Medtech and pharma: heed stricter China clinical trial rules for hospitals

Medical device and drug companies that sponsor clinical trials in hospitals in China are being advised to review their internal policies governing such studies in light of tough new rules for medical institutions conducting trials[1,2].

In addition, companies "need to be mindful" that the new requirements might lead to delays in the conduct of clinical studies, warns Katherine Wang, partner at the Shanghai office of law firm Ropes & Gray.

The "Administrative Measures for the Clinical Study Projects of Medical Institutions"[3] became effective on 16 October. The measures aim at tightening supervision over clinical trials in China. They introduce a number of new requirements for hospitals conducting studies as clinical sites, including new rules for managing study funds and for approving studies, which, according to Ms Wang, add new layers of approvals within hospitals that might delay trials.

"An immediate step [for companies] is to clarify how each of the current study sites may respond to the new measures and the review/approval processes at major study sites," Ms Wang told *Scrip Regulatory Affairs*.

"Payment arrangements may also need to be adjusted to reflect the new requirements under the measures," she adds. "Last but not least, companies should closely monitor the detailed rules for the filing of hospitals' administrative approvals at local health authorities and comply with the latest requirements."

The new measures comprise a specific code of conduct for "research behaviors" of hospitals and physicians, Ms Wang says, noting that the requirements supplement the current regulatory regime. "China regulates clinical studies primarily by a compulsory ethics committee (EC) review regime, a clinical trial authorization system for all drugs and certain high risk devices, the good clinical practices (GCP) governing drugs and devices respectively, and, last but not least, a certification system to permit eligible hospitals to undertake studies," she explains. The measures should also be read in conjunction with the general anti-corruption disciplinary rules in the "nine prohibitions" issued in late 2013[4].

As for how long trials might be delayed by the additional layers of approvals that come with the new measures, Ms Wang says "it is difficult to give a precise estimate" at this time. "The notice does not specify how hospitals' administrative review procedures interact with the current approval procedures at the China Food and Drug Administration (concerning clinical trial authorizations) and the EC," she explains. "It also does not clarify if hospitals' administrative review can move in parallel to the other approval processes. The interplay between these approvals is yet to be ascertained."

According to the Ropes & Gray lawyer, the key requirements for hospitals in the new measures relate to: the administration of clinical studies; managing funding for studies; and approving studies.

More specifically, Ms Wang explains, hospitals must establish internal rules and SOPs for administering clinical studies. In addition to an EC, hospitals must also form a Clinical Study Administration Committee (CSAC). "The CSAC, composed of the hospital's relevant leaders, division chiefs and clinical study experts, will make supervisory decisions over study-related matters of the hospital," she says. "A subordinate implementing body, Clinical Study Administration Division (CSAD), also needs to be created to handle daily administration of study projects," she adds.

Funding of clinical studies must be channeled to a dedicated hospital account and not to a particular clinical department or an individual physician involved in the project. Ms Wang explains that "the use and distribution of the clinical study funds must follow the hospital's financial rules and the budget plan for the specific study project". If a sponsor has already covered any of the participating subject's expenses, such as the cost of study drugs or a physical exam, the hospital cannot charge the patient subject for such fees, she says.

The hospital must approve all clinical study projects before implementation. Ms Wang says that the applying physician must submit relevant information to the hospital for approval, such as the CV and qualifications of the investigators, summary of the scientific basis of the research, study protocol, quality management protocol, risk evaluation and risk management proposal, form of informed consent letter for patients, any covenant on intellectual rights, and the financial sources sponsoring the study. She says that the hospital EC will carry out the first round review of the project. "If the application passes the first round, the CSAD will submit the application for approval by the CSAC."

After the hospital approves the project, it must within 30 days file the clinical study project for record with the local counterpart of the National Health and Family Planning Commission that has granted its medical practice license, in addition to a filing with the local FDA as per current rules, Ms Wang says.

She adds that the CSAC and CSAD must continuously oversee the study throughout its entire course. "They must periodically evaluate the project with regard to the research ethics, safety, effectiveness, and financial compliance and commercial bribery risks." The hospital must report any irregularities found during such evaluation to the local health authority and should adjust, suspend or terminate the study where necessary, subject to CSAC approval, Ms Wang concludes.

neena.brizmohun@informa.com

References

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