China Issues Implementation Rules for Its New Pharmaceutical and Medical Device Blacklist System

On December 27, 2013, China’s National Health and Family Planning Commission (NHFPC) published an agency rule to update the “blacklist system” for pharmaceutical and medical device companies convicted of commercial bribery (see Sidley update here). On February 26, 2014, NHFPC issued a notice that clarifies important implementation issues under the new blacklist system.

The NHFPC notice contains some new, important requirements that are not included in the December 2013 rules, and highlights are:

- **Local implementation is emphasized.** NHFPC requires provincial health authorities to amend their local blacklist systems and promulgate detailed implementation rules by March 2014.

- **Reporting obligations are extended to hospitals.** If hospitals employees are cited in commercial bribery penalty decisions, or if the hospitals learn of non-compliant activity by any party in audits, they must report the names of implicated drug or device manufacturers or distributors or their agents to health authorities.

- **Reporting obligations for local health authorities are heightened.** County-level health authorities are required to report to higher-level authorities commercial bribery penalty decisions that come to their knowledge within five working days.

- **Integrity Agreement requirements are detailed.** These requirements include:
  
  1. If hospitals and drug or device suppliers entered into product supply relationships before the enactment of the new blacklist rules, they are required to sign Integrity Agreements by April 1, 2014.

  2. The Integrity Agreement must be signed by “the parties to the product supply agreement,” which in many instances means hospitals and local drug or device distributors (not drug or device manufacturers or importers). In such cases, it seems that only the local drug distributors are directly bound by the requirements of the Integrity Agreement.

  3. In the Integrity Agreement, the drug or device supplier must designate the “Sales Representative” for drug or device promotion at the hospital. Also, Sales Representatives may only communicate with physicians at a “designated location” of the hospital, and may not conduct product promotional activities in patient treatment or hospitalization areas.
The NHFPC notice provides useful clarifications on some key issues, but uncertainties still exist. Particularly, NHFPC is pressing provincial health authorities to promulgate local implementation rules, and it is possible that these local rules will be stricter than the central agency rules. For example, it is believed that some provincial health authorities may require drug or device manufacturers to “co-sign” the Integrity Agreement together with their local distributors, which would essentially make them jointly liable for violations by local distributors. Also, this would create difficulties for normal promotional activities of drug or device manufacturers. Therefore, multinational drug and device companies in China should look at both central agency rules and local variations to establish a complaint promotional strategy.

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