



Press release

**On 25 March 2024 the Swiss Round Table on Antibiotics will publish its white paper  
«Effective antibiotics for the Swiss health care system: today and in the future»**

***The global problem***

Globally, and also in Switzerland, people die from infections that can no longer be treated with the currently available antibiotics. This happens when bacteria have adapted and become resistant to several antibiotics (multi-drug-resistance).

Despite the urgent need for new antibiotics several pharmaceutical companies have pulled out of their research and development, and SMEs are finding it extremely difficult to obtain funding for their antibiotic programmes. Other therapeutic areas such as oncology are much more lucrative.

With effective antibiotics lacking the achievements of modern medicine, especially in the treatment of cancer and in surgery, are on shaky grounds. It is therefore in everyone's interest that investments in the development of new antibiotics and resilient supply chains should become worthwhile again.

***Swiss contribution to a solution***

Medicinal products are developed with a view to the markets of high-income countries. These countries can use alternative reimbursement models to motivate industry to reinvest their profits in antibiotic development programmes again. The traditional approach of simply remunerating higher prices per pack is not viable: Such prices only take into account the benefit of the drug for the patient being treated, whereas antibiotics also provide a benefit for public health, for example by preventing the transmission of pathogenic germs to other people or by being immediately available like a fire brigade in cases where standard antibiotics fail.

We therefore propose annual lump-sum payments (a so-called subscription or Netflix model), regardless of the quantity of product sold. The amount of the lump sum should reflect the value of the antibiotic for public health and the benefit to patients and enable manufacturers to earn an appropriate return.

Two European countries have already conducted pilot trials and other countries are preparing to do so.  
**We recommend doing the same in Switzerland.**

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**About the Swiss Round Table on Antibiotics**

The multidisciplinary, non-profit Swiss association is committed to measures that promote the development of antimicrobial technologies and ensure their availability in order to safeguard the future functioning of health care systems. Its members come from the healthcare sector, science, politics, industry and other areas of expertise. The association promotes public awareness of the increasing development of resistance and the need to take countermeasures, with two focal points: (1) financial incentive models that promote the research and development of new antimicrobial technologies, (2) security of supply in Switzerland and worldwide of new and existing antibiotics. In doing so, it is in dialogue with players at international level.

Please also refer to the 10vor10 broadcast of 10. November 2022: <https://www.srf.ch/play/tv/10-vor-10/video/antibiotika-droht-zu-versiegen?urn=urn:srf:video:d4cb4366-12b4-494a-bbab-901136229a76>

## Dossier

### extract from the White Paper

#### Introduction

Since their advent in the early decades of the 20<sup>th</sup> century, antibiotics have saved countless lives. However, bacteria are continually adapting to their environment, naturally evolving resistance to these critical drugs. The situation is exacerbated by human actions, particularly the overuse and misuse of antibiotics, which accelerates the development of resistant strains and diminishes the effectiveness of existing treatments. As a result, antibiotic resistance has escalated into a global crisis, now recognised as one of the top 10 public health threats worldwide<sup>1</sup>.

Effective antibiotics are the foundation of modern medicine. Their absence would make treatments excessively risky or even impossible in fields such as surgery, oncology, and general infection management, posing a grave threat to society. Research indicates that each year, infections caused by resistant bacteria claim the lives of approximately 300 people in Switzerland<sup>2</sup>, 35,800 in Europe<sup>1</sup>, 35,000 in the United States<sup>3</sup>, and a staggering 1.27 million globally<sup>4</sup>. However, these statistics only scratch the surface of this **“silent pandemic”**. Managing antibiotic-resistant infections often requires multiple treatment attempts, each with its own set of potential adverse effects, as well as prolonged stays in hospitals and intensive care units, and longer recovery times. The consequences are many: diminished patient health and well-being, high health care costs, and socioeconomic losses due to sick leave and incapacity to work<sup>5</sup>.

