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CFDA Accelerates Implementation of Drug Electronic Monitoring Network

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Food & Drug

On January 4, 2015, the China Food and Drug Administration (CFDA) released two notices intended to fully implement its Electronic Drug Monitoring Network ("the Network") for drug products by the end of 2015. The Twelfth Five Year Plan for Drug Safety calls for the establishment of this network that can trace all drug products through the supply chain. After launching electronic monitoring pilot projects in some of the provinces, CFDA has been gradually implementing the network on a national level since around 2011, with a target end date of 2015 for total coverage. This system requires manufacturers to place barcodes on the "various levels" of drug packaging and scan and verify those products as they move through the supply chain. Manufacturers, distributors, and healthcare institutions must be on the Network and transmit information obtained through scanning and verifying product identifiers to a database administered by CFDA.

CFDA's first notice, the Notice on Matters Related to the Complete Implementation of the Electronic Monitoring for Drugs ("First Notice"), sets specific deadlines for the inclusion of the remainder of domestic manufacturers, foreign manufacturers of imported drugs, and distributors into the system. Specifically, "all" domestic and foreign drug product manufacturers must be using the Network by December 31, 2015. Once listed on the Network, they must comply with the requirements in CFDA's Guiding Opinion on Drug Electronic Monitoring Work released in 2012, which mandates that a China electronic drug monitoring number must be printed on or affixed to different levels of sales packaging. Manufacturers must participate in data collection and transmission via the China Drug Electronic Monitoring Platform, which is run by CFDA. The First Notice does not state whether this requirement includes manufacturers of drug ingredients.

Foreign manufacturers that import their drugs into China have an intermediate deadline to meet. If they have not registered with the Network, they must designate an agent for their electronic monitoring work and have that agent report to CFDA by April 30, 2015 to begin registering. Pursuant to the Notice on Import Drug Electronic Monitoring, which CFDA released in 2013, manufacturers of imported drugs must designate a drug manufacturer, wholesale distributor, or their own subsidiary or other operational institution in China as a drug electronic monitoring agent. These agents are intended to be a liaison between CFDA and the foreign manufacturer in order to assist the manufacturer in performing its obligations under the electronic monitoring system and to assist with concrete measures, such as product recalls.

The First Notice also calls for all wholesale distributors and retailers to register with the system before the end of 2015. For those who register, they are required to scan in all drug products that have the required barcode and transmit complete and accurate information. It also requires distributors and retailers to "seriously handle" any early warning information available in the monitoring system.

In addition, the First Notice requires that all manufacturers, distributors, and agents of foreign manufacturers attend the trainings conducted by China's provincial food and drug regulatory authorities about electronic monitoring. Manufacturers, distributors, and agents of foreign manufacturers must also "optimize their facilities and systems and reasonably transport their flow of operations" to meet their obligations to join the electronic monitoring network, barcode their products, and transmit and verify product information.

The second CFDA notice is entitled the Notice on Fully Completing the Implementation Electronic Drug Monitoring Work ("Second Notice"). The Second Notice requires China's provincial food and drug regulatory authorities to supervise the progress of integrating manufacturers and distributors into the Network. These provincial regulatory agencies are to encourage full coverage as fast as possible and facilitate that transition through training and management. This work includes, among other things, facilitating the entry and training of agents of foreign manufacturers. The local governments must report on their progress periodically throughout the year, on May 10, 2015 (for progress on importers only), July 10, 2015, November 10, 2015, and January 10, 2016. Each report covers the work completed up to the end of the prior month.

The Second Notice also directs the provincial-level food and drug regulatory authorities and those at lower-levels of local government (e.g., municipality) to increase supervision of whether manufacturers and distributors in the Network are complying with their obligations. If manufacturers are not barcoding and properly transmitting data, then the local authorities are directed to issue orders to them to correct their behavior. The Second Notice does not specify additional consequences for repeated noncompliance, except to say that if the noncompliance causes fake or substandard drugs to enter the market, then manufacturers and distributors shall bear "appropriate legal responsibility." For distributors, noncompliance may be dealt with as a violation of China's drug good supply practices. Provincial-level food and drug regulatory authorities must appoint the requisite personnel to accomplish these tasks, draft a training schedule for stakeholders, and create local forms to carry out their work by January 20, 2015. They must report this progress to CFDA.

Stakeholders should take note of these deadlines and monitor for further guidance on the implementation of the Network.

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