

Acknowledgment of antimicrobial resistance in frameworks for drug approval could improve access to new antibiotics

July 14 2022, by Erta Kalanxhi, Giridara Gopal, Rati Kapoor, Gilbert Osen, Jyoti Joshi, Ramanan Laxminarayan



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The appropriate use of existing antibiotics and the development of new antibiotics targeting drug-resistant infections can slow the emergence, spread, and consequences of antimicrobial resistance (AMR); however, antibiotic research and development (R&D) has not responded to the

urgent need for new antibiotics. Antibiotics are costly to produce and their low prices and restricted use do not make their development economical. While financial incentives and market reforms are critical for sustainable progress, addressing regulatory hurdles to accelerate approval of new antibiotics can also help improve their development and access.

A landscape analysis by One Health Trust researchers highlights the importance of explicitly recognizing new antimicrobials targeting serious or life-threatening infections as a critical unmet medical need, formalizing their inclusion in regulatory frameworks for accelerated drug approval.

The recommendations provided to accelerate the approval of [antibiotics](#) include:

- Creating a specific category for antimicrobials that target serious and life-threatening infections within the [regulatory framework](#) provided for accelerated approval pathways.
- Leveraging existing programs for expedited approval for drugs targeting TB, HIV, and COVID-19 to accelerate the approval of antimicrobials targeting serious and life-threatening infections, such as multidrug-resistant infections.
- Increasing regulatory authorities' capacities to deal with the complexity of AMR and novel clinical trials.
- Promoting regulatory harmonization to facilitate the adoption of reliance pathways for accelerated approval of antimicrobials.

According to the Director of One Health Trust, Dr. Ramanan Laxminarayan, "Much has been written about the growing morbidity and mortality caused by [antibiotic resistance](#), especially in low- and middle-income countries. The problem is frequently blamed on the overuse of antibiotics and appropriately so, but insufficient attention has been given

to the underlying problem of lack of access to antibiotics. Appropriately, this report identifies the acknowledgment of AMR in regulatory frameworks for drug approvals as an opportunity to improve the wider availability of new antibiotics."

More information: Full report: cddep.org/wp-content/uploads/2022/07/acknowledgment-antimicrobial-resistance-frameworks-drug-2022.pdf

Provided by Center for Disease Dynamics, Economics & Policy

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