Global Surveillance of Newly Approved Antibiotics (2010–2025): A Systematic Review of Post-Marketing Resistance and Consumption Monitoring

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INTRODUCE
Optimized strategies for introducing new antibiotics in healthcare to preserve patient safety and counteract AMR

Objective: Identify and characterise systems monitoring the use of and resistance to antibiotics newly approved in Europe, North America, Israel and Turkey, Jan 2010 – Jun 2025.

BACKGROUND

New last-resort antibiotics: unequal access, divergent national approaches, and **no systematic surveillance of their use and emerging resistance**

- Post-marketing surveillance of antimicrobial resistance (AMR) and consumption (AMC) is critical to detect emerging resistance and support antimicrobial stewardship (AMS).
- Industry-led databases dominate the evidence base but prioritise proprietary interests; WHO/ECDC initiatives depend on standardised national data that often lacks structures for newer agents.

METHODS AND RESEARCH QUESTIONS

SEARCH	**MEDLINE (PubMed), Embase, Web of Science** · published January 2010 – June 2025 · no language restriction
SELECTION	Rayyan · two independent reviewers (title/abstract, full text) · third reviewer for disagreements · PRISMA 2020
ANTIBIOTICS	Systemic antibiotics **approved January 2010 – June 2025** by FDA, EMA, MHRA, Health Canada, TİTCK or Israeli MoH (list in backup)
INCLUDED	National, regional or multicentre systems reporting AMR and/or AMC · human health, all care settings · peer-reviewed and grey literature
EXCLUDED	Single-institution or one-off studies · anti-TB and *C. difficile* agents · animal, environmental, food chain · lab or PK/PD only · editorials · adverse events only

Q1: Identify regional, national, international systems for monitoring **use** of newly approved systemic antibiotics

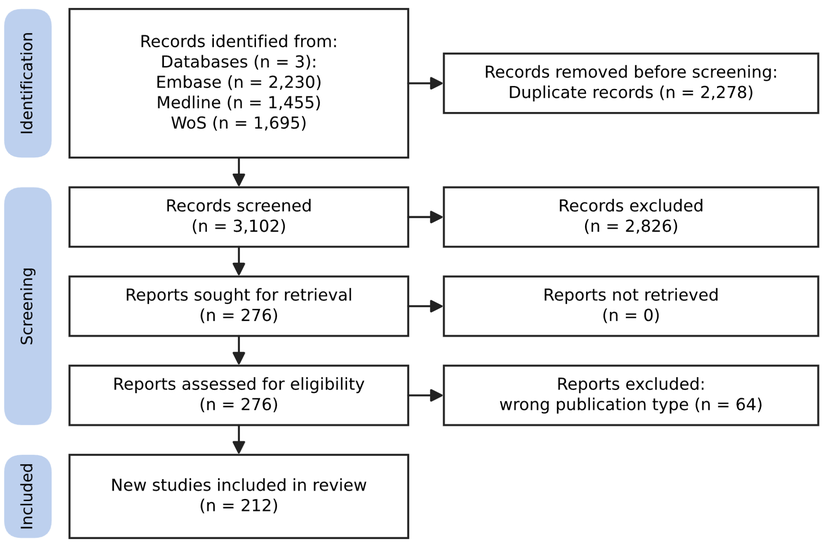
Q2: Identify regional, national, international systems for monitoring **resistance** to newly approved systemic antibiotics

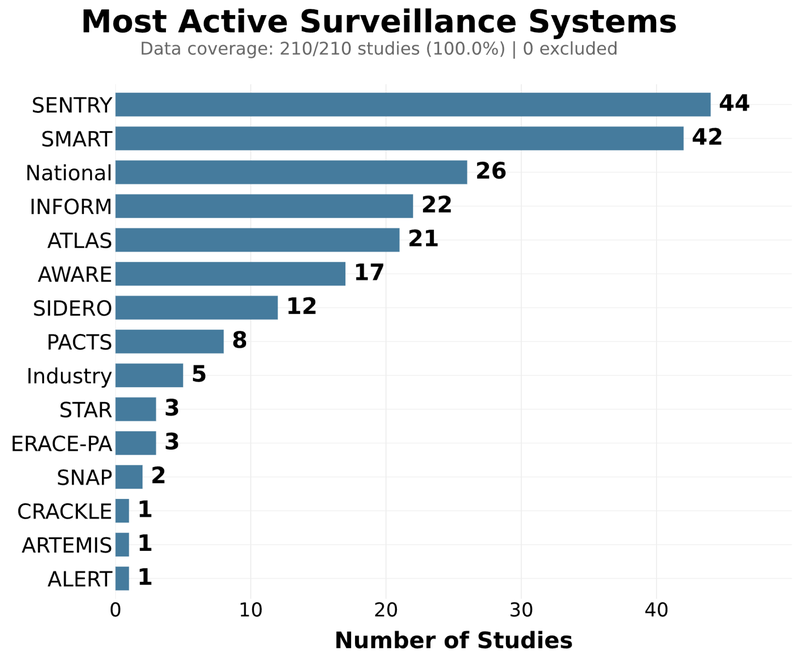
Q3: Describe the **features** of the identified systems

