



## Roadmap to a Swiss Pull Incentive Scheme for Novel Antibiotics

### Background and summary

The Confederation's Strategie Antibiotikaresistenzen Schweiz (StAR) aims to implement stewardship measures to prevent the uncontrolled spread of antimicrobial resistance (AMR). In addition, StAR outlines a range of actions to improve the availability of first-line antibiotics and promote the development of new antibacterial agents.<sup>1</sup> To this end, members of the Swiss Federal Assembly have submitted 18 procedural requests since 2019 to accelerate government efforts to create a conducive framework and incentive system for antibiotic development (see Annex).<sup>2</sup> The Federal Council has responded by pointing to the steps that have been taken so far and highlighting further measures that may be considered in 2024.<sup>3</sup> To make best use of the time until then, the Round Table on Antibiotics proposes pursuing a strategy of piloting and evaluating the effects of pull incentives.<sup>4</sup> This paper reviews the measures already undertaken by the Federal Council to incentivise the development of new antibiotic agents and presents the Round Table on Antibiotics' strategy to further advance these endeavours.

### Antimicrobial resistance and its implications

Antimicrobial resistance describes the ability of microorganisms, especially bacteria, to resist the effects of antibiotics used to treat infectious diseases. AMR compromises the effectiveness of health systems in treating bacterial infections, increasing the risk of many medical procedures and the likelihood of poor outcomes. This is particularly the case for vulnerable groups such as immunocompromised cancer patients receiving chemotherapy, elderly multi-morbid individuals undergoing surgery, and neonates, whose immune systems are not yet fully developed. AMR is dynamically driven by each use of antibiotics in humans, animals, and agriculture and will always spread due to global cross-border travel. It can never be fully eradicated because bacteria continually adapt to antibiotics and the environment. Consistent and sustainable activities to control AMR have therefore been a top priority of the World Health Organization (WHO), the United Nations, the European Union, and Switzerland for many years. Nevertheless, if governments around the world do not make bold decisions now to develop effective countermeasures, humanity risks losing the race against pathogenic bacteria.<sup>5</sup>

### WHO Global Action Plan

The Global Action Plan on Antimicrobial Resistance adopted in 2015 defines a comprehensive set of objectives and related measures to fight AMR, which we have grouped into the categories of "Stewardship" and "New Products". *Stewardship* covers all measures to prevent the inappropriate use of antibiotics, one of the main factors contributing to the spread of AMR. These include the creation of awareness through effective communication, education, and training; surveillance and research to understand antibiotic resistance and consumption; infection prevention, hygiene, and effective sanitation; and the optimised use

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<sup>1</sup> StAR Action Field 8 framework/Incentive systems, measure 3.8.3.

<sup>2</sup> The procedural requests have included postulates, interpellations, questions, and motions.

<sup>3</sup> BAG 2022, Massnahmen des Bundes zur Stärkung der biomedizinischen Forschung und Technologie-Bericht 22–26, Massnahme 9c

<sup>4</sup> Pull incentives are decoupled reimbursement models that allow for adequate revenue and profit to be achieved regardless of the volumes of products sold. Pull incentives exert their effect after a product has obtained market authorisation and been launched. There are various types of pull incentive. The simplest is a **market entry premium**. In this case, companies are promised a one-off payment that is made as soon as they have developed a product with predefined properties and launched it on the market. **Subscription models** entail payments to the manufacturer over a period of time after a product has been launched. These models incentivise companies to offer their products over the long term and not just to benefit from the one-off payment. Other pull models entail **simplification and acceleration of the approval process** or an **extension of the patent term**.

<sup>5</sup> The WHO's 2021 report "Antibacterial agents in clinical and preclinical development: an overview and analysis" concludes, "Overall, the clinical pipeline and recently approved antibiotics are insufficient to tackle the challenge of increasing emergence and spread of antimicrobial resistance."

of antimicrobial medicines in humans and animals. The *New Products* category covers increased investment in new medicines or treatment approaches, diagnostic tools, vaccines, and other interventions to control the growing problems caused by AMR, particularly the difficulty of treating infections for which existing antibiotics have failed.

### Swiss government actions

The Federal Council has repeatedly acknowledged that AMR poses a serious and growing threat to public health, with significant long-term social and economic implications. To combat this threat, it established StAR, its cross-sectoral National Action Plan, in 2015,<sup>6</sup> which defines nine fields of action in the categories of *Stewardship* and *New Products* that are aligned with the WHO Global Action Plan.

