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China's COVID Vaccine Charm Offensive: Can It Leave Scandal-Ridden Past Behind?

Global Orders Roll In But Past Haunts Sector

by **Brian Yang**

As China gears up to roll out millions of doses of its own vaccines to help fend off the coronavirus around the world, a scandal-ridden past continues to haunt the aspiring sector but is fading with improved regulation.

From receiving its first emergency use authorization outside China to a large order from Mexico, China's vaccines sector is poised to mount a charm offensive in the fight against the global pandemic.

Just days after the United Arab Emirates (UAE) approved the emergency use of vaccines made by China's state-owned [Sinopharm Group Co. Ltd.](#)'s [China National Biotech Group](#) (CNBG), Mexico said it had signed an order for 35 million doses of vaccines from another Chinese developer, [CanSino Biologics Inc.](#)

Both vaccines are still under late Phase III development and CNBG's is pending approval with Chinese regulators. A recently issued regulatory guideline in China allows conditional approval of such vaccines for use in public health crises, as long as efficacy is demonstrated from initial or second assessments of Phase III studies.

Apart from CNBG and CanSino, another leading Chinese vaccine developer, [Sinovac Biotech Ltd.](#), is also in line to file for the conditional approval of its inactivated virus-based candidate CoronaVac.

Relying largely on the proven inactivated virus technology, China's vaccines sector is touting its competitive advantages as multiple vaccines either reach or move near the market globally, such as quick response, no need for ultracold storage, and cost-effectiveness.

Amid expected huge demand, China plans to have 610 million doses ready to use within the year, to cover not only China but other countries where the vaccines are in trials, including Brazil, Mexico, Indonesia, Turkey and the UAE. The last granted emergency use approval to Sinopharm's inactivated vaccine, citing its 86% effectiveness.

Haunted Past

But just three years ago, Sinovac found itself involved in a high-profile bribery scandal that sent shockwaves through the whole sector, in the country with the largest national immunization program in the world.

The Nasdaq-listed company made public disclosures acknowledging that its then general manager Yin Weidong paid bribes to accelerate the regulatory approval process for its vaccines. Beijing court documents showed Yin paid CNY550,000 (\$84,100) in cash, including a never-returned loan, to official Yin Hongzhang (no relation).

Yin Hongzhang was then head of Biologics Products Registration at the then State Food and Drug Administration (SFDA), overseeing and signing off clinical trial and registration approvals for biologic, plasma and cell therapy products in China. In 2009, Sinovac filed for approval of its pandemic flu vaccine, for which it gained marketing clearance in April 2011; the product was included in the National Stockpiling Scheme later the same year.

Sinovac was just one of at least five domestic vaccine makers found to be involved in the bribery case. Du Weimin, the founder and CEO of another major Chinese developer, Shenzhen-based [Kangtai Biological Products Co. Ltd.](#), who was also the legal representative of Beijing Minhai Biotech, was found to have paid Yin Hongzhang CNY170,000 to accelerate vaccine approvals.

In total, the official - who later became deputy director of China's new Center for Drug Evaluation - along with his wife and son were found to have received more than CNY356m in cash and gifts, and he was sentenced to a 10-year prison term in 2017.

Besides regulators, designated vaccine distributors in China such as the Centers for Disease Prevention and Control have also been prone to scandal. In October 2018, the director of a district center in Fuyang, Anhui Province was found by a court to have accepting cash of

Rapid Response, No Ultracold: China Sees Global Opening For Vaccine Supplies

By **Brian Yang**

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SinoVac's rapid antibody response, CanSino's easier logistics requirements - plus cost advantages - make Chinese developers optimistic about supplying the world with COVID vaccines.

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CNY260,000 in exchange for benefits to manufacturers.

