

Swiss Round Table on Antibiotics June 2024 Newsletter

Dear Members, Partners and Friends of the Swiss Round Table on Antibiotics,

Just before the start of the holiday season we are glad to provide you with the new edition of our newsletter and updates about our activities and selected international news.

During the last three months, we have achieved major milestones in our Pull-project such as an invitation to a hearing at the Social Security & Health Committee of the National Council and the first working group meeting on the AMR-related Swiss unmet medical need and important pathogens list.

On the international stage, the implementation of a permanent facility in the UK for the “Provision of antimicrobial products via a subscription payment model” is a key milestone and boost for the broader acceptance and consideration of subscription-based pull incentives in industrialised countries such as Switzerland.

Apart from additional updates, we continued our series on "Other Initiatives" and introduce profiles of two further organisations that aim to promote the implementation of AMR countermeasures (ARMoR in the UK and DNAMR in Germany).

Wishing you an interesting read – and some restful and refreshing vacation days!

Barbara Polek
Managing Director

PS: You can register to or deregister from our newsletter list by [sending us a message](#).

Our Activities



RTA invited to a hearing at the Social Security & Health Committee of the National Council

On 3 May 2024, a delegation of RTA experts in infectiology, health economics and health policy informed the parliamentary committee on the AMR situation and strategic countermeasures, including a subscription model. The RTA delegation appreciated the lively Q&A session and the Committee decided to closely follow the further development of AMR and related alternative reimbursement and financing models (see [press release](#) second but last item).



RTA pull project – First meeting of the working group on Swiss AMR-related unmet medical need

On 16 May 2024, a group of experts convened for the first of a series of meetings to

- i) identify the unmet medical need regarding difficult-to-treat bacterial infections and emerging antibiotics-resistant strains in Switzerland, and
- ii) to agree on a list of the priority pathogens that should be addressed by new or existing antibiotics.

The priority pathogens and related infections shall be identified irrespective of whether they are treated with antibiotics that are already available in Switzerland, antibiotics that are available in other countries but not in Switzerland, or novel drugs that may still have to be developed and authorised. The first step is to agree on the main criteria for identifying the unmet medical need in Switzerland.



Webinar on antibiotic challenge held by Swiss Round Table on Antibiotics (RTA)

([Link](#) to the recording)

The RTA webinar “Why do we need a pull incentive to push antibiotics onto the market?” was hosted by the BEAM Alliance. The RTA panel made clear why pull incentives are needed and why pull incentives are essential to make funding of the development phase a sustainable investment.

Rudolf Blankart’s intro presentation elaborated on the paradox of the antibiotics market being far less attractive than the markets for other pharmaceuticals, despite the huge value of these life-saving drugs to individual patients and the health care systems. The combination of low prices, short treatment periods and antibiotic stewardship results in low or negative return on investment, which makes finding investors for clinical development of new antibiotics a threatening challenge. The impact of the insufficient remuneration of antibiotics was illustrated

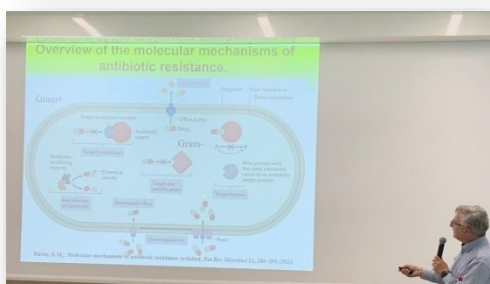
by Barbara Polek referring to a medium-sized company that presented successful clinical data at an investor conference, yet the only response was “Nice data, but where is your business case?”.

Limitations of push and challenges to pull incentives were outlined by Chantal Morel. While push incentives such as R&D partnership models are intended to attract companies to invest in the development of new antimicrobials, there remains the lack of an attractive and sufficiently funded pull signal from the market as issue. However, a viable business case of an approved product is the key criterion for industry’s decisions on investments and whether to put/keep a product on the market. Challenges to the implementation of pull incentives include the aversion to interfere in the market (although this is well-established in other sectors) and that antimicrobial resistance is not a publicly perceived and emotionally loaded health problem such as other diseases. To overcome these challenges the cost of pull models must be put in context of the costs in terms of lost lives and increased health care expenses if no action is taken.

A lively Q&A discussion was moderated by Kosta Shatrov and the webinar finally concluded:

- Reimbursement of antimicrobials must reflect the values of reducing transmission and enabling medical procedures that have a risk of infections or immunosuppression.
- Without pull incentives to ensure a business case, even push-funded new antibiotics won’t reach the market and the patients.