#### *Stewardship*

The Federal Council has initiated a range of measures to monitor and improve awareness of AMR through research, effective communication, education, and training. For example, three reports have been published, including the results of a survey on levels of awareness of AMR in society, providing important baseline data for future initiatives. As early as 1994, the Federal Office of Public Health (FOPH) instigated the founding of Swissnoso, the National Center for Infection Prevention. Another measure was a study commissioned by the FOPH that reinforced the importance of existing stewardship activities in humans and suggested further measures, including the increased use of point-of-care tests, immediate feedback on prescribing practices for antibiotics, and enhanced surveillance.<sup>7</sup> Additionally, by funding the National Research Programmes NRP 49 and NRP 72, and by establishing ANRESIS, the Swiss Centre for Antibiotic Resistance, the Federal Council has been actively engaged in surveillance and research activities to understand antibiotic resistance and consumption, and to discover novel mechanisms to address patterns of bacterial resistance.

#### *New Products*

The Federal Council and the Canton of Geneva have contributed to the development of new products by providing US\$ 2 million over an 8-year period (2016-2023) to GARDP,<sup>8</sup> a public-private partnership based in Geneva that co-develops antibiotics in the clinical stage with innovator companies and fosters their accessibility globally, with a special focus on low- and middle-income countries and vulnerable populations. In addition, new approaches to revitalise antibiotic discovery are being pursued by the National Center of Competence in Research, NCCR AntiResist, which is funded by the Swiss National Science Foundation and the University of Basel. Furthermore, the FOPH commissioned the Swiss Federal Institute of Intellectual Property (IPI) to perform a review of intellectual property (IP) measures to incentivise the development of novel antibiotics.<sup>9</sup> Acknowledging that the development of new antimicrobial medicines requires a global effort, the Federal Council has engaged with a range of institutions worldwide, including the Global AMR R&D Hub,<sup>10</sup> JPIAMR,<sup>11</sup> and the UN Interagency Coordination Group (IACG) on AMR.

### Assessment

We commend the Swiss government for its actions, particularly in the fields of stewardship, basic research, and early development. However, we believe that Switzerland, as an important player in pharmaceutical research and development, should do more to ensure a steady supply of new antibiotics in the future. This

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<sup>6</sup> The cross-sectoral One Health approach was suggested by National Councillor Bea Heim in her motion 12.4052.

<sup>7</sup> Frick U., Dey M., Wenger A., Manthey J., Rehm J. (2018) Marktmechanismen und Anreizsysteme bezüglich Antibiotikaverbrauch in der Humanmedizin. - Literaturanalyse und Delphi-Befragung - Forschungsbericht No. 384 aus dem Schweizer Institut für Sucht- und Gesundheitsforschung ISGF, Zürich, im Auftrag des Bundesamtes für Gesundheit.

<sup>8</sup> GARDP was founded in 2016 by the WHO and DNDi (Drugs for Neglected Diseases initiative).

<sup>9</sup> IGE 2022 Antimicrobial Resistance (AMR) – Analyse möglicher Anpassungen des Patentrechts zur Attraktivitätssteigerung der Entwicklung neuer Antibiotika in der Schweiz

<sup>10</sup> The Global AMR R&D Hub was founded in Berlin in 2018 in response to a call to action by the G20 group of countries. The information collected and presented by the Hub is meant to inform AMR research and development decisions, as well as international cooperation.

<sup>11</sup> JPIAMR, the Joint Programming Initiative on Antimicrobial Resistance, engages 29 nations and the European Commission. The initiative coordinates national research and facilitates collaborative approaches to curb AMR. Switzerland's participation is managed by the Swiss National Science Foundation.

conclusion has been shared by the many procedural requests that have been submitted since 2019 and which have sought to spur the creation of a framework incentivising the development of new antibiotics (see Annex).

Unless the environment for developing new antibiotics is made more attractive, the Federal Council's investments in AMR basic research may fail to translate into tangible results. Because of a lack of appropriate financial incentives, even promising antibacterial drug candidates from basic research are rarely taken up by the industry and developed into products that can be delivered to patients in need. The international engagement of the Confederation is commendable, but so far has not had the effect of incentivising private investment in new product development. We welcome the engagement of Switzerland in GARDP, which is a typical push mechanism.<sup>12</sup> These contributions are in line with G7 and G20 Health Minister declarations that have called for additional funding for GARDP to achieve its goal of delivering five new treatments by 2025. The activities in the Global AMR R&D Hub and in JPIAMR have strengthened those networks but have not yet resulted in Switzerland contributing its own ideas, models, and evidence to them despite its strong position in medicine and science and its substantial pharmaceutical and biotech industry. The IPI report concluded that IP measures will have little success in incentivising the development of new antibiotics. This implies that alternative approaches are needed.

