

ORIGINAL RESEARCH ARTICLE

Eur J Med Transl Biosci. 2026;1(1):49–81 · Open Access · CC BY 4.0 · Selected from ICMTB, peer reviewed by members of the editorial board

ANTIBIOTIC REIMBURSEMENT AS A POLICY LEVER FOR ANTIMICROBIAL STEWARDSHIP: ALIGNMENT WITH WHO AWaRe AND ESSENTIAL MEDICINES LIST RECOMMENDATIONS IN ALBANIA

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Abstract

Antibiotic misuse, partly resulting from gaps in health policy, is a major driver of antimicrobial resistance (AMR). The World Health Organization developed the AWaRe classification, the Essential Medicines List, and the Essential Medicines List for Children (EML/EMLc) to support appropriate antibiotic use. Reimbursement influences which antibiotics are financially covered. This study developed the Multidimensional Antibiotic Reimbursement Assessment Framework (MARAF) and applied it to Albania's reimbursement system to identify priorities for policy review. A cross-sectional descriptive analysis of antibiotic reimbursement data was conducted. The policy analysis used the 2024 national reimbursement data, the 2023 WHO AWaRe classification and EML/EMLc, national AMR surveillance data, the 2025 reimbursement list, and reimbursed prescription data. Antibiotics were evaluated by International Nonproprietary Name, utilization, AWaRe category, EML/EMLc inclusion, formulation, and strength. Integrating these findings with AMR relevance, changes in reimbursement lists, and geographic distribution enabled the prioritization of antibiotics and counties for further review. In 2024, Access accounted for 62.8% of the total reimbursed quantity, Watch accounted for 37.2%, and no Reserve antibiotics were identified. Amoxicillin-clavulanic acid accounted for 63.5% of the reimbursed Access quantity, while cefaclor, which was absent from the WHO EML/EMLc, accounted for 25.2% of the total reimbursed quantity. Under the alignment classifications, 14 of 28 product entries (50.0%) were classified as fully aligned with WHO recommendations. Structural alignment was similar in the 2025 list, with 21 of 40 entries (52.5%) fully aligned. The prioritization process identified cefaclor as the main priority, while other antibiotics also warranted assessment. Shkodër and Dibër had the highest reported population-adjusted reimbursement rates, while Tirana had the highest absolute prescription volume. Assessment across complementary sources identified structural concerns that were not apparent from a single stewardship indicator. MARAF integrates reimbursement, stewardship, AMR, and geographic evidence to establish priorities. It supports reimbursement review within antimicrobial stewardship without evaluating individual prescriptions.

Keywords: Antibiotic reimbursement, antimicrobial stewardship, AWaRe classification, Essential Medicines List, Albania, MARAF

1. Introduction

Antimicrobial resistance (AMR) is a major global public health threat because it reduces the effectiveness of antimicrobial treatment and increases illness, disability, mortality, and healthcare expenditure [1]. In 2019, bacterial AMR was estimated to have directly caused approximately 1.27 million deaths and to have been associated with approximately 4.95 million deaths worldwide [2]. Although resistance can arise naturally, antimicrobial exposure creates selective pressure that favors resistant organisms, while transmission is influenced by infection-control practices, sanitation, population movement, and other health-system and environmental factors [3]. Accordingly, antimicrobial stewardship encompasses coordinated actions intended to optimize whether and how antimicrobials are used, including agent selection, dosage, route of administration, and treatment duration, while maintaining access to effective therapy for patients who need it [4–6].

Common antimicrobial stewardship interventions include evidence-based prescribing guidelines, prospective audit and feedback, formulary restriction or preauthorization, professional education, microbiological surveillance, and infection prevention and control [6]. However, stewardship can also operate at national and health-system levels through policies that shape the context in which antimicrobial decisions are made [5]. One such policy is the inclusion of medicines in publicly funded reimbursement schemes. By determining which antibiotics, dosage forms, strengths, and products receive public financial support, and under what conditions, reimbursement policy shapes the financially accessible range of treatment options in outpatient care. Pharmaceutical reimbursement policies can influence affordable access to medicines, while restrictions or authorization requirements may affect prescribing patterns and adherence to treatment guidelines [7,8]. Reimbursement policy may therefore be conceptualized as both a financing mechanism and a potential upstream antimicrobial stewardship lever. Nevertheless, reimbursement status alone cannot establish whether an antibiotic is clinically appropriate for an individual patient.

The World Health Organization (WHO) has developed several complementary frameworks that can be used to assess antibiotic policy. The Access, Watch, and Reserve (AWaRe) classification categorizes antibiotics according to their recommended stewardship role and potential contribution to resistance. The 2023 AWaRe framework specified a country-level benchmark of at least 60% of total antibiotic consumption coming from the Access group, whereas the subsequent global target calls for at least 70% of human antibiotic use to come from Access antibiotics by 2030 [1,9]. Because the present study assessed Albania's 2024 reimbursement system using the 2023 AWaRe framework, the 60% threshold was retained as the prespecified benchmark. Importantly, the AWaRe target formally applies to total antibiotic consumption; its application to reimbursement-utilization data should therefore be interpreted as a stewardship benchmark for the publicly financed outpatient segment rather than as an estimate of total national antibiotic consumption.

The WHO Model List of Essential Medicines (EML) and Model List of Essential Medicines for Children (EMLc) identify medicines considered important for priority healthcare needs and specify recommended dosage forms and strengths [10,11]. National AMR surveillance provides complementary epidemiological evidence by identifying important pathogen-antibiotic combinations and resistance patterns, while medicine-utilization data can quantify the volume, concentration, and temporal distribution of pharmaceutical exposure [12,13]. Reimbursement records further identify which products account for publicly financed exposure and how that exposure is distributed across medicines, periods, and geographic areas.

Each evidence source nevertheless addresses only part of the reimbursement-policy question. AWARe describes the stewardship profile of antibiotics but does not determine whether the dosage form or strength of a reimbursed product corresponds to an EML or EMLc recommendation. EML and EMLc comparisons can identify discrepancies in medicine selection, formulation, and strength, but they do not show how extensively each product is reimbursed or whether its use is relevant to national resistance priorities. AMR surveillance identifies epidemiologically important pathogens and antibiotic classes but does not demonstrate whether those priorities are reflected in reimbursement policy. Similarly, utilization and geographic data describe the scale and distribution of exposure but cannot independently determine its stewardship significance. A comprehensive policy assessment therefore requires these evidence streams to be interpreted together rather than as isolated indicators [9–11,13,14].

Previous studies have evaluated the correspondence between national reimbursement lists and the WHO EML in Croatia and the Federation of Bosnia and Herzegovina [15,16]. Research has also examined the effects of restricted reimbursement policies for particular antibiotics. For example, a Canadian timeseries study found that a quinolone reimbursement restriction improved concordance with formulary guidelines and affected prescribing for specific outpatient indications, although it did not significantly reduce overall quinolone utilization [7]. More broadly, evidence on national adaptation of the WHO EML indicates that implementation depends on governance arrangements, the capacity to evaluate evidence, and effective links between medicine selection, financing, procurement, and prescribing systems [17].

In Albania, Petro et al. [18] compared the 2022 reimbursement list of the Mandatory Healthcare Insurance Fund with the 2021 WHO EMLc. Although the lists contained numerous active ingredients in common, the authors identified substantial discrepancies in dosage forms, strengths, and indications. These findings demonstrate the importance of assessing the pharmaceutical products supported by public reimbursement rather than limiting comparisons to active ingredients. Nevertheless, structural alignment, stewardship classification, AMR relevance, utilization volume, temporal continuity, and geographic distribution have generally been evaluated separately. To our knowledge, no previous published study has integrated these dimensions into a single national framework for prioritizing the review of antibiotic reimbursement.

Albania provides a relevant setting in which to apply such an approach. The 2024 reimbursement list issued by the Albanian Compulsory Healthcare Insurance Fund (Fondi i Sigurimit të Detyrueshëm të Kujdesit Shëndetësor, FSDKSH) specifies the active ingredient and strength, dosage form, commercial product, price, and reimbursement information for medicines available through open-network pharmacies, thereby defining public pharmaceutical coverage at the product and formulation level [18,19]. National surveillance findings have also identified important resistance concerns. Data reported for the second half of 2024 indicated high resistance to penicillins and fourth-generation cephalosporins, while fluoroquinolones, aminoglycosides, and third- and fourth-generation cephalosporins were among the most frequently reported antibiotic classes in the surveillance system [12]. Assessment of the Albanian reimbursement system should therefore extend beyond calculating the proportions of Access and Watch antibiotics or comparing active-ingredient names with the WHO Model Lists. It should also consider dosage form and strength, reimbursed quantity, continuity across successive reimbursement lists, relevance to national AMR findings, and geographic variation.

The present study therefore developed and applied the Multidimensional Antibiotic Reimbursement Assessment Framework to Albania's publicly funded outpatient reimbursement system. The framework integrated WHO AWARe classification, alignment with WHO EML and EMLc recommendations,

pharmaceutical formulation and strength, national AMR priorities, reimbursement-utilization volume, changes across successive reimbursement lists, and county-level distribution. These dimensions were combined to establish differentiated priorities for structured reimbursement review. The study was not designed to evaluate the appropriateness of individual prescriptions or to recommend automatic inclusion or removal of particular antibiotics. Rather, it aimed to demonstrate how routinely available evidence can be integrated into a transparent policy-screening tool for identifying antibiotics, pharmaceutical products, and geographic areas that warrant more detailed examination and for assessing whether the approach may be transferable to other reimbursement systems.