To date, England and Sweden already conducted successful pilots of subscription or revenue guarantee models and other countries such as Canada, Japan, Australia and Switzerland aim to implement similar pilots in their national contexts. Notably, the UK just recently implemented a provision of antimicrobial products via a subscription payment model (see article in the category “International policies and news” below).



General Assembly, 29 May 2024

The president of the RTA (Rudolf Blankart) and the managing director (Barbara Polek) reported on the progress that was achieved during the last year. The RTA-activities focused on the Pull project that aims to have a subscription model implemented in Switzerland for the remuneration of selected antibiotics. The white paper described in the

March 2024 edition of our [newsletter](#) laid the grounds for a pilot project intended to start in 2025. Major organisational milestones comprised the enlargement of the RTA’s operational team to four people, the strengthening of the organisation’s governance structure, and the rental of an office located in the Swiss Institute for Translational and Entrepreneurial Medicine (sitem-insel) in Bern. You can find further information about the activities of the Swiss Round Table on Antibiotics in our [annual report](#).

Following the assembly’s closed part, Professor Andreas Widmer provided an insightful talk on the emergence and rapid spread of multi-drug resistant pathogens in Switzerland. Particularly the growing prevalence of bacteria with extended-spectrum beta-lactamases (ESBL) pose a considerable threat to health care provision, because they can impede the prophylactic use of antibiotics in medical procedures and treatments of other diseases.



UK: Provision of antimicrobial products via a subscription payment model

The UK is the first country going to implement a subscription scheme as a regular procedure. Learnings from the pilot and a consultation performed by NHS England informed the terms of a permanent public procurement scheme for selected antimicrobials that foresees payment via a subscription model. The permanent scheme is about to start, with NHS issuing Invitations To Tender (ITT) to bidder candidates on 15 July 2024. First product procurements are planned to be made in January 2026.

The annual budget assigned by England for remuneration of all eligible products identified in the 2024-25 procurement process amounts to a maximum of 90 million GBP in total. For evaluation of a particular product, a group of experts scores the product's characteristics and evidence for 17 criteria in three categories: (a) relative effectiveness and unmet medical need; (b) pharmacological benefit; and (c) health system benefit. The total score determines the maximum annual income of the product from a four-tiered value band which, for England, foresees maximum payments of 5, 10, 15, and 20 million GBP respectively. Mandatory performance criteria to be fulfilled by the marketing authorisation holder will include security of supply, antimicrobial stewardship commitments, and manufacturing and environmental commitments.

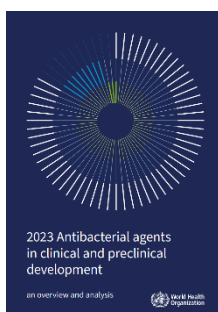
For more details about this new model, please [contact the RTA](#).



German parliamentary group formed to combat AMR

Members of five parties of the German Bundestag formed a parliamentary group on 13 June 2024 to tackle AMR and the development of new antibiotics. The spokesperson of the group, Georg Kippels MdB, emphasised the severe impact of AMR on healthcare and particularly for patients

undergoing surgery, transplantation and immunosuppressive therapies. (Photo: DNAMR/Tillmann Konrad)



WHO pipeline analysis of antibacterial agents in clinical and preclinical development

The WHO pipeline analysis sheds light on the progress made in combating AMR through R&D on new therapeutic options and evaluates to what extent the present pipeline addresses infections caused by drug-resistant bacterial pathogens according to the new 2024 WHO bacterial priority pathogen list (see publication [here](#)).

Overall, 97 antibacterial agents and/or combinations that include at least one new therapeutic entity are in clinical development. Of those, 57 are traditional agents and 40 are non-traditional

(e.g. phages, antibodies). Four products are in New Drug Application (NDA) or Marketing Authorisation Application (MAA) stage. Only a small fraction of agents targets critical bacterial priority pathogens, most are against high or medium priority bacterial pathogens. Almost half of the traditional antibacterial agents are β -lactams or β -lactam/ β -lactamase inhibitor combinations with a major gap in activity against metallo- β -lactamase producers.



