Amid concerns about potential shortages of crucial medicines to treat patients with COVID-19 and other conditions, the European Medicines Agency (EMA) said that new European Union (EU)-level measures are being put into place to help prevent and mitigate supply issues.

"The continued availability of medicines, in particular those used for patients with COVID-19, is of critical concern for EMA and its partners in the European medicines regulatory network in light of the medical emergency presented by the pandemic," the agency said in a statement.

The EMA noted that some EU member states have reported that they were either already beginning to see shortages of some medicines used for patients with COVID-19 or expect to experience medication shortages "very soon." These medicines include certain anesthetics, antibiotics, and muscle relaxants used in intensive care units as well as drugs used off label for COVID-19.

The agency outlined strategies to help prevent and ease supply problems related to medications used in treating COVID-19. These strategies include efforts to work with the pharmaceutical industry to monitor supply chain issues for relevant medications as well as regulatory actions to assist companies in boosting the supply of critical medicines. The EMA will act as the central EU coordinator, supporting the member states' activities in addressing the problem.

Similar concerns about shortages of critical medications have emerged in the United States. The US Food and Drug Administration warned in February that the agency was concerned about potential disruptions posed by the coronavirus outbreak in China. The Washington Post reported that hospitals in areas with large numbers of patients with COVID-19 are facing potential shortages of sedatives, anesthetics, and paralytic agents needed for patients requiring mechanical ventilation, as well as shortages of antibiotics, antivirals, asthma drugs, and other medications.

In Europe, in an April 3 letter to pharmaceutical companies published by the London-based nonprofit the Bureau of Investigative Journalism, EU Health and Safety Commissioner Stella Kyriakides noted that several EU member countries had reported to EMA that they had only 1 week's stock of critical medicines for patients with COVID-19. "With my colleague Commissioner Thierry Breton, we therefore call on the pharmaceutical industry, whether research-based, [over the counter] or [active pharmaceutical ingredient] producers and as a matter of extreme urgency, to increase their production of medicines used to treat seriously ill COVID-19 patients," she wrote.

Shortages of pharmaceuticals have become more frequent in recent years, but that trend has been dramatically worsened by factors stemming from the COVID-19 pandemic. These include increased demand for medications used to treat patients with the infection; quarantine-related factory lockdowns; and logistical problems caused by border closures, export bans, and lockdowns in countries supplying pharmaceutical products to the EU.

In addition, stockpiling of medicines by some hospitals and others contributes to the shortages, the EMA said. Some EU member states have responded by restricting the amounts of pharmaceuticals that can be prescribed to patients or purchased by citizens.

To help monitor supplies of critical medications, the EU Executive Steering Group on shortages of medicines caused by major events is working with the pharmaceutical industry to set up a system involving the appointment of an "industry single point of contact" (i-SPOC) in each pharmaceutical company who will feed information directly to the EMA about current or anticipated shortages of
critical medicines used for COVID-19 treatment. The companies will also continue reporting such shortages to the national health authorities in affected countries.

The European medicines regulatory network—a partnership between the European Commission, regulatory authorities in EU member states and the European Economic Area, and the EMA—is assembling a list of the medications now being used across the EU to treat patients with COVID-19.

“The list will comprise active substances identified by the national competent authorities that are currently deemed crucial for the treatment of the infection, particularly in intensive care units (ICUs),” the EMA explained on April 10. “A subset of the medicines used in ICUs which are at greater demand will be closely monitored for any possible disruption in the supply using the i-SPOC system.”

Testing of the i-SPOC system was expected to begin “as soon as the composition of the i-SPOC is agreed upon with industry representatives,” the EMA noted.

In addition, the agency and the EU network are considering regulatory actions to help companies boost the available supply of critical medications, such as speeding the approval of a new manufacturing line or site.

The EMA noted that the EU Executive Steering Group discussed allowing more flexible application of regulatory requirements related to pharmaceuticals during the COVID-19 crisis. The agency and the EC have released a question-and-answer document to provide guidance to stakeholders, including “extraordinary procedures that can be applied to ensure the continued supply of these crucial medicines.”

ARTICLE INFORMATION

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