

Swiss Round Table on Antibiotics

April 2025 Newsletter

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Our Activities

Survey on imports of antibiotics not authorised in Switzerland



Switzerland's health care system is committed to providing patients with the most effective antibiotic treatments available. Yet, with its market of less than 10 million residents and a reimbursement system that currently doesn't fully recognise the value of antibiotics many new antibiotics are not registered in Switzerland. The RTA conducted a survey on the import practices of critical antibiotics under special legislation that allows health care professionals to access medications not currently registered in Switzerland.

The survey was conducted among the five university hospitals and the Ente Ospedaliero Cantonale in the first quarter of 2025. The survey asked for information about their imports of seven "reserve" antibiotics authorised by the European Medicines Agency and/or FDA in the period of 2018-2024, as well as further antibiotics, as applicable. All of the latter antibiotics belonged to the "access" category.

All six institutions imported Cefiderocol and five of the six institutions imported Fosfomycin IV in 2023 and 2024. The other mentioned antibiotics were imported by one or two institutions in one or both years. The total value of the reported imports amounted to more than CHF 1 million in each year. In some cases, the prices paid by different institutions differed considerably. While the amount looks moderate, the indirect costs and implications of such imports are not:

- To get the costs of the imported drugs refunded, the prescribers have to seek individual and advance approval by the patient's health insurance, implying a significant administrative effort and potentially delayed access which may put patients' timely recovery or life at risk.
- The obligation for Swiss marketing authorisation holders of systemic antibiotics to maintain a safety stock cannot be enforced for drugs not authorised in Switzerland, which exacerbates the fragility of their supply, particularly during shortage episodes.
- While exceptional imports may be a legitimate means of closing occasional treatment gaps, they come at relevant direct and indirect costs, and risks for patients, if they become the norm.

A subscription scheme offers the government a promising opportunity to incentivise manufacturers of selected critical antibiotics to pursue marketing authorisation in Switzerland.

International Policies and News

Study on the import of unregistered antimicrobials in Australia



In its March member update, AAMRNet informed about a recent study conducted in Australia about trends in prescriber applications to access unapproved antimicrobials in Australia during 2018-2023¹.

Although Australia's population is almost three times the size of the Swiss population it faces similar access issues for antimicrobials as Switzerland. However, unlike Switzerland, Australian legislation offers tailored ways to access unapproved antimicrobials, depending on the urgency and prevalence of the need:

- **Category A** unapproved medicines can be imported to cover an urgent medical need of critically ill patients. No prior approval is required. More than a quarter of all requests for import to access an unapproved antimicrobial belonged to this category.
- **Category B** includes drugs not urgently needed and belonging neither to Category A nor Category C. A clinical justification is required to support the application for import of an unapproved product. Approval of the request is required prior to supply. Overall, 97% of Category B applications were approved within 20 days.
- **Category C** unapproved medicines are included in a list of therapeutic goods with an established history of use for specified indications. Their import requires a streamlined approval process. The vast majority of Category C applications concerns older drugs.

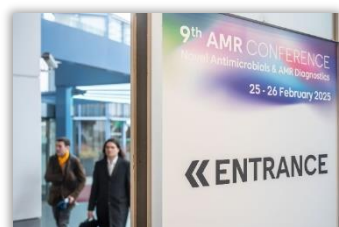
The Australian import practices entail remarkably similar challenges to the import practice of Switzerland: absence of mandatory safety stock holding within the country, potential delays in accessing last-resort antibiotics for life-threatening conditions, and no confirmation of product quality by the national regulatory authority as TGA strict quality standards cannot be enforced for imported unapproved drugs.

The authors concluded that “to protect the entire healthcare system, the Australian Government allocation of funding resources to address AMR needs [should] also consider ensuring the availability of antibacterial treatments for people infected with resistant organisms.”

¹ N. T. Hillock, A. Cheng, and A. Bowskill, 'Do policies that allow access to unregistered antimicrobials address the unmet need? Australia as a case study of a high-income country with universal healthcare', *JAC-Antimicrobial Resistance*, vol. 7, no. 1, p. dlac216, Dec. 2024, doi: [10.1093/jacamr/dlae216](https://doi.org/10.1093/jacamr/dlae216).

Conferences and Events

Takeaways from the 9th AMR Conference in Basel



Once again the AMR Conference provided many insightful and inspiring presentations. We selected two of them for a closer look and brief summary:

Pan-European pilot of a revenue guarantee scheme

The representative of HERA, the Health Emergency Preparedness and Response Authority, started the panel session by informing about the cancellation of the pilot of a pan-European revenue guarantee scheme shortly before year end 2024, following the withdrawals of Shionogi and A. Menarini. A second attempt at establishing a revenue guarantee model in EU/EEA is planned in 2026.

The panel discussion unveiled a significant lack of trust between HERA and the manufacturers which prevented the co-creation of a scheme that meets the needs and expectations of both parties. While the manufacturers reminded that the budgeted funds would not accommodate a European “fair-share” and hence risked leaving the problem of an insufficient pipeline of novel antibiotics unsolved, the representatives of HERA and the Dutch Ministry of Health criticised a lack of transparency regarding production costs and profits from the manufacturers’ side.

RTA comment: Building on lessons learned from the pilot of a revenue guarantee model in the United Kingdom, future efforts should consider its success factors. The participating manufacturers particularly appreciated the open cooperation with authorities during the design and implementation, allowing for timely resolution of issues and adjustments to contracts. This collaborative approach could help address the trust deficit evident in the recent unsuccessful European attempt.

Rising player in the global health market

The Kingdom of Saudi Arabia (KSA), represented by Abdulrhman Mohana of the Public Health Agency, pursues a growth strategy for their health market targeting \$20 billion by 2030, i.e. about double the size it had during the pandemic. The Agency aspires to grow its role in the global health care system by hosting ministerial conferences, attracting startups and offering mentorship, establishing a One-Health learning hub, and expanding knowledge and experience in the Middle East and Africa, e.g. by supporting the transfer of the Global High-Level Ministerial Conference on Antimicrobial Resistance from the KSA to Nigeria.

INTERFINITY Festival in Basel: Surviving Superbugs – A Dance To Resist



Have you ever experienced challenges in explaining the mode of action of antibiotics, strategies of bacteria to escape the effects of antibiotics by developing resistance mechanisms, and approaches and challenges of antibiotic research and development?

The 2025 edition of the INTERFINITY Festival in Basel dedicated its legendary cross-disciplinary type of performance to this task. Lukas Loss, Director of INTERFINITY, brought world-renowned musicians and dancers together with scientists of the Swiss research programme “NCCR Antiresist”. Members of the RTA Board supported a previous panel discussion and engaged in discussions with the audience of the music and dance performance. Their feedback was enthusiastic!

Take a look at the trailer of the performance on YouTube: [Surviving Superbugs – A Dance To Resist](#)