1] For full text of the plan, see Xinhua News Agency, *The Reform Plan of the Institutions of the State Council* (March 17, 2018), *available at* http://www.gov.cn/guowuyuan/2018-03/17/content_5275116.htm.

[2] Chinese name: 国家市场监督管理总局.

[3] Chinese name: 国家工商行政管理总局.

[4] Chinese name: 国家质量监督检验检疫总局.

[5] Chinese name: 国家认证认可监督管理委员会.

[6] Chinese name: 国家标准化管理委员会.

[7] Chinese name: 国家食品药品监督管理总局.

[8] Chinese name: 反垄断与反不正当竞争执法局. This is a bureau governed by the SAIC.

[9] Chinese name: 国家发展和改革委员会. The NDRC undertakes its antitrust and price regulation duties through the Price Supervision and Anti-monopoly Bureau (Chinese name: 价格监督检查与反垄断局).

[10] Chinese name: 商务部. The MOFCOM's Anti-monopoly Bureau (Chinese name: 反垄断局) has been the regulator of potential "concentration of undertakings" as a result of merger and acquisition transactions.

[11] Chinese name: 国务院反垄断委员会. The Anti-monopoly Commission of the State Council will be kept, with its functions and duties transferred to SMRA.

[12] Chinese name: 国家知识产权局.

With the change, the Chinese leadership has tapped the SMRA as the single most powerful market regulator to address the public's ever-mounting concerns, including drug and food safety, protection of intellectual property and product quality issues in general. As such, the SMRA will have a broad mandate, overseeing everything from drug safety supervision, quality inspection, fair competition and commercial bribery, issuance of business registrations, certifications and accreditations, management of intellectual property rights and comprehensive supervision and management of the market order.

For regulating the life sciences and healthcare space in particular, the restructuring also establishes a new State Drug Administration (SDA),[13] which will be supervised by the SMRA. This move appears to acknowledge that the regulation of drugs, medical devices and cosmetics products still requires a highly specialized and dedicated government agency (which was the purpose of the former CFDA). The new SDA will maintain its own branches at the provincial level and leave the post-approval enforcement duties at the lower municipal and county levels to the consolidated SMRA branches.

| Before | Status | After |
|---|---|---|
| **SAIC** | Dismantled | **SMRA** |
| **AQSIQ** | Dismantled | |
| **CFDA** | Dismantled; reformed as new SDA to operate under SMRA | |
| **Anti-monopoly and Anti-unfair Competition Bureau (SAIC)** | Functions merged into SMRA | |
| **Price Supervision and Anti-monopoly Bureau (NDRC)** | Functions merged into SMRA | |
| **Anti-monopoly Bureau (MOFCOM)** | Functions merged into SMRA | |
| **Anti-monopoly Commission (State Council)** | Office will be kept; functions merged into SMRA | |
| **CAC** | Office will be kept; functions merged into SMRA | |
| **SAC** | Office will be kept; functions merged into SMRA | |
| **SIPO** | Merged into SMRA | |

The SMRA and SDA will be led by powerful figures from the PRC government. The SMRA will be led by the administration's Communist Party Secretary and Deputy Director, Jingquan Bi[14] (formerly Director of the CFDA), and the administration's Deputy Communist Party Secretary and Director Mao Zhang[15] (formerly Director of the SAIC). The SDA will be led by Communist Party Secretary Li Li[16] (formerly deputy governor of Jiangxi Province),

[13] Chinese name: 国家药品监督管理局.

[14] Chinese name: 毕井泉.

[15] Chinese name: 张茅.

[16] Chinese name: 李利.

and Director Hong Jiao[17] (formerly Deputy Director of the CFDA). Despite the appointments of key leadership positions at the SMRA, the new agency is not expected to start operation until mid-April, and probably would not move into full swing until after June 2018. Its predecessor agencies will continue their work during the transition period.[18]

As the restructuring continues to unfold, how would these broad institutional reforms affect multi-national companies doing business in China? It will depend on the answers to several questions:

- **Smooth Transition and New Policy Agendas?** Merging several large bureaucratic institutions is challenging. Former officials will need to be assigned new roles and responsibilities that carry different priorities from their former positions. New leadership often means new policy goals, and new teams will need to be formed to execute those policies. It will be important to watch how quickly new policies will be released and how functions within the SMRA will be organized. An equally important question is how efficiently personnel and staffing decisions will be made in order for those functions to get up to speed.

