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China To Issue New Rules On Adverse Event Reporting To Enhance Surveillance

SHANGHAI - China's State FDA is accepting public comments until July 27 on its new draft regulation for reporting adverse events. Posted on the agency's website, the new measure aims to tighten surveillance on adverse event reporting to enhance safety and better control risk, the agency said.

The current measure, which was originally implemented in 2004, was China's first regulation on AE reporting.

According to the draft, SFDA will require drug makers to update drug safety information for new drugs every year. For imported drugs, distributors in China will need to submit drug safety reports every year for the first five years of a drug's life and then once every five years from then on.

"The new version has expanded significantly. ... It clearly spells out the reporting timeline for cases involving a death, as well as adverse events and serious adverse events," Zhang Dan, co-founder and CEO of Fountain Medical Development, told *PharmAsia News*.

"It clearly identifies the role of city and provincial level and the State FDA's role and responsibilities in handling AE and SAE cases. The new draft also highlights the handling of individual AEs/SAEs versus group AEs/SAEs," said Zhang, who is the former VP and member of Quintiles Transnational executive committee.

"Another striking difference from the old version is that the SAE definition in the current version is completely in line with the U.S. FDA's definition, while the SAE definition in the 2004 version had some differences from the U.S. FDA definition," said Zhang, who received his medical training from Peking Union Medical College and finished his economics and management training from Harvard and the Wharton School of the University of Pennsylvania.

Fountain Medical Development is one of the leading clinical contract research organizations in China.

"One last point that needs to be highlighted is that the current version establishes a reporting philosophy: As long as there is any suspicion that the safety event is drug related, it has to be reported. This is in line with ICH guidelines. And there is no mention of this rather important reporting philosophy in the 2004 version," he said.

The new version also stipulates online reporting of AE/SAEs, which would ensure that safety databases are more accurate.

"If the new version can be implemented successfully, it will solve most of the reporting problems, provided that sufficient training and on-site random auditing will be conducted to enforce the new guideline," Zhang summarized.

Still Needs Improvement

However, one thing that is not clear in the document, according to Zhang, is the role of CROs in reporting AEs on behalf of sponsors.

Regulators should ask manufacturers and service providers to prepare risk management plans for newly approved products, he said, adding that unexpected and drug-related SAEs should also be filed directly to SFDA. Under the current draft, unexpected and drug-related SAEs are submitted to city and provincial level FDAs.

"Allowing SFDA to receive these SAEs is important for getting a quick, nation-wide response for certain SAEs that would have a huge impact on the Chinese population," he said.

Compared with the current measure, the new draft also establishes fines and punishments for violations and failure to report AEs in a timely manner. Fines range from RMB 30,000 (\$4,390), and in serious cases manufacturers could see their drugs pulled from the market and their manufacturing licenses revoked. Drug distributors could also lose their licenses in the most serious violations.

"Penalties for noncompliance could be more severe in order to enforce the new guideline," Zhang added.

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