

10 Nov 2016 |

China Keeping Eye On Key Regulatory Dialog After Trump Win

by **Brian Yang**

Although Chinese President Xi Jinping has expressed the country's willingness to work with the newly elected US president to promote ties in a constructive way, potential setbacks for bilateral trade and regulatory talks are worrying observers.

US President-elect Donald Trump had already publically voiced during the election campaign his general opposition to global trade practices that disadvantage the US, and in particular to China's "currency manipulation" and the impact of its imports on American jobs, saying he would add new tariffs to Chinese goods if elected.

But so far, pharma executives in China see the biggest impact from the stunning US election results on the country's continued push to foster a more innovation-enabling environment.

Continued healthcare collaboration with the US will be vital to propelling China forward in its bid to become an innovation-based nation by 2030, many stakeholders say. A recent report released by a local industry trade group, the R&D based Pharmaceutical Association Committee (RDPAC, which represents multinational drug makers in China), ranked China as still a Tier 3 innovator, compared to the US as a Tier 1 innovative nation and Germany and the UK in Tier 2 (Also see "[Where Is The Reward? New Drug Developers See Red In China](#)" - Scrip, 3 Nov, 2016.).

Aligning more closely with US FDA standards and setting up a science-based regulatory system is seen in China as key to directing the country towards the goal of becoming a true pharma innovator, said the report.

To this end, China has recently looking at aligning its IND more closely with US and international norms at major regulators. (Also see "[Mission: Ongoing! China Looks To Align With FDA In Landmark IND Push](#)" - Pink Sheet, 31 Oct, 2016.)

By way of comparison, the US FDA currently has 625 guidelines for the pharma industry, compared to just 156 from the China FDA, plus a streamlined process to accelerate innovative new drugs from clinical trials to the market that China is looking to emulate more closely.

Dialog Under Threat?

An important component in the development of China's drug development environment (and indirectly, in the push towards innovation) so far has been the health and pharma regulatory reform collaboration between the US FDA and the CFDA as one of the priorities under the broader bilateral US-China Strategic and Economic Dialogue (S&ED), held twice annually.

But now, with the surprise win of Donald Trump in the US election, this key process - which had catalyzed some important regulatory changes in China - faces an uncertain future, say some observers in China.

In an earlier round of S&ED talks held in Chicago for instance, Chinese Vice

Premier Wang Yang promised some important changes to accelerate approvals for new drugs, erase the approval lag, and install a rolling review mechanism. Since then, the CFDA has launched a plethora of initiatives including a crackdown on clinical data forgeries, and had halved the approval backlog of over 20,000 products as of this October.

In the latest round of the talks held in Beijing in June, the two countries also decided to accelerate cooperation with Asian nations to fight infectious diseases and establish a center for disease control, and to continue joint contributions to the Global Fund to Fight AIDS, Tuberculosis, and Malaria.

So far, the US-China S&ED talks seem to be proceeding as planned, and the next round is due to be held in the US next month. But whether the various initiatives will carry on unchanged under the new Trump administration is as yet unclear.

One thing is clear for now - as both sides go back to work ahead of the US inauguration, the

More In-Depth Analysis Of US Election Impact

- (Also see "[Trump's ACA Repeal: What's In It For Biopharma?](#)" - Scrip, 9 Nov, 2016.)
- (Also see "[Trump Victory: What Impact For Pharma In A Post-Referendum EU?](#)" - Scrip, 9 Nov, 2016.)
- (Also see "[Pharma Is Ready And Waiting For A Tax Holiday Under Trump](#)" - Scrip, 9 Nov, 2016.)
- (Also see "[President Trump And Drug Pricing: What To Expect](#)" - Scrip, 9 Nov, 2016.)
- (Also see "['Trump Shock' Rattles Japan But Pharma Plays Wait And See](#)" - Scrip, 9 Nov, 2016.)

future direction of healthcare collaboration between the US and China will be closely watched by the pharma industry in China.

From the editors of PharmAsia News.