Treatment gaps in resistant bacterial infections in Switzerland – and how to fill them

A contribution to the discussion

Swiss Round Table on Antibiotics

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Summary

The global economic and regulatory framework for antimicrobials presents significant challenges. Due to relatively poor revenue prospects, only few new antibiotics are developed, and manufacturers often choose to launch them in only a few major markets. Switzerland is also affected by the manufacturers' selective launch strategies: Clinicians are faced with significant challenges when infections caused by resistant bacterial pathogens cannot be treated with the best available therapy. Furthermore, antimicrobial resistance weakens the effectiveness of the antibiotics also in Switzerland. **(Chapter 1).**

If a required antibiotic is not authorised or marketed in Switzerland, healthcare professionals may import that antibiotic. Because such imports cause a substantial bureaucratic and financial burden, they are credible indicators of an unmet need.

In order to get hints at antibiotics addressing an unmet medical need in Switzerland, the RTA conducted a survey of 11 university and regional hospitals to learn about the antibiotic agents imported in 2023 and 2024. The survey collected quantities of imported antibiotics in grams of the main substance, and prices paid in CHF by gram.

Notably, the largest number of imported antibiotics belonged to the WHO Reserve group (7 antibiotics), closely followed by 6 antibiotics of the Access group. In addition, the hospital pharmacies reported imports of 2 Watch antibiotics and 4 antimycobacterial drugs.

The analysis used the collected raw data, generated further data from the raw data, and consulted complementary information from other sources, including the Sanford Guide to Antimicrobial Therapy, and expert assessments by scientists and clinicians. The outcome of the analysis is a shortlist of 4 Reserve-antibiotics whose regular availability in the Swiss healthcare system under a Swissmedic authorisation is deemed highly desirable: Cefiderocol, Sulbactam-Durlobactam, Aztreonam-avibactam, and Fosfomycin i.v. **(Chapter 2)**

Chapter 3 describes two regulatory pathways to a Swissmedic marketing authorisation for the shortlisted antibiotics, and the legislative basis for imports of antibiotics not authorised in Switzerland, and informs about related reimbursement options.

Terms and abbreviations

Abbreviation	Explanation
AMR	Antimicrobial resistance
ANRESIS	Swiss Centre for Antibiotic Resistance, a nationwide, representative surveillance system and research instrument for antibiotic resistance and consumption
AWaRe	A classification system developed by the WHO's EML working group to categorise antibiotics based on their potential for resistance and importance in human medicine. Three groups are defined: **A**ccess, **Wa**tch, and **Re**serve[1]
CHI	Compulsory health insurance
CNS	Central Nervous System
CPE	Carbapenemase-producing Enterobacteriaceae
CRAB	Carbapenem-resistant *Acinetobacter baumannii*
CRE	Carbapenem-resistant Enterobacterales
DDD	Defined Daily Dose, the assumed average maintenance dose per day for a drug used for its main indication in adults
EFTA	European Free Trade Association
EMA	European Medicines Agency
EML	WHO's Essential Medicines List
FDA	The U.S. Food and Drug Administration
HMA	Heads of Medicines Agency
ICU	Intensive Care Unit
INN	International Nonproprietory Name
KVV	Krankenversicherungsverordnung / ordinance on health insurance
LTCF	Long-Term Care Facilities
MBL	Metallo-β-lactamases

[1] Zanichelli et al. - 2023 - The WHO AWaRe (Access, Watch, Reserve) antibiot.pdf:
Access antibiotics are antibiotics with a narrow spectrum of activity, generally with less side-effects, a lower potential for the selection of antimicrobial resistance and of lower cost. They are recommended for the empiric treatment of most common infections and should be widely available.
Watch antibiotics generally have a higher potential for the selection of antimicrobial resistance and are more commonly used in sicker patients in the hospital facility setting. Their use should be carefully monitored to avoid overuse.
Reserve antibiotics are last-resort antibiotics that should only be used to treat severe infections caused by multidrug-resistant pathogens.

Abbreviation	Explanation
MDR	Multidrug resistance / multidrug resistant
NARA	Nationales Referenzlaboratorium zur Früherkennung und Überwachung neuartiger Antibiotikaresistenzen / National reference laboratory for the early detection and monitoring of novel antibiotic resistance
NDM	New Dehli metallo-β-lactamase
RTA	Swiss Round Table on Antibiotics
Sanford Guide	The Sanford Guide to Antimicrobial Therapy: a collection of evidence-based, regularly updated clinical guidelines for the treatment of infectious diseases
SL	Spezialitätenliste / Swiss positive list of medicinal products reimbursed by the compulsory health insurance
TPA	Therapeutic Products Act
Ucml	Union list of critical medicines
WHO	World Health Organization

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Strengths and limitations of this survey

Strengths

- To the best knowledge of the authors this survey is the first one addressing Swiss hospitals' imports of medicinal products, here: antimicrobials, which do not have a Swissmedic authorisation but may be imported under special provisions to fill treatment gaps.
- The participating hospitals cover the three major language regions of the country and therefore may experience different unmet medical needs.

Limitations

- This survey involved only a small number of eleven university and cantonal hospitals. Neither were smaller and more peripherally located hospitals nor Long-Term Care Facilities (LTCF) included. Therefore, this survey cannot claim statistical significance of its results.
- The collected data was accepted as reported by the hospital pharmacies and was not systematically validated for correctness and completeness.
- Information about the actual delivery times was not solicited. Timely delivery of last-resort antibiotics is of critical importance.

