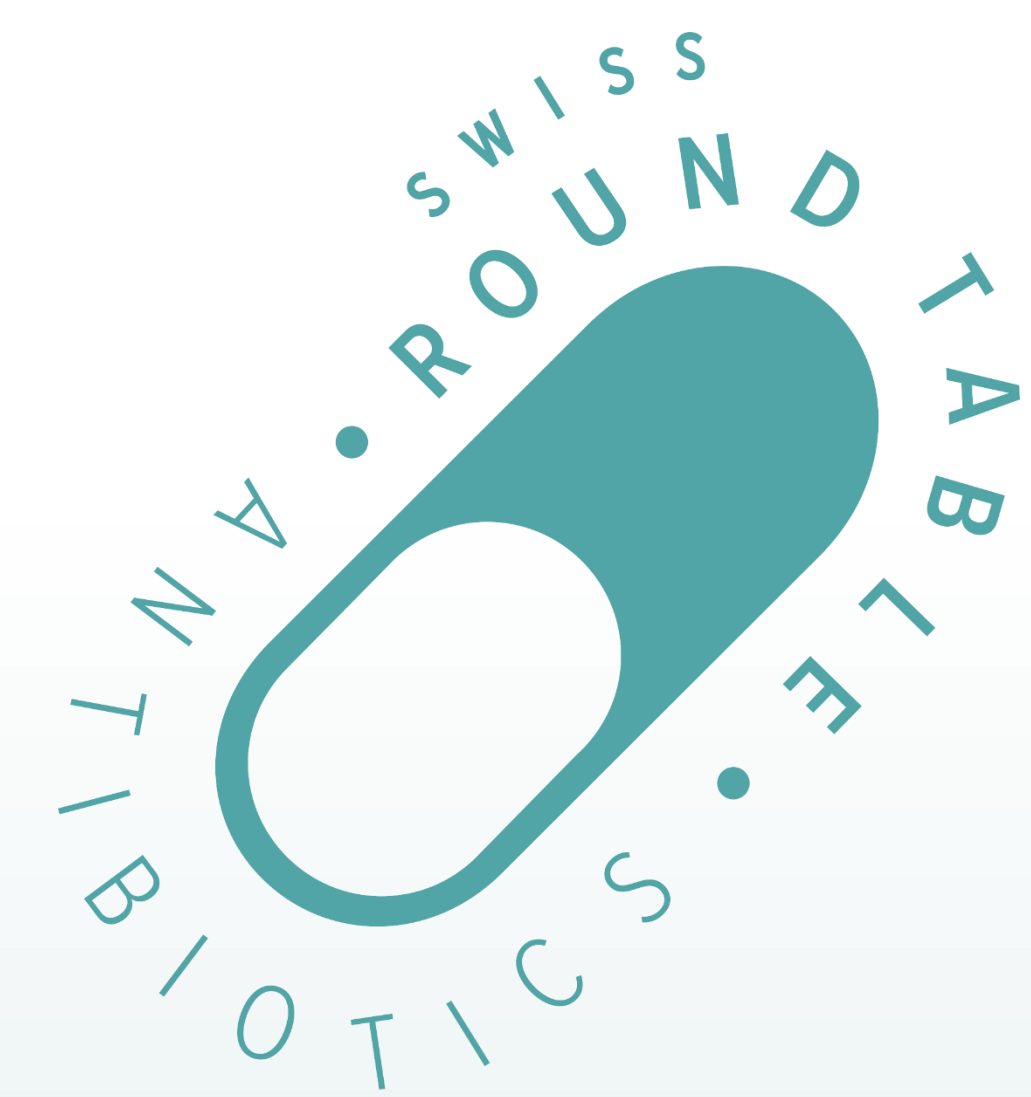


The Swiss Round Table on Antibiotics, a multi-disciplinary initiative to foster the development and availability of antibiotics



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INTRODUCTION

- Antimicrobial resistance (AMR) is among the top ten global public health threats¹:
 - o Annual 1.27 million deaths globally and about 300 deaths in CH related to resistant bacteria^{2,3}.
 - o 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 shutdowns of antibiotic research programs^{4,5}.
- The last new antibiotics classes (oxazolidinones, lipopeptides) were launched >20 years ago⁶.
- Currently available incentives focus on push-funding of research and development of new antibiotics but lack signals for economically viable marketing (Fig. 1).
- Pull-incentives shall encourage strategic business decisions towards bringing new antibiotics to the (Swiss) market and keeping already approved antibiotics in the market.

