CHINA'S VACCINE SCANDAL 2018: PHARMACEUTICAL COMPANIES FACING HEIGHTENED REGULATORY RISKS

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Executive Summary

1. China's aim to move up the value-added chain and build its own brand names has been shattered by a string of food/medicine safety scandals in the last few years, with Changsheng Bio-technology's ineffective vaccines as the latest.

2. The scandal had more than 40 government officials investigated including seven at the provincial/ministerial level, some of whom have been sacked. At Changsheng, at least 18 staff, including the firm's chairwoman, were arrested.

3. Newly incepted in March 2018, the capability of the State Market Regulatory Administration (SMRA) was to centralise power overseeing food and drug safety that was once scattered among various government agencies. The scandal has put SMRA to the test.

4. SMRA holds the responsibilities previously held by the State Administration for Industry and Commerce, General Administration of Quality Supervision, Inspection and Quarantine, Certification and Accreditation Administration, Standardisation Administration of China and China Food and Drug Administration (CFDA).

5. CFDA was renamed State Drug Administration (SDA) which now comes under the SMRA. As the SDA retains the basic administrative structure of the former CFDA on drug safety, the restructuring has little impact on the existing central-local relationship on food and drug safety supervision.

6. While the impact of the power concentration of the new SMRA on China's notorious food and drug safety problems is uncertain in the long run, in the short term, the authorities' crackdown on firm executives and supervisory officials highlighted increasing regulatory risks faced by domestic producers.

7. In China, Chinese vaccines are classified into two categories: planned and nonplanned. Planned vaccines refer to those provided by the government at no

charge and mandatory for citizens, while the nonplanned ones are those produced by manufacturers based on market demand and purchased by consumers voluntarily.

8. The two kinds of vaccines could be purchased from the provincial public recourse trading platforms set up by local disease prevention and control institutions.

9. Few private and foreign entities are involved in the business of planned vaccines. In contrast, the market of nonplanned vaccines is far more open to both state-owned and private producers, though the participation of foreign actors is still rather limited.