## Dem Ausschuss ist das vorliegende Dokument in nicht barrierefreier Form zugeleitet worden.

# Incentivizing investment into antibiotic R&D – what is needed?

James Anderson, IFPMA

#### **Deutscher Bundestag**

Ausschuss für Gesundheit UA Globale Gesundheit

Ausschussdrucksache 20(14-1)115

TOP 3 UA GlobG S. 11.11.2024

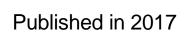
11.11.2024



## Germany has a long-standing commitment towards a healthy AMR R&D ecosystem











Launched in May 2018

"Concurrently, in collaboration with relevant experts including from the OECD and the WHO, we will further examine practical market incentive options." (G20 2017 Leaders' Declaration)



July 2023

#### GERMAN GOVERNMENT RENEWS COMMITMENT TO CARB-X

Millions injected into antimicrobial resistance research and development



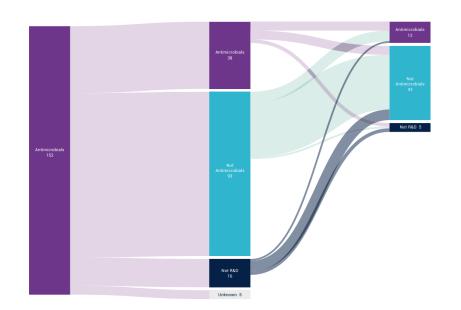
September 2024

Global Antibiotic Research & Development Partnership

Funders invest an unprecedented EUR 60 million in innovative antibiotic R&D and access partnership



## Economic challenges cause bankruptcies and shortages of experienced scientists



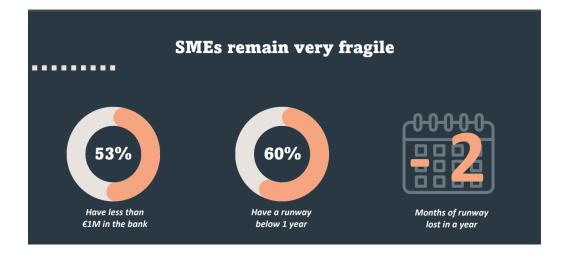
~75% of scientists leave anti-infective R&D after their company goes bankrupt. Less than 10% remain in anti-infective R&D after a second career change.

From AMR Industry Alliance, Leaving the Lab (2024). <a href="https://www.amrindustryalliance.org/wp-content/uploads/2023/02/Leaving-the-Lab final-1.pdf">https://www.amrindustryalliance.org/wp-content/uploads/2023/02/Leaving-the-Lab final-1.pdf</a>

### nature

## The antibiotic paradox: why companies can't afford to create life-saving drugs

Paratek Pharmaceuticals successfully brought a new antibiotic to the market. So why is the company's long-term survival in question?



"In the absence of a clear signal that the market failure can be fixed quickly, business closures will continue, perhaps even at a faster pace"

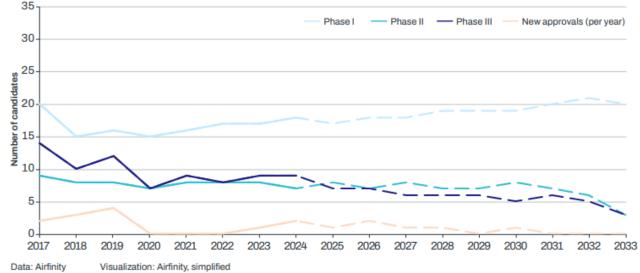
From BEAM SMEs Barometer, 2nd edition (2024). https://beam-alliance.eu/wp-content/uploads/2024/05/2024-05-15-beam-barometer-2024-v1-0.pdf



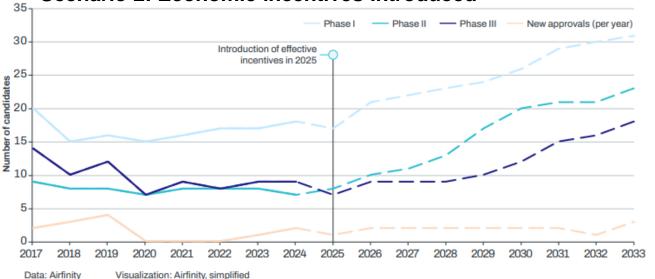
## The antibiotic pipeline will continue to decline unless economic incentives are introduced

