The landscape of antibiotic development and regulation in the United States and Europe, alongside evolving industry incentive strategies

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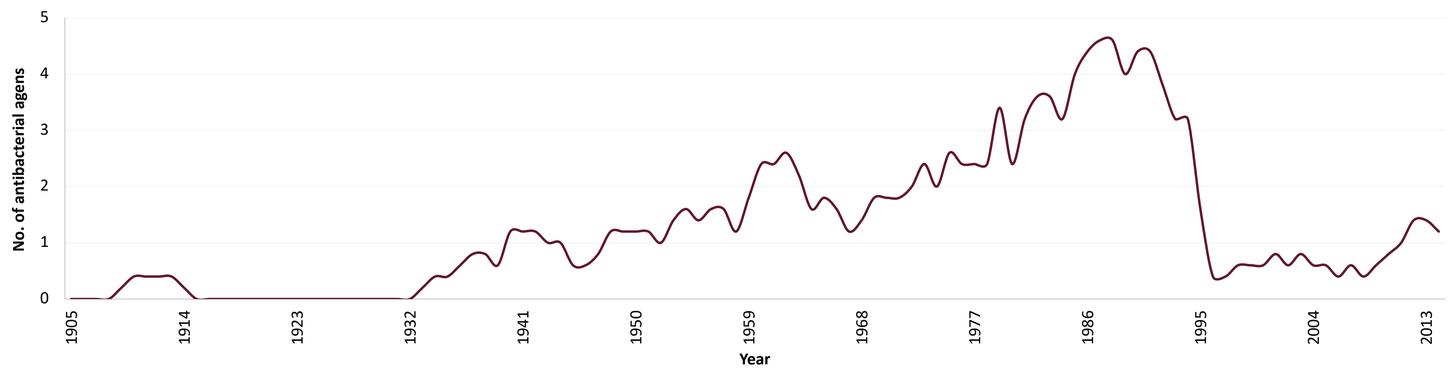
Introduction

Antibiotic resistance has emerged as one of the most pressing global health threats of the 21st century, driven largely by the widespread misuse and overuse of antibiotics. This growing crisis not only compromises the effectiveness of existing treatments, but also increases the burden on healthcare systems through prolonged illness, higher medical costs, and elevated mortality rates (1).

Despite the urgent need for new antibiotics, development pipelines remain sparse. Pharmaceutical innovation in this space faces significant scientific, financial, and regulatory barriers. High failure rates in clinical development, coupled with historically weak market incentives, have discouraged investment from industry stakeholders (2). This is reflected in historical data (Figure 1), which show a mid-1980s peak in antibacterial discoveries, driven by the breakthrough of penicillin, followed by a decline that began in the 1990s and continued into the 2000s (3,4).

Recent policy efforts have introduced new incentive models aimed at revitalising antibiotic innovation (1). However, the impact of these incentives remains uncertain. Understanding approval trends and incentive effectiveness is critical to shaping future strategies.

Figure 1: Rolling 5-year average number of antibacterial agent discoveries up to 2015 (3,4)



Objectives

The research objectives were to:

1a Assess and compare trends in antibiotic approvals by the FDA and EMA over the past decade

1b Summarise the antibiotics approved, their clinical indications, and targeted bacterial pathogens

2 Analyse planned or implemented industry incentives, highlighting their potential benefits and drawbacks

Methods

Antibiotic approvals

Data on antibacterial drug approvals by the US Food and Drug Administration (FDA) for the past 10 years were sourced from Garcia-Castro et al (2023) (5) (2015 to 2021), and targeted searches of FDA Novel Drug Approvals (6) and News & Events for Human Drugs (7) (2022 to 2025).

The European Medicines Agency (EMA) data were extracted from a public Excel® file (8) and filtered by the "Pharmacotherapeutic group (human)" column to isolate entries classified under "Antibacterials for systemic use".

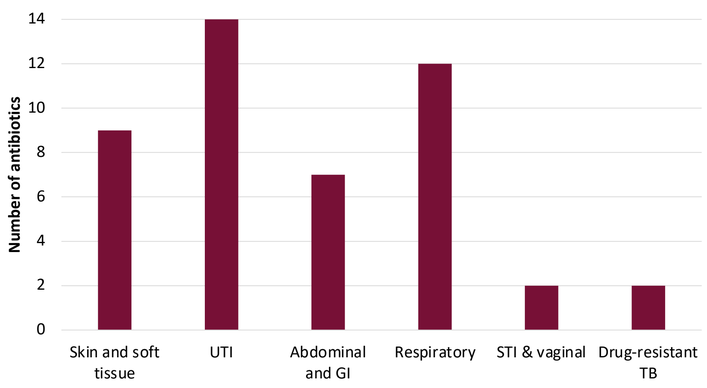
Only antibiotics used for treatment, not prevention, were included. For each antibiotic, approval year, primary clinical use based on both agencies, and relevance to the World Health Organization's (WHO's) Bacterial Priority Pathogens List 2024 (9), divided into critical, high, and medium priority groups, for research and development were recorded.

