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E-ALERT | Food & Drug

June 3, 2014

CHINA FOOD & DRUG ADMINISTRATION RELEASES DRAFT MEASURES ON UNANNOUNCED PHARMACEUTICAL DRUG INSPECTIONS

On May 12, 2014, the China Food and Drug Administration (CFDA) released draft Measures on Unannounced Drug Inspections (draft Measures) for public comment. The comments are due on June 12, 2014. The draft Measures permit CFDA and the provincial drug regulatory authorities to conduct unannounced site inspections of drug manufacturers and distributors within their respective jurisdictions. CFDA currently has authority to conduct unannounced inspections, for example, with regard to drug Good Manufacturing Practice Violations (as well as in the food and medical device spaces), but the draft Measures are a more comprehensive framework than prior rules. The draft Measures come at a particularly important time, because CFDA is currently working on draft revisions to the Drug Administration Law (DAL),[1] which would provide CFDA with an enhanced role in post-marketing supervision and enforcement. Therefore, comments on the draft Measures and any experience resulting from their ultimate implementation could influence the DAL revision process.

Under the draft Measures, the CFDA would be responsible for "organizing" unannounced inspections that reach national scope, while the provincial drug regulatory authorities would be responsible for inspections within their respective jurisdictions. The draft Measures do not make it clear what the specific division of labor would be between the CFDA and the provincial drug regulatory authorities in terms of "organizing" inspections and carrying them out. Local officials in governments below the provincial level, i.e., the county level, would be required to assist with the unannounced inspections.

The draft Measures would provide CFDA and the local authorities with fairly wide discretion to conduct these inspections. They may conduct an inspection when prompted by a complaint, product quality risks, adverse events, and when monitoring and spot-checks indicate that it is necessary to inspect. Even though CFDA and provincial drug regulatory authorities will primarily conduct the inspections, they may use the police and news media "when necessary." It is not clear how exactly the CFDA would connect with the police or media in order to "organize" an inspection. It is possible that the Agency would use these avenues to receive information about facilities where violations may be present or to confront facilities through force or shaming. CFDA may also turn the case over to the local police if violations are tantamount to crimes.

The draft Measures require that inspections be conducted by groups of two or more inspectors, who must create an inspection plan prior to entering a facility. They must carry appropriate credentials, and must record all legal and regulatory violations discovered during the inspection with photographs or other records. They may take samples when necessary. The draft Measures state that sampling determinations and procedures must be conducted according to specific regulations on drug sampling. When urgent circumstances present themselves, such as those demanding a recall or constituting a crime, the inspectors must immediately report to the relevant drug regulatory authorities. Otherwise within three days of the inspection, or within 24 hours in urgent

[1] Although the DAL will ultimately need to be passed by China's National People's Congress (NPC) before it becomes law, the drafting is currently taking place within CFDA. The draft DAL will likely be distributed both internally in the government and also to the public for comment before going to the NPC.

circumstances, the inspectors must prepare a report and present it to the relevant drug regulatory authorities.

Once the report is submitted, CFDA or the relevant local drug regulatory authority will determine what measures to take, including correction of the issues within a prescribed time, a warning letter, a consultation meeting with the inspected entity, a recall, withdrawal of the entity's credentials, and temporary suspension of manufacturing and distribution activities. In the case of criminal violations, which is becoming one of the most common ways of punishing serious non-compliance with food and drug laws in China, the local authorities may report the case to the local police.

The draft Measures would require the inspectors to protect commercial secrets (technical and business information) during the inspections. However, some violations may result in public disclosure. Specifically, under the enforcement section of the draft Measures, officials would have wide-discretion to report on the inspection internally within government agencies, and the authorities may also report the inspection information to the public. When the results of the inspection reveal example or typical cases – which are often released in China for educational and deterrence purposes – the authorities may publicize the information via the media. In the draft Measures, this discretion appears to be unqualified.

The draft Measures would require all drug regulatory authorities to allocate a portion of their annual budget to unannounced site inspections. Expenses for inspections and sample testing would be reimbursed to manufacturers on the basis of actual costs. In other words, under the draft Measures, drug manufacturers and distributors would not be required to bear inspection costs for the authorities.

Drug manufacturers and distributors doing business in China should considering commenting on this regulation and should continue to monitor for the final rule.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our firm:

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