## From resistance to resilience: What could the future antibiotic pipeline look like? Number of candidates in: S2 Phase III clinical trials Phase II clinical trials Phase I clinical trials Number of new approvals S1: Scenario one (without new incentives) May 2024 S2: Scenario two (with effective incentives)

#### Scenario 1: Economic challenges unchanged



#### Scenario 2: Economic incentives introduced





## Investing in new antibiotics delivers strong returns to public sector and health systems

Consensus for public incentives (G7, G20, WHO, GLG, R&D Hub, OECD, etc); Doing nothing is not an option. Robust analysis shows:

- Lack of action leads to increasing costs and lives lost
- Public Investment in antibiotic pull incentives delivers strong Rol (4.6x for Germany)...
- ...and predicted to save >3000 lives over 10 years and significant costs (AMR costs ~€2.6bn/yr already in Germany)

Similar to investing in infrastructure eg fire extinguishers, flood defenses, etc – not to standard medicine purchasing

Question is how and how much to invest:

- EU Transferable Exclusivity Voucher cost estimate €300-400m (Germany's share estimated at ~€70-95m/antibiotic)
- Germany average per antibiotic of €27m/year to encourage investment into R&D and match UK, Italy, US, etc.
- Preferential "reserve" antibiotic status and AMNOG has not delivered a step change
- Key point to attract R&D investment is the combined value of the EU and German incentive and urgency to implement











#### AMR.Solutions

Italy's Health Minister Orazio Schillaci announced that the Italian Ministry of Health, together with the Italian Ministry of Finance and the Italian Medicines Agency, is working on a new pull incentive to accelerate innovation and access to muchneeded antibiotics.



FERGUSON JOINS SENATORS BENNET, YOUNG TO REINTRODUCE PASTEUR ACT TO FIGHT ANTIMICROBIAL RESISTANCE

BIPARTISAN, BICAMERAL LEGISLATION WOULD SUPPORT DEVELOPMENT OF INNOVATIVE ANTIBIOTICS TO TREAT RESISTANT INFECTIONS AND IMPROVE APPROPRIATE ANTIBIOTIC USE

, April 27, 2023







Antimicrobial Products Subscription Model: guidance on commercial arrangements



#### **Additional resources**

- Leaving the Lab: Tracking the Decline in AMR R&D Professionals (AMR Industry Alliance) https://www.amrindustryalliance.org/mediaroom/leaving-the-lab-tracking-the-decline-in-amr-rd-professionals/
- Estimating The Appropriate Size Of Global Pull Incentives For Antibacterial Medicines (Health Affairs) https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2021.00688
- From resistance to resilience: what could the future antibiotic pipeline look like? (IFPMA) https://www.ifpma.org/publications/from-resistance-to-resilience-what-could-the-future-antibiotic-pipeline-look-like/
- G7 Investments in New Antibiotics Would Pay Off Big—For Everyone (CGD) <a href="https://www.cgdev.org/blog/g7-investments-new-antibiotics-would-pay-big-everyone">https://www.cgdev.org/blog/g7-investments-new-antibiotics-would-pay-big-everyone</a>
- Advancing global antibiotic research, development and access (Nature) <a href="https://www.nature.com/articles/s41591-024-03218-w">https://www.nature.com/articles/s41591-024-03218-w</a>
- Estimating the Return on Investment of Pull Incentive Policies for New Antimicrobials: Insights for the EU and Beyond (ARMoR) <a href="https://www.armoramr.org/post/estimating-the-return-on-investment-of-pull-incentive-policies-for-new-antimicrobials-insights-for">https://www.armoramr.org/post/estimating-the-return-on-investment-of-pull-incentive-policies-for-new-antimicrobials-insights-for</a>
- Forecasting the Fallout from AMR: Economic Impacts of Antimicrobial Resistance in Humans (CGD) https://www.cgdev.org/sites/default/files/forecasting-fallout-amr-economic-impacts-antimicrobial-resistance-humans.pdf
- Breaking through the Wall (GUARD initiative) A Call for Concerted Action on Antibiotics Research and Development (BMG)

https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/5 Publikationen/Gesundheit/Berichte/GUARD Follow Up Report Full Report final.pdf





## Thank you

in /company/ifpma