1 Unmet medical need in treating infections by resistant bacterial pathogens

The global economic and regulatory framework for antimicrobials presents significant challenges. Due to relatively poor revenue prospects, only few new antibiotics are developed, and manufacturers often choose to launch them in only a few major markets. With less than 10 million inhabitants and a relatively low rate of infections with multidrug resistant (MDR) pathogens Switzerland is not a very attractive market for antibiotics and experiences the effects of the manufacturers' selective launch strategies: Clinicians are faced with significant challenges when infections caused by resistant bacterial pathogens cannot be adequately treated with the antibiotics authorised and marketed in our country.

An analysis of the antibiotics recommended by the Sanford Guide to Antimicrobial Therapy (Sanford Guide) illustrates this situation: Out of 39 antibiotics recommended for treatment of 12 bacterial priority pathogens 16 or 31% are currently not authorised in Switzerland – this concerns both new innovative and older agents. Refer to Appendix A and Table 1, col. A

Adequate treatment is further put at risk by antimicrobial resistance (AMR). A project team convened by the RTA in 2024 to identify the unmet medical need in treating infections by resistant bacterial pathogens in Switzerland created pathogen-specific "treatability rates": They are defined for each bacterial pathogen as the number of (potentially) effective first-line antibiotics in Switzerland (with susceptibility rates ≥75%) divided by the total number of antibiotics authorised in Switzerland to treat that pathogen.

The susceptibility rates were provided by ANRESIS, the Swiss Centre for Antibiotic Resistance (ANRESIS) for the outpatient and inpatient settings, and intensive care units (ICU). The expert team, renowned clinicians and scientists, agreed that susceptibility rates ≥75% can be assumed to indicate (potentially) effective first-line treatment options. Refer to Table 1, col. B for the treatability rates of five priority bacterial pathogens in the ICU-setting.

Table 1 *No. of Swissmedic-authorised antibiotics compared to no. of antibiotics recommended by Sanford Guide, and treatability rates*

Pathogens on proposed Swiss BPPL	**A** **No. of Swissmedic-authorised antibiotics compared to antibiotics recommended by Sanford Guide (Appendix A)**	**B** **Treatability rates in the ICU setting (ANRESIS, unpublished data)**
Carbapenem-resistant Enterobacterales	range: 7/13 or 54% (*K. pneumoniae*) – 11/14 or 79% (*Serratia spp*)	See *E. coli* as representative
Carbapenem-resistant *E. coli*	7/11 or 64%	4%
Carbapenem-resistant *Acinetobacter baumannii*	4/9 or 44%	0%
Carbapenem-resistant *Pseudomonas aeruginosa*	8/10 or 80%	17%
Vancomycin-resistant Enterococcus faecium	5/6 or 83%	21%
Methicillin-resistant Staphylococcus aureus	8/10 or 80%	42%

The low treatability rates across all priority bacterial pathogens listed in Table 1, and particularly the Enterobacterales and *A. baumannii* in the ICU setting, suggest that the largest antibiotics gaps in Switzerland affect the pathogens causing the majority of bacterial infections in Switzerland [01], and *A. baumannii,* one of the most feared nosocomial pathogens in ICUs – particularly burn units.

2 Importing antibiotics to fill treatment gaps in Switzerland – Outcome of a hospital survey conducted in 2025

Special regulatory provisions in Switzerland[2] allow healthcare professionals to import drugs not authorised in Switzerland. This enables treatment of individual patients who cannot be adequately treated with the drugs authorised in Switzerland.

Imports of unauthorised antibiotics signal deficiencies in the arsenal of authorised antibiotics. Because they come at a bureaucratic and financial burden, they are credible indicators of an unmet need.

Therefore, in early 2025, the RTA conducted a survey of hospital imports of antibiotics in 2023 and 2024.

Survey of antibiotics imports by Swiss hospitals in 2023 and 2024

2.1 Survey setup

The pharmacies of 11 hospitals participated, including those of the University Hospital Zürich (USZ), University Hospital Basel (USB), Insel Gruppe, Hôpitaux Universitaires de Genève (HUG), and Centre Hospitalier Universitaire Vaudois (CHUV), the Ente Ospedaliero Cantonale (EOC), the cantonal hospitals Baselland, Baden, St. Gallen (HOCH Health Ostschweiz), Hôpital du Valais, and Solothurner Spitäler, securing coverage of the three major language regions of Switzerland.

The survey collected quantities of annually imported antibiotics in grams of the main substance and prices paid in CHF by gram of the main substance in the years 2023 and 2024, respectively.

The following antibiotics were explicitly listed in the questionnaire:

- Aztreonam-avibactam
- Cefiderocol
- Eravacyclin
- Fosfomycin i.v.
- Imipenem-cilastatin-relebactam
- Sulbactam-Durlobactam

All but Sulbactam-Durlobactam are classified as Reserve antibiotics in the WHO list of essential medicines (2025) [02]. Sulbactam-Durlobactam has not yet been classified but is highly likely to be attributed to the Reserve category.

The pharmacists were invited to provide data for any further antibiotics imported by their institutions in 2023 and 2024.