AIMS

- Explore different pull incentive models and international experience.
- Propose a pull-incentive model to foster availability of new and existing antibiotics in Switzerland.

METHODS

- The RTA uses a multi-faceted approach, establishing the dialogue between stakeholders from health care, academia, politics, and industry.
- The project follows several phases:
 - o Assess models and experience in other countries.
 - o Assess Swiss-specific legal framework and needs.
 - o Identify a preferred model to be tested in the Swiss health care system.

RESULTS

Assessments of incentive models, experiences in other countries as well as the Swiss-specific legal framework and needs have been summarized (Table 1). These are currently discussed with stakeholders from politics, industry and insurers to identify models and eligibility criteria deemed suitable for a pilot project in Switzerland.

Subscription models

- Guarantee a certain amount of annual revenue from marketed antibiotics (new and existing ones).
- Decouple revenue from sales volume which is key for antibiotic stewardship.
- Are transparent about cost and payer.

Two pilot programs were implemented in Europe⁷. The Swedish Revenue Guarantee Scheme focused on securing the supply of a basket of selected antibiotics (Zerbaxa, Recarbrio, Fetcroja, Vaborem, Fosfomycin) whereas the UK Subscription Model focused on encouraging innovation by selecting two 'novel' antibiotics (Zavicefta, Fetcroja).

Transferable Exclusivity Extension (TEE) models

- Grant a tradable voucher to extend marketing exclusivity of a newly approved antibiotic.
- Do not guarantee that the incentivised new antibiotics are marketed⁸.
- Are not transparent about the actual cost and payers and will affect the generics market.

High price model

- Justifies a high price for antibiotics by demonstrating their broader value for public health.
- Requires measures to quantify societal benefit that are not available yet and difficult to define.
- Allocates financial burden to only a few patients and their insurers.

Prevalence model

- Originates in an attempt to promote early access to innovative drugs.
- Sets a price/pack that depends on patient prevalence and shall ensure a viable revenue from start while at the same time containing the budget impact (i.e. the exact opposite of the market situation for antibiotics).
- If a predefined revenue threshold is exceeded, substantial rebates are applied.
- If applied to innovative antibiotics, it would have to be similar to a revenue guarantee scheme.

ABOUT US

The Swiss Round Table on Antibiotics, a multi-disciplinary, non-profit Swiss association, supports the development of and access to new antibiotics⁹.