Swiss Biotech Day panel discussion “AMR: From Awareness to Action. The Time to invest is now”

The RTA followed the panel discussion and the subsequent Q&A

session with great interest. The high calibre panel included

- Najy Alsayed, Global Therapeutic Area Head for infectious diseases at Menarini Group,
- Morgane Vanbiervliet, Market Intelligence & Business Development Manager for infectious diseases at Debiopharm International SA,
- Yann Ferrisse, Director Business Development & Partner Engagement at the Global Antibiotic R&D Partnership (GARDP), and
- William Burns, Board Chair of the AMR Action Fund.

The topic of investment inspired forward-looking and solution-oriented speeches which identified areas that urgently need solutions including but not limited to ICH-facilitated harmonisation of regulatory requirements across major regulators’ territories, market fragmentation (particularly in low-resource geographies) and payer reluctance to enable appropriate use of diagnostics. Furthermore, Najy Alsayed and Yann Ferrisse, highlighted the importance of a “designation” of antimicrobials (comparable to the Orphan Drug Designation) that earmarks promising antimicrobial drug candidates to raise potential investors’ interest.

A massive underreporting of the AMR-related burden of disease is indicated by a study of Debioharm International that was performed in the UK under NICE-standards for qualitative interviews. Despite shortcomings of current frameworks, William Burns encouraged companies that have “good data” to go for it rather than bothering about the “broken market” – trusting that industry will find solutions as it has done on other occasions in the past. With this encouraging prospect the panel closed.

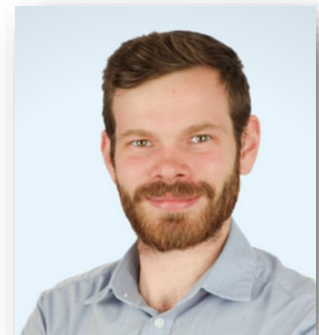
Other Initiatives



ARMoR, the Alliance for Reducing Microbial Resistance, is a non-profit organisation aiming to reduce AMR through evidence-based policy change (armoramr.org). The organisation focuses on policies designed to (a) incentivise the development of new antimicrobials, and (b) improve access to new and existing antimicrobials. Working in collaboration with NGOs, academia, industry and governments, ARMoR gathers robust evidence and advocates for the adoption of pull incentives within the EU. They emphasise the need to move quickly on implementing these policies to support the failing antimicrobial pipeline. Additionally, they aim to ensure that pull incentive policies best meet global health needs and support access to antimicrobials for vulnerable populations in areas of high unmet need. ARMoR's current work includes economic modelling, demonstrating the benefits of investing in antimicrobial development, policy research to support governments in overcoming implementation barriers and direct advocacy to push for governmental action on this critical issue.

The consensus is clear, there is a need to swiftly implement push and pull incentives to support the failing antimicrobial pipeline. For Switzerland such a scheme could mean ...

David McKinney, Co-founder and Director of ARMoR



... saving 6,000 lives and generating over \$7 billion in benefits over a period of 30 years.

Aanika Dalal, Co-Founder & Director



DNAMR, the German Network against AMR, is an information platform that promotes market incentives to secure the continuous flow of new antibiotics (dnamr.de). The network supports measures aimed at strengthening basic research – a segment of the development cycle of antibiotics that does not see the same degree of funding across all European countries.

DNAMR promotes market conditions that will secure the return on investment that would enable companies to bring new, resistance-breaking reserve antibiotics on the market. Suitable instruments, that have already been identified, must be applied consistently. Both push and pull measures shall be implemented to strengthen basic and clinical research, and to create incentives for pharmaceutical companies to invest in new antibiotics. The DNAMR therefore advocates transferable exclusivity vouchers as the most appropriate way forward in the European Union. Other countries or regions, such as the UK, may find different solutions for the problem.

The following research institutions and non-governmental organisations were among the founding members of the DNAMR: the German Association of Research-Based Pharmaceutical Companies (vfa), the German Center for Infection Research (DZIF), the BEAM Alliance, the Global AMR R&D Hub, the German Society for Infectiology (DGI), and the Paul Ehrlich Society for Infection Therapy (PEG).

The DNAMR endeavors the set-up of a Parliamentary Group to support the work of the DNAMR in the German Federal Parliament.

The DNAMR is a strong advocacy group that seeks to reach politics and society, raising their awareness of the need for action against antimicrobial resistance.

Harald Zimmer, Spokesman of the DNAMR



The DNAMR invites patient organisations to support its efforts by joining the network. Because Time to Act is Now!

**Dr. Ingrid Wanninger, Managing Director
HYpharm GmbH**