2.2 Data analysis

The analysis of the survey data provided insights into different aspects of the imported antibiotics and antimycobacterials (together referred to as antimicrobials): relevance of the medical need addressed, cost-effectiveness, and costs.

Relevance of the medical need

Looking for indicators of the relevance of the medical need addressed by the imported antimicrobials the following data or information from the survey or generated from survey data or contributed by other sources of information were considered:

[2] Therapeutic Products Act (TPA), article 20, para. 2; Arzneimittelbewilligungsverordnung (AMBV), article 49

WHO AWaRe classification of essential medicines (AWaRe) [02]. The AWaRe class serves as an indicator of the location of the medical need addressed by the imported antimicrobials: Access drugs should be used for empiric treatment of most common infections, and should be widely available; Watch drugs are used in sicker patients in the hospital setting; Reserve drugs should only be used as last-resort treatments of severe infections caused by MDR pathogens.

Sanford Guide. To assess the imported antibiotics for their relevance in treating infections caused by priority pathogens we matched the imported antibiotics to those recommended by the Sanford Guide. The Sanford Guide recommends 39 antibiotics for treatment of infections caused by eight pathogens of the Enterobacterales group, and *A. baumannii, P. aeruginosa, E. faecium,* and *S. aureus*. Refer to Appendix A.

Number of hospitals importing a particular drug. The more hospitals import a particular antibiotic the more widespread is the medical need.

Defined Daily Doses (DDD) and number of average treatments. The reported grams of main substance provided the basis for the calculation of the DDD and the number of average treatments. The higher the number of average treatments the higher is the medical need addressed by the imported drug.

Expert advice. To underpin conclusions drawn from the quantitative criteria of no. hospitals and no. average treatments we sought advice by scientists from the National reference laboratory for the early detection and monitoring of novel antibiotic resistance (NARA) and clinical experts to prioritise certain antibiotics over others.

NARA's assessment is informed by the monitoring of emerging bacterial resistances. Their advice takes a forward-looking perspective and highlights the therapeutic value of innovative antibiotics.

The clinical experts' advice highlights the unique values of three innovative and one older Reserve-antibiotics, as well as one Access antibiotic.

Union list of critical medicines (Ucml, 2026, [03]). The Ucml addresses basic public health needs and identifies antimicrobials of particular relevance for the basic functioning of the EU healthcare systems. Continuity of their supply is a priority, and shortages should be avoided.

Cost-effectiveness

Coverage of pathogens. From a cost-effectiveness perspective, the breadth of pathogens covered by a drug is a relevant consideration: The broader the coverage of an antibiotic the smaller the number of antibiotics required to fill treatment gaps. Antibiotics with a broad coverage might be preferred over antibiotics addressing the same bacterial class(es) but covering less pathogens, provided that their scoring in other criteria does not outweigh the potential cost-effectiveness gains.

The Sanford Guide data in Appendix A informs about the "no. of bacteria covered" by each of the listed antibiotics.

Costs

Prices and price spread. The multiplication of the imported grams of the main substance by the CHF prices paid by gram provided the total costs of the imported drugs, by drug. The price information allowed to calculate the spread of prices paid by different hospitals for the same drug.

2.3 Results

An overview of the results of the survey, complemented by further data generated from the raw data collected in the survey and additional information from renowned clinicians and scientists is provided in Appendix 2. The cost data is provided in Table 2.

However, caution is warranted when drawing conclusions from the reported data: The dataset may not necessarily cover all types of antimicrobials or their total expected quantities. This limitation may reflect differences in hospital procurement pathways which can vary depending on whether the drugs are intended for use in the hospitals' inpatient or ambulatory areas with predominantly i.v. or, respectively, oral formulations. Medication for treatment of tuberculosis may be procured by specialised teams and via external pharmacies. To ensure adherence to the complex and evolving tuberculosis treatment regimens, these drugs may be administered within hospitals even for outpatients.

These factors may explain why the imports of certain drugs - including some Access antibiotics and all antimycobacterials - were reported by only one or two hospital pharmacies. Their total reported quantities were therefore lower than expected by some reviewers of this report.

Relevance of the medical need

AWaRe class of imported antibiotics: In the period of 2023-2024 nineteen (19) antimicrobials were imported, comprising 15 antibiotics and 4 antimycobacterials. Out of the 15 antibiotics, 7 (including Sulbactam-Durlobactam) belonged to the Reserve class, 2 to the Watch class, and 6 to the Access class. Antimycobacterials are not AWaRe-classified.
The AWaRe class of the listed antimicrobials is provided in Appendix 2, col (1).

Number of hospitals: Out of the 11 participating hospitals 10 imported Cefiderocol, and 8 imported Fosfomycin i.v. Each of Imipenem-cilastatin-relebactam, Gentamicin, and Benzathine-Benzylpenicillin were imported by two hospitals. All other antimicrobials were imported by only one hospital. See Appendix 2, col (3)

Numbers of DDD and average treatments[3]: Three Access antibiotics supported the largest numbers of average treatments: Trimethoprim (1,125), Gentamicin (390), and Benzathine-Benzylpenicillin (265). The two Reserve antibiotics imported by the largest number of hospitals supported triple-digit numbers of average treatments: Cefiderocol (181) and Fosfomycin i.v. (120). All other antibiotics and the antimycobacterials supported single- or double-digit numbers of average treatments. See Appendix 2, cols (4) and (5)

The relevance of Cefiderocol and Fosfomycin i.v. is also documented by data collected by ANRESIS: Antimicrobials, even if not authorised in the country, are shown in this surveillance system once laboratories have reported a sufficient number of isolates for the data to be considered representative.

