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China to accept overseas clinical trial data

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The Chinese government has announced plans to accept data from clinical trials carried out overseas, in order to speed up approvals.

Reuters reported that the move was announced by the Chinese cabinet late on Sunday. It is a development that will be welcomed by international pharma companies, as medicines' approvals are frequently held up because of stringent clinical trial data requirements.

Firms looking to launch drugs in China also face competition from the country's homegrown pharma companies, and a tough government-controlled pricing environment.

The draft proposals state that the clinical trial data from overseas centres can be used for filings with its CFDA regulator as long as trial centres comply with Chinese drug and medical device registration requirements.

Firms looking to register drugs or medical devices for the first time will need to provide clinical trial data related to genetic differences in the Chinese population.

China is trying to shift away from use of generics and towards more innovative medicines and medical equipment.

The country's State Council added the changes would make the country's industry more competitive and help meet the clinical needs of its nearly 1.4 billion people.

China is becoming increasingly important to pharma companies because of the size of its population, prevalence of certain diseases, and its developing healthcare sector.

Cancer biotech BeyondSpring hopes to do the bulk of R&D for its new lung cancer drug plinabulin in China, a strategy that will cut development costs because of its links with hospitals and regulators.

Other companies have used similar strategies – Boehringer Ingelheim's lung cancer drug Giotrif was approved by the FDA in trials where 72% of patients in a pivotal phase 3 trial were from China.

International pharma are also interested in developing diabetes drugs in China – AstraZeneca and Novo Nordisk are among the companies that are targeting the market, where around 150 million people are predicted to develop type 2 diabetes by 2040.

Novo Nordisk is hoping to gain a foothold with GLP-1 class diabetes drugs such as Victoza (liraglutide) and its developmental successor semaglutide.

And AstraZeneca late last month said it plans filings of its Bevespi Aerosphere COPD drug in China, where older drugs such as salmeterol and formoterol are commonly used to manage COPD symptoms.