2. Materials and Methods

2.1. Study Design and Conceptual Approach

This cross-sectional descriptive and analytical study evaluated the alignment of reimbursed outpatient antibiotics in Albania with World Health Organization (WHO) antimicrobial stewardship frameworks. The analysis was conducted at the national level and focused on the structure and characteristics of the outpatient antibiotic reimbursement system. The main study period was July–December 2024, while supplementary data used for the structural comparison and geographic analysis extended into 2025 (Table 1). The study adopted a systems-oriented conceptual approach, recognizing antimicrobial resistance (AMR) as a health system outcome influenced by patterns of antibiotic exposure. Within this framework, reimbursement policy was conceptualized as a key determinant of population-level antibiotic exposure because it influences which antibiotics are financially accessible, routinely prescribed, and structurally standardized within outpatient care. The analytical approach therefore combines descriptive epidemiological assessment with policy-oriented interpretation of stewardship implications.

Table 1. Study components, data sources, and analytical periods. The table distinguishes the July–December 2024 main analysis from the supplementary 2025 reimbursement-list comparison and county-level geographic analysis.

Study component	Data source	Period/reference year	Role in the analysis
Main reimbursement analysis	National outpatient reimbursement data provided by FSDKSH	July–December 2024	Main study period used to assess reimbursed antibiotic utilization, AWaRe distribution, EML/EMLC correspondence, formulation, strength, and overall structural alignment
Reimbursement-list comparison	Albanian outpatient reimbursement list	2025	Supplementary structural comparison used to determine whether alignment concerns persisted following revision of the reimbursement list; utilization was not assessed
Geographic analysis	County-level reimbursement data provided directly by FSDKSH	November 2024–October 2025	Supplementary analysis of reimbursed prescriptions, treated patients, population-adjusted rates, and absolute prescription volumes
National AMR context	National AMR surveillance bulletin published by the Albanian Institute of Public Health	July–December 2024	Identification of pathogens and antibiotic classes relevant to national resistance priorities
International comparison standards	WHO AWaRe classification, WHO EML, and WHO EMLc	2023 for the 2024 analysis; 2025 for the supplementary 2025 list assessment	Classification of antibiotics and assessment of medicine inclusion, formulation, and strength alignment
Policy translation	Internal FSDKSH reimbursement-review document	Accessed with authorization (2025)	Source of proposed reimbursement-review and removal criteria

2.2. Study Setting

Public financing of outpatient medicines in Albania is regulated through the national reimbursement system and its designated reimbursement list. This list defines the antibiotics eligible for reimbursement and the products financially covered in outpatient care [19]. Reimbursed antibiotics represent the publicly financed component of outpatient antibiotic use. The analysis therefore evaluated them as indicators of reimbursement policy and stewardship orientation.

2.3. Data Sources

The analysis was based on national reimbursement data obtained from the Albanian Compulsory Healthcare Insurance Fund (FSDKSH) for 2024. The dataset included antibiotics eligible for public reimbursement, together with information on dosage forms, strengths, formulations, and dispensing quantities within the outpatient reimbursement system. The national reimbursement list and public reimbursement statistics provided additional policy context [19,20]. Aggregated dispensing data were used to assess population-level exposure patterns rather than individual prescribing behavior. National AMR data, including reported resistance percentages and the antibiotic classes highlighted during the study period, were obtained from the 2025 bulletin published by Albania's Institute of Public Health [12]. WHO reference frameworks were used as international comparators. The 2023 WHO AWaRe classification

was used to categorize antibiotics according to stewardship priority and resistance potential [9]. The 2023 WHO EML and EMLc were used to evaluate inclusion status, recommended formulations, and recommended strengths [10,11]. These versions were selected to maintain temporal alignment with the 2024 reimbursement data. The 2025 reimbursement list was assessed against the updated 2025 WHO documents [21–24]. Only systemic antibiotics intended for oral or parenteral administration were included; topical formulations, including creams, ointments, eye drops, and ear drops, were excluded.

2.4. Analysis of the Draft Reimbursement Review Framework

In addition to publicly available national reimbursement data and WHO reference documents, the study analyzed an internal draft reimbursement review framework developed by FSDKSH. The document was accessed with authorization for research purposes and was used to identify proposed criteria for the revision, restriction, substitution, monitoring, or removal of reimbursed medicines. The framework was reviewed qualitatively to identify decision-making criteria relevant to antibiotic reimbursement. These criteria were synthesized and incorporated into the policy translation component of the study. They were not used to determine alignment with WHO recommendations. Instead, the internal framework served as a complementary policy reference for interpreting how identified structural discrepancies could inform reimbursement review within the Albanian healthcare system.

2.5. Data Processing and Standardization

National reimbursement datasets and WHO reference lists were converted into Microsoft Excel workbooks to enable systematic data cleaning, harmonization, and comparative analysis. Antibiotics were identified using International Nonproprietary Names (INNs) to ensure consistency across products and formulations. Non-antibiotic medicines were excluded from the analysis. The standardization process included:

- mapping commercial products to corresponding INNs;
- harmonizing naming conventions;
- standardizing measurement units;
- removing duplicate entries; and
- grouping dosage forms into standardized categories, including oral solid, oral liquid, and injectable formulations.

For EML/EMLc and AWaRe comparisons, each dosage form and strength was retained as a separate analytical variable to allow detailed evaluation of structural alignment with WHO recommendations.

2.6. Alignment Assessment Framework

Alignment with WHO recommendations was assessed using a structured framework incorporating four interrelated dimensions.

2.6.1. EML/EMLc Inclusion

Each reimbursed antibiotic was assessed for inclusion within the WHO Essential Medicines List or WHO Essential Medicines List for Children. Inclusion in either list was interpreted as an indicator of global clinical prioritization and stewardship relevance. Antibiotics absent from both lists were classified as nonEML/EMLc antibiotics.

2.6.2. Formulation Alignment

Formulation alignment was assessed by comparing reimbursed dosage forms with WHO recommended formulations. Particular attention was given to child-appropriate formulations, including oral suspensions. Antibiotics were considered formulation-aligned if at least one reimbursed formulation corresponded to WHO recommendations [10,11].

2.6.3. Strength Alignment

Strength alignment was evaluated by comparing reimbursed strengths with WHO-recommended strengths [10,11]. Strengths requiring substantial dose manipulation, such as tablet splitting or dose approximation, were considered non-aligned because they may complicate accurate dosing and appropriate administration.

2.6.4. Structural Consistency

Structural consistency was assessed by identifying duplication in reimbursed strengths and formulations. Although some variability may be clinically justified, excessive duplication may contribute to prescribing variability and inconsistent antibiotic exposure. Duplication was assessed descriptively through comparison of reimbursed strengths and formulations within the same antibiotic, without applying predefined numerical thresholds.

2.6.5. Overall Alignment Classification

Overall alignment status was determined by combining all four dimensions. Antibiotics were classified as fully aligned if they met all assessed criteria, including:

- inclusion in EML/EMLc;
 - formulation alignment;
 - strength alignment; and
 - absence of major structural inconsistencies.
- Antibiotics failing one or more criteria were classified as non-aligned.

2.7. Definition of AMR-Relevant Antibiotics

Antibiotics with greater relevance to antimicrobial resistance were identified using a three-criterion classification framework. An antibiotic was classified as AMR-relevant if it met at least one of the following conditions:

- Membership in antibiotic classes highlighted in national AMR surveillance. This included penicillins, cephalosporins, fluoroquinolones, and aminoglycosides. The bulletin reported high resistance percentages for penicillins and fourth-generation cephalosporins and identified fluoroquinolones, aminoglycosides, and third- and fourth-generation cephalosporins among the most frequently reported classes [12].
- Structural misalignment with WHO recommendations. Antibiotics with discrepancies in formulation or strength relative to WHO guidance were considered potentially relevant to resistance because such inconsistencies may contribute to dosing difficulties or pharmacokinetic variability.
- Classification within stewardship-sensitive categories. This included antibiotics categorized as Watch or Reserve under the WHO AWaRe framework, broad-spectrum antibiotics, and antibiotics not included in the WHO EML/EMLc [9–11].

This classification was designed as an exploratory analytical framework to identify antibiotics potentially associated with increased resistance pressure through multiple structural and stewardship-related pathways.

2.8. Identification of Non-Aligned Antibiotics

Using the alignment framework described above, antibiotics were systematically reviewed to identify those classified as non-aligned with WHO recommendations. Non-aligned antibiotics were defined as those failing at least one assessed criterion related to EML/EMLc inclusion, dosage form, or strength alignment. This subgroup was selected for further analysis because structural inconsistencies within reimbursement systems may contribute to dosing difficulties and stewardship challenges.

2.9. Analytical Framework: Multilayer Model

A three-layer analytical model was used to interpret the relationship between reimbursement structures and antimicrobial resistance relevance. The analysis focused on identifying structural patterns and stewardship implications rather than testing statistical hypotheses.

2.9.1. Layer 1: Resistance Context

The first layer examined antibiotic classes highlighted in Albanian national surveillance to establish the epidemiological context of resistance pressure [12].

2.9.2. Layer 2: Reimbursement Structure

The second layer evaluated structural characteristics of the reimbursement system, including:

- distribution across AWaRe categories;
- EML/EMLc correspondence;
- formulation alignment;
- strength alignment;
- variability in reimbursed formulations and strengths.

2.9.3. Layer 3: Interaction Between Resistance and Structure

The third layer explored how structural characteristics of the reimbursement system may interact with resistance-related mechanisms, including broad-spectrum exposure, selection pressure, ecological disruption, and pharmacokinetic inconsistency. Each structurally non-aligned reimbursed antibiotic was therefore evaluated according to the analytical framework. Antibiotics fulfilling multiple prioritization criteria were classified as higher-priority candidates for structured reimbursement review than antibiotics demonstrating isolated structural discrepancies.

2.10. Geographic Stewardship Prioritization

To extend the policy relevance of the analysis, geographic stewardship prioritization was performed using county-level reimbursement data supplied directly by FSDKSH for November 2024 through October 2025. Antibiotic utilization was standardized as reimbursed antibiotic prescriptions per 100,000 residents to enable comparisons across counties with different population sizes [25]. Counties were ranked by standardized utilization, and the three highest-ranking counties were identified as geographic priorities for targeted surveillance and stewardship activities. The county with the highest absolute number of reimbursed antibiotic prescriptions was identified separately to acknowledge its contribution to total reimbursed outpatient antibiotic exposure. This analysis was intended as a policy translation exercise

demonstrating how reimbursement data can support geographically targeted stewardship planning and resource allocation.

