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AWARE-BASED COMPARISON OF ANTIBIOTIC DOSAGE FORMS IN POLAND AND UKRAINE

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ABSTRACT

The aim of the work was to comparatively analyze antibacterial medicinal products registered in Poland and Ukraine according to the World Health Organization AWaRe classification, with emphasis on dosage form diversity, age-specific orientation, and rational antibiotic use.

Materials and Methods. A descriptive comparative analysis was conducted using official data from the State Register of Medicinal Products of Ukraine and the Polish Medical Register as of early 2025. The dataset included 904 antibacterial products registered in Ukraine and 737 in Poland. Quantitative structural analysis was applied to assess the distribution of dosage forms within the Access, Watch, and Reserve groups, with particular focus on oral, parenteral, inhalation, pediatric-, and dysphagia-adapted formulations.

Results and Discussion. Marked structural differences between the two markets were identified. In Poland, oral dosage forms predominated in the Access (71.41%) and Watch (66.66%) groups, whereas in Ukraine their shares were lower (64.77% and 44.18%, respectively). Parenteral formulations were more prevalent in Ukraine, accounting for 55.08% of the Watch group and 67.91% of the Reserve group, compared with 37.54% and 58.66% in Poland. Pediatric- and dysphagia-adapted dosage forms were more consistently represented in Poland (19.04% of Access and 17.85% of Watch antibiotics) than in Ukraine (17.61% and 9.61%, respectively). Inhalation antibacterial medicines constituted 1.76% of registered products in Poland and