



Estimating the EU “Fair Share” of a Global Antibacterial Pull Incentive

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EU fair share of a global antibacterial pull incentive

1. Calculate the EU % share of the global pull incentive
2. Calculate the global pull incentive required
3. Multiply 1 and 2

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Prior estimates of EU fair share

- Berdud et al. (OHE) (2019) estimated 28.8%
 - Apportioned by **pharmaceutical sales**
- Boluarte, T. & Schulze, U. (BCG) (2022):
 - 29-39% of G7+EU
 - 22-27% of G7+EU+PRC
 - Apportioned by GDP and **GNI (in PPP)**
- Wilsdon, Robson and Lu (CRA for EFPIA) (5 Sept. 2022) estimated 30%, based on these sources

My method

- GDP data from OECD
 - Transparent, approximates ability to pay
 - Other options (historic sales revenues) are less transparent and lock in current market distortions
 - GNI and PPP adjustments are also feasible choices
- Numerator is EU27
- Denominator could be G7, G7+EU27, G20, or OECD
 - G20 and OECD excluded as not likely in next 5 years
 - Smaller denominator (G7+EU27) results in higher fair share
 - Should not use G7 as denominator when the numerator is EU27
 - Other countries (LMICs) not expected to contribute to R&D costs, but will benefit from access and contribute with IPC and stewardship

Results for EU27

**% of a global pull incentive,
if denominator is:**

G7+EU27 → 39.1%

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Estimating The Appropriate Size Of Global Pull Incentives For Antibacterial Medicines

- Best estimate for a global antibacterial subscription = **\$3.1B (range: \$2.2B-\$4.8B)** per drug over 10 years, fully delinked
 - The PASTEUR Act is within this range, as is the global pull incentive implied by the UK pilot
- Best estimate for a global partially delinked program (MERs / TEEs) = **\$1.6B (range: \$900M-\$2.6B)**
- Both push and pull incentives are necessary for sustainable and robust antibacterial drug development

How large should antibacterial pull incentives be?

Prior estimates were \cong \$1B (2021\$), but:

- Estimates are partially delinked market entry rewards, not subscriptions
- Most assume increased push incentives
- Most understate CMC¹ and post-approval costs
- Most used erroneous assumption on preclinical success rates
- Global peak year sales assumptions were based on daptomycin, which is unrealistic in today's market
- Figures have not been inflation adjusted to 2021
- ***Correcting these issues will tend to increase the appropriate size of pull incentives***

5 gov't reports:

- Sertkaya 2014 (HHS/ERG)
- AMR Review 2016 (UK/O'Neill)
- GUARD 2017 (German BMG/BCG)
- DRIVE-AB 2018 (IMI)
- WHO 2020


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¹Chemistry, manufacturing, and controls

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Collectively, these adjustments entirely close the gap between the prior estimates and my best estimate of \$3.1B for a subscription

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Other points to consider

- The published parameter data are generally based on extensions of known classes, but the intent here is to bring highly innovative, groundbreaking therapies to patients
 - If such programs are higher risk or higher cost (or both), the required pull incentive would need to be higher
- Ranges are appropriate, with higher amounts for drugs deemed to be more valuable to society, and many drugs receiving no awards

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Fair share results for EU27 (US\$M)

	Denominator	
	G7 + EU27	
Fully delinked	86.1	Low
	121.3	Mid
	187.9	High
Partially delinked	35.2	Low
	62.6	Mid
	101.8	High

Per drug, per year, paid for 10 years

Data available at Open BU data repository:
<https://open.bu.edu/handle/2144/42568> (Oct. 2022)

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	Denominator	
	G7 + EU27	
Fully delinked	86.1 121.3 187.9	Low Mid High
Partially delinked	35.2 62.6 101.8	Low Mid High

Assuming G7+EU27 participation and very low other (non-delinked) sales in EU27, the range for EU27 is US\$86-188M, with a best estimate of US\$121M

Per drug, per year, paid for 10 years

Data available at Open BU data repository:
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Adjustments

- My estimates assume that antibacterial pull incentives will be reduced for all *clinical* push incentives on that drug paid by the government paying the pull incentive (here, EU)
- For fully delinked estimates, the assumption is no profits from sales in the territory (here, EU)
 - If some sales revenues occur in the territory, the pull incentive should be reduced to account for those non-delinked profits
 - No such adjustment is necessary for partially-delinked estimates
- Ranges are appropriate, with higher amounts for drugs deemed to be more valuable to society, and many drugs receiving no awards

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Questions?

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