2.11. Formal Criteria for Reimbursement Review

Following completion of the three-layer analytical assessment, the identified structurally non-aligned antibiotics were evaluated using the predefined reimbursement review framework to determine their potential classification for structured policy review.

A medicine or device may be removed from the list if:

- It is no longer used in medical practice.
- It is unavailable on the pharmaceutical market.
- It lacks a declared or approved price by the Medicines Pricing Commission.
- It is deregistered in Albania.
- Significant price differences exist between dosage forms of the same active ingredient without a corresponding difference in pharmacological efficacy.
- It is not recommended for use by WHO, the European Medicines Agency (EMA), or the US Food and Drug Administration (FDA).

2.12. Ethical Considerations

This study used aggregated, non-identifiable data obtained from the national reimbursement system and publicly available national reports. No patient-level information was accessed or analyzed. Therefore, the study did not constitute human subjects research according to applicable ethical standards, and formal ethical approval was not required.

3. Results

3.1. Characteristics of the Albanian Outpatient Antibiotic Reimbursement List

The 2024 Albanian outpatient reimbursement list included 16 unique systemic antibiotic International Nonproprietary Names (INNs) represented by 28 reimbursed product entries, comprising different pharmaceutical formulations and dosage strengths (Table 2). The analysis was performed at the product entry level because WHO recommendations specify not only essential medicines but also recommended pharmaceutical formulations and dosage strengths. Consequently, each reimbursed formulation and strength combination was assessed individually against WHO reference standards.

Reimbursed antibiotics represented multiple therapeutic classes, including penicillins, cephalosporins, macrolides, fluoroquinolones, tetracyclines, aminoglycosides, nitroimidazoles, nitrofurans, and sulfonamides. Pharmaceutical presentations included oral solid formulations, oral liquid formulations intended primarily for pediatric use, and injectable preparations. Oral solid dosage forms accounted for 17 of 28 entries (60.7%), followed by oral liquids with 8 entries (28.6%) and injectable formulations with 3 entries (10.7%) (Table 2).

Several antibiotics were reimbursed in multiple pharmaceutical presentations and strengths. Consequently, the number of reimbursed product entries substantially exceeded the number of unique antibiotics, allowing separate assessment of formulation- and strength-specific alignment with WHO recommendations. This product-level approach formed the basis for subsequent structural alignment analysis.

Table 2. Reimbursed systemic outpatient antibiotic product entries in Albania, July–December 2024. The table presents the 28 product entries included in the main analysis by INN, AWaRe category, formulation, and strength. The national list is the source for reimbursed product characteristics [19].

Antibiotic (INN)	AWaRe	Formulation	Strength
Amoxicillin	Access	Capsule	500 mg
Ampicillin	Access	Capsule	500 mg
Ampicillin	Access	Injection	1 g
Doxycycline	Access	Tablet	100 mg
TMP-SMX	Access	Tablet	400/80 mg
TMP-SMX	Access	Tablet	800/160 mg
TMP-SMX	Access	Suspension	240 mg/5 mL
Nitrofurantoin	Access	Tablet	100 mg
Metronidazole	Access	Tablet	250 mg
Gentamicin	Access	Injection	40 mg/2 mL
Gentamicin	Access	Injection	80 mg/2 mL
Cephalexin	Access	Tablet/capsule	500 mg
Cephalexin	Access	Suspension	250 mg/5 mL
Amoxicillin + clavulanic acid	Access	Suspension	250 + 62.5 mg/5 mL
Amoxicillin + clavulanic acid	Access	Suspension	457 mg/5 mL
Amoxicillin + clavulanic acid	Access	Tablet	375 mg
Amoxicillin + clavulanic acid	Access	Tablet	625 mg
Amoxicillin + clavulanic acid	Access	Tablet	1000 mg
Cefaclor	Watch	Capsule	500 mg
Cefaclor	Watch	Suspension	250 mg/5 mL
Ciprofloxacin	Watch	Tablet	500 mg
Cefixime	Watch	Suspension	100 mg/5 mL
Clarithromycin	Watch	Tablet	500 mg

Antibiotic (INN)	AWaRe	Formulation	Strength
Azithromycin	Watch	Tablet	250 mg
Azithromycin	Watch	Suspension	200 mg/5 mL
Erythromycin	Watch	Tablet	250 mg
Erythromycin	Watch	Suspension	250 mg/5 mL
Spiramycin	Watch	Tablet	250 mg

Note. INN denotes International Nonproprietary Name; TMP-SMX denotes trimethoprim-sulfamethoxazole. Solid combination strengths are expressed in sulfamethoxazole/trimethoprim order.

3.2. Layer 1 National AMR Context

The national surveillance bulletin reported high resistance to penicillins and fourth-generation cephalosporins during the second half of 2024. Fluoroquinolones, aminoglycosides, and third- and fourth-generation cephalosporins were among the most frequently reported antibiotic classes [12]. These findings provided the national resistance context for the subsequent analytical framework.

Comparison of the surveillance findings with the reimbursement list identified overlap at the level of broad antibiotic classes. Reimbursed antibiotics belonging to penicillins, cephalosporins, fluoroquinolones, or aminoglycosides included amoxicillin, amoxicillin-clavulanic acid, ampicillin, cephalexin, cefaclor, cefixime, ciprofloxacin, and gentamicin.

Overall, 8 of the 16 reimbursed antibiotics (50.0%) belonged to the broad antibiotic classes highlighted in national AMR surveillance (Table 3). These included both Access and Watch agents. Class membership was used as a policy-screening signal and did not establish a resistance percentage for an individual reimbursed antibiotic.

The resistance-context analysis established the first analytical layer of the study and provided the epidemiological basis for subsequent structural alignment and prioritization analyses.

Table 3. Reimbursed antibiotics belonging to broad classes highlighted in Albania's national AMR surveillance, July–December 2024 [12]. The table identifies class-level correspondence; it does not establish resistance to each listed antibiotic or cephalosporin generation.

Penicillins	Cephalosporins	Fluoroquinolones	Aminoglycosides
Amoxicillin	Cephalexin	Ciprofloxacin	Gentamicin
Ampicillin	Cefaclor		
Amoxicillin + clavulanic acid	Cefixime		

3.3. Layer 2 Stewardship Profile and Structural Alignment

Among the 16 reimbursed antibiotics, counted by unique INN, 9 (56.3%) belonged to the Access category and 7 (43.8%) belonged to the Watch category. No reimbursed antibiotics were classified as Reserve. Based on the quantities in Table 4, Access antibiotics accounted for 64,931 of 103,349 reimbursed units

(62.8%), and Watch antibiotics accounted for 38,418 units (37.2%). These quantity-weighted shares differ from the proportions based on unique INNs. Amoxicillin-clavulanic acid accounted for 41,260 units, representing 63.5% of Access antibiotic quantity and 39.9% of total reimbursed quantity.

The reimbursed Access antibiotics included amoxicillin, amoxicillin-clavulanic acid, ampicillin, cephalexin, doxycycline, nitrofurantoin, TMP-SMX, gentamicin, and metronidazole. The Watch category comprised azithromycin, erythromycin, cefaclor, cefixime, spiramycin, ciprofloxacin, and clarithromycin [9].

Application of the corresponding classification framework to the 2025 reimbursement list showed a lower proportion of Access antibiotics by unique INN count. Access antibiotics accounted for 9 of 19

unique antibiotics (47.4%), while Watch antibiotics accounted for 10 (52.6%) (Table 5) [21,24].

Utilizationweighted shares were not calculated for the 2025 list.

Assessment at the product-entry level demonstrated substantially greater variability than evaluation using AWARe classification alone. Under the recorded classifications, 14 of 28 reimbursed antibiotic product entries (50.0%) were classified as fully aligned with WHO recommendations (Table 4).

According to the inclusion flags in Table 4, 25 of 28 entries (89.3%) corresponded to medicines included in at least one WHO reference list. The remaining 3 entries comprised cefaclor, and spiramycin products. The inclusion flags in Table 5 indicated correspondence for 33 of 40 entries (82.5%) in the 2025 list.

Strength discrepancies were the most frequent source of structural misalignment in the recorded 2024 classifications. The number of entries classified as non-aligned increased from 14 of 28 (50.0%) in 2024 to 20 of 40 (50.0%) in 2025. This was a descriptive comparison; no test of statistical significance was performed.

The recorded assessment of the 2025 reimbursement list indicated that 21 of 40 product entries (52.5%) were classified as fully aligned (Table 5). This proportion was similar to the recorded 2024 figure of 50.0%.

Table 4. Recorded product-entry alignment of reimbursed outpatient antibiotics with 2023 WHO recommendations, July–December 2024 [9-11]. The table reports EML/EMLc inclusion, dosage-form match, strength match, duplication concerns, overall alignment, and reimbursed quantity for each product entry.

