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Brazil Clarifies ANVISA Oversight Roles for Devices

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Brazil's National Surveillance Agency released an order mapping out the specific oversight roles for federal, state and local ANVISA branches for medical devices.

Order RDC 215/2018 clarified that the federal ANVISA office will oversee device registration and Brazilian GMP inspections.

ANVISA audits all Class III and Class IV devices, and companies will need certification until they can market their devices in the country. Additional local requirements also may apply.

However, the agency said it would conduct risk assessments for international devices including reviews of technical documents rather than on-site GMP inspections, depending on the level of risk identified. The change will mean greater flexibility in determining risk for certain Class III or Class IV devices.

Backlog

ANVISA has made a lot of recent changes geared toward streamlining operations. The agency was earlier criticized for taking so long to approve products, which resulted in a backlog, said Marcelo do Ó, managing director and partner at L.E.K. Consulting, in São Paulo, Brazil.

In 2016, ANVISA took a number of steps in the direction of rationalization, better planning and listening to different stakeholders to improve processes, he said.

As part of this effort, the authority developed a regulatory agenda for the future that highlighted 15 macro topics and 127 themes to address from 2017 to 2020. The regulatory agenda has 11 topics relating to devices.

One of those changes was to extend the registration period for high-risk Class III and Class IV devices and in vitro diagnostics from five years to 10 years (*IDDM*, Feb. 5).

ANVISA made the decision to extend the license period on Jan. 16 after consulting with the ANVISA board of directors and industry. The authority had announced in August 2017 that it was considering doubling the registration period for devices and IVDs, saying the move would cut costs for industry and reduce bureaucratic layers.

"The first topic on the medical device agenda for 2017-2020 is registration and post-registration," do Ó said. "There will be a number of non-critical products that will not require a registration, but just a notification. Our expectation, though, is that critical products such as heart implants, hip implants and other orthopedic products, for example, will have higher quality standards on registration, post-registration, market monitoring, manufacturing quality certification and technovigilance."

Improved Access

Extending the medical device registration period for higher-risk devices to 10 years will substantially improve market access, BMI Research Analyst Karen Simpkins told *FDAnews*.

"For comparison, medical device registrations are valid for five years in Argentina and Mexico. The extended validity timeframe, along with other recent regulatory developments, will further enhance the attractiveness of the Brazilian market, which already has one of the lowest regulatory risks in the Latin American region," Simpkins said.

Brazil's device market is worth about $11 billion, and is growing at a rate of 5 percent to 7 percent, according to the Brazilian Association of High Technology Medical and Hospital Equipment, Products and Suppliers.

"ANVISA is the highest standard regulatory organization across Latin America, and often times used as a reference in the region," do Ó said.

Other regulatory developments in the works include regulation of software as a medical device, medical device traceability, a national implant registry and medical device marketing," do Ó said.