Abbreviations: PRISMA = Preferred Reporting Items for Systematic Reviews and Meta-Analyses; FDA = US Food and Drug Administration; EMA = European Medicines Agency; MHRA = UK Medicines and Healthcare products Regulatory Agency; TİTCK = Turkish Medicines and Medical Devices Agency; MoH = Ministry of Health; TB = tuberculosis; PK/PD= pharmacokinetics/pharmacodynamics.

RESULTS

SEARCH RESULTS





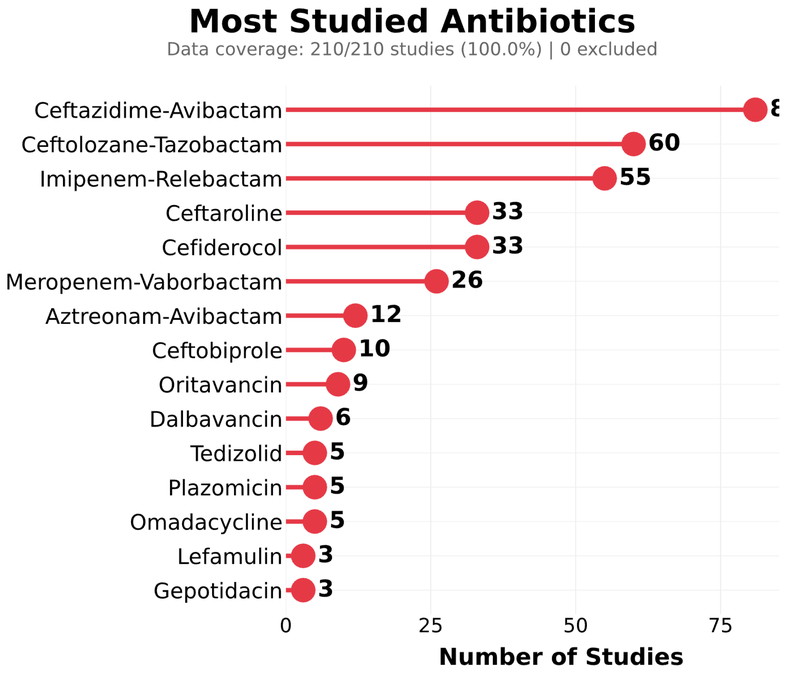
Monitoring of antibiotic use: 2 of 212 studies;
n=1 Germany, n=1 Canada

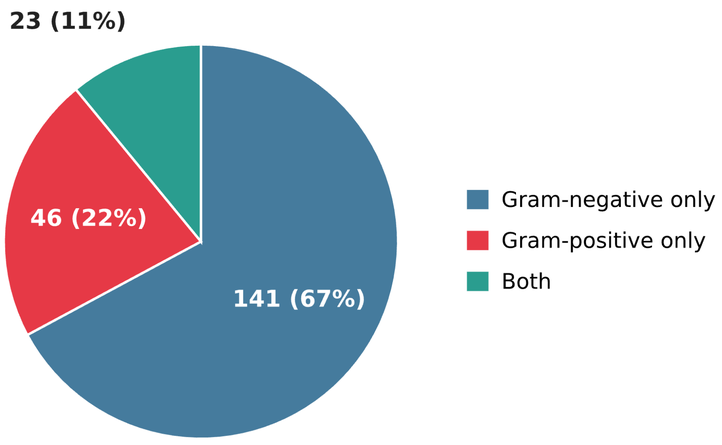
Monitoring antimicrobial resistance: n=210
158 / 210 (75%) from six programmes:
SENTRY, SMART, INFORM, ATLAS, AWARE, SIDERO