A note about Aztreonam-avibactam: The European Medicines Agency (EMA) granted marketing authorisation for Aztreonam-avibactam only in 2024. This explains the lack of imports in 2023 and very limited imports in 2024. However, given the increasing detection of New Delhi metallo-β-lactamase (NDM)–producing carbapenemase-producing Enterobacteriaceae (CPE) in Switzerland, this agent is likely already being procured at scale by Swiss tertiary care centers. Alternatively, a combination of Ceftazidime-avibactam with Aztreonam is applied.

Expert advice: Refer to Box 1 and Box 2 which point to the high value of Cefiderocol and Aztreonam-avibactam in addressing the increasing threat implied by metallo-β-lactamase (MBL)-producing Enterobacterales. Consequently, the prioritisation of Sulbactam-Durlobactam's availability for treatment of infections caused by *A. baumannii* is recommended.

The clinical experts highlighted special values of the innovative Reserve-antibiotics Cefiderocol, Sulbactam-Durlobactam, Aztreonam-avibactam, and the older Reserve-antibiotic Fosfomycin i.v., as well as the Access-antibiotic Benzathine-Benzylpenicillin for treatment of syphilis. Refer to Box 3.

[3] No WHO DDD has yet been determined for Aztreonam-avibactam nor Sulbactam-Durlobactam. The estimated DDD for these antibiotics reflect clear dosage recommendations.

NARA's and the clinical experts' advice is referenced in Appendix 2, col (6).

Ucml: Given that the drugs on the Ucml address basic medical needs only 2 of the 11 listed Reserve antibiotics (Fosfomycin i.v. and Imipenem-cilastatin-relebactam), but 5 of the 6 listed Access antibiotics (of which the imported Ampicillin) and all four imported antimycobacterials are included in the Ucml. Refer to Appendix 2, col (7).

Box 1 Treatment options for Carbapenem-resistant Enterobacterales (CRE) / E. coli

Carbapenem resistance can be mediated either by enzymes (carbapenemases) or other mechanisms (permeability defects mainly). For treatment of infections caused by carbapenem-resistant strains, several therapeutic options are currently available, including Ceftazidime-avibactam, Meropenem-vaborbactam, Imipenem-relebactam*, or Cefiderocol*.

Among carbapenemase-producers, the major threat is related to those producing metallo-β-lactamases (MBL), corresponding infections being extremely difficult to treat due to a critical lack of therapeutic options, considering reduced susceptibility or even resistance to Cefiderocol being commonly observed for such strains. Next to Cefiderocol*, only the highly effective Aztreonam-avibactam* combination option remains available.

* antibiotics not authorised in Switzerland

Box 2 Treatment options for Carbapenem-resistant Acinetobacter spp. (CRAB)

Isolates of carbapenem-resistant *Acinetobacter baumannii* are most often resistant not only to all β-lactams, but also to many other molecules belonging to distinct antibiotic classes.

Sulbactam-Durlobactam* is an important therapeutic option, currently only available in the USA. Even if this drug combination remains ineffective against MBL-producing isolates, the predominance of OXA-23-producing isolates in Europe (including Switzerland) which are most often susceptible to Sulbactam-Durlobactam therefore highlights the great value of this therapeutic option for *Acinetobacter baumannii*-associated infections.

Availability of Sulbactam-Durlobactam should be considered as a priority.

* antibiotics not authorised in Switzerland

Box 3 Special clinical values of prioritised Reserve- and Access antibiotics

Cefiderocol: This antibiotic agent reached the highest scores compared to all other drugs in terms of the number of importing hospitals (10 of 11), the broad coverage of all 8 pathogens of the Enterobacterales group listed in Appendix A, as well as *A. baumannii* and *P. aeruginosa*, and its first rank among all Reserve-antibiotics in terms of the number of average treatments supported in the two-year period (181). Thus, this drug undoubtedly addresses a high unmet medical need in Switzerland. Its leading position in terms of the money spent on imported drugs (see Table 2) reflects a high willingness to pay.

Despite small order quantities and orders by only one hospital each Sulbactam-Durlobactam's and Aztreonam-avibactam's eminent roles as last-resort treatment options is emphasised:

Sulbactam-Durlobactam: A case study from the burns unit at the University Hospital Zürich, presented at the RTA members event in November 2024, illustrated the life-saving role of Sulbactam-Durlobactam, a drug currently only authorised by FDA and under review by EMA: On day three of the treatment course an infection by *A. baumannii* with OXA-23 resistance mechanism was detected. The culture results identified resistance against all 11 tested antibiotics. Sulbactam-Durlobactam and Colistin were the only antibiotics with adequate susceptibility based on reported susceptibilities in the literature.
A further illustration of the relevance of Sulbactam-Durlobactam was provided by the dramatic clincal situation after the Crans-Montana incident in the night of 31 December 2025, with related CRAB infections and clusters that implied an unprecedented need for Sulbactam-Durlobactam in several European countries, including Switzerland.

