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From: 5.1.2e)
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Onderwerp: EU meds regulators plan automatic certification extensions through 2021

EU meds regulators plan automatic certification extensions through 2021

-- By 5.1.2e
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The European Medicines Agency outlined plans for remotely assessing regulatory compliance while the COVID-19 pandemic limits travel.

The EMA and national regulators today published updates to a Q&A document for drugmakers and distributors.

Broadly, the regulators said that existing certifications of good manufacturing practice (GMP) should be extended automatically until 2021, barring any changes or red flags. For new facilities, regulators may perform a "distant assessment" to determine whether a GMP certificate can be granted.

"It is stressed that the obligation of manufacturers and importers to comply with GMP is not waived," the guidance says, adding that in-person checks should resume as soon as travel restrictions are lifted.

The regulators outline a similar process for good distribution practice certifications.

The guidance also includes a new section about reporting adverse reactions to medications, which takes into account the likelihood that industry may be short-staffed during the pandemic. The regulators lay out how companies should prioritize reporting; serious side effects related to treating the coronavirus should be the top priority, followed by other serious side effects.

Separately, the EMA and national regulators today published a readout of the April 15 meeting of the EU Executive Steering Group on Shortages of Medicines Caused by Major Events. The Amsterdam regulator said it is "fine-tuning the details" of the industry single point of contact system, or i-SPOC, which would help the EMA coordinate shortage notifications and potentially take steps to mitigate them.

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