There is therefore an urgent need for effective new antibiotics<sup>6</sup>. However, there is a lack of innovation in Switzerland and worldwide, and the supply of existing antibiotics is characterised by bottlenecks and market withdrawals of existing products, both in Switzerland<sup>7</sup> and globally. This puts health care systems around the world at risk of not being able to cope with the increasing number and severity of difficult-to-treat multidrug-resistant infections.

This innovation shortfall does not stem from a lack of ideas or insurmountable technological barriers, but rather from a lack of incentives. The prevailing economic and regulatory environment of the infectious disease area is daunting and makes it far more lucrative for researchers, clinicians, and industry to channel their expertise, workforce, and financial resources into other medical fields, such as immunology, oncology, or gene therapies.

The conventional and most common pull incentive relies on generating revenue through the sale of products at a per-unit price. However, this approach inherently encourages higher product volumes. In

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<sup>1</sup> WHO and European Centre for Disease Prevention and Control (ECDC), “Antimicrobial resistance surveillance in Europe,” 2023

<sup>2</sup> Eidgenössisches Departement des Innern and Bundesamt für Gesundheit, “Massnahmen des Bundes zur Stärkung der biomedizinischen Forschung und Technologie. Bericht 2022-2026,” Bern, Jun. 2022. [Online]. Available: <https://www.bag.admin.ch/dam/bag/de/dokumente/biomed/Biomedizinische%20Forschung&Technologie/schlussbericht-2022-2026.pdf.download.pdf/schlussbericht-2022-2026.pdf>

<sup>3</sup> Centers for Disease Control and Prevention (CDC), *National Estimates for Antibiotic Resistance*. Atlanta, GA: U.S. Department of Health and Human Services, 2019. [Online]. Available: [www.cdc.gov/DrugResistance/Biggest-Threats.html](http://www.cdc.gov/DrugResistance/Biggest-Threats.html)

<sup>4</sup> C. J. Murray *et al.*, “Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis,” *The Lancet*, vol. 399, no. 10325, pp. 629–655, Feb. 2022, doi: 10.1016/S0140-6736(21)02724-0

<sup>5</sup> H. Lucy, “Embracing a One Health Framework to Fight Antimicrobial Resistance,” *OECD Health Policy Studies*, Sep. 2023

<sup>6</sup> A. F. Widmer, “Emerging antibiotic resistance: Why we need new antibiotics!,” *Swiss Med Wkly*, vol. 152, no. 4546, p. 40032, Nov. 2022, doi: 10.57187/smw.2022.40032

<sup>7</sup> Bundesamt für wirtschaftliche Landesversorgung BWL, *Meldestelle für lebenswichtige Humanarzneimittel: Bericht 2021-2022*. Eidgenössisches Departement für Wirtschaft, Bildung und Forschung WBF, 2023. [Online]. Available: <https://www.bwl.admin.ch/dam/bwl/de/dokumente/themen/heilmittel/meldestelle/meldestelle-jahresbericht-2021-2022.pdf.download.pdf/Bericht%20Meldestelle%20Humanarzneimittel%202021-2022.pdf>

the case of antibiotics, this is counterproductive because increased use of these drugs can lead to a loss of effectiveness. To prevent or slow down this self-defeating cycle, healthcare professionals, including doctors and pharmacists, should only prescribe or dispense antibiotics, and patients should only use them, when there is clear clinical justification, in line with the motto of the Federal Office of Public Health (FOPH), “antibiotics: use wisely, take precisely”. In international terminology, measures that promote the appropriate use of antibiotics are referred to using the English term “**stewardship**”.

Stewardship measures are intentionally designed to reduce the use of antibiotics. However, when these are combined with the relatively modest prices that can be achieved even for new antibiotics, the result is lower revenue and profit. The conventional revenue model, based on “price times quantity”, cannot simultaneously promote the preservation of antibiotic efficacy (through stewardship) and increased investment in the development and availability of antibiotics (by ensuring a reasonable return for manufacturers).

As a result, there is a great need for alternative remuneration mechanisms, especially for new and innovative antibiotics, to ensure their development and availability. Ideally, these mechanisms should decouple revenue from product volume.

