

The Round Table on Antibiotics, a multi-disciplinary Swiss initiative to foster the development and availability of antibiotics



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INTRODUCTION

Antimicrobial resistance (AMR) is among the top 10 global public health concerns¹.

- Antibiotic-resistant infections cause >700,000 deaths/year worldwide (>270 deaths in CH)^{2,3}.
- Among E.coli isolates 53.1% (EU/EEA) and 46.8% (CH) were aminopenicillin-resistant in 2021¹.
- Among P. aeruginosa isolates, 18.7% and 10.9% were piperacillin-tazobactam resistant and 12.6% and 6.4% had combined resistance to ≥3 antimicrobial groups¹.

The antibiotics market is characterized by supply shortages, withdrawals of existing products and shut down of antibiotic research programs^{4,5}.

- Only two new antibiotics classes (oxazolidinones, lipopeptides) were launched in the last 60 years⁶.

The Round Table on Antibiotics (RTA), a multi-disciplinary, non-profit Swiss association, supports the development of and access to new antibiotics⁷.

AIMS

Explore financial incentive models that can be established in Switzerland to make the marketing and development of antibiotics attractive.

METHODS

Gather Swiss and international stakeholders from healthcare, academia, politics, and industry.

Assess currently discussed incentive models.

Evaluate experience with pilots of incentive models in other countries and their feasibility for use in Switzerland.

CONTACT INFORMATION

www.roundtableantibiotics.ch

RESULTS

Push incentives

To push the identification of new drug candidates, their non-clinical and clinical development (Fig. 1).

Pull incentives

To pull drug candidates towards successful regulatory approval and profitable marketing (Fig 1).

Subscription models

Two pilot programs implemented in Europe⁸:

1. In Sweden, a Revenue Guarantee Scheme of ~ 0.32 M CHF/y/drug and, if sales exceed that amount, a fixed fee of ~ 32 K CHF to hold a safety stock was tested. The pilot included 4 pharma companies (MSD, Shionogi, Pharmaprim, Unimedica Pharma) and 5 antibiotics (Zerbaxa, Recarbrio, Fetcroja, Vaborem, Fosfomycin).
2. In the UK, a Subscription Model providing a guaranteed revenue of ~ 11.1 M CHF/y/drug for max. 10 years was tested. The pilot included 2 pharma companies (Pfizer, Shionogi) and 2 antibiotics (Zavicefta, Fetcroja).

Subscription models incentivize only marketed antibiotics (new and existing ones), are transparent about cost and payer, and can decouple revenue from sales volume which is key for antibiotic stewardship.

Transferable Exclusivity Extension (TEE) models

TEE is discussed (though not piloted) in the EU⁹.

Upon European regulatory approval of a new antibiotic, the manufacturer would receive a TEE voucher to extend the marketing exclusivity of a product (does not need to be the new antibiotic and the voucher can be sold to another company).

In Canada, patent extensions for new drugs have been issued since 2017¹⁰. The Canadian experience confirms that exclusivity extension does not guarantee that new antibiotics are marketed.

Applying a TEE voucher to other products blurs the cost volume, imposes the cost on patients who may not need the new antibiotic and will affect the generics market and patient access.