Antibiotic (INN)	AWARe	Dosage form	Strength	Qty.	EML	EMLc	Form match	Strength match	Dup. concern	Overall
Amoxicillin	Access	Capsule	500 mg	696	Yes	Yes	Yes	Yes	No	Yes
Ampicillin	Access	Capsule	500 mg	1300	Yes	Yes	No	Yes	No	No
Ampicillin	Access	Injection	1 g	70	Yes	Yes	Yes	Yes	No	Yes
Doxycycline	Access	Tablet	100 mg	722	Yes	Yes	Yes	Yes	No	Yes
TMP-SMX	Access	Tablet	400/80 mg	9492	Yes	Yes	Yes	Yes	No	Yes
TMP-SMX	Access	Tablet	800/160 mg	188	Yes	Yes	Yes	No	No	No
TMP-SMX	Access	Suspension	240 mg/5 mL	4	Yes	Yes	Yes	Yes	No	Yes
Nitrofurantoin	Access	Tablet	100 mg	5331	Yes	Yes	Yes	Yes	No	Yes

Antibiotic (INN)	AWaRe	Dosage form	Strength	Qty.	EML	EMLc	Form match	Strength match	Dup. concern	Overall
Metronidazole	Access	Tablet	250 mg	1728	Yes	Yes	Yes	Yes	No	Yes
Gentamicin	Access	Injection	40 mg/2 mL	90	Yes	Yes	Yes	Yes	No	Yes
Gentamicin	Access	Injection	80 mg/2 mL	220	Yes	Yes	Yes	No	No	No
Cephalexin	Access	Tablet/capsule	500 mg	3823	Yes	Yes	Yes	No	No	No
Cephalexin	Access	Suspension	250 mg/5 mL	7	Yes	Yes	Yes	Yes	No	Yes
Amoxicillin + clavulanic acid	Access	Suspension	250 + 62.5 mg/5 mL	49	Yes	Yes	Yes	Yes	Yes	Yes
Amoxicillin + clavulanic acid	Access	Suspension	457 mg/5 mL	4	Yes	Yes	Yes	No	Yes	No
Amoxicillin + clavulanic acid	Access	Tablet	375 mg	2446	Yes	Yes	Yes	No	Yes	No
Amoxicillin + clavulanic acid	Access	Tablet	625 mg	30026	Yes	Yes	Yes	Yes	Yes	Yes
Amoxicillin + clavulanic acid	Access	Tablet	1000 mg	8735	Yes	Yes	Yes	No	Yes	No
Cefaclor	Watch	Capsule	500 mg	25364	No	No	No	No	No	No
Cefaclor	Watch	Suspension	250 mg/5 mL	640	No	No	No	No	No	No
Ciprofloxacin	Watch	Tablet	500 mg	8512	Yes	Yes	Yes	No	No	No
Cefixime	Watch	Suspension	100 mg/5 mL	6	Yes	Yes	Yes	Yes	No	Yes
Clarithromycin	Watch	Tablet	500 mg	621	Yes	Yes	Yes	No	No	No
Azithromycin	Watch	Tablet	250 mg	652	Yes	Yes	Yes	Yes	No	Yes
Azithromycin	Watch	Suspension	200 mg/5 mL	12	Yes	Yes	Yes	Yes	No	Yes
Erythromycin	Watch	Tablet	250 mg	1456	No	Yes	No	No	No	No
Erythromycin	Watch	Suspension	250 mg/5 mL	60	No	Yes	No	No	No	No
Spiramycin	Watch	Tablet	250 mg	1095	No	No	No	No	No	No

Note. Qty., reimbursed quantity; EML/EMLc, inclusion in the WHO adult/child lists; form match, dosage-form correspondence; Dup. concern, duplication concern; Overall, recorded alignment across the assessed criteria. Combination strengths require component-specific interpretation. Category percentages are rounded independently.

Table 5. Recorded product-entry alignment of the 2025 outpatient antibiotic reimbursement list with 2025 WHO recommendations [21-24]. The table applies the product-level assessment to the 2025 list using the updated WHO comparator documents.

Note. The 2025 reimbursement-list entries were assessed using the 2025 WHO AWaRe classification, the 24th WHO Model List of Essential Medicines, and the 10th WHO Model List of Essential Medicines for Children [21-23].

Antibiotic (INN)	AWaRe	Dosage form	Strength	EML	EMLc	Form match	Strength match	Dup. concern	Overall
Doxycycline	Access	Tablet	100 mg	Yes	Yes	Yes	Yes	No	Yes
Doxycycline	Access	Dispersible tablet	100 mg	Yes	Yes	Yes	Yes	No	Yes
Oxytetracycline	Watch	Tablet	250 mg	No	No	No	No	No	No
Ampicillin	Access	Suspension	125 mg/5 mL	Yes	Yes	No	No	No	No
Ampicillin	Access	Capsule	500 mg	Yes	Yes	No	Yes	No	No
Ampicillin	Access	Injection	1 g	Yes	Yes	Yes	Yes	No	Yes
Amoxicillin	Access	Suspension	125 mg/5 mL	Yes	Yes	Yes	Yes	No	Yes
Amoxicillin	Access	Suspension	250 mg/5 mL	Yes	Yes	Yes	Yes	No	Yes
Amoxicillin	Access	Capsule	250 mg	Yes	Yes	Yes	Yes	No	Yes
Amoxicillin	Access	Capsule	500 mg	Yes	Yes	Yes	Yes	No	Yes
Amoxicillin + clavulanic acid	Access	Suspension	250 + 62.5 mg/5 mL	Yes	Yes	Yes	Yes	Yes	Yes
Amoxicillin + clavulanic acid	Access	Tablet	375 mg	Yes	Yes	Yes	No	Yes	No
Amoxicillin + clavulanic acid	Access	Tablet	500 mg + 125 mg	Yes	Yes	Yes	Yes	Yes	Yes
Amoxicillin + clavulanic acid	Access	Suspension	457 mg/5 mL	Yes	Yes	Yes	No	Yes	No
Amoxicillin + clavulanic acid	Access	Tablet	1000 mg	Yes	Yes	Yes	No	Yes	No
Cephalexin	Access	Suspension	250 mg/5 mL	Yes	Yes	Yes	Yes	No	Yes
Cephalexin	Access	Capsule/tablet	500 mg	Yes	Yes	Yes	No	No	No
Cefuroxime	Watch	Suspension	125 mg/5 mL	Yes	Yes	No	No	No	No
Cefaclor	Watch	Suspension	125 mg/5 mL	No	No	No	No	No	No
Cefaclor	Watch	Suspension	250 mg/5 mL	No	No	No	No	No	No
Cefaclor	Watch	Capsule/tablet	500 mg	No	No	No	No	No	No
Cefixime	Watch	Suspension	100 mg/5 mL	Yes	Yes	Yes	Yes	No	Yes
TMP-SMX	Access	Suspension	240 mg/5 mL	Yes	Yes	Yes	Yes	No	Yes
TMP-SMX	Access	Tablet	400 + 80 mg	Yes	Yes	Yes	Yes	No	Yes
TMP-SMX	Access	Tablet	800 + 160 mg	Yes	Yes	Yes	No	No	No

Antibiotic (INN)	AWaRe	Dosage form	Strength	EML	EMLc	Form match	Strength match	Dup. concern	Overall
Erythromycin	Watch	Tablet	250 mg	No	Yes	No	No	No	No
Erythromycin	Watch	Suspension	250 mg/5 mL	No	Yes	No	No	No	No
Spiramycin	Watch	Tablet	250 mg	No	No	No	No	No	No
Clarithromycin	Watch	Tablet	250 mg	Yes	Yes	Yes	Yes	No	Yes
Clarithromycin	Watch	Tablet	500 mg	Yes	Yes	Yes	No	No	No
Clarithromycin	Watch	Extended release tablet	500 mg	Yes	Yes	No	No	No	No
Azithromycin	Watch	Suspension	200 mg/5 mL	Yes	Yes	Yes	Yes	No	Yes
Azithromycin	Watch	Tablet	250 mg	Yes	Yes	Yes	Yes	No	Yes
Gentamicin	Access	Injection	40 mg/2 mL	Yes	Yes	Yes	Yes	No	Yes
Gentamicin	Access	Injection	80 mg/2 mL	Yes	Yes	Yes	No	No	No
Ciprofloxacin	Watch	Tablet	250 mg	Yes	Yes	Yes	Yes	No	Yes
Ciprofloxacin	Watch	Tablet	500 mg	Yes	Yes	Yes	No	No	No
Metronidazole	Access	Tablet	250 mg	Yes	Yes	Yes	Yes	No	Yes
Nitrofurantoin	Access	Tablet	100 mg	Yes	Yes	Yes	Yes	No	Yes
Rifampicin	Watch	Capsule	300 mg	Yes	Yes	Yes	Yes	No	Yes

Table 6. Policy-relevant additions, changes, and persistent non-alignment between the 2024 and 2025 reimbursement lists. The table summarizes newly added entries, changes in AWaRe or alignment status, and selected products that remained non-aligned across both lists.

Note. The 2024 entries were assessed using the 2023 WHO comparator documents, whereas the 2025 entries were assessed using the corresponding 2025 WHO documents. A change in classification or alignment may therefore reflect a change in the comparator or assessment rather than a change in the reimbursed product [9–11,21–23]. A dash indicates that the entry was absent in the specified period.

