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 Onderwerp: EMA increasing role to address ICU medicine shortages

EMA increasing role to address ICU medicine shortages

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The European Medicines Agency will act as a "central coordinator" to address shortages of critical medicines in intensive care units due to heightened demand in the coronavirus pandemic.

The shortages include anesthetics, antibiotics and muscle relaxants, "as well as medicines used off-label for COVID-19," the agency said in a press statement.

European hospitals began raising the alarm on the issue last month, and the Commission asked drugmakers last week to increase production.

Shortages of these medicines have increased over recent years, but the COVID-19 pandemic has "aggravated" the issue due to border closures, export bans, lockdowns in non-EU countries and increased demand, the agency said.

The EMA will now step in as a "central coordinator" — a new role for the agency which means it "is having to put in place new ad hoc processes and prioritise resources to this activity."

The agency has been "proactively" gathering information about shortages, and is discussing with member countries the effect of India's export ban on 14 active pharmaceutical ingredients.

The EU and the EMA are also looking into regulatory actions that could boost production of these medicines, for example, by speeding up the approval of a new manufacturing site.

The EU Executive Steering Group on Shortages of Medicines Caused by Major Events is considering further regulatory flexibility to secure these medicines.

The group is creating a system called "i-SPOC" — industry single point of contact system — to speed up communication with industry and "allow better oversight" of supply issues.

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