Product regulatory systems in low-and middle-income countries must be strengthened

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When regulatory systems for medical products in low-and middle-income countries work, people live but when such systems fail, people die, according to experts from the US Food and Drug Administration (FDA) writing in this week's *PLOS Medicine*.

Charles Preston, Mary Lou Valdez, and Katherine Bond from the Office of International Programs at the FDA, argue that few global initiatives focus on strengthening the medical product regulatory systems in low-and middle-income countries but that globalization and the scaling up of medicines and vaccines to these countries are highlighting the urgent need for systems to assure product efficacy, safety, and quality.

Using recent examples, such as the successful MenAfriVac (a vaccine against meningitis designed for African populations), the authors argue that although the global health community is gradually awakening to the role that regulatory systems play in low- and middle-income countries, more needs to be done to make strengthening these systems a global health priority.

The authors propose several elements that all regulatory systems, whether in high, middle, or low-income countries should have, such as firm rules and a mechanism to take regulatory action when necessary. They say: "To this end, it will be important to begin a global dialogue on the subject of regulatory system strengthening in low- and middle-income countries."

The authors conclude: "As the challenges of globalization mount, and efforts to provide medical products to low- and middle-income countries scale up, there is no better time to put regulatory system strengthening squarely on the global health and development agenda."

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