Antibiotic (INN)	Formulation and strength	AWaRe, 2024 → 2025	2024 alignment	2025 alignment	Comparison
Doxycycline	Dispersible tablet, 100 mg	- → Access	-	Aligned	Added; aligned
Oxytetracycline	Tablet, 250 mg	- → Watch	-	Not aligned	Added; not aligned
Ampicillin	Suspension, 125 mg/5 mL	- → Access	-	Not aligned	Added; not aligned
Ampicillin	Capsule, 500 mg	Access → Access	Not aligned	Not aligned	Retained; unchanged

Antibiotic (INN)	Formulation and strength	AWaRe, 2024 → 2025	2024 alignment	2025 alignment	Comparison
Amoxicillin	Suspension, 125 mg/5 mL	- → Access	-	Aligned	Added; aligned
Amoxicillin	Suspension, 250 mg/5 mL	- → Access	-	Aligned	Added; aligned
Amoxicillin	Capsule, 250 mg	- → Access	-	Aligned	Added; aligned
Amoxicillin + clavulanic acid	Tablet, 375 mg	Access → Access	Not aligned	Not aligned	Retained; unchanged
Amoxicillin + clavulanic acid	Suspension, 457 mg/5 mL	Access → Access	Not aligned	Not aligned	Retained; unchanged
Amoxicillin + clavulanic acid	Tablet, 1,000 mg	Access → Access	Not aligned	Not aligned	Retained; unchanged
Cephalexin	Capsule/tablet, 500 mg	Access → Access	Not aligned	Not aligned	Retained; unchanged
Cefuroxime	Suspension, 125 mg/5 mL	- → Watch	-	Not aligned	Added; not aligned
Cefaclor	Suspension, 125 mg/5 mL	- → Watch	-	Not aligned	Added; not aligned
Cefaclor	Suspension, 250 mg/5 mL	Watch → Watch	Not aligned	Not aligned	Retained; unchanged
Cefaclor	Capsule/tablet, 500 mg	Watch → Watch	Not aligned	Not aligned	Retained; unchanged
TMP-SMX	Suspension, 240 mg/5 mL	Access → Access	Aligned	Aligned	Retained; unchanged
TMP-SMX	Tablet, 800/160 mg	Access → Access	Non aligned	Not aligned	Retained; unchanged
Spiramycin	Tablet, 250 mg	Watch → Watch	Not aligned	Not aligned	Retained; unchanged
Clarithromycin	Tablet, 250 mg	- → Watch	-	Not aligned	Added; not aligned
Clarithromycin	Extended-release tablet, 500 mg	- → Watch	-	Not aligned	Added; not aligned
Gentamicin	Injection, 80 mg/2 mL	Access → Access	Not aligned	Not aligned	Retained; unchanged
Ciprofloxacin	Tablet, 250 mg	- → Watch	-	Aligned	Added; aligned

Antibiotic (INN)	Formulation and strength	AWaRe, 2024 → 2025	2024 alignment	2025 alignment	Comparison
Ciprofloxacin	Tablet, 500 mg	Watch → Watch	Not aligned	Not aligned	Retained; unchanged
Rifampicin	Capsule, 300 mg	- → Watch	-	Aligned	Added; aligned
Erythromycin	Suspension, 250 mg/5 mL	Watch → Watch	Not aligned	Not aligned	Retained; unchanged
Amoxicillin + clavulanic acid	Tablet, 500 mg + 125 mg	- → Access	-	Aligned	Added; aligned

3.4. Characterization of Structurally Non-Aligned Antibiotics

Under the recorded classifications, the remaining 14 of 28 product entries (50.0%) were classified as structurally non-aligned with WHO recommendations. Non-alignment involved EML/EMLc inclusion, formulation, strength, or combinations of these criteria. The non-aligned products included both Access and Watch antibiotics, indicating that structural discrepancies were distributed across stewardship categories.

3.4.1. Antibiotics Absent from WHO EML/EMLc

Comparison with the WHO EML and EMLc identified 3 reimbursed product entries (10.7%) recorded as absent from both reference lists. These comprised the spiramycin entry, and both cefaclor entries.

Cefaclor accounted for 26,004 reimbursed units (25.2% of the total), combining 25,364 capsule units and 640 suspension units. It was the second-largest contributor to total reimbursed quantity by antibiotic, after amoxicillin-clavulanic acid, despite its absence from the WHO EML/EMLc.

3.4.2. Formulation-Related Discrepancies

The formulation-match column in Table 4 identified 6 mismatches among 28 entries (21.4%). These affected oral solid and oral liquid products; no injectable entry was marked as a formulation mismatch.

The recorded formulation mismatches comprised ampicillin capsules, spiramycin tablets, both cefaclor entries, erythromycin entries and clarithromycin tablets.

The corresponding assessment of the 2025 list recorded 12 formulation mismatches among 40 entries (30.0%) (Table 5).

3.4.3. Strength Discrepancies

The strength-match column in Table 4 recorded 13 mismatches among 28 entries (46.4%), the most frequent structural discrepancy in the original classification.

The recorded strength discrepancies affected multiple therapeutic classes, including penicillins, cephalosporins, macrolides, aminoglycosides, and fluoroquinolones. Examples in Table 4 included:

- amoxicillin-clavulanic acid tablets 375 mg and 1,000 mg, and suspension 457 mg/5 mL;

- cephalexin tablets or capsules 500 mg;
- gentamicin injection 80 mg/2 mL;
- ciprofloxacin tablets 500 mg.
- TMP-SMX tablets 800/160 mg

Eight of the 16 unique antibiotics (50.0%) had more than one reimbursed strength, formulation, or both: ampicillin, TMP-SMX, gentamicin, cephalexin, amoxicillin-clavulanic acid, cefaclor, azithromycin, and erythromycin. Alignment classifications could therefore differ between entries containing the same active ingredient.

3.4.4. Multiple Structural Discrepancies

Three of 28 reimbursed entries (10.7%) had recorded discrepancies across more than one alignment dimension, combining absence from the WHO reference lists with formulation and strength mismatches.

These entries comprised both cefaclor formulations, and the spiramycin tablet entry. They represented the greatest recorded divergence across the assessed WHO comparison dimensions.

3.5. Layer 3: Integrated Prioritization of Structurally Non-Aligned Antibiotics

Among the non-aligned products, antibiotics meeting multiple prioritization criteria combined structural non-alignment with membership in classes highlighted in national AMR surveillance, Watch classification, broad-spectrum activity, or high reimbursed quantity.

Watch cephalosporins and fluoroquinolones were prominent among the antibiotics prioritized under the recorded framework. Cefaclor combined absence from the WHO reference lists with Watch classification and high reimbursed quantity. Ciprofloxacin was prioritized on the basis of its Watch classification, broad-spectrum activity, and recorded strength mismatch.

Selected Access antibiotics also met several prioritization criteria. Amoxicillin-clavulanic acid combined recorded strength discrepancies with high reimbursed quantity. Gentamicin and TMP-SMX were also included because of recorded structural discrepancies and additional stewardship considerations.

Conversely, several structurally non-aligned antibiotics fulfilled relatively few prioritization criteria because they demonstrated limited reimbursement utilization or lacked additional stewardship-related characteristics. These products remained structurally non-aligned but represented lower priorities for reimbursement review within the integrated analytical framework.

The 2025 reimbursement list changed the composition of the assessed antibiotic products without reducing the recorded number of structurally non-aligned entries. Products with persistent discrepancies remained candidates for continued review. Changes in alignment status must be interpreted in light of both the reimbursement list and the WHO comparator used.

Table 7. Integrated prioritization profiles of selected structurally non-aligned reimbursed antibiotics. The table combines recorded structural alignment, AWaRe category, reimbursed quantity, and class-level national AMR relevance. The rankings represent the study's policy prioritization rather than a validated quantitative score.

Rank	Antibiotic / product scope	AWaRe	Recorded structural alignment	Quantity (%)	Stewardship and national AMR context
1	Cefaclor (capsules and suspension)	Watch	Not in WHO EML/EMLc	25.2%	Watch cephalosporin absent from WHO EML/EMLc; high reimbursed quantity. National findings provide broad cephalosporin context, not cefaclor-specific resistance.
2	Ciprofloxacin (oral-solid)	Watch	Recorded non-alignment; strength mismatch	8.2%	Watch fluoroquinolone; the class was frequently reported in national surveillance. Individual drug susceptibility was not measured.
3	Amoxicillin-clavulanic acid (375 mg and 1,000 mg tablets)	Access	Recorded strength mismatch; duplication concern	10.8%	High reimbursed quantity of an Access penicillin combination; the national bulletin reported high penicillin resistance at the class level.
4	Spiramycin (oral-solid)	Watch	Not in WHO EML/EMLc	1.1%	Watch macrolide absent from WHO EML/EMLc. The cited national bulletin does not establish spiramycin-specific resistance.
5	Clarithromycin (oral-solid)	Watch	No overall alignment	0.6%	Watch macrolide requiring interpretation of the recorded structural classification. Drug-specific national resistance was not established.
6	Gentamicin 80 mg/2 mL (parenteral)	Access	No overall alignment	0.2%	Access aminoglycoside; the class was frequently reported in national surveillance. Drug-specific resistance and treatment failure were not assessed.
7	Erythromycin (oral-solid)	Watch	Recorded non-alignment	1.4%	Watch macrolide with recorded nonalignment. Drug-specific national resistance was not established.
8	Ampicillin (oral-solid)	Access	Recorded non-alignment; formulation mismatch	1.3%	Access penicillin with a recorded oral formulation mismatch. National surveillance provides penicillin-class context.

Note. Percentages use the Table 4 total of 103,349 reimbursed units. Cefaclor combines both formulations; the amoxicillin-clavulanic acid percentage includes only the two tablet strengths specified. TMP-SMX suspension accounted for 4 units (0.004%), displayed as 0.0% after rounding. National AMR relevance is interpreted at the class level; drug-specific resistance was not measured [9,12,14].

3.6. Geographic Stewardship Prioritization

Regional analysis showed geographic variation in reimbursed outpatient antibiotic utilization from November 2024 through October 2025 (Table 8). Approximately 9,400 reimbursed antibiotic prescriptions were reported for 7,444 patients, with a reported national average of 1.27 prescriptions per patient.

Among counties with reported counts, Tirana had the highest prescription volume (2,347 prescriptions; 24.8%), followed by Shkodër (1,542; 16.3%), Elbasan (1,431), Vlorë (1,091), and Dibër (1,000). The lowest

reported counts were in Durrës (47), Fier (96), and Gjirokastër (96) (Figure 1).

A total of 7,444 patients were reported as receiving reimbursed antibiotics during the study period. Among counties with available patient counts, Tirana had the highest number (1,937; 26.0%), followed by Shkodër (1,191; 16.0%), Elbasan (1,031; 13.8%), Vlorë (878; 11.8%), and Dibër (816; 11.0%). The lowest reported counts

were in Durrës (36), Fier (74), and Gjirokastër (85) (Figure 2).