Aztreonam-avibactam: This antibiotic represents the treatment of choice for war-wounded patients from Ukraine and for patients returning from Asia with trauma-related injuries. As an alternative to the import of this antibiotic under special provisions, a combination therapy is used (Ceftazidime-avibactam plus Aztreonam). However, this alternative solution can result in daily treatment costs of up to CHF 900.

Fosfomycin i.v. is an output of European research & development, has not been well studied, and got FDA approval only lately. It is very useful for specific indications, either related to biofilm infections or infections of the Central Nervous System (CNS) by MDR-organisms in the absence of other suitable alternatives. It has excellent CNS penetration and biofilm activity. The survey results suggest its broad use.

Benzathine-Benzylpenicillin is highly important as first-line treatment option for syphilis. The imports by only two hospitals may therefore not reflect the perceived broad use of this antibiotic by Swiss hospitals.

As Extencilline (INN: Benzathine-Benzylpenicillin) got a Swissmedic authorisation on 16. October 2025, this product will no longer have to be imported under special provisions. By the date of this report, however, the product has not yet got an SL price (SL: Spezialitätenliste, positive list of products reimbursed by the Compulsory Health Insurance (CHI).

Cost-effectiveness

Coverage of pathogens. The Sanford Guide data in Appendix A shows that except for Omadacyclin the antibiotics recommended for treatment of infections caused by Enterobacterales address at least two and a maximum of all eight listed pathogens in this class. Some of them are also recommended for treatment of infections caused by pathogens from other classes. The ranking by breadth of coverage is led by Cefiderocol (10 pathogens), followed by Aztreonam-avibactam and Imipenem-cilastatin-

relebactam (both 7 pathogens). The antibiotics addressing *A. baumannii, P. aeruginosa, E. faecium* or *S. aureus* act more specifically, each one covering only one or two pathogens. Refer to Appendix 2, col (2).

Costs

The costs incurred for the imports of the 11 hospitals are provided in Table 2. The relative expenditures for each imported antimicrobial is dominated by Cefiderocol which accounts for 75.6% of the total spending in the period of 2023-2024.

Table 2 Costs of 19 antimicrobial drugs imported by 11 Swiss hospitals in 2023 and 2024

Antibiotics / Antimycobacterials	2023	2024	CHF 2023-2024	% of CHF 2023-2024
Cefiderocol	CHF 993'334	CHF 881'737	**CHF 1'875'071**	**75.6%**
Gentamicin	CHF 117'797	CHF 126'054	**CHF 243'851**	**9.8%**
Sulbactam-durlobactam	CHF 34'608	CHF 69'216	**CHF 103'824**	**4.2%**
Fosfomycin i.v.	CHF 28'281	CHF 32'482	**CHF 60'763**	**2.5%**
Imipenem-cilastatin-relebactam	CHF 35'625	CHF 24'613	**CHF 60'238**	**2.4%**
Bedaquilin	CHF 22'678	CHF 8'004	**CHF 30'682**	**1.2%**
Eravacycline	CHF 25'908	CHF 4'572	**CHF 30'480**	**1.2%**
Benzathin-Benzylpenicillin	CHF 11'726	CHF 12'773	**CHF 24'499**	**1.0%**
Aztreonam-avibactam	CHF 0	CHF 21'840	**CHF 21'840**	**0.9%**
Dalbavancin	CHF 7'660	CHF 0	**CHF 7'660**	**0.3%**
Penicillin G	CHF 3'600	CHF 3'180	**CHF 6'780**	**0.3%**
Ampicillin-Sulbactam	CHF 4'426	CHF 1'199	**CHF 5'624**	**0.2%**
Ethambutol	CHF 1'710	CHF 3'515	**CHF 5'225**	**0.2%**
Ampicillin	CHF 1'215	CHF 405	**CHF 1'620**	**0.1%**
Streptomycin	CHF 0	CHF 330	**CHF 330**	**0.0%**
Isoniazid	CHF 65	CHF 65	**CHF 130**	**0.0%**
Erythromycin ethylsuccinat	CHF 125	CHF 0	**CHF 125**	**0.0%**
Clofazimin	CHF 60	CHF 40	**CHF 100**	**0.0%**
Trimethoprim	CHF 0	CHF 81	**CHF 81**	**0.0%**
all imported drugs	CHF 1'288'818	CHF 1'190'105	CHF 2'478'923	100.0%

Price spread: The relation of the highest compared to the lowest prices paid per gram of the antimicrobials imported by 2 and more hospitals reached quite substantial orders:

- Cefiderocol 2.4 (CHF 150 – 360)
- Imipenem-cilastatin-relebactam 1.6 (CHF 475 – 747)
- Fosfomycin i.v. 1.3 (CHF 8 – 10)
- Gentamicin 8.0 (CHF 42 – 335)
- Benzathine-Benzylpenicillin 6.4 (CHF 5 – 32)

Note: In December 2024 and October 2025 Swissmedic granted marketing authorisations to the Swiss army pharmacy for Gentamicin and to Leman SKL SA for Extencilline (INN: Benzathine-Benzylpenicillin), respectively. The dosage forms and strengths of both antibiotics now authorised in Switzerland correspond to the ones of the imported antibiotics. Thus, except for in situations described in sub-chapter 3.3 the import of these drugs under special provisions is no longer allowed.