### **Contribution by the Round Table on Antibiotics**

The WHO Global Action Plan outlines a comprehensive set of measures to fight AMR. Importantly, these are designed to be complementary rather than exclusive, achieving their full effect in combination. While StAR has prompted significant action in the four areas of stewardship including awareness, surveillance, and research, infection prevention and the optimised use of antimicrobials, so far only initial steps have been taken to tackle the incentivisation of new antibiotics development.

A multi-disciplinary Swiss association with experienced members from medicine, science, politics, and industry, the Round Table on Antibiotics is ideally placed to design a framework to incentivise new product development. To spur action, it has developed a plan recommending the following steps:

- Identifying and specifying a suitable incentive scheme that builds on pull incentives that have been discussed by the international community for many years and on reimbursement and financing mechanisms in use or discussed in Switzerland.
- Piloting this pull incentive scheme in Switzerland to gain know-how and experience.
- Sharing the Swiss experience with other countries, with advice and support from the Ambassador for Global Health in the FOPH. Broad international adoption of pull incentives will ensure that the national schemes jointly generate the appropriate incentive size.
- Adopting the pull incentive scheme for regular implementation in the Swiss healthcare system.

If Switzerland delivers on this plan, it will send a strong and credible signal of its commitment to the global industry and Switzerland's partners in the global healthcare hub in Geneva. It will also send a powerful signal to the local industry and start-ups in antibiotics development looking to settle and grow in an ecosystem designed to facilitate their innovative projects. Importantly, too, manufacturers whose pharmaceutical products benefit from a viable incentive mechanism will be better able to ensure their uninterrupted availability.

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*President on behalf of the entire Board of the Round Table on Antibiotics*

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<sup>12</sup> Push incentives are designed to pay for research and development of new antibiotic technologies prior to market launch.

## **Annex: Selected procedural requests 2019 – 2022**

*Note: Procedural requests focusing on sectors other than the human sector of One Health, on product availability, or on migration are not included in this list.*

- Interpellation Buillard-Marbach (22.3731): Die Relevanz des Kampfes gegen die Antibiotikaresistenz für die Schweiz und die Welt
- Interpellation Feri (22.3256): Die Kosten der Antibiotika-Krise für das Gesundheitswesen und Anreize für neue Antibiotika
- Interpellation Feri (21.4233): Antibiotikakrise. Kosten für das Gesundheitswesen?
- Motion von Falkenstein (21.4539): Schaffung von Anreizen, um neue Antibiotika in der Schweiz zu entwickeln und auf den Markt zu bringen
- Interpellation Sommaruga (21.3299): Engagement gegen Antibiotikaresistenzen. Langfristige Unterstützung der GARDP
- Motion Fiala (20.4529): Antibiotika-Forschung durch Pull-Anreize verbessern
- Anfrage Eymann (20.1027): Tut die Schweiz genug, um die Bevölkerung mit Blick auf drohende Antibiotikaresistenzen zu schützen?
- Interpellation Gschwind (19.4501): Ist die Erstellung einer Datenbank über den Antibiotika-Einsatz in der Humanmedizin denkbar?
- Motionen Béglé (19.4266) Eymann (19.4326), Heim (19.4327) und Reimann (19.4328): Internationale Ministerkonferenz in der Schweiz mit dem Ziel, forschungsfreundliche Rahmenbedingungen zur Bekämpfung von Antibiotikaresistenzen zu schaffen
- Postulat Heim (19.4291): Antibiotikakrise. Die Erforschung und Entwicklung innovativer Antibiotika erfordert neue finanzielle Anreize
- Postulat Béglé (19.3860): Nicht warten bis zu einer schweren Epidemie. Schaffung eines Fonds zur Förderung der Erforschung und der Entwicklung neuer antimikrobieller Mittel
- Motion Reimann (19.3859): Förderungsmöglichkeiten im Bereich der Antibiotikaresistenzen stärken
- Motion Heim (19.3858): Schaffung eines nationalen Kompetenzzentrums zur Erforschung neuer Antibiotika
- Interpellation Page (19.3088) und Motion Page (19.3551): Forschungs- und Entwicklungskosten für neue Antibiotika. Anreize in Form von Steuerabzügen schaffen