### **Signals of a dysfunctional global antibiotic market**

Signs that the antibiotic market can no longer effectively meet current and future needs are evident across the entire value chain, from R&D to the launch of products and the maintenance of marketing authorisation.

**R&D activities are insufficient:** There is a conspicuous shortfall in the development of new antibiotic technologies, both in Switzerland and globally. The last new chemical classes, oxazolidinones and lipopeptides, were discovered in 1978 and 1987 respectively and launched in 2000 and 2003. Hence there have been no marketing authorisations for new chemical classes of antibiotics in the last 20 years<sup>8</sup>. Major international pharmaceutical companies have shuttered their antibiotic research programmes<sup>9</sup>, and even developers who have recently launched new products have had to file for bankruptcy<sup>10</sup>. The World Health Organization (WHO) has concluded that “overall, the clinical pipeline and recently approved antibiotics are insufficient to tackle the challenge of increasing emergence and spread of antibiotic resistance”<sup>11</sup>.

**Launch rates of new antibiotics remain low:** Among the 18 antibiotics authorised by the medicines agencies of the United States, European Union (EU), Japan, or Canada from 2010 to 2020, the majority were introduced in just three out of 14 markets (United States, United Kingdom, and Sweden), as demonstrated by a recent international study. In 11 high-income countries, fewer than half of these antibiotics were accessible. The median annual sales for these 18 antibiotics in the first launched market, typically the United States, were very low, amounting to only USD 16.2 million<sup>12</sup>.

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<sup>8</sup> L. L. Silver, “Challenges of Antibacterial Discovery,” *Clinical Microbiology Reviews*, vol. 24, no. 1, 2011, doi: 10.1128/cmr.00030-10

<sup>9</sup> B. Plackett, “Why big pharma has abandoned antibiotics,” *Nature*, no. 586, pp. 50–52, 2020, doi: 10.1038/d41586-020-02884-3

<sup>10</sup> N. P. Taylor, “Achaogen seeks near-term sale through bankruptcy process,” *FierceBiotech*, Apr. 16, 2019. Accessed: Apr. 15, 2021. [Online]. Available: <https://www.fiercebiotech.com/biotech/achaogen-seeks-near-term-sale-through-bankruptcy-process>

<sup>11</sup> World Health Organization (WHO), “Antibacterial agents in (pre-)clinical development (infographic).” 2021. [Online]. Available: <https://cdn.who.int/media/docs/default-source/antimicrobial-resistance/amr-gcp-irc/2020-antibacterial-agents-in-clinical-and-preclinical-development.pdf>

<sup>12</sup> K. Outtersson, E. S. F. Orubu, J. Rex, C. Årdal, and M. H. Zaman, “Patient Access in 14 High-Income Countries to New Antibacterials Approved by the US Food and Drug Administration, European Medicines Agency, Japanese Pharmaceuticals and Medical Devices Agency, or Health Canada, 2010–2020,” *Clinical Infectious Diseases*, vol. 74, no. 7, pp. 1183–1190, Apr. 2022, doi: 10.1093/cid/ciab612

In Switzerland, only nine systemic antibiotics and drugs for the treatment of tuberculosis were registered from 2010 to 2022, accounting for a mere 39% of the total registered in the EU during the same period (according to our own analysis).

**Shortages and market withdrawals affecting essential antibiotics:** Antibiotics that have reached the market have become increasingly susceptible to supply disruptions, both in Switzerland<sup>13</sup> and globally. As of autumn 2023, supply disruptions in Switzerland have extended beyond hospitals to the community sector, with troubling shortages observed for oral antibiotics and vaccines<sup>14</sup>. This long-standing problem stems mainly from the complexity of global supply chains and the lack of, or inappropriate investment in, their resilience. The last remaining fully integrated production chain for antibiotics in Western Europe, Sandoz's Kundl facility, only narrowly avoided closure thanks to substantial subsidies from the Austrian government in 2020<sup>15</sup>.