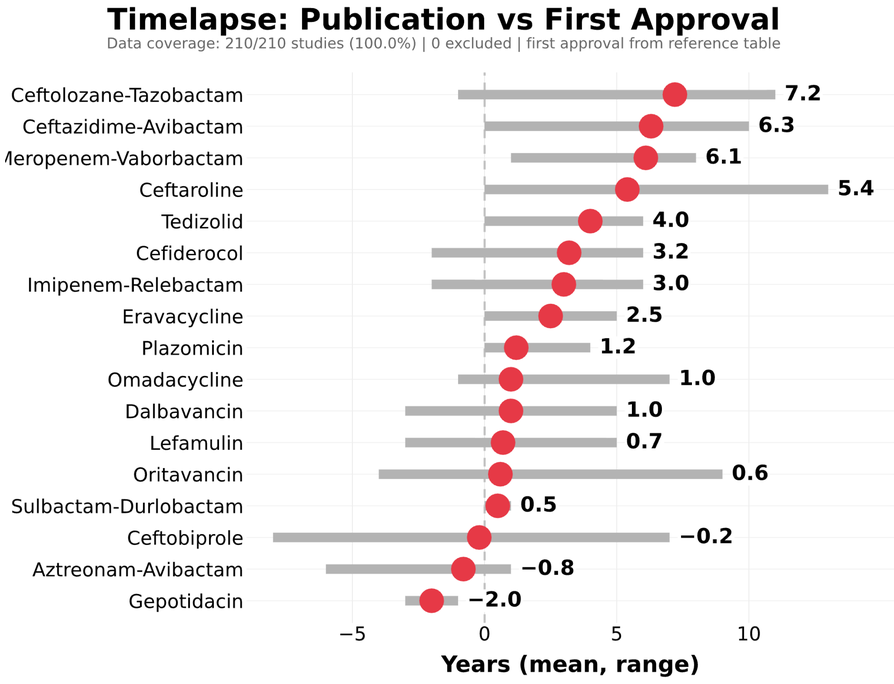
108 / 195 (55%) sponsored by three companies:
Merck/MSD, Pfizer, Shionogi

26 / 210 (12%) from **national surveillance** systems

FEATURES OF THE SYSTEMS







Mean per antibiotic (dot) and range (bar). Recently approved drugs cannot show long lags: this partly reflects time on the market.

Newly approved antibiotics surveillance data is:

NARROW - almost only about resistance; BIASED - mostly directed by industry; and LATE - publication is too slow.

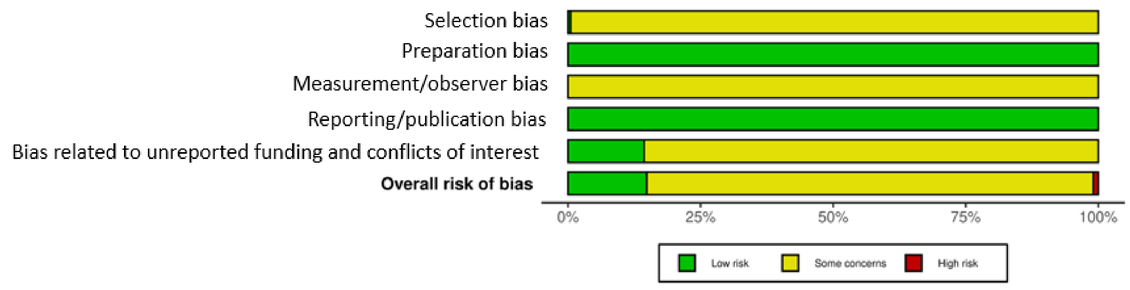
DISCUSSION & CONCLUSIONS

- Industry determines which bug/drug combinations are prioritised for surveillance, and drives the generation and dissemination of the resulting data.
- The lag between industry data collection and publication risks leaving public authorities blind to emerging resistance and consumption trends.
- Public health systems are structurally better positioned to serve stewardship goals, but lack new antibiotic coverage and capacity.

Coordinated international action is needed to implement standardised post-marketing surveillance and strengthen independent, publicly funded monitoring infrastructure.

LIMITATIONS AND RISK OF BIAS

Relies on declared sponsorship and published data; heterogeneous reporting across the 17 identified systems limits comparability.



PROTOCOL & CONTACT

Systematic review registered on PROSPERO; search strategy & assessment matrices available in the online appendices.

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Falagas ME, Ragias D, Kontogiannis DS, Romanos LT, Farazi PA. Proposed Risk of Bias Assessment Tool for *In Vitro* Antimicrobial Susceptibility Studies. Pathogens. 2026 Apr 7;15(4):396. doi: 10.3390/pathogens15040396. PMID: 42075723; PMCID: PMC13119129.