2.4 Conclusions

While the largest number of imported antibiotics belonged to the Reserve group (7 antibiotics) it was interesting to see also 6 Access and 2 Watch antibiotics, as well as 4 antimycobacterials for the treatment of susceptible but also MDR tuberculosis, on the hospital pharmacies' shopping list. This observation signals that treatment gaps do not only affect the high-end medicine but also the basic healthcare supply in Switzerland.

As suspected at the beginning of sub-chapter 2.3, the reported import of **Benzathine-Benzylpenicillin** by only two hospitals may reflect an underreporting, possibly due to the application of procurement pathways for this product which differ from the regular ones used by hospital pharmacies. With Extencilline now available in Switzerland under a Swissmedic authorisation, imports under special provisions are no longer permitted except for in situations described in sub-chapter 3.3.

Likewise, the clinical reviewers suspected the perceived high demand for **antimycobacterials** to be underreported in the survey. Generally, the procurement of entire sets of drugs included in the treatment schemes presents a huge challenge which is exacerbated if the drugs do not have a marketing authorisation in Switzerland. A separate analysis of the supply situation is recommended, involving clinicians and drug procurement teams specialising in tuberculosis.

Not all four **Reserve antibiotics** featured below have been imported by many hospitals or in substantial quantities. However, their important clinical value was highlighted both by NARA scientists and clinical experts. Their regular availability in the Swiss healthcare system under a Swissmedic authorisation would be highly desirable to enhance security of supply and timely availability for treatment of critically ill patients, but also stewardship control and cost-efficiency.

Cefiderocol's widespread use and dominance in terms of the CHF expenditure is proof that it meets a significant unmet medical need in Switzerland. However, the extent of imports observed for Cefiderocol raises concerns in several respects:

Compliance: A systematic and broad use of a drug is not in line with the regulators' intent which is to enable access to treatment options for individual patients who cannot be adequately treated with drugs authorised in Switzerland.

Supply: In case of shortage of supply the manufacturers will first serve countries where they have a marketing authorisation. Serving import requirements of other countries will have second priority. Dependence on imports under special provisions for a widely used drug such as Cefiderocol poses a significant risk to the sustainable supply of a last-resort treatment option.

Time to effective treatment: Drugs for resistant pathogens should be available for targeted therapy on the same day of confirmed microbiological diagnosis. This may not be the case if the drug has to be ordered from other countries under special provisions. Delayed access to treatment may risk patient lives.

AMR: The broad use of Cefiderocol in Switzerland promotes development of resistance: Box 1 mentions that the "reduced susceptibility or even resistance to Cefiderocol [is] commonly observed for such strains" [i.e. carbapenemase-producers, and particularly those producing metallo-β-lactamases].

Price spread: The widely varying prices paid by different hospitals for the same drug highlights an inefficient use of healthcare budgets. This is particularly relevant for Cefiderocol with annual spending in the million CHF order of magnitude.

Sulbactam-Durlobactam: This antibiotic has a pivotal role in burns units to treat infections by OXA-23-producing *A. baumannii*. Its current unavailability in Europe implies lengthy import procedures – with potentially life-threatening consequences.

Aztreonam-avibactam: Switzerland's location at the heart of Europe, coupled with its open economy and affluence, encourages extensive travel, which in turn facilitates the cross-border spread of infections and resistance. Options for treatment of travellers returning from Asia with trauma-injuries

and infections with MBL-producing pathogens are limited to Cefiderocol and Aztreonam-avibactam. The same limitation also affects adequate treatment of MDR-infections, including infections with MBL-producing pathogens of war-wounded patients.

Fosfomycin i.v. appears to be broadly used in hospitals. In the survey 8 of 11 hospitals reported imports supporting 120 average treatments. It is very useful for specific indications, either related to biofilm infections or infections of the CNS by MDR-organisms in the absence of other suitable alternatives. It has excellent CNS penetration and biofilm activity.

Outlook

Given the dynamics of AMR and the evolving medical needs, and also new antibiotics making it to the market, this shortlist of antibiotics should be updated on a regular basis. The update rhythm could follow the bi-annual edition of the Swiss antibiotic resistance report[4].

[4] Federal Office of Public Health and Federal Food Safety and Veterinary Office. Swiss Antibiotic Resistance Report 2024. Usage of Antibiotics and Occurrence of Antibiotic Resistance in Switzerland. November 2024.

3 Regulatory pathways to a Swissmedic authorisation for the shortlisted Reserve antibiotics

This chapter describes three ways of making the shortlisted antibiotics medicinal products available in Switzerland, as well as matching reimbursement options.

3.1 Regular Swissmedic marketing authorisation

TPA, article 11 lists the requirements of the regular Swissmedic marketing authorisation pathway for drugs including new active substances.

Reimbursement/remuneration options

The holders of a Swissmedic marketing authorisation may apply for regular reimbursement of the authorised drug by the compulsory health insurance (CHI). Alternatively, they may choose to negotiate prices directly with hospitals.

The revised version of the Epidemics Act, if adopted, will provide the legislative basis of a further remuneration option which is tailored to the specific situation of antibiotics: Article 51a empowers the federation to make payments delinked from the product volume, topping up the annual turnover to an agreed annual revenue level not exceeding CHF 4 million. This revenue guarantee or subscription model incentivises innovative antibiotics that address infections caused by stated resistant bacterial pathogens. The delinkage of revenue from product volume facilitates the achievement of two otherwise conflicting aims: the generation of an adequate revenue, and abidance by stewardship requirements which tend to restrict the use of the antibiotics.

