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Improving Regulatory Practices to Sustain Antibiotic Innovation

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Webinar Background & Overview

Regulatory hurdles hinder antibiotic development and access among varied markets

Factors that slow or stall antibiotic research and development (R&D) are varied and often challenging to overcome. Poor underlying marketplace fundamentals prevent most large pharmaceutical companies from investing in antibiotics. And small-to-medium biotechnology companies—which conduct the vast majority of antibiotic R&D—typically require or partner with larger companies to take investigational antibiotics through clinical research to regulatory approval and distribution.

Investments in antibiotic R&D are further hindered by regulatory hurdles. These hurdles can include complex or redundant approval processes that slow time-to-market and patient access to new antibiotics—particularly among low- and middle-income countries. Additional regulatory challenges impact pediatric antibiotic development, largely related to clinical research. And innovative bacterial diagnostics that allow clinicians to quickly detect and treat potentially resistant infections face similar hurdles.

The *status quo* encourages an overreliance on older, broad-spectrum antibiotics when newer options may be more appropriate, contributing to antimicrobial resistance.

Regulatory harmonization—in other words, aligning the requirements drug developers must meet among varied governments' drug regulators—may speed antibiotic approvals, and signal a government's commitment to increasing antibiotic access.

Key Takeaways & Recommendations

- Steps toward regulatory harmonization can improve the odds that new antibiotics reach patients more rapidly among low- and middle-income countries and high-income countries. Notably, these steps toward regulatory harmonization ought to be guided by patient safety and global access and occur in combination with incentives that encourage antibiotic innovation.
- Harmonized regulatory expectations and a focus on leveraging and enabling adaptive clinical trial designs can preempt known challenges that arise during the review process.
- To establish umbrella guidelines and advance capacity-building and training for clinical trials, stakeholders ought to support global regulatory networks. Antibiotic developers that engage public-private partnerships and pooled resources can benefit from diversified knowledge and expertise from stakeholders among different markets.
- Drug and diagnostic companies ought to interact with regulators during antibiotic development to agree on expectations and preempt common challenges, especially when working in low- and middle-income countries, where executing clinical trials and collecting data involve unique hurdles.
- Regulators and antibiotic developers can do more to understand the unique challenges that impact pediatric antibiotic development, especially those related to country-specific needs. For pediatric patients, access to novel antibiotics can lag 5 to 10 years behind initial adult approvals due to challenges like slow clinical trial recruitment. And disjointed regulatory processes can be a compounding factor. Accordingly, pediatric clinical trial designs must reflect specific needs and limitations.
- The role of animal models, especially as part of the study of narrow-spectrum antibiotics, as well as the role of real-world evidence, should continue to be advanced.

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