

# Delinkage for antibiotics

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# Antibiotics are special because

- Everyone recognizes that the business model needs fixing
  - Commercial success requires high volume; preserving the effectiveness of the drug requires low utilization.
  - Davos Declaration: delinkage is “needed”
- Many countries have very poor quality usage of antibiotics, leading to increased resistance
- Externalities occur across borders
- There are externalities across products as well, when different products have a similar mechanism of action

# A framework for paying for innovation with delinkage

1. Governments just fund R&D directly
2. Private sector innovates
  1. Rewards based on cost
    - Eg: patent buyout based on estimated “average” cost of innovation; tax credits
  2. Rewards based on value
    - Eg: Sanders bills, Health Impact Fund
  3. Rewards based on hypothetical profitability
    - Eg: Kremer’s model - auction reveals expected profits
    - Doesn’t solve any of the problems for antibiotics

# Rewards based on cost

- Rewards based on cost alone are likely to encourage products that are just adequate for approval
- These are the easiest to develop and the least useful
- So, there should almost certainly be a relationship to value
- Tax credits may help, but only if there is still some residual reward based on value.

# Rewards based on value

- Rex and Outterson (2016) propose that payments should be based on technical characteristics of the product, with higher payments for products that
  - Address important needs
  - Have a new mechanism of action
  - Treat multiple pathogens
  - Feature oral dosing
- Similar in nature to the Advanced Markets pneumococcal vaccine mechanism
- Arguably the technical characteristics can't be fully specified in advance. (side effects? Actual effectiveness?)

# O'Neill Commission

- Provide a market entry reward based on “value to society”
  - \$0.8bn - \$1.3bn - payment depends on level of unmet need, toxicity, efficacy, ability to counter resistance, etc
  - Measurement occurs ex post; rewards are staggered over time
- Product rights remain with developer
- Conditions for reward include an access scheme for low- and middle-income countries; commitment to responsible marketing by the seller.
- Essential to improve antimicrobial stewardship in all countries, but support for low- and middle-income countries is key

# Challenges for delinkage in antibiotics

- Companies want rewards that are highly predictable (measuring technical innovation)



- Payers want rewards that motivate investment in the highest value innovations (measuring social value)

- Low prices to enable access



- Controls on access to prevent inappropriate use

# Thanks!

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