Applicability

This option is applicable for the 3 following innovative Reserve antibiotics :

- Cefiderocol
- Sulbactam-Durlobactam
- Aztreonam-avibactam

3.2 Simplified authorisation procedure

This procedure, addressed in TPA, article 14, 1a^{bis}, may be used for medicinal products whose active substances are used in a medicinal product which, by the date of the marketing authorisation application, has been authorised as a medicinal product for at least 10 years in at least one EU or EFTA country and which is comparable in terms of indications, dosage and method of administration. Hence, this procedure is applicable for older established drugs, including antibiotics.

Reimbursement

By the date of this report, there is no clearly regulated reimbursement process in place.

Applicability

The simplified authorisation procedure could be applicable for older antibiotics such as:

- Fosfomycin i.v.

However, unless a suitable reimbursement process is put in place for drugs authorised under the simplified procedure they would have to continue being imported and reimbursed as described in the next sub-chapter.

3.3 Import of ready-to-use medicinal products not authorised in Switzerland

TPA, article 20, paragraph 2, and AMBV, article 49, paragraph 1 allow the import of ready-to-use medicinal products not authorised in Switzerland if there is no appropriate treatment alternative authorised in Switzerland, or the authorised treatment is not available, or a replacement by an alternative treatment is not reasonable. This option is accessible to medical professionals, provided that the required medicinal product is authorised in a country with comparable regulatory controls. Presumably, the hospital imports described in this report were executed under the terms of these provisions.

Reimbursement

The ordinance on health insurance (Krankenversicherungsverordnung (KVV) provides a regulated reimbursement process for drugs imported under the terms of TPA, article 20, paragraph 2, and AMBV, article 49, paragraph 1: According to article 71c the CHI reimburses the costs of imported drugs upon prior authorisation by the patient's health insurer which is backed by the insurer's trusted medical doctor.

Applicability

This pathway is the fall-back option for Fosfomycin i.v. as long as the reimbursement issue of drugs authorised via the simplified procedure has not been solved. It is also applicable for any other medicinal product whose manufacturers do not intend to seek a Swissmedic marketing authorisation.

Of note: In the context of the Federal Council's efforts to enhance security of supply, during an interim period, importers and wholesalers may apply for authorisation to place medicinal products not authorised in Switzerland on the market in the required quantities, rather than only for named patients. The interim scheme will be replaced by a new legislative basis to be created during the forthcoming revision of the TPA.

References

[01] M. Gasser et al: Attributable deaths and disability-adjusted life-years caused by infections with antibiotic-resistant bacteria in Switzerland; www. thelancet.com/infection Vol 19 January 2019; http://dx.doi.org/10.1016/S1473-3099(18)30708-4

[02] The selection and use of essential medicines, 2025: WHO AWaRe (access, watch, reserve) classification of antibiotics for evaluation and monitoring of use. Geneva: World Health Organization; 2025. https://doi.org/10.2471/B09489

[03] European Medicines Agency (EMA), Heads of Medicines Agencies (HMA, European Commission; Union list of critical medicines, version 2.1 (revision 1); EMA/361872/2025, last updated on 19. January 2026; EMA/4040/2026. Union list of critical medicines | European Medicines Agency (EMA)

Appendix A Antibiotics recommended by Sanford Guide for treatment of 12 resistant bacterial pathogens (1 of 2)

		WHO BPPL (2024) - Critical Group									WHO BPPL (2024) - High Group		
Petrol coulered antibiotics authorised in Switzerland by February 2026		*E. coli*	*K. pneumoniae complex*	*C. freundii complex*	*C. koseri*	*M. morganii*	*P. non-mirabilis*	*Serratia spp*	*K. aerogenes*	*A. baumannii*	*P. aeruginosa*	*E. faecium*	*S. aureus*
		Enterobacterales											
Antibiotics	**no. covered bacteria**												
Meropenem	10	x	x	x	x	x	x	x	x	x	x		
Cefiderocol	10	x	x	x	x	x	x	x	x	x	x		
Ceftazidime-Avibactam	9	x	x	x	x	x	x	x	x		x		
Meropenem-Vaborbactam	8	x	x	x	x	x	x	x	x				
Ertapenem	8	x	x	x	x	x	x	x	x				
Aztreonam	8	x	x	x	x	x	x	x	x				
Ceftriaxone	7	x	x		x	x	x	x				x	
Aztreonam-avibactam	7		x	x	x	x	x	x	x				
Imipenem-Cilastatin-Relebactam	7	x	x	x	x	x			x		x		
Cefepime	6			x		x		x	x	x	x		
Ciprofloxacin	6				x	x	x	x	x		x		
Ceftolozane-Tazobactam	6			x	x	x	x	x			x		
Temocillin	6			x	x	x	x	x	x				
Plazomicin	4	x	x		x		x						
Ceftazidime	3					x		x			x		
Eravacycline	3	x	x	x									
Fosfomycin i.v.	3			x	x				x				
Nitrofurantoin	3	x	x	x									
Piperacillin-Tazobactam	3					x		x			x		
Aminoglycoside	2						x				x		
Cefepime-Enmetazobactam	2			x			x						
Omadacycline	1		x										