1A: Hurdles on an antibiotic's path from research to being marketed

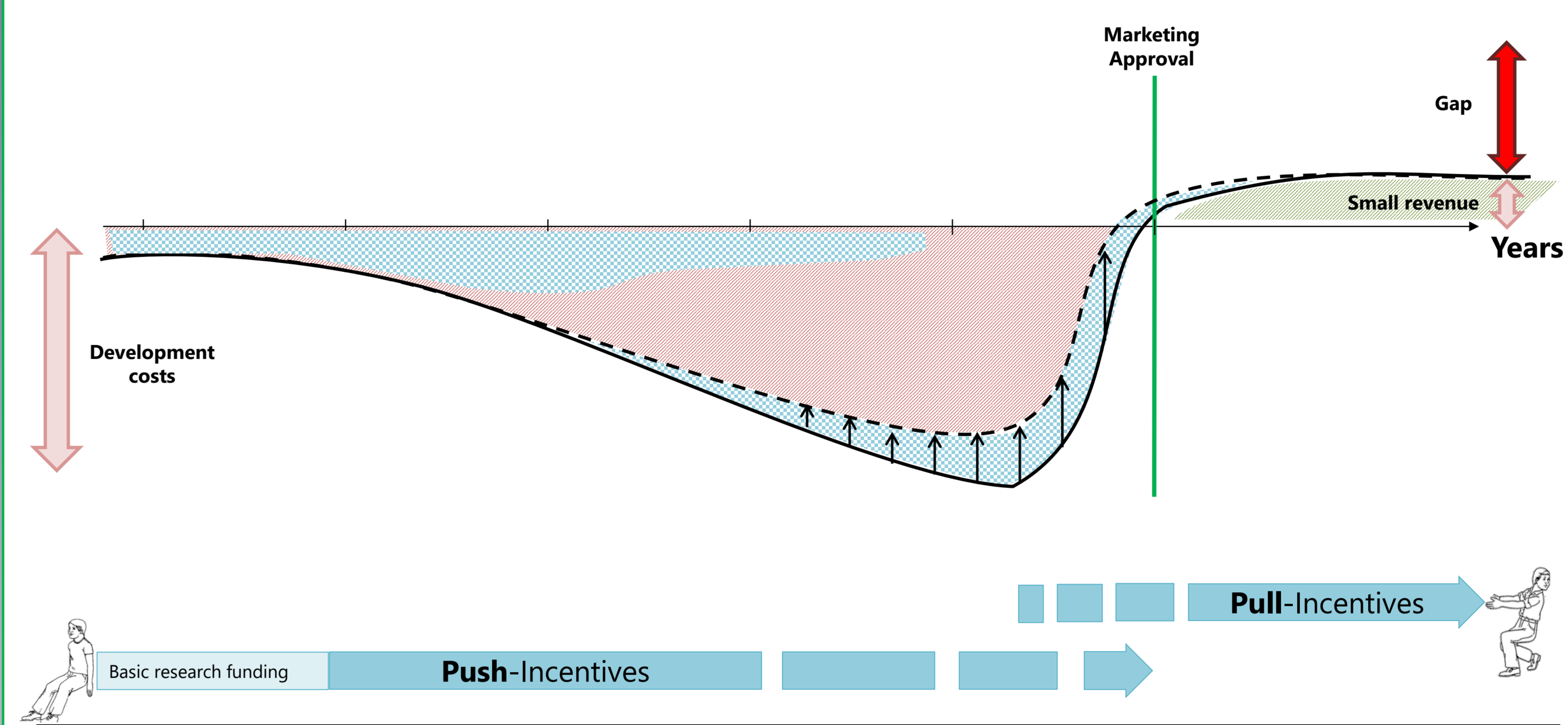


Fig. 1A: Bringing an antibiotic to the market faces three major hurdles i) development costs, ii) marketing authorization, and iii) a broken market that generates insufficient financial revenue.