In 2021 and 2022, the highest numbers of withdrawals from the Swiss market were recorded for antibiotics in a list of seven product categories<sup>7</sup>. The most frequent reason for market withdrawals is the inability to generate sufficient revenue to cover the costs of maintaining marketing authorisation, including pharmacovigilance and related reporting.

### Reasons for dysfunctional antibiotics market

The above observations paint a picture of what is sometimes called a “broken market”. Despite the evident need, this market fails to respond by increasing investments in new product development or enhancing the resilience of product supply chains.

While the underlying reasons for this situation are manifold, they share a common economic denominator: a lack of proper financial incentives and adequate methodologies to determine the reimbursement value for antibiotics. Left unaddressed, this situation poses a significant threat to health care globally and at the national health level, including in Switzerland, affecting both community and hospital settings, and endangering the lives and wellbeing of patients, both now and in the future.

### Common reimbursement procedures do not do justice to the full value of antibiotics for health care systems

When companies make decisions about drug supply chains and drug development, they adopt a global perspective. Industry decision-makers allocate their expertise, along with human and financial resources, to projects that are lucrative on a global scale. When considering investments, they take into account R&D risks, costs, subsidy availability, administrative and regulatory burdens, and, ultimately, the potential for financial gain in the market. Companies naturally prioritise projects that offer the highest profit potential, and they avoid unprofitable ventures. Given that investments in antibiotics are associated with low profit margins, losses, and even bankruptcies, entrepreneurial decision-makers often give precedence to investments in other areas, whether developing new drugs or strengthening product supply chains<sup>16</sup>.

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<sup>13</sup> K. E. Blankart and S. Felder, “Do Medicine Shortages Reduce Access and Increase Pharmaceutical Expenditure? A Retrospective Analysis of Switzerland 2015-2020,” *Value in Health*, vol. 25, no. 7, pp. 1124–1132, Jul. 2022, doi: 10.1016/j.jval.2021.12.017

<sup>14</sup> Schweizerische Eidgenossenschaft, Eidgenössisches Departement für Wirtschaft, Bildung und Forschung, Wirtschaftliche Landesversorgung, “WL-Lagebeurteilung,” Schweiz, WBF, WL, 03.10.2023, Oct. 2023. [Online]. Available: <https://www.bwl.admin.ch/bwl/de/home/bereiche/versorgungslage.html>

<sup>15</sup> A. Liu, “Novartis bolsters antibiotics manufacturing ties in Europe with €150M Austrian deal,” *FiercePharma*, Jul. 27, 2020. Accessed: Apr. 15, 2021. [Online]. Available: <https://www.fiercepharma.com/manufacturing/novartis-bolsters-antibiotics-manufacturing-tie-europe-eu150m-austrian-deal>

<sup>16</sup> T. Boluarte and U. Schulze, “The Case for a Subscription Model to Tackle Antimicrobial Resistance,” *Boston Consulting Group*, Feb. 2022.

The conventional perception of the pharmaceutical sector as a free market driven by customer preference and willingness to pay is not entirely accurate, particularly in high-income countries like Switzerland with their tightly regulated health care systems. In these countries, drug pricing, reimbursement policies, and procedures for monitoring the continued justifiability of drug prices are shaped by health care regulations and are thus influenced by political priorities and budgetary constraints. Given this environment, the pharmaceutical industry's reluctance to invest in antibiotics is a logical response to policy frameworks that often fail to recognise the life-saving potential of antibiotics and their critical contribution to the effectiveness and safety of modern health care systems.

### **Shared responsibility of wealthier countries**

Given that pharmaceutical development and marketing decisions are made with the world market in mind, Switzerland's remuneration strategies will always be evaluated in terms of their viability in the wider global context. Indeed, unless the remuneration offered by Switzerland and other nations together allows manufacturers to achieve reasonable global revenue targets, we will not obtain the antibiotics we need.

