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

5 Strategies to Mitigate Current 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 first 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.

Mitigating current shortages

1. **Use data to forecast shortages.** Conduct immediate analysis to compare recently imported products with historical utilization trends to predict imminent shortages. Identify alternate sources for medical products and consumables currently on shortage or most prone to shortages.
2. **Rely on medicines approvals obtained in other countries.** Utilize waivers and related instruments to facilitate the availability of critically needed products not yet approved in-country, which have undergone stringent regulatory approval in other countries.[1]
3. **Monitor quality of inactive ingredients.** To mitigate potential risks from the rise in use of analgesics, regulatory agencies should develop and share a list of local suppliers for inactive ingredients, or excipients. Many local pharmaceutical manufacturers source excipients from unregulated chemical dealers. Cheaper, toxic, industrial-grade ingredients often enter into the supply chain. In 2008, the use of diethylene glycol for the manufacture of *My Pikin* – acetaminophen syrup teething medication led to the death of 54 children in Nigeria. In order to maintain production during the COVID-19 crisis, local manufacturers might turn to new, unknown suppliers, which could compromise the product's safety and be harmful to patients.
4. **Compounding pharmacists can fill in gaps.** Compounding practices need to be reviewed and strengthened. Regulators should collaborate with Pharmacy Council and other pharmacy practice regulatory agencies to strengthen Good Compounding Practices.
5. **Lean on local medical equipment manufacturers.** Regulatory authorities should link hospitals with local manufacturers of personal protective equipment (PPE) such as gloves, masks and other medical devices such as respirators. To ensure continuous availability of hand sanitizers, several organizations including the U.S. Pharmacopeia Compounding Expert Committee, the World Health Organization, and the U.S. Food and Drug Administration have issued recommendations for preparing alcohol-based hand sanitizers.

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

[1] Article 13:2 of the AU Model law The Agency/Authority may from time to time determine that a medical product or category of medical products or part of any class or category of medical products shall be subject to exemption from marketing authorization in terms of this law.

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