Comparison of prescription numbers with patient counts showed regional variation in prescriptions per patient. The reported ratio ranged from 1.12 in Berat to 1.55 in Lezhë. Most reported ratios were approximately 1.2–1.3, although Elbasan and Lezhë had higher ratios (Table 8).

To account for regional population differences, reimbursed prescriptions were standardized using 2023 census population estimates. The reported national rate was approximately 393 prescriptions per 100,000 residents. The highest reported county rates were Shkodër (998), Dibër (933), Vlorë (744), Elbasan (615), Korçë (511), and Lezhë (509). Lower rates were reported for Tirana (309), Gjirokastër (160), Berat (140), Fier (40), and Durrës (21). All rates are expressed as reimbursed antibiotic prescriptions per 100,000 residents (Figure 3; Table 8).

The geographic prioritization framework therefore identified two distinct categories of regional stewardship relevance:

1. Counties with the highest population-standardized rates of reimbursed antibiotic prescriptions, indicating greater reimbursed prescribing intensity; and
2. Counties contributing the largest absolute numbers of reimbursed antibiotic prescriptions, indicating greater contributions to reimbursed outpatient exposure.

The regional utilization analysis provided the geographic component of the multidimensional prioritization framework and was subsequently integrated with structural alignment and antimicrobial resistance relevance to identify reimbursement review priorities.

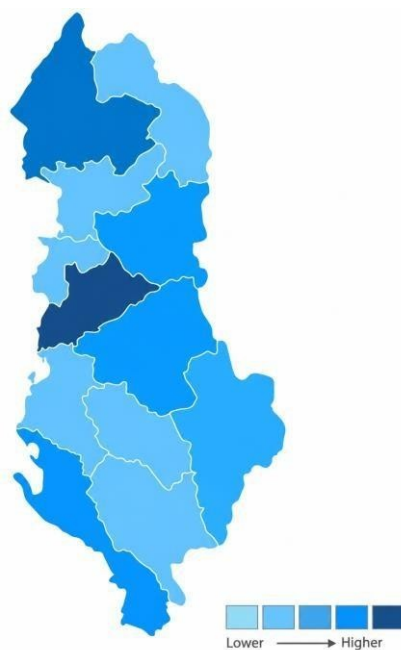


Figure 1. Absolute number of reimbursed outpatient antibiotic prescriptions by county, November 2024–October 2025. The map shows the geographic distribution of absolute reimbursed prescription volume.

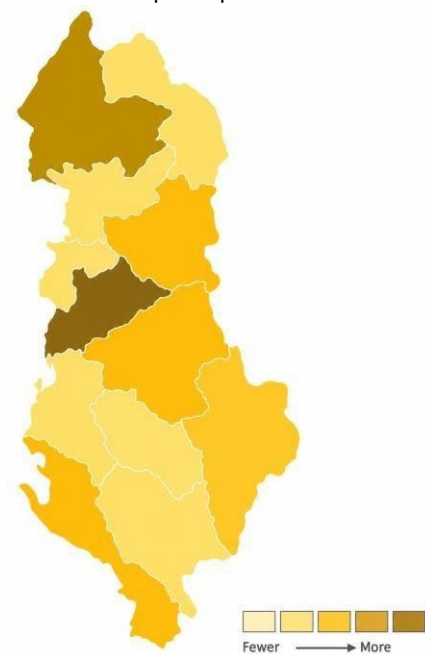


Figure 2. Number of patients receiving reimbursed outpatient antibiotics by county, November 2024–October 2025. The map shows the geographic distribution of patients with at least one reimbursed antibiotic record.

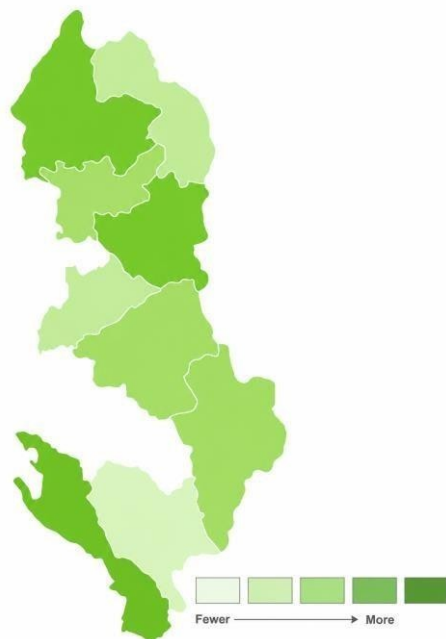


Figure 3. Reimbursed outpatient antibiotic prescriptions per 100,000 residents by county, November 2024–October 2025. The map presents population-adjusted reimbursed prescription rates to permit comparison between counties of different population sizes.

Table 8. County-level reimbursed outpatient antibiotic utilization and geographic rankings, November 2024–October 2025. The table reports prescriptions, patients receiving antibiotics, prescriptions per patient, population-adjusted rates, and recorded rankings by absolute and standardized utilization.

Note. n indicates the number of reimbursed prescriptions or patients. Population-standardized rates used resident population counts from the 2023 Albanian Census (Table 6, pp. 64–65) [25]. Absolute volume rank refers to reimbursed prescription counts; standardized utilization rank refers to prescriptions per 100,000 residents. A dash indicates unavailable or unreported data.

County	Reimbursed prescriptions (n)	Patients receiving antibiotics (n)	Prescriptions per patient	Prescriptions per 100,000 inhabitants	Absolute volume rank	Standardized utilization rank
Tirana	2,347	1,937	1.21	309	1	7
Shkodër	1,542	1,191	1.29	998	2	1
Elbasan	1,431	1,031	1.39	615	3	4
Vlorë	1,091	878	1.24	744	4	3
Dibër	1,000	816	1.23	933	5	2
Korçë	-	-	-	511	-	5
Lezhë	-	-	1.55	509	-	6
Berat	-	-	1.12	140	-	9
Gjirokastrë	96	85	1.13	160	8-9	8
Fier	96	74	1.30	40	8-9	10
Durrës	47	36	1.31	21	10	11

3.7. Application of the Reimbursement Review Framework

Antibiotics with isolated structural discrepancies and no additional prioritization signals were classified as candidates for routine reimbursement review (Figure 4). Watch classification was considered an additional stewardship signal rather than a structural mismatch.

Under the recorded classifications, products including amoxicillin-clavulanic acid, cefaclor, spiramycin, clarithromycin, ciprofloxacin, and gentamicin 80 mg/2 mL combined structural discrepancies with additional stewardship considerations. These included Watch classification, membership in broad classes highlighted in national AMR surveillance, broad-spectrum activity, or high reimbursed quantity. Such products were considered candidates for more comprehensive reimbursement assessment. Cefixime suspension 100 mg/5 mL was recorded as fully aligned in both Tables 4 and 5 and was therefore not classified as structurally non-aligned.

Application of the reimbursement review framework resulted in four principal review outcomes:

1. antibiotics demonstrating complete structural alignment with WHO recommendations required no further structural-alignment review within this framework and were considered structurally consistent with the analytical framework;
2. antibiotics demonstrating isolated structural discrepancies were classified as candidates for routine reimbursement review to determine whether modification of formulation or dosage strength would improve correspondence with WHO recommendations;
3. antibiotics demonstrating multiple structural discrepancies together with AMR-relevant characteristics were classified as high-priority candidates for comprehensive reimbursement review; and

4. antibiotics demonstrating persistent structural non-alignment across successive reimbursement lists were identified as candidates for continued monitoring during future reimbursement revisions.

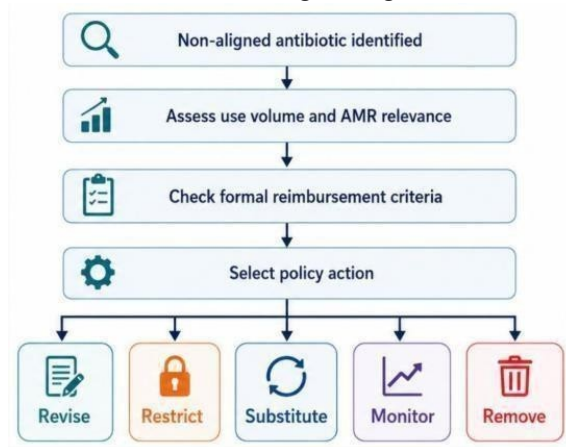


Figure 4. Reimbursement review pathway for translating multidimensional assessment findings into potential policy responses. The figure shows the sequence from identifying non-alignment and assessing utilization and AMR relevance to considering formal reimbursement criteria and selecting a policy response.

4. Discussion

4.1. Principal Findings

The findings support considering antibiotic reimbursement policy as part of antimicrobial stewardship [26,27]. Reimbursement decisions determine which antibiotics, formulations, and strengths receive public financial support and can influence access and prescribing [7,28]. To our knowledge, this is the first national outpatient study to apply a Multidimensional Antibiotic Reimbursement Assessment Framework integrating WHO guidance, national AMR priorities, utilization, pharmaceutical alignment, and geographic patterns.

Achieving one stewardship objective does not establish full alignment across the reimbursement system. A list can have a relatively high quantity-weighted share of Access antibiotics while retaining gaps in medicine selection, formulation, or strength. WHO classifications and previous Albanian alignment research support examining these dimensions separately [9–11,18].

The comparison of the 2024 and 2025 lists also illustrates that updating a reimbursement list does not necessarily eliminate recorded alignment gaps. Products may be added, removed, or altered while discrepancies persist. Reimbursement review should use explicit criteria and consider medicine selection, formulation, strength, stewardship category, utilization, and national resistance priorities [9–11,14,26,28].

Different non-aligned products may warrant different policy responses. An isolated technical discrepancy may require review of a formulation or strength. A product with several prioritization signals, such as high reimbursed quantity, Watch classification, absence from the WHO EML/EMLc, or persistent non-alignment, may warrant broader assessment. These are interpretations of the combined study findings rather than conclusions established by any single source [9–12,18].

