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FDA Wants To Make Permanent COVID-19 Supply Chain Guidance To Prevent Product Shortages

by Ferdous Al-Faruque

The US agency issued a new draft guidance to require medical device and diagnostics manufacturers and distributors to report supply chain issues in the event of a public health emergency.

The US Food and Drug Administration wants to make permanent a previous guidance that requires medtech manufacturers and distributors to notify the agency of a product shortage during a public health emergency. The previous November 2020 guidance expires with the COVID-19 pandemic health emergency, but the agency wants to make sure it stays in place for future emergencies.

According to the *draft guidance published on 10 January*, device and diagnostics makers would need to notify the FDA through its website at least a month before a shortage or discontinuation, but no later than a week after. If they don't do so and have no good reason for not notifying regulators, the agency plans to name the company on its website for noncompliance. (Also see "*Revised FDA Guidance Says Makers Of Tests, Hospital Beds, More Should Tell Agency Of Shortages*" - Medtech Insight, 22 Jun, 2020.)

"FDA is issuing this guidance to clarify and make recommendations regarding who should notify FDA, what information to include in the notification, and how to notify FDA, during or in advance of a public health emergency, regardless of the type of public health emergency," the draft guidance says. "During a specific public health emergency, FDA may issue additional supplemental information to this guidance, through supplemental guidance, FDA's website, or other communications, to assist manufacturers in providing a notification."

If the agency concludes that there is likely to be a critical product shortage it may use its

authority to prioritize inspections, accelerate product reviews and take other measures to try mitigating the problem, the guidance explains.

John Serio, a partner at the Withers law firm, says he's already seen how companies have benefited from the FDA getting involved with ensuring pandemic-critical products facing shortages are given priority. He notes that two of his clients were importing N95 face masks from Asia but the products were delayed at the border by US customs on a technicality until the FDA got involved in the case, which came to a favorable conclusion for the firm.

Serio says the draft guidance is essentially a call from the FDA to industry to get input on how they can work together to prevent shortages of critical medical products in future health emergencies.

> *"If you're a medical device manufacturer you really don't want to get on the wrong side of the agency." – John Serio*

"What the agency wants to be able to do in responding to emergencies is make sure that in the event a manufacturer is having a supply problem, a regulatory problem, whatever problem, that they can then prioritize maybe inspections of other plants, approvals of other regulatory applications, to address the gap of a discontinuance of a medical device," he told Medtech Insight in an 11 January interview.

While right now there are no serious repercussions for not updating the FDA on potential product shortages, Serio cautions: "If you're a medical device manufacturer you really don't want to get on the wrong side of the agency."

He also said those commenting on the draft guidance may also ask that companies that don't comply be penalized in some way for not notifying the agency.

Serio further says the FDA should consider expanding the draft beyond just public health emergencies to ensure medically critical products are never in short supply because it's hard to predict when a public health emergency may happen.

"Why should this be just limited to public health emergencies?" he asked. "If these are critical medical devices it should be any time … that you communicate to the FDA of a supply problem."

And Serio wants to go several steps beyond even that. He says there is technology available today to track mail and deliveries that various industries and the federal government should use to constantly track critical products to make sure there aren't shortages in the supply chain – and alert the public if there is.

"I think you'll see this happen coming out of the pandemic that how we alert the public to supply shortages needs to be far better than what it is right now," Serio said. "I can order something from any online retailer, and I can see not only where it's at in the distribution, but I can see when it's going to arrive and I'm told where it was delivered to.

"I think the industry needs to adopt some of the practices of other industries that seem to be very good at delivering things and notifying you when things are backordered," he added.

Serio also said standardizing the supply chain distribution system of FDA-regulated products is probably warranted and perhaps should be part of the agency's efforts to set up a better supply chain alert system.

Update: On 4 February the FDA announced it had received requests to extend the comment period for the document by another 30 days. Stakeholders can now comment on the draft guidance until 11 April under docket No. *FDA-2022-D-0053* on *Regulations.gov*.