1B: Push- and Pull-Incentives to stimulate the antibiotics market

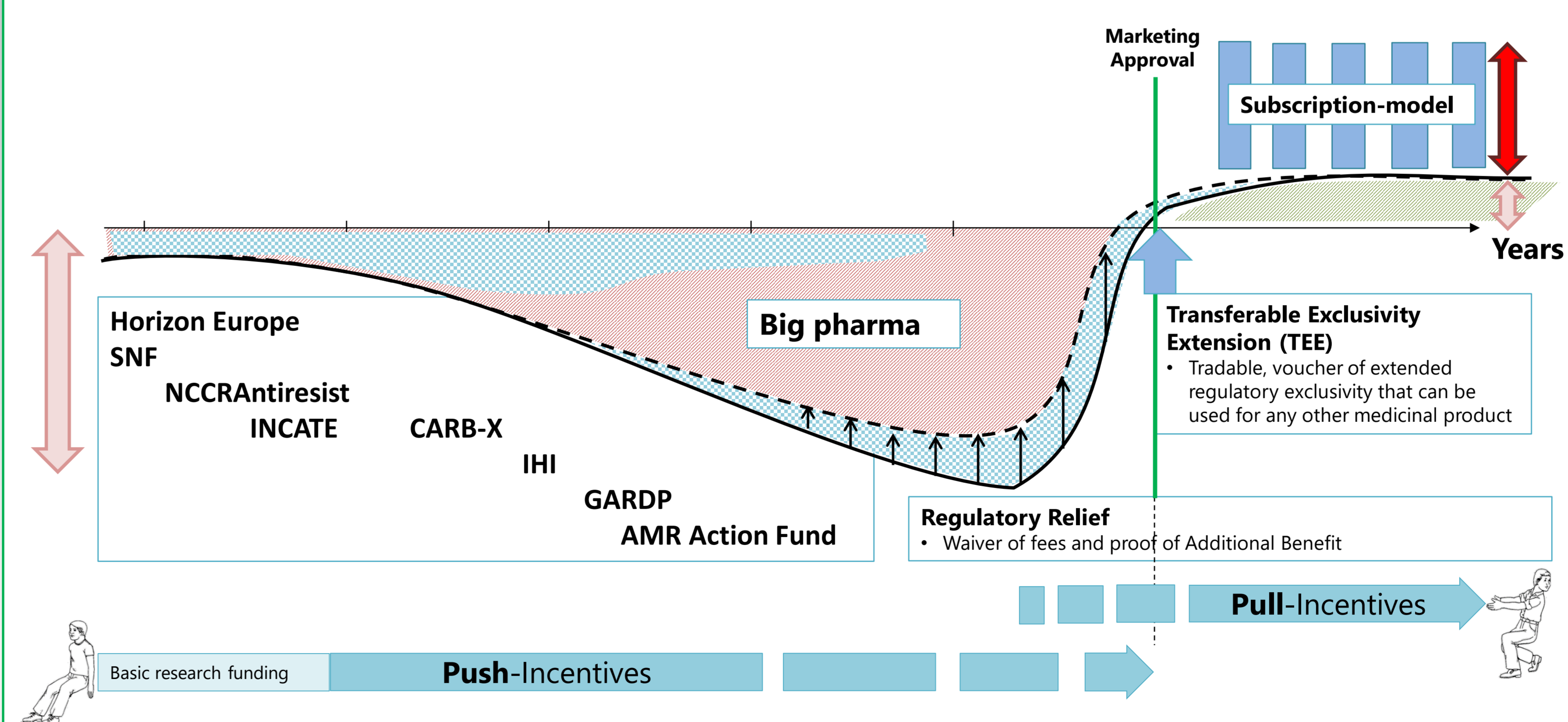


Fig. 1B: Different push and pull incentives are intended to stimulate the antibiotics market and close the gap between development costs and revenue. AMR Antimicrobial Resistance; CARB-X Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator; EU European Union; GARDP Global Antibiotic Research and Development Partnership; IHI innovative Health Initiative; INCATE Incubator for Antibacterial Therapies in Europe; MDR Multi-Drug Resistance; NCCR National Centres of Competence in Research; RKI Robert Koch Institute; SNF Swiss National Fund "push" incentive models; TEE Transferable Exclusivity Extension.

CONCLUSIONS

1. Due to rigid reimbursement and public health need for antibiotic stewardship, revenues do not cover the cost of developing nor the cost of producing and distributing antibiotics.
2. Incentivizing the development and marketing of new and existing antibiotics and addressing public health aspects is needed.
3. Incentive models guarantee a minimum annual revenue per marketed antibiotic (subscription) or foresee a tradeable exclusivity extension of a new approved antibiotic.
 - Subscription models are transparent in terms of cost and payers, incentivize only marketed antibiotics, support antibiotic stewardship and can be tested/implemented on a national basis.
 - Exclusivity extension models are opaque about cost and payers and will disrupt the generics market and thus access to affordable medicines.

The Round Table on Antibiotics recommends a **Swiss subscription model** that

- is flexible to secure availability of existing antibiotics and innovation, and
- allows for national implementation and control.

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