4.2. Rationale and Novelty of the Multidimensional Antibiotic Reimbursement Assessment Framework

The Framework for a Multidimensional Assessment of Antibiotic Reimbursement was built on a fundamental policy principle, namely that no one source of evidence by itself can provide a complete

assessment of an antibiotic reimbursement system. Each of the layers addresses a different aspect of the policy question. National AMR surveillance identifies the resistance problems of greatest concern.

Structural assessment examines whether reimbursed antibiotics and their formulations correspond with stewardship and Essential Medicines recommendations. The final layer combines these findings with utilization and geographical data to determine priorities for policy review. The framework's value is therefore to be found in the way its various layers are linked together rather than in any one of the individual indicators.

National AMR reports provide the epidemiological context for the study [12]. They identify reported pathogens and antibiotic classes of concern but do not establish whether specific products are reimbursed, how they are listed, or how extensively they are used. Surveillance can therefore inform relevance without independently determining an appropriate reimbursement response.

The information provided by the WHO AWaRe classification is of a different kind; it categorizes antibiotics according to their importance with regard to stewardship and helps in the monitoring of the use of Access, Watch, and Reserve antibiotics [9]. Yet the AWaRe system was not intended to evaluate the full structure of a reimbursement system [9]. Antibiotics that belong to the same AWaRe category can vary in whether they are included in the WHO Essential Medicines Lists, the reimbursed formulations, the dosage strengths, their level of use, and their connection with national resistance concerns. While AWaRe can show the general stewardship stance of an antibiotic, it cannot decide whether a particular reimbursed product has been properly chosen or structured.

The WHO's Essential Medicines List and the Essential Medicines List for Children provide selection of medicines and guidance regarding the recommended formulations and strengths [10,11]. It can be that medicine is included in these lists, and that a national reimbursement decision is appropriate. A drug might be included by the WHO but still be reimbursed at a formulation or strength that is not in line with the recommended one. Likewise, being left out from the lists should not result in automatic restriction or removal. National reimbursement decisions should also consider local epidemiology, clinical guidelines, availability, and the needs of the health system [10,11,17]. Essential medicines correspondence is therefore a basis for structured review rather than a final reimbursement decision.

Previous research by Petro et al. [18] provides the closest methodological foundation for the present study. Their evaluation compared Albania's reimbursement medicines list for children with the WHO Essential Medicines List for Children and assessed alignment in medicine inclusion, dosage forms, strengths, and indications [18]. The Multidimensional Antibiotic Reimbursement "health system [10,11,17]" Assessment Framework builds on this structural approach but addresses a different policy question. Rather than stopping after the identification of alignment gaps, it focuses specifically on systemic antibiotics and integrates structural findings with WHO AWaRe classification, national AMR priorities, reimbursement utilization, changes across successive reimbursement lists, and geographical variation. These dimensions are then combined to establish differentiated priorities for policy review. The originality of the present framework therefore lies not in formulation or strength assessment alone, but in converting several complementary sources of evidence into an ordered stewardship and reimbursement-policy tool.

The framework also incorporates both therapeutic and structural alignment within the same evaluation. Therapeutic alignment refers to whether the international guidelines support antibiotics that are appropriate from the point of view of essential medicines and AWaRe [9–11]. Structural alignment relates to whether the antibiotics in question are reimbursed in appropriate formulations and dosage strengths

[10,11]. These two aspects offer different kinds of information; an antibiotic might represent an appropriate therapeutic option but could still be poorly supported by unsuitable pharmaceutical presentations. On the other hand, a product might conform to the recommended formulation and strength and yet still warrant attention due to its Watch classification, usage patterns, or relevance to national resistance trends [9,12]. It therefore follows that assessing only one type of alignment could result in an incomplete policy judgement.

Utilization data provide an important indication of exposure. While structural analysis reveals what the reimbursement system makes available, it is utilization that shows which parts of that system are most frequently used. High levels of utilization do not on their own suggest poor stewardship; they might indicate the appropriate use of a recommended first-line Access antibiotic [9]. Similarly, a product that is not structurally aligned may have only a small effect on the population if it is rarely used. Utilization becomes more informative when it is considered alongside medicine selection, pharmaceutical alignment, AWARe classification, and national AMR relevance.

Another notable feature of the framework is that it includes a geographical analysis of reimbursement. The county-level data on outpatient antibiotic prescriptions and patients who received them were supplied directly by the Albanian Compulsory Healthcare Insurance Fund for this study. This enabled the assessment to go beyond the national figures and look at how antibiotic exposure among patients who had their prescriptions reimbursed varied throughout Albania. To our knowledge, this study is the first in Albania to incorporate the geographical distribution of outpatient antibiotic consumption into an evaluation of antibiotic reimbursement policy. Geographical data alone are also restricted. The variations in antibiotic use among different regions might be due to factors such as population structure, the level of disease burden, access to healthcare, clinical practice [29–31], the extent of data coverage, or other local circumstances. They must therefore not be regarded as direct proof of inappropriate prescribing [30]. The value of geographical analysis for policy purposes lies in the fact that it can help to identify areas where further investigation might be warranted and then interpret those areas in the broader context of stewardship and reimbursement.

The geographical aspect included two complementary methods of prioritization. One involves the use of population-standardized rates to highlight the counties in which reimbursed antibiotic use is most intensive, whereas the other looks at absolute prescription volumes to show which counties contribute the most to the total national reimbursed exposure. Since these indicators address different policy questions, it is possible for a small county to have a high standardized rate but only a relatively small number of prescriptions, while a large county might have a moderate rate yet be responsible for a major portion of national usage. Only by taking both measures into account can a more balanced ranking be obtained than by relying on just one of them.

The antibiotic-prioritization procedure is also a significant methodological contribution. In traditional alignment studies, the medicines are usually divided into those that are aligned and those that are not [15,16,18]. While this shows whether or not a discrepancy is present, it treats problems which have very different possible policy implications as if they were of equal importance. A single mismatch regarding dosage strength is not the same as an antibiotic which has structural non-alignment. A Watch classification, is relevant for antimicrobial resistance, is widely used and has remained on successive reimbursement lists [9,24]. Although a binary classification can point out a problem, it cannot determine its relative priority.

The Multidimensional Antibiotic Reimbursement Assessment Framework treats non-alignment as the starting point of assessment. An isolated discrepancy may prompt routine review, while several converging signals may warrant more detailed assessment. Higher priority does not establish that an antibiotic is inappropriate or should be restricted, substituted, or withdrawn. It indicates a need for review of clinical indications, national guidelines, alternatives, patient access, costs, and the likely effects of a policy change.

The Multidimensional Antibiotic Reimbursement Assessment Framework considers a lack of alignment to be the starting point of the policy assessment rather than its end point; if there is just one discrepancy it may be sufficient to call for a routine review, whereas if several issues come together, it may warrant a more in-depth assessment. Higher prioritization does not imply that an antibiotic is inappropriate or that it should automatically be restricted, substituted or withdrawn; it only means that the drug merits a closer examination incorporating further factors such as clinical need, national treatment guidelines, the availability of alternatives, patient access, cost, and the likely effects of a change in policy

What makes the three-layer model special is the way it integrates the evidence in an ordered manner. The first layer sets out the context of national resistance. The second looks at the therapeutic and structural aspects of the reimbursement list. The third considers how the relevance of resistance and the structure of the reimbursement interact with utilization, persistence throughout changes to the list, and geographical distribution. Nothing among these layers can take the place of the others. Surveillance of antimicrobial resistance gives information on relevance without identifying the reimbursement mechanism. A structural assessment shows where there are policy gaps without indicating the level of exposure. Data on utilization and geographical distribution describe the level of exposure without establishing its stewardship significance.

It shows through the Albanian example just how important this integration is. If the various indicators are looked at on their own, certain aspects of the reimbursement system may seem to be broadly acceptable. But when the different factors are brought together, a consistent pattern emerges among a number of the more important antibiotics. This pattern involves structural misalignment or being omitted from the WHO Essential Medicines list, together with being given a Watch classification, belonging to antibiotic classes that are highlighted in the national AMR surveillance, having a high level of reimbursed usage, and still being included in the revised 2025 reimbursement list [24]. None of the individual indicators by themselves reveals the full significance of this pattern; it is only when all the evidence is combined that the importance of the pattern becomes clear. This point is at the heart of the framework's policy objective. The findings from Albania are not merely of a national character; they illustrate empirically how individually incomplete indicators can together produce a more robust and significant signal. By means of the Multidimensional Antibiotic Reimbursement Assessment Framework, data which is routinely collected through surveillance and reimbursement processes is turned into a structured tool for stewardship. The framework's value is not in providing yet another separate measure, but in offering a way of spotting when several kinds of evidence come together and thus give a stronger justification for reviewing antibiotic or geographical policy.

4.3. International Evidence Supporting Reimbursement Review as a Stewardship Policy Tool

International experience supports treating reimbursement as an active health-policy tool [28,32]. Australia, Canada, New Zealand, and the United Kingdom have developed centralized processes that assess clinical and economic evidence to inform public medicine coverage. These processes aim to

improve consistency, transparency, and the use of evidence [32]. The WHO Regional Office for Europe has also emphasized clear priority-setting criteria, evidence-based decisions, transparent processes, regular evaluation, and strategic policy design [28]. Such arrangements can influence which medicines are selected, funded, and used.

Evidence on pharmaceutical pricing and reimbursement policies indicates that policy changes can affect medicine use and expenditure [7,33,34]. Reference pricing and reimbursement restrictions may

encourage the use of preferred medicines or reduce spending, but effects depend on policy design, implementation, available alternatives, and the healthcare setting [28,33,34]. Evidence on broader clinical outcomes is less certain, supporting careful monitoring [33,34]. Direct antibiotic evidence comes from Alberta, Canada. Manns et al. [7] evaluated a restricted reimbursement policy intended to encourage guideline-consistent outpatient quinolone prescribing. Overall quinolone use did not decrease significantly, but prescribing became more consistent with formulary guidance and decreased for selected indications. Mortality and infection-related hospitalization did not change, although small increases in all-cause hospitalization and subsequent outpatient physician visits were reported [7]. These findings suggest that reimbursement rules can influence antibiotic selection, while overall effects may remain limited and require clinical guidance, monitoring, and access to alternatives.