Review of industry incentive strategies

Desk-based research was conducted to identify planned or existing financial incentives for antibiotic manufacturers. Publicly available sources were identified through targeted keyword searches using online search tools.

For each incentive, country of implementation and mechanism type were recorded, along with potential benefits and drawbacks.

Figure 2: Main antibiotic indications based on FDA and EMA



Results

Antibiotic approvals

In total, 29 antibiotics were identified via the database search from the last 10 years, with more introduced via the FDA (29/29 [100%]) than the EMA (20/29 [69.0%]). Only three (10.3%) represented new antibiotic classes with unique mechanisms of action; four (13.8%) were novel antibiotics developed within existing classes. The remaining treatments (75.9%) were derivatives, new combinations, or reformulations of existing antibiotics. Most antibiotics were approved by FDA before EMA, reflecting differing manufacturer priorities.

The main drug indications are summarised in Figure 2. The most frequent indication was urinary tract infection (UTI) with a high focus on complicated UTIs such as pyelonephritis (11/14 [78.6%]). Antibiotics frequently received approval for multiple indications, underscoring their broad therapeutic value across various infection types. Of the 29 antibiotics identified, five (17.2%) targeted three distinct indications, while seven (24.1%) targeted two.

Of the antibiotics, 18 (62.1%) targeted at least one pathogen from WHO's critical priority group, with 2 (6.9%) targeting pathogens responsible for tuberculosis (9). 15 (51.7%) were active against up to 4 out of 7 pathogens from the high group. 10 (34.5%) targeted at least 1 out of 4 from the medium group.

Review of industry incentive strategies

Desk research identified several industry incentives (Table 1) that are key for supporting antimicrobial development. These provide financial support, regulatory advantages, and guaranteed returns to accelerate drug development and address the antimicrobial funding gap, though some are short-term solutions. The Pioneering Antimicrobial Subscriptions to End Upsurging Resistance (PASTEUR) Act was also proposed as an incentive in the US in 2020 but faced heavy criticism and was never passed into law (10).

Table 1: Planned or implemented industry incentives offering benefits to manufacturers

Incentive	Country (introduction year)	Mechanism	Benefits/drawbacks
UK Subscription Model (11)	UK (2022)	NHS England pays a fixed annual fee to the pharmaceutical company for new antibiotics, guaranteeing return regardless of usage	Ensures access and supports stewardship by de-linking income from use, but demands substantial public funding
BARDA (12,13)	US (2006)	Provides non-dilutive funding and technical support across all stages of development	Addresses private funding gaps and enables successes, such as Moderna's mRNA vaccine, but is vulnerable to changing political priorities
QIDP Designation (14,15)	US (2012)	Qualifying drugs are given a 5-year exclusivity extension, priority review, and Fast Track status to expedite development and approval	Priority review shortens FDA approval from 10 to 6 months, accelerating market access. Extended exclusivity boosts development incentives but mainly favours existing drug modifications over new drugs
AMR Action Fund (16)	Multinational (global) (2020)	A US$1 billion pharmaceutical companies-backed fund supporting late-stage antibiotic development	A vital short-term investment to close the antimicrobial development gap and support funding reforms, but not a permanent fix

Conclusion

Over the past decade, antibiotics have been approved by the FDA and EMA at different times and to varying extents, with more approvals occurring through the FDA than the EMA, reflecting manufacturers' priorities and reimbursement considerations. Only a small fraction of approved antibiotics were developed with a novel mechanism of action or as new agents within existing classes, underscoring a gap in innovation and the persistent threat of diseases caused by resistant pathogens. Although a growing landscape of innovative incentives shows promise, meaningful progress will require sustained investment and robust international collaboration.

Scan for a video walkthrough and references

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Abbreviations

AMR, antimicrobial resistance
BARDA, Biomedical Advanced Research and Development Authority
EMA, European Medicines Agency
FDA, Food and Drug Administration
GI, gastrointestinal
NHS, National Health Service
PASTEUR, Pioneering Antimicrobial Subscriptions to End Upsurging Resistance
QIDP, Qualified Infectious Disease Product
STI, sexually transmitted infection
TB, tuberculosis
UTI, urinary tract infection
WHO, World Health Organization