Pandemic Preparedness for Regulators in Low- and Middle-Income Countries

4 Strategies to strengthen surveillance systems for medical product shortages

The spread of coronavirus (COVID-19) has turned into a global pandemic with alarming speed, prompting many to have questions about the stability of global medical product supply chains. Many low- and middle-income countries may face greater risk of medical product shortages as a result of COVID-19, and the pandemic may also exacerbate the ongoing problem of substandard and falsified medicines.

This is the second of five sets of strategies to help regulatory authorities mitigate medical product shortages, prepare the public, and protect patients during the COVID-19 pandemic and beyond. See usp.org/lmic-drug-shortages for more information.

Strengthening shortage surveillance systems

1. **Establish early warning systems to identify imminent shortages.** Develop guidance for detection and notification of shortages of medical products, and require manufacturers to disclose supply disruptions.[1]
2. **Model potential supply disruptions.** Regulatory authorities should review the risk for supply chain disruption for critically-needed medicines based on their country's epidemiology. Consider developing a supply chain vulnerability risk assessment that will model hypothetical situations for future disruptions.
3. **Design strategies for rapid response.** Consider establishing supply disruption mitigation teams to rapidly respond to major supply chain disruptions. The teams, which can meet virtually, will map sources of supply for the country's pharmaceutical value chain, report on immediate or potential impact, and advise on mitigation strategies.
4. **Develop recommendations for the local pharmaceutical industry.** Regulatory authorities should recommend actions to reduce manufacturing disruptions related to potential issues such as limited staff, supply disruptions for active pharmaceutical ingredients (APIs) and inactive ingredients (excipients), equipment failures, and spike in demand for medical products essential to the COVID-19 response.

The four other topics in this series include: mitigating current medical product shortages, sharing information during the COVID-19 pandemic, protecting patients from substandard and falsified medical products, and establishing policies to mitigate future shortages.

[1] Provide a notice to remind manufacturers of those requirements where they exist. For instance, South Africa section 19(2) of the Medicines and related Substances Act (Act 101 of 1965) as amended, requires manufacturers to notify SAHPRA of any anticipated disruptions in supply, any shortages of products experienced, and any planned withdrawals of products from the market.

For more information:
usp.org/lmic-drug-shortages