Studies comparing reimbursement lists with the WHO EML also support evidence-based review [15,16]. In Croatia, Jeličić Kadić et al. [15] identified medicines absent from the WHO list, including products previously rejected or removed by the WHO Expert Committee, as well as differences in dose, formulation, and indication. They recommended using high-quality evidence when both adding new medicines and reassessing existing coverage. This supports extending review beyond new reimbursement applications.

The study in the Federation of Bosnia and Herzegovina compared reimbursement lists with the WHO EML and examined evidence supporting additional medicines [16]. It highlighted the role of independent evidence from the WHO EML, systematic reviews, and health technology assessments, interpreted in the national context. The Croatian and Bosnian studies support using international reference standards to identify medicines warranting further review while recognizing that final decisions depend on national requirements [15,16].

Pediatric studies similarly demonstrate the need to assess more than the presence of an active ingredient. Research in Serbia identified gaps in the availability and reimbursement of formulations suitable for children, including limited availability of WHO EMLc medicines [35]. The Armenian study found discrepancies among WHO recommendations, national medicine lists, registration, clinical guidance, and availability; its comparisons did not comprehensively assess formulation and strength [36]. These studies support examining access and pharmaceutical presentations alongside medicine selection.

The earlier Albanian study likewise identified differences between the national reimbursement list for children and the WHO EMLc in medicine inclusion, dosage forms, strengths, and indications [18]. It demonstrates that agreement at the active-ingredient level can coexist with differences in pharmaceutical presentations. The present antibiotic-focused assessment extends that approach by adding stewardship, utilization, and policy-prioritization dimensions.

The reviewed literature supports three relevant considerations. Reimbursement decisions can influence medicine selection and use [7,32–34]. Comparisons with WHO essential medicines recommendations can identify gaps requiring review [15,16,18,35,36]. Policy effects depend on implementation, supporting evidence, and monitoring [7,28,33,34]. These studies addressed clinical or economic review, medicine

availability, essential medicines correspondence, or the prescribing effects of a specific antibiotic restriction. The present framework proposes integrating those policy perspectives with WHO stewardship guidance, national AMR context, reimbursement structure, and utilization to identify priorities for review.

4.4. Policy Implications and Operationalization of the Multidimensional Antibiotic Reimbursement Assessment Framework

The Multidimensional Antibiotic Reimbursement Assessment Framework could be incorporated into routine development and revision of reimbursement lists. It could inform assessment of proposed additions, renewal or modification of existing entries, and monitoring after implementation when utilization data become available. This would incorporate stewardship considerations into reimbursement policy design and ongoing review.

The internal reimbursement-review criteria supplied by FSDKSH provide a proposed mechanism for translating assessment findings into revision, restriction, substitution, monitoring, or removal. The document specifies potential removal criteria concerning clinical use, market availability, approved pricing, national registration, unjustified price differences between dosage forms, and recommendations from WHO, EMA, or FDA. These criteria describe possible review responses; they do not establish that an antibiotic should be removed solely because it is absent from the WHO EML/EMLc.

The two frameworks thus have complementary roles; the Multidimensional Antibiotic Reimbursement Assessment Framework determines which antibiotics need to be addressed and the extent of the review they require, whereas the draft FSDKSH criteria indicate the kind of reimbursement response that may be taken.

The framework could also improve transparency in reimbursement updates. Recording the concern identified, evidence reviewed, decision reached, and rationale for retaining or changing an antibiotic would distinguish unresolved issues from decisions based on clinical need, availability, regulation, or cost.

Geographic prioritization may help identify counties for further assessment. Previous research has documented regional variation in outpatient antibiotic prescribing [29]. Population-adjusted rates and absolute prescription counts describe different dimensions of reimbursed exposure and may help guide the scope of local investigation, education, prescribing audits, and monitoring.

The framework's use would involve cooperation between reimbursement authorities, clinicians, pharmacists, microbiologists, AMR surveillance experts, regulatory bodies, and pharmacoeconomic specialists. There should also be monitoring of utilization, patient access, expenditure, and the shift toward alternative antibiotics following changes in reimbursement [7,34]. In this way, reimbursement policy could become an active part of national antimicrobial stewardship at an upstream level rather than merely a financing mechanism.

4.5. Strengths, Limitations, and Future Research

The study has a number of important strengths since it brings together national AMR priorities, the WHO AWaRe classification, the WHO Essential Medicines recommendations, information on pharmaceutical formulation and strength, reimbursement utilization, the changes that have taken place in successive reimbursement lists, and geographic distribution all in one evaluation. The analysis carried out at the product-entry level also enabled differences to be identified which would have remained hidden if the antibiotics had been compared merely based on their active substance. Moreover, the county-level data

and the formal removal criteria supplied directly by FSDKSH increased the practical relevance of the study by linking the analytical results with the current national reimbursement system.

Comparing the 2024 and 2025 reimbursement lists brought a temporal aspect to the policy. It enabled the study to determine if the structural issues noted in one list were still there after the list had been revised. Yet the comparison was restricted to the reimbursement structure since the relevant utilization

data for the 2025 reimbursement list were not available. Consequently, the findings do not allow us to conclude that the revision led to any changes in prescribing or in the use of reimbursed antibiotics.

Other limitations should be considered. The study assessed reimbursement policy rather than individual prescribing decisions. The aggregated data did not include age, diagnosis, clinical indication, microbiological results, treatment duration, adherence, or health outcomes. They therefore cannot establish the appropriateness of an individual prescription or a causal relationship between reimbursement characteristics and clinical outcomes. The analysis covers reimbursed outpatient antibiotics and excludes non-reimbursed purchases and inpatient antibiotic use.

The issue of antimicrobial resistance should also be approached with caution. While national surveillance data were employed to identify the relevant pathogens and antibiotic groups, the study did not directly assess the resistance linked to individual reimbursed antibiotics. Furthermore, the resistance data were mostly available at the national level rather than the county level. It follows that the geographic analysis can only point out differences in exposure to reimbursed antibiotics and indicate areas that need further investigation, rather than being able to establish whether regional prescribing practices were inappropriate or whether greater usage was connected with higher local resistance. Since the reimbursement, surveillance, and geographic data cover different observation periods, their integration must be seen as a policy-prioritization exercise rather than as a synchronized causal analysis.

The Multidimensional Antibiotic Reimbursement Assessment Framework has not been externally validated. The priority ordering reflects qualitative investigator judgment, and different assessors may assign different relative priorities to the same product profiles. Reproducibility, agreement between assessors, and usefulness for reimbursement decision-making require further evaluation.

Future research should use the framework in countries that have different reimbursement systems, different epidemiological profiles, and different healthcare structures. By linking reimbursement data with records of electronic prescriptions, diagnoses, microbiological results, and patient outcomes, later studies will be able to look at whether changes in the reimbursement structure result in measurable changes in prescribing and in antibiotic exposure. Regional surveillance of antimicrobial resistance could also be combined with reimbursement data at the county level in order to improve geographic priority settings. Moreover, upcoming evaluations should investigate the effects of changes in reimbursement on utilization, expenditure, patient access, substitution toward other antibiotics, and resistance patterns. Economic assessments together with consultation with the relevant reimbursement authorities and clinical experts would also help to develop a validated and practical policy tool.

5. Conclusions

Antibiotic reimbursement systems warrant assessment across medicine selection, formulation, strength, utilization, and stewardship context. In the supplied 2024 data, Access antibiotics accounted for 62.8% of total reimbursed quantity, exceeding the prespecified 60% comparison threshold for this outpatient reimbursement segment. The recorded multidimensional assessment also identified structural

discrepancies with WHO essential medicines recommendations. The proposed framework combines WHO stewardship guidance, national AMR context, utilization, and geographic distribution to identify priorities for reimbursement review. Cefaclor emerged as the main priority under the study's recorded classifications because it combined Watch status, absence from the WHO EML/EMLc, and high reimbursed quantity. The framework prioritizes review rather than prescribing a specific policy response. Its use in Albania and other health systems requires reliable product-level classifications, clear prioritization criteria, and further validation. Regular multidimensional review could support more transparent reimbursement policy and strengthen its contribution to antimicrobial stewardship.

Data Availability: FSDKSH data, obtained with permission, included antibiotic reimbursement and prescription data, geographical data on their distribution across counties, and the proposed criteria for the revision, restriction, substitution, monitoring, or removal of reimbursed medicines. All other data supporting the findings of this study are included in the manuscript. The WHO documents and relevant national documents are publicly available and are cited in the manuscript.

Funding: This research received no external funding.

Declaration of Generative AI and AI-Assisted Technologies: Grammarly.com was used solely for grammar correction and language refinement. It was not used to generate scientific content, data, analyses, interpretations, or conclusions. All suggestions were reviewed by the authors, and all scientific and intellectual content is original and was developed and verified by the authors.

Author Contributions: (CRediT taxonomy): Conceptualization: MP, MS, EP; Methodology: MP, MS, EP; Formal analysis: MP, MS, EP; Data curation: MP; Writing – original draft: MP; Writing – review & editing: MP, MS, EP. All authors contributed equally to conceptualization, methodology, formal analysis, and writing – review & editing. All authors have read and approved the final version of the manuscript and agree to be accountable for the work.

Conflict of Interest: The authors declare no conflicts of interest.

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How to cite: Përgjegji M, Shllaku M, Petro E. Antibiotic Reimbursement as a Policy Lever for Antimicrobial Stewardship: Alignment with WHO AWaRe and Essential Medicines List Recommendations in Albania. *Eur J Med Transl Biosci*. 2026;1(1):49–81.