

## EU-JAMRAI-2 WP9 (Access): Barrier analysis guide

This barrier analysis guide was developed in 2024 and applied within EU-JAMRAI 2, Work-Package 9 (WP9, Access). It may be used by any country/organisation interested in facilitating a similar process.

**The aim of the barrier analysis is to identify the specific barrier(s) negatively influencing or hindering access (or reliable access) to each focus product in the specific context of your country.** This understanding will assist to develop tailored interventions later addressing these barriers national, sub-national, and/or multi-country level.

This document lists a series of suggested questions to help you identify and analyze potential barriers from different angles. It is not mandatory to answer these questions, rather they are to be viewed as a guide and starting point to support you in the process of identifying barriers as well as prompts to start discussion with your national stakeholders. They are general and may not unearth the barrier(s) specific to your national context. Feel free to tailor them to fit your needs and the type of product you are assessing (antibiotic for human or veterinary use, veterinary vaccine). Read through the questions, and think about what is already known, what you think you know but want to verify, and what data gaps exist that you want to further examine through a discussion. Oftentimes products have multiple barriers hindering access. If you have utilized the antibiotic assessment guide and template to identify focus products, those data may also be considered in this, more extensive, analysis.

### Stakeholder involvement

One of the aims of the access work package is to develop and establish strong collaboration within and between national stakeholders working on access to antibiotics. We have suggested a list of national stakeholders that may provide useful feedback and/or data. Of course, relevant stakeholder groups will vary by country, depending upon the structure and characteristics of your healthcare system. Also, the relevant stakeholders will vary depending on the type of product (primary care antibiotic, secondary care antibiotic, veterinary antibiotic or a veterinary vaccine). You may not need to involve all the groups mentioned below but it is encouraged that the key national stakeholders participate in your barrier analysis, at the very least giving confirmation and feedback on your barrier analysis to fill out any gaps. Stakeholders can actively engage through the entire process. Perhaps it would be useful for you to speak to key national stakeholders through interviews, workshops or focus group discussions to discuss the barriers?

### What type of stakeholder input could you include in your analysis?

Regulatory, animal and public health, general practitioners including pediatricians, hospital “A-team” members, hospital clinicians, veterinarians (both livestock and companion animals), farmers/ranchers, national AMR competency center(s), antibiotic guideline developers, community pharmacists, hospital pharmacists, nursing home physicians or prescribing nurses, dentists, HTA-experts, national medicine reimbursement and pricing specialists, medicine procurement specialists, wholesalers, distributors, antibiotic and vaccine vendors, industry associations, and others.

## Questions to guide the barrier analysis

### Economic

- Look back at your antibiotic assessment guide and template to find already collected information that could be economic barriers to access such as sales value, national consumption and unit price. Otherwise collect/supplement these data.
- Does industry perceive the market as economically unattractive? Is the national market considered loss-making due to operational expenses exceeding sales revenues?
- What else is known of the most important barriers to access for the specific product from an economic perspective?
- Are there elements within the pricing process that could be considered barriers to access for these products?
- Is the unit price considered low by industry? Or high by the buyers/users?
- Is it lucrative for community pharmacies, wholesalers or vendors to purchase large quantities of the product, thereby resulting in an uneven local availability?
- Are there incentives for community pharmacies, wholesalers or vendors to sell an alternative product with higher revenues?
- Have stocks of the antibiotic/vaccine been destroyed in the last years due to insufficient shelf life or other circumstances?
- Has industry abandoned the product due to shrinking European and global demand?

### Regulatory

- Look back at your antibiotic assessment guide and template to find already collected information that could be regulatory barriers to access, such as national registration status, number of and perhaps which MAHs. Otherwise collect/supplement these data.
- Are there regulatory barriers negatively influencing or hindering availability of the product? For instance: annual fees, not possible to use sunset clause, queue before assessment, demand for updated information of the registration file.

### Manufacturing and supply chain

- What is known of the most important barriers to access for the specific product from a manufacturing and supply chain perspective?
- Look back at your antibiotic assessment guide and template to find already collected information that could be manufacturing and supply chain barriers to access, such as critical shortages and the duration/frequency of these, formulations that seems to be especially vulnerable. Otherwise collect/supplement these data.
- Does industry struggle to access active pharmaceutical ingredients or other necessary ingredients for the product?
- Has industry rationed the supply of the antibiotic/vaccine in the recent years?
- Does industry consider the market size highly variable and struggles to predict quantities of the antibiotic/vaccine needed?
- Are there any aspects of procurement processes that could influence access?

### Use of antibiotics and veterinary vaccines

- What is known of the most important barriers to access for the specific product from a prescriber or demand perspective?
- Is the antibiotic included in prescribing guidelines/recommendations (revisit the antibiotic assessment template to)? Are guidelines being followed? Are the guidelines/recommendations national, regional, other?
- Are prescribers (community physicians, clinicians, veterinarians, dentists or others) aware that the antibiotic is included in prescribing guidelines?
- Do prescribers have access to appropriate diagnostics to prescribe the antibiotic?
- Are there concerns about the perceived availability of the product, unit price, local resistance levels, or other factors, that influence prescribers, perhaps leading prescribers to prescribe alternative products?
- Is the product's regulatory documentation, like the Summary of Product Characteristics (SmPC), absent or out-of-date causing complications for prescribing the antibiotic or the vaccine?
- Is any product characteristic influencing the prescriber behavior or decision, such as administration, taste, dosing regimen, size of tablet/capsule, or other characteristics?
- Do patients/farmers/ranchers/pet owners prefer another antibiotic/vaccine for diverse reasons?
- Are veterinarians/farmers/ranchers/pet owners aware that the vaccine exists?
- Do veterinarians struggle to secure vaccine supplies and therefore do not prescribe it?
- Is a prescription necessary to purchase and administer the vaccine?
- Does the vaccine likely result in future cost savings for the farmer/rancher?
- Are veterinarians concerned about the efficacy of the vaccine?
- Are veterinarians concerned that the vaccine has a difficult dosing regimen? Do farmers/ranchers/pet owners prefer not to use the vaccine for certain reasons?

### Industry outreach

We suggest that as one of your first steps you reach out to your local industry associations (not specific companies) to gather feedback. In this way, you will receive their feedback at about the same time as you complete your analyses, so that the two may be compared. You may disagree with industry's rationale, but it will hopefully be useful to hear their perspectives.