

## EU-JAMRAI-2 WP9 (Access) Barrier Analysis Overview

### Introduction

**Purpose:** All countries participating in WP9 (n=16) were requested to perform an analysis of their focus products, identifying barriers to availability locally and regionally. This document identifies common barriers across countries as well as context-specific challenges.

**Scope:** 14 countries completed a barrier analysis for their focus products (Belgium, Bulgaria, Denmark, Finland, France, Greece, Iceland, Italy, Malta, Netherlands, Norway, Slovenia, Spain, and Sweden) as of February 2026.

### Methodology

National participants identified the availability barriers through dialogue with diverse stakeholders (including industry) and assessment of public and confidential data. WP9 Leadership provided a template to assist identification, giving examples within the categories of economics, regulatory, manufacturing and supply chain, use/consumption, and other factors. WP9 Leadership also reviewed the completed barrier analyses, providing specific feedback, for each country's consideration.

### Economic barriers

- In general there are persistently low prices for antibiotics, especially older ones.
- The market for antibiotics is often considered economically unattractive by the pharmaceutical industry, even in large European countries, due to low sales volumes and unpredictable demand.
- Small or micro markets face additional challenges due to small populations and low demand.
- Regulated and static drug prices do not adjust to increased production costs, exacerbating financial strain and reducing profit margins.
- Lack of volume predictability or small order quantities creates market uncertainty and discourages companies seeking or maintaining marketing authorizations.
- Reductions in antibiotic prescribing (as is warranted under good stewardship practices) make markets less attractive – this holds especially true for veterinary antibiotics.
- High diversity in procurement and reimbursement systems across countries makes some markets less attractive for investment.
- Price variations within the EU could lead to lack of access in certain countries, as Europe competes internally for access to older antibiotics.
- Pricing policies in some countries can influence prices in other markets due to external reference pricing.
- Operational costs may exceed sales revenues, making production unsustainable.

- Many antibiotics have been withdrawn from the market due to national economic unviability.
- In small-scale markets, it is difficult to strike a balance between the need to have several MAHs in place to secure supply in the event of shortages, and the coexistence of multiple MAHs sharing limited volumes, which further reduces economic viability and individual profit margins.

### Regulatory barriers

- Some critical products are simply not nationally authorized or authorized but not marketed in certain countries.
- Lengthy and time-consuming regulatory processes could delay market entry and availability.
- Outdated regulatory documentation makes it difficult to introduce old antibiotics into new markets and to attract new Marketing Authorization Holders (MAHs).
- Limited regulatory flexibility in some countries hinders utilization of existing or new processes that ultimately could benefit availability.
- Lengthy pricing procedures and in some countries and difficulty of increasing the existing unit price affect product availability.
- National packaging requirements, including language requirements and authorization number, increase the administrative burden and costs and fragment the market. Some products with modest national markets could benefit from regional or European markets but national packaging requirements do not allow for this collaboration.
- Products are frequently withdrawn from markets due to economic challenges, and there are few proactive mechanisms to anticipate these economic challenges to avoid withdrawals. Once a company has decided to withdraw a product, it is often too late to change the decision.
- Regulations regarding expiration dates could result in destruction of viable products before their expiration date has been reached.

### Manufacturing and supply chain barriers

- Few active pharmaceutical ingredient (API) producers exist for certain substances, creating supply vulnerabilities.
- While Europe still hosts many API producers for essential AWaRe-classified “access” antibiotics, production capacity is under pressure due to high energy costs and other factors.
- Fragmented markets, formulations for certain populations (i.e. pediatric) or unique packaging requirements per country present difficulties in producing or acquiring batches that meet the manufacturer’s minimum order quantity, thus influencing availability.
- Many countries procure hospital antibiotics per hospital, thus significantly fragmenting the market and not fully utilizing the country’s full buying power.
- Low consumption relative to batch sizes exacerbates waste and inefficiency.
- European production may have a cost disadvantage due to factors like carbon footprint regulations, wastewater surveillance requirements, and high energy prices.
- Manufacturing issues, although temporary in nature, frequently cause shortages and stock-outs.

- API manufacturers located out of EU may be not well aware about EU GMP requirements, notably in case of recent changes (i.e. Annex 1 for veterinary sterile products) and may therefore lose their GMP/CEP certification because of non compliance.
- Countries looking for rapid fixes to acquire products in shortage may be unsuccessful due to limited production capacity, long lead times, and inflexibility to meet sudden demand increases.
- Lack of transparency in supply chains makes it impossible to identify alternative suppliers, not influenced by the same temporary production issues.
- Labeling requirements, multilingual packaging and country-specific legislation could prolong lead times and reduce availability.
- Few or a single MAHs are marketing each product, which in many cases makes the market more vulnerable.
- Increased demand is unpredictable, meaning that production capacity cannot be adjusted to meet changing demand landscape, leading to delays and unmet needs.
- Industry reports rising manufacturing costs, further straining supply chains.
- Wholesalers often require minimum procurement amounts, which can be difficult to meet in low-demand markets.
- National regulations prevent or complicate the redistribution of products between regions, hospitals, or pharmacies.
- Marketing authorization holders may be required to pay for removing antibiotic residues from urban wastewater under new EU regulations, which would be prohibitively expensive and likely consolidate antibiotic manufacturing and supply even further.

#### Use/Demand barriers

- For certain antibiotics, no specific guidelines exist for their use, leading to inconsistent prescribing practices.
- Different indications, strengths, durations, and doses are recommended for the same infection across Europe, which further fragments small markets with similar needs.
- The currently available pack sizes are often the result of historical choices or based on therapeutic indications that no longer reflect current clinical practice.
- Small markets struggle to compete for supply, especially when demand is high in other countries.
- Low global or regional demand results in small markets, this is especially true if there is local/national demand for odd package sizes or strengths.
- Some products have decreasing clinical demand.
- Prescribing guidelines are based on availability rather than clinical need, which does not incentivize the introduction of older antibiotics (that may be better for stewardship practices).
- General practitioners (GPs) and veterinarians may avoid prescribing certain antibiotics due to high out-of-pocket prices, concerns about the product availability, time or more familiarity with broader alternatives.
- Regulations requiring strict adherence to the Summary of Product Characteristics (SPC) limit flexible use of veterinary medicinal products (VMPs).
- Concerns about treatment failure and resistance sometimes lead to the prescription of broader-spectrum alternatives, even when narrower options are available.

- Some antibiotics are not included in lists of reimbursed or recommended medicines, reducing their use and accessibility.
- During shortages, prescribers may default to broader alternatives, further reducing demand for targeted treatments.
- AMS efforts focus on reducing antibiotic use and promoting the use of narrow-spectrum antibiotics when necessary, but shortages or limited availability of these products can lead prescribers to use broader-spectrum alternatives, which may contribute to increased antimicrobial resistance.

#### Other barriers

- Insufficient communication between regulators, procurers, and healthcare/clinicians may result in mismatches between demand and supply.
- Initiatives are often tied to short-term initiatives, with insufficient long-term planning or systematic follow-up.
- Agencies in different countries have varying mandates - some proactively engage with companies, while others are more reactive, which may influence market outcomes.
- Difficulty in tracking national, regional, and European initiatives due to lack of centralized oversight.
- No or lack of political support to work with access questions relating to AMR.

#### Conclusions

As demonstrated above, the availability barriers are numerous but often context-specific to not only the specific antibiotic but also the national and regional market. Thus, fixing one barrier will not dramatically improve access across multiple products. Interventions need to be tailored to the specific market and country context and take into account the complexity of barriers to ensure that interventions actually strengthen sustainable access to the focus product.