Appendix A Antibiotics recommended by Sanford Guide for treatment of 12 resistant bacterial pathogens (2 of 2)

Petrol coulered antibiotics authorised in Switzerland by February 2026		WHO BPPL (2024) - Critical Group									WHO BPPL (2024) - High Group		
		E. coli	*K. pneumoniae* complex	*C. freundii* complex	*C. koseri*	*M. morganii*	*P. non-mirabilis*	*Serratia spp*	*K. aerogenes*	*A. baumannii*	*P. aerugionsa*	*E. faecium*	*S. aureus*
		Enterobacterales											
Antibiotics	**no. covered bacteria**												
Ceftaroline (fosamil)	2											x	x
Daptomycin	2											x	x
Linezolid	2											x	x
Vancomycin	2											x	x
Ampicillin	1											x	
Ampicillin-Sulbactam	1									x			
Cefazolin	1												x
Ceftobiprole	1												x
Dalbavancin	1												x
Flucloxacilllin	1												x
Imipenem-Cilastatin	1									x			
Minocycline	1									x			
Oritavancin	1												x
Polymyxin B	1									x			
Sulbactam-Durlobactam	1									x			
Tigecyclin	1									x			
Telavancin	1												x
No. and percentage of Sanford-recommended antibiotics with Swissmedic authorisation		**7/11 (64 %)**	**7/13 (54 %)**	**8/15 (53 %)**	**8/14 (57 %)**	**11/15 (73 %)**	**9/14 (64 %)**	**11/14 (79 %)**	**7/12 (58 %)**	**4/9 (44%)**	**8/10 (80%)**	**5/6 (83%)**	**8/10 (80%)**

Appendix B Overview of antibiotics and antimycobacterials recommended by the Sanford Guide and/or imported by Swiss hospitals in 2023-2024

Antibiotics and antimycobacterials	(1) AWaRe class	(2) Sanford Guide: no. of covered pathogens	(3) Survey no. hospitals	(4) Survey DDD 2023-2024	(5) Survey no. avg. treatm'ts 2023-2024	(6) Expert advice	(7) Ucml
Sulbactam-Durlobactam	not yet classified	1	1	42.00	6	CRAB burns patients	no
Cefiderocol	Reserve	10	10	1,815.00	181	CRE, CRAB effective in large number of pathogens	no
Aztreonam-avibactam	Reserve	7	1	17.50	2	CRE, CRAB war-wounded patients and patients with trauma injuries returning from Asia	no
Fosfomycin i.v.	Reserve	3	8	854.75	120	excellent CNS penetration and biofilm activity	yes
Benzathine-Benzylpenicillin[5]	Access	-	2	341.11	265	Important first-line treatment option for syphilis	yes

[5] Note that on 16. October 2025 Extencilline (INN: Benzathine-Benzylpenicillin) got a Swissmedic authorisation. Therefore, this product will not have to be imported under special provisions any longer.

Antibiotics and antimycobacterials	(1) AWaRe class	(2) Sanford Guide: no. of covered pathogens	(3) Survey no. hospitals	(4) Survey DDD 2023-2024	(5) Survey no. avg. treatm'ts 2023-2024	(6) Expert advice	(7) Ucml
Imipenem-cilastatin-relebactam	Reserve	7	2	56.50	6	CRE	yes
Eravacyclin	Reserve	3	1	171.43	25	-	no
Dalbavancin	Reserve	1	1	1.50	2	-	no
Omadacyclin	Reserve	1	-	-	-	-	no
Minocycline	Reserve	1	-	-	-	-	no
Polymyxin B	Reserve	1	-	-	-	-	no
Telavancin	Reserve	1	-	-	-	-	no
Erythromycin ethylsuccinat	Watch (Erithromycin)	-	1	12.50	3	-	no
Streptomycin	Watch	-	1	1.00	1	-	no
Temocillin	Watch	6	-	-	-	-	no
Cefepime-Enmetazobactam	only Cefepime: Watch	2	-	-	-	-	no

Antibiotics and antimycobacterials	(1) AWaRe class	(2) Sanford Guide: no. of covered pathogens	(3) Survey no. hospitals	(4) Survey DDD 2023-2024	(5) Survey no. avg. treatm'ts 2023-2024	(6) Expert advice	(7) Ucml
Gentamicin[6]	Access	-	2	3,895.83	390	-	yes
Trimethoprim	Access	-	1	5,625.00	1,125	-	yes
Penicillin G	Access	-	1	941.66	64	-	yes
Ampicillin-Sulbactam	Access	1	1	281.50	40	-	no
Ampicillin	Access	1	1	90.00	13	-	yes
Clofazimin (antimycobacterial)	N/A	-	1	500.00	2	-	yes
Bedaquilin (antimycobacterial)	N/A	-	1	267.44	2	-	yes
Ethambutol (antimycobacterial)	N/A	-	1	45.00	1	-	yes
Isoniazid (antimycobacterial)	N/A	-	1	0.30	0.2	-	yes

[6] Note that in December 2024 Swissmedic granted the Swiss army pharmacy marketing authorisation for Gentamicin 20 mg/2mL and 80 mg/2 mL solution for i.m. and i.v. injection. First commercial batches became available in October 2025.