This reality binds the wealthier nations together in a shared responsibility, with each expected to contribute its fair share to a globally viable remuneration amount. It is important to recognise that a pull incentive can achieve an appropriate impact at the global level without the need to adopt an internationally harmonised model. Country-specific reimbursement procedures are the norm for pharmaceuticals, even in the EU. What counts is having a reward whose magnitude encourages manufacturers to invest in research, development, and product availability in many markets. Nevertheless, even a modest contribution from a single country's pull incentive can shift the dialogue within pharmaceutical companies, potentially expediting access to innovations or alleviating shortages.

We have evaluated two innovative remuneration models that have been or are being widely discussed internationally, one of them being tested in pilot projects. We have contrasted these with two versions of the traditional model in Switzerland which generates revenue using the "price times quantity" mechanism. The white paper describes and evaluates these four models with regard to their potential use for selected antibiotics in Switzerland.

### **Our contribution to a solution**

#### **The Swiss Round Table on Antibiotics' preferred subscription or flat-fee Netflix model is designed to accommodate the specific characteristics of antibiotics.**

The subscription model entails an annual guaranteed remuneration that is decoupled from sales volume and grants the manufacturer a fixed annual revenue agreed in advance<sup>17</sup>. The model thus offers financial planning security to the healthcare system and the manufacturer alike. This **"guaranteed revenue"** is intended to help amortise the costs of R&D, market entry, ongoing market presence, and to yield a fair profit. In return, the manufacturer commits to ensuring the availability of the new antibiotic to meet health care demands<sup>18</sup>. Additionally, by decoupling revenue from product volume, the guaranteed revenue eliminates the manufacturer's incentive to increase sales beyond a clinically justified level. This helps slow down the development of resistance and preserves the effectiveness of antibiotics for longer.

Innovative antibiotics offer substantial medical benefits not only to individual patients but also to society and the healthcare system as a whole. This broad impact can justify a significantly higher price. To place

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<sup>17</sup> C. Årdal *et al.*, "Antibiotic development — economic, regulatory and societal challenges," *Nat Rev Microbiol*, vol. 18, no. 5, pp. 267–274, May 2020, doi: 10.1038/s41579-019-0293-3

<sup>18</sup> M. Perkins and D. Glover, "How the 'NHS model' to tackle antimicrobial resistance (AMR) can set a global standard," NHS England. Accessed: Jan. 16, 2023. [Online]. Available: <https://www.england.nhs.uk/blog/how-the-nhs-model-to-tackle-antimicrobial-resistance-amr-can-set-a-global-standard/>

a value on the societal benefits, Rothery *et al.* (2018) propose applying STEDI criteria<sup>19</sup>. These criteria can be used to assess the characteristics of an antibiotic based on its spectrum of use (**s**pectrum), its role in reducing spread to other individuals through effective treatment (**t**ransmission), its ability to enable access to medical treatment by preventing infections during surgery and other medical interventions (**e**nablement), its role in increasing the variety of treatment options available (**d**iversity), and its ability to function as a last-resort treatment (**i**nsurance) within the healthcare system and society. As part of the pilot project in England, National Institute for Health and Care Excellence (NICE) developed different methods for evaluating STEDI criteria and gained initial experience with them.

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<sup>19</sup> C. Rothery, B. Woods, L. H. M. Schmitt, K. P. Claxton, S. J. Palmer, and M. Sculpher, "Framework for value assessment of new antimicrobials: implications of alternative funding arrangements for NICE Appraisal," Policy Research Unit in Economic Evaluation of Health and Care Interventions (EEPRU), Sheffield, Sep. 2018. [Online]. Available: [https://orda.shef.ac.uk/articles/report/Framework\\_for\\_value\\_assessment\\_of\\_new\\_antimicrobials\\_implications\\_of\\_alternative\\_funding\\_arrangements\\_for\\_nice\\_appraisal/25219094/1/files/44544536.pdf](https://orda.shef.ac.uk/articles/report/Framework_for_value_assessment_of_new_antimicrobials_implications_of_alternative_funding_arrangements_for_nice_appraisal/25219094/1/files/44544536.pdf)