  Of course, what the SMRA intends to achieve is a different question. Companies may wish to closely monitor the policy announcements by the new SMRA leadership to assess its new priorities.

- **Coordinated Enforcement Across Functions?** A key policy objective for establishing the SMRA is to enhance enforcement efficiency and consistency. It is likely that SMRA officials might have access to databases and enforcement records that previously were "silo-ed" at respective regulatory bodies. After the merger, it may become easier for different enforcement teams to share information and coordinate enforcement efforts more efficiently, leading to more streamlined and effective enforcement actions.

  The SMRA now also has more enforcement tools and resources at its disposal. For example, absorbing the NDRC's antitrust function has made SMRA the sole enforcement agency against market behaviors that would restrict fair competition. In the past, such behaviors were the target of separate enforcement actions taken respectively by the NDRC and the SAIC.

  With the formation of the SDA, however, drug and medical device companies could still face the challenge of having to answer to multiple regulatory bodies. It is unclear at this point whether local MRAs and the national or provincial SDAs will interpret rules and regulations consistently—this will be a critical question going forward. Given that a large proportion of the local MRA officials were former SAIC and AQSIQ's enforcement personnel, it remains uncertain if they can correctly interpret and enforce the drug and device regulations.[19]

- **Whom to Call?** As inter departmental communication and cooperation will most likely increase within the SMRA, businesses might also need to update their regulator contacts and "windows." The SMRA's broad regulatory, inspection and enforcement responsibilities also mean that it will have extensive touchpoints with businesses. While companies historically may have to interact with SMRA's different predecessor agencies to

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[17] Chinese name: 焦红.

[18] Xinhua News Agency, *Han Zheng: To Insist on the Party's Leadership, to Ensure the Good Implementation of the Tasks, to Firmly and Orderly Further the Institutional Reform Work at the State Council* (March 31, 2018), *available at* http://www.xinhuanet.com/politics/2018-03/31/c_1122620209.htm.
According to China's Vice Premier Han Zheng, the State Council has set up a timetable for its newly-formed departments to put up shingles in mid-April and to determine their intra-structures and staffing before the end of June.

[19] Since 2014, the Chinese government has piloted an initiative to consolidate market supervision and enforcement resources on the county-level. As of March 13, 2018, 70% of the former SAIC, CFDA and AQSIQ's enforcement powers have already been combined at the municipal and county levels, which are the branches that actually carry out investigations and enforcements actions. Kang Yu & Wen Longxin, The Paper, *Experts Interpret the Formation of SMRA, quoting Wang Yukai, Professor at the Chinese Academy of Governance* (March 13, 2018), *available at* https://www.thepaper.cn/newsDetail_forward_2027298.

resolve operational issues in China, the integration hopefully can result in simplified and uniform procedures, and allow company to communicate with one government "window" instead of many.

At the same time, however, the integration could also complicate existing relationships. The integrated SMRA may be a player and a judge in the same playground. For example, in the context of laboratory and analytical equipment and products, the former General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) and its regional and local counterparts procured instruments and consumables to conduct quality inspections. Companies that supply products and services to the former AQSIQ may find its client now a regulator of many aspects of its businesses.

## Conclusion

Further information about SMRA's restructuring and appointments, as well as any new policy goals and initiatives, are expected to be released in the coming months. Such details can offer helpful insight into assessing how quickly and smoothly the new SMRA is transitioning into a fully functioning organization. It will also be important to see whether the SMRA will change direction from the course set by its predecessor agencies.

For multinational companies operating in the life sciences space, with Deputy Director Bi sitting in a key leadership position, the new SDA body under the SMRA could continue to implement the previous CFDA reform initiatives driven by Deputy Director Bi. However, the personnel reshuffle on the next level of bureaucracy might delay actual implementation of these initiatives.

Hence, multinational companies may wish to pay close attention to further organizational and policy announcements, and adjust their China strategy in response.

If you would like to discuss the foregoing or any other related matter, please contact Katherine Wang, Mimi Yang, David Zhang, or your usual Ropes & Gray advisor.