Published on *The National Law Review* https://natlawreview.com

China FDA Restructures Medical Device Adverse Event Regulations

Article By:

John C. Balzano

Following a significant ***revision of its framework medical device regulation, the China Food and Drug Administration ("CFDA") and the*** National Health and Family Planning Commission ("NHFPC") have released a proposed revision to the Administrative Measures on Monitoring Medical Device Adverse Events and Re-Evaluation ("proposed Measures"), which is the primary regulation for medical device adverse events. The proposed Measures contain the requirements for reporting, evaluating, and remediating adverse events and serious adverse events for both imported and domestically manufactured devices in China. The comment period closed on December 20th. We describe some of the key points of the proposed Measures below.

The proposed Measures are a revision of a 2008 rule of the same name. The proposed Measures contain a number of changes to the medical device adverse event reporting system, including

- the addition of a new definition of serious adverse event (SAE),
- a system of enhanced monitoring for certain devices, and
- a set of detailed requirements and timelines for government agencies, manufacturers, distributors, and healthcare institutions to monitor, report on, and analyze adverse events.

This system will rely upon the coordination of government designated medical device adverse event monitoring technical institutions ("monitoring institution") at the central, provincial, and municipal levels of government. CFDA committed to expand these institutions in 2013.

The proposed Measures divide all medical device adverse events into SAEs and "normal" adverse events. The proposed measures do not change the existing broad definition of adverse event, which provides that a "medical device adverse event" refers to a "harmful event" in which an approved medical device, meeting quality standards and used under normal conditions, causes or could cause harm to the human body.

The proposed Measures set forth five circumstances in which an adverse event would constitute an

SAE: (1) the device causes death; (2) the device endangers human life; (3) the device results in permanent loss of a bodily function or permanent structural damage to the body; (4) the injury caused by the device requires medical intervention to prevent permanent damage; or (5) circumstances in which, due to a defect in the device, its usability, or other such problem, a device could lead to one of the other four circumstances.

The proposed Measures have more detailed reporting requirements than the 2008 rule. The primary entities responsible for reporting SAEs are "use entities" (i.e., healthcare institutions), manufacturers and distributors. Individuals may also report suspected adverse events. For an SAE, a manufacturer or healthcare institution must report it through CFDA's medical device adverse event monitoring information website, or if that is not possible, to a "local" monitoring institution using a paper form. The manufacturer or healthcare institution must report the event within 15 days of its occurrence or of learning of its occurrence. If the SAE causes death, a report must be submitted within five days. For normal adverse events, the report must be submitted within 30 days.

In addition, both Chinese domestic medical device manufacturers that distribute their devices outside of China and foreign device manufacturers must report SAEs that occur abroad. Foreign manufacturers must make those reports within 15 days of the event or of knowledge of the event.

Once reported, monitoring institutions at different levels of government (provincial and municipal) will evaluate those events and report to the provincial food and drug regulatory agency (for Class I and Class II devices) or the CFDA (for Class III and imported devices). If CFDA or the provincial food and drug authorities determine that additional steps are necessary to control the event, then they will communicate that decision to local healthcare regulatory authorities. It is not clear what "control" action the healthcare authorities might take in these instances.

Devices with frequent or more severe adverse events may be subject to enhanced monitoring. In that case, provincial monitoring institutions must monitor the device according to a special plan determined by the provincial food and drug authorities. Manufacturers are required to "actively gather" adverse event reports, conduct a risk analysis, and report the results to a monitoring institution in their municipality or province.

Devices with problematic records may also require re-evaluation. Specifically, if reported adverse events raise questions about the safety or the effectiveness of the device, either the manufacturer or the provincial food and drug regulatory authorities can re-evaluate the device to determine necessary measures need to be taken to control those issues.

The proposed Measures also include a general section on "remediation." For example, manufacturers that know that their device could cause an adverse event shall make that clear in the package insert and "other accompanying documentation." When a manufacturer discovers a safety defect that could cause harm, it shall take "recall measures," such as training, warnings, inspections, repairs, and relabeling and amendment of the package insert, software upgrades, replacement of the device and destruction. If the event is determined to be the result of a medical accident, healthcare authorities must take steps to resolve the problem, although the proposed Measures do not include detail as to that process.

The proposed Measures impose penalties for failing to properly monitor or report adverse events, such as fines or, in more extreme cases, orders to stop production or cancel licenses. The proposed Measures also state, however, that the content of adverse event reports and related risk analyses may not serve as the basis for disputes or litigation surrounding medical treatment or for resolving

incidents related to medical device quality.

All device manufacturers that distribute their devices in China should continue to monitor the progress of this rule, and its implementation.

National Law Review, Volume V, Number 355