Kangtai as a company was also at the center of a controversy in 2013, after as many as 17 newborn babies reportedly died after being inoculated with the company's hepatitis B vaccines, used in China's national immunization program. Although the National Health and Family Planning Commission and the SFDA cleared the vaccine from any quality and safety issues, 27 provincial authorities halted supplies the following year.

Besides leading a little-known firm to international headlines, Du also made the news in 2019 for a record-setting divorce settlement with his Canadian citizen wife, in which assets worth CNY23.5bn were awarded to her.

More recently, Kangtai has moved into the global coronavirus spotlight after [AstraZeneca PLC](#) signed an exclusive agreement with the firm for mainland China development, manufacturing and commercialization rights to the UK company and the [University of Oxford](#)'s COVID-19 vaccine candidate AZD1222.

Quality Control Scandal

Bribery scandals aside, China's vaccine sector has also been at the epicenter of a nationwide crackdown on production manipulation that has led to reprimands of scores of state- and provincial-level officials.

In July 2018, a rising vaccine star and officially recognized high-tech enterprise, [Changchun Changsheng Life Sciences Limited](#), was found during an unannounced inspection to have forged expiration dates for its rabies vaccines. An investigation then found a previously manufactured batch of different vaccines to be substandard but still sold to the market in Shandong province.

Listed in Shenzhen, Changsheng has been hailed as a fast-growing vaccine developer with large cash reserves in its coffers; coincidentally, Du had previously served as a sales director at the company.

Soon after the data quality forgery, 18 executives of the company including its CEO were detained and the firm was eventually delisted. The following year, Changsheng was declared bankrupt.

In comparison, the operations involved in the other bribery scandals have largely escaped without commercial scratches. An executive of another Chinese vaccine

***Vaccine Maker Bankruptcy Shows
Regulatory Perils Of Business In China***

company, Wuhan-based [BravoVax Co Ltd](#), told the *Pink Sheet* that there could be a balancing act between stirring up public fears over vaccine quality, vaccination programs in the vast country and large-scale punishments for multiple manufacturers.

The rationale may be “to choose the least harmful” approach, it was suggested.

Tougher Legislation

Against this background and to reign in the problem-prone sector, the government pushed to issue the first-ever national legislation for such products, the China Vaccines Administration Law, which took effect in December 2019.

The move aimed to lift entry barriers to manufacturing and distribution, prohibiting contract manufacturing for vaccines. To keep a check on executives, it also required the heads of producers to maintain a good credit record and to have relevant industry background and experience.

Additionally, it required registration studies for vaccines to be conducted at top-level 3A class hospitals or provincial disease prevention centers. One year since the law's passing, there have been no reports of quality or manufacturing violations.

To further increase oversight of the sector, China is stepping up efforts to consolidate its many small players. “If you have one child, it’s easier to supervise; if you have eight children, you probably have less supervision over all of them,” the BravoVax executive told the *Pink Sheet*.

Worldwide Opening

One year since the first law devoted to the vaccine sector took effect, many Chinese manufacturers now seem eager to take on the world, aided by the opportunity provided by the global pandemic.

China has largely brought the virus outbreak under tight control and with fewer than dozens of cases officially reported each day, the nation has said it will provide the vaccines as a global “public good”, a charm offensive seen as “vaccine diplomacy.”

Many see the move is intended to refurbish an image tarnished by China’s early handling of the coronavirus, and a counter to COVID-19 vaccine nationalism underlined by the US Trump

By **Brian Yang**

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China's Changchun Changsheng Biotech has been officially declared bankrupt, ending long-running speculation. The major vaccine maker's dramatic fall has several take-away lessons for health companies operating in China, where several new regulations are taking effect.

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administration's "America First" policy.

Countries in Southeast Asia, the Middle East and Latin America are said to have procured made in China coronavirus vaccines. Mexico aside, both Malaysia and the Philippines are securing supplies to help fight the virus still wreaking havoc outside China, and Malaysia signed a deal in November to be a priority recipient, with Manila poised to get its first doses.