

China prepares for big entry into vaccine market

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In this photo taken on Thursday, Nov. 24, 2011, a worker inspects the label on vials containing H1N1 flu vaccine produced by Beijing-based drug maker Sinovac Biotech Ltd. in Beijing. The world should get ready for a new Made in China product, vaccines. After years of supplying its own market, China's vaccine makers are gearing up to push exports in a move that should lower costs of lifesaving immunizations for the world's poor and provide major new competition for the big Western pharmaceutical companies. (AP Photo/Andy Wong)

(AP) -- The world should get ready for a new Made in China product - vaccines.

China's vaccine makers are gearing up over the next few years to push exports in a move that should lower costs of lifesaving immunizations for the world's poor and provide major new competition for the big Western pharmaceutical companies.

However, it may take some time before some parts of the world are ready to embrace Chinese products when safety is as sensitive an issue as it is with vaccines - especially given the food, drug and other scandals the country has seen.

Still, China's entry into this market will be a "game changer," said Nina Schwalbe, head of policy at the GAVI Alliance, which buys vaccines for 50 million children a year worldwide.

"We are really enthusiastic about the potential entry of Chinese [vaccine manufacturers](#)," she said.

China's vaccine-making prowess captured world attention in 2009 when one of its companies developed the first effective vaccine against swine flu - in just 87 days - as the [new virus](#) swept the globe. In the past, new vaccine developments had usually been won by the U.S. and Europe.

Then, this past March the [World Health Organization](#) announced that China's [drug safety](#) authority meets international standards for vaccine regulation. It opened the doors for Chinese vaccines to be submitted for WHO approval so they can be bought by U.N. agencies and the GAVI Alliance.

"China is a vaccine-producing power" with more than 30 companies that have an annual production capacity of nearly 1 billion doses - the largest in the world, the country's State [Food and Drug Administration](#) told The Associated Press.

But more needs to be done to build confidence in Chinese vaccines overseas, said Helen Yang of Sinovac, the NASDAQ-listed Chinese biotech firm that rapidly developed the H1N1 [swine flu vaccine](#). "We think the main obstacle is that we have the name of 'made in China' still. That is an issue."

China's food and drug safety record in recent years hardly inspires confidence: in 2007, Chinese cough syrup killed 93 people in Central America; one year later, contaminated blood thinner led to dozens of deaths in the United States while tainted milk powder poisoned hundreds of thousands of Chinese babies and killed six.

The government has since imposed more regulations, stricter inspections and heavier punishments for violators. Perhaps because of that, regulators routinely crack down on counterfeit and substandard drugmaking.

While welcoming WHO's approval of China's drug safety authority, one expert said it takes more than a regulatory agency to keep drugmakers from cutting corners or producing fakes.

"In the U.S., we have supporting institutions such as the market economy, democracy, media monitoring, civil society, as well as a well-developed business ethics code, but these are all still pretty much absent in China," said Yanzhong Huang, a China health expert at the Council on Foreign Relations. "For China, the challenge is much greater in building a strong, robust regulative capacity."

Last year, a Chinese newspaper report linked improperly stored vaccines to four children's deaths in northern Shanxi province, raising nationwide concern. The Health Ministry said the vaccines did not cause the deaths, but some remained skeptical.

Meanwhile, Chinese researchers reported in the *New England Journal of Medicine* earlier this year that a pandemic flu vaccine given to 90 million people in 2009 was safe.

WHO's medical officer for immunization, Dr. Yvan Hutin, said WHO's approval of the Chinese drug regulatory agency is not "a blank check." Each vaccine will be evaluated rigorously, with WHO and Chinese inspectors given access to vaccine plants on top of other safety checks, he said.

Vaccines have historically been a touchy subject in the Western world, rife with safety concerns and conspiracy theories. Worries about vaccine safety resurfaced in the late 1990s triggered by debate over a claimed association between the vaccine for measles, mumps and rubella and autism. The claim was later discredited.

For China, the next few years will be crucial, as biotech companies upgrade their facilities and improve procedures to meet the safety and quality standards - a process that is expected to be costly and challenging. Then they will submit vaccines to the U.N. health agency for approval, which could take a couple of years.

First up is likely to be a homegrown vaccine for Japanese encephalitis, a mosquito-borne disease that can cause seizures, paralysis and death. The vaccine has been used for two decades in China with fewer side effects than other versions. Its manufacturer expects WHO approval for it in about a year. Also in the works are vaccines for polio and diseases that are the top two killers of children - pneumonia and rotavirus, which causes diarrhea.

Vaccines also are a significant part of a \$300 million partnership with the Bill & Melinda Gates Foundation for the development of new health and farming products for poor countries.

China's entry into this field is important because one child dies every 20 seconds from vaccine-preventable diseases each year. UNICEF, the children's agency and the world's biggest buyer of vaccines, has been in talks with Chinese companies, said its supply director Shanelle Hall. The fund provides vaccines to nearly 60 percent of the world's children, and last year spent about \$757 million.

Worldwide, vaccine sales last year grew 14 percent to \$25.3 billion, according to healthcare market research firm Kalorama Information, as drugmakers which face intensifying competition from generic drugs now see vaccines as key areas of growth, particularly in Latin America, China and India.

China's vaccine makers, some of whom already export in small amounts, are confident they will soon become big players in the field.

"I personally predict that in the next five to 10 years, China will become a very important vaccine manufacture base in the world," said Wu Yonglin, vice president of the state-owned China National Biotec Group, the country's largest biological products maker that has been producing China's encephalitis vaccine since 1989.

CNBG will invest more than 10 billion yuan (\$1.5 billion) between now and 2015 to improve its facilities and systems to meet WHO requirements, Wu said. The company also intends to submit vaccines to fight rotavirus, which kills half a million kids annually, and polio for WHO approval.

Smaller, private companies are also positioning themselves for the global market.

Sinovac is now testing a new vaccine for enterovirus 71, which causes severe hand, foot and mouth disease among children in China and other

Asian countries. It is also preparing for clinical trials on a pneumococcal vaccine Yang says could rival Pfizer's Prevnar, which was the top-selling vaccine worldwide last year with sales of about \$3.7 billion.

Pneumococcal disease causes meningitis, pneumonia and ear infection.

"In the short term, everyone sees the exporting opportunities, because outside of China the entire vaccine market still seems to be monopolized by a few Big Pharma (companies)," Yang said.

The entry of Chinese companies is expected to further pressure Western pharmaceutical companies to lower prices. Earlier this year, UNICEF's move to publicize what drugmakers charge it for vaccines showed that Western drugmakers often charged the agency double what companies in India and Indonesia do.

The aid group Doctors Without Borders criticized the vaccine body GAVI for spending hundreds of millions of dollars on anti-pneumonia vaccines from Western companies, saying it could put its buying power to even better use by fostering competition from emerging manufacturers like those in China.

GAVI's Schwalbe said the [vaccine](#) body has to buy what is available and negotiates hard for steep discounts. "We need to buy vaccines now to save children's lives now. We can't wait."

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