www.roundtableantibiotics.ch

Figure 1: Push-funding and pull-incentives along an antibiotic's life-cycle

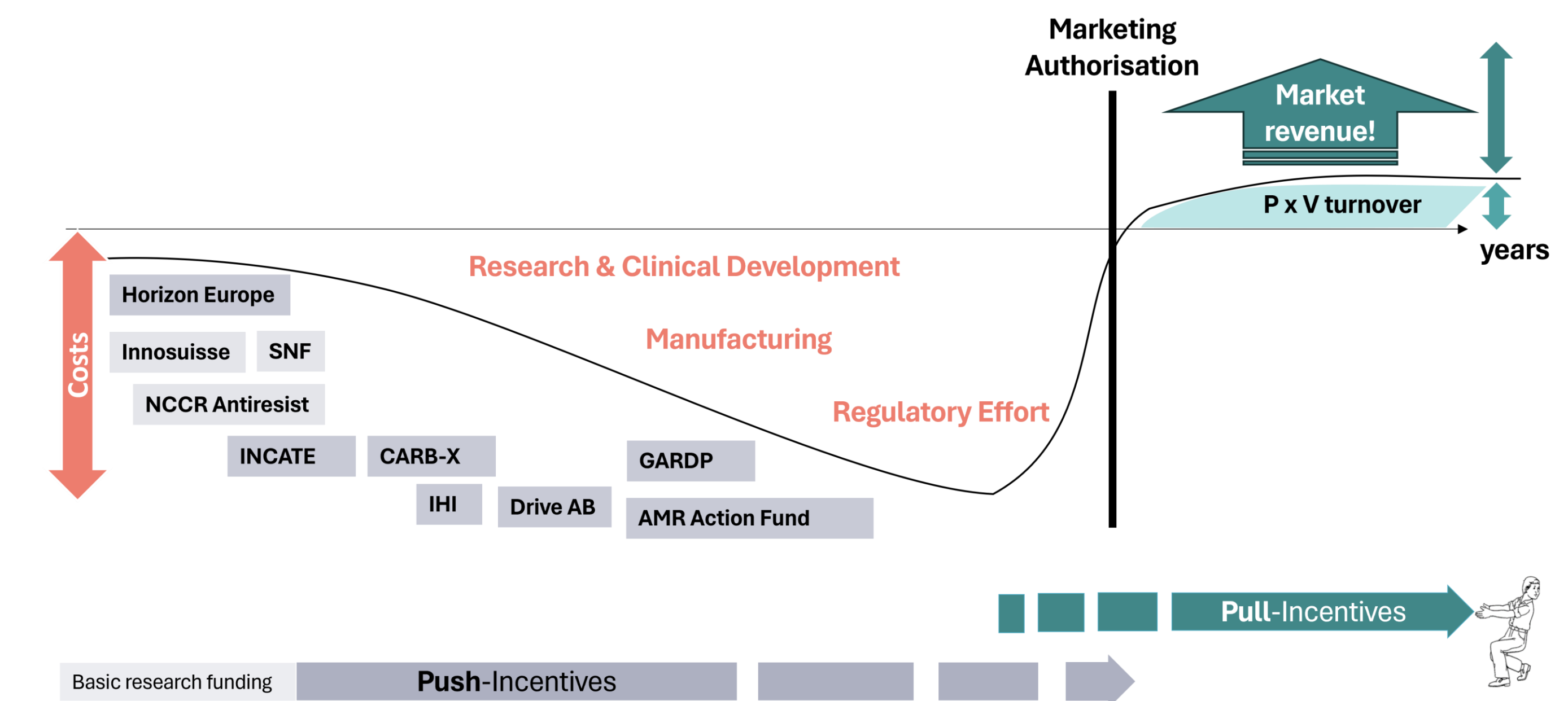


Fig. 1: Bringing an antibiotic to the market faces three major hurdles i) development costs, ii) marketing authorization, and iii) a broken market that generates insufficient financial revenue. Different push and pull incentives are intended to stimulate the antibiotics market and close the gap between development costs and revenue. Abbreviations: AMR Antimicrobial Resistance; CARB-X Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator; GARDP Global Antibiotic Research and Development Partnership; IHI Innovative Health Initiative; INCATE Incubator for Antibacterial Therapies in Europe; NCCR National Centres of Competence in Research; SNF Swiss National Fund "push" incentive models.

Table 1: Evaluation of pull incentive models for Switzerland

	Subscription	TEE	High price	Prevalence
Effectiveness				
Society obtains antibiotic it needs	HIGH	HIGH	MEDIUM	MEDIUM-HIGH
Stewardship	YES	NO*	NO	LOW
Security of supply	YES	NO*	YES	YES
Successful precedents	YES	NO	NO	NO
Speed of implementation				
Extent of legislative changes	MEDIUM	MEDIUM-HIGH	LOW	LOW
Effort for implementation	MEDIUM-HIGH	HIGH	LOW	MEDIUM
Societal acceptance				
Acceptance by assigned payer	Depending on assigned payer*	?	YES	YES
Payer=Beneficiary?	YES	NO	PARTIALLY	PARTIALLY
Transparency	YES	NO	LIMITED	LIMITED
Tailored reward size depending on drug meeting stated criteria	YES	DIFFICULT	MEDIUM	MEDIUM

* Shortcomings of the TEE model may be addressed by a staggered pay-out of the voucher sale proceeds to the antibiotic manufacturer
* If health insurances are assigned as payer, rather NO. If the Federation (legislator) is assigned as payer, rather YES.

CONCLUSIONS

1. Among discussed pull-incentives, only subscription models have significant real-world evidence from pilot projects in Europe.
2. Subscription models are – in contrast to exclusivity extension models – transparent in terms of cost and payers, and do not disrupt the generics market.
3. Only subscription models incentivise marketed antibiotics AND support antibiotic stewardship.

The Swiss Round Table on Antibiotics recommends Swiss policy makers to **implement a pilot project of a subscription model** that

- secures the availability of existing antibiotics
- encourages regulatory submissions of new antibiotics to Swissmedic, and
- allows for governance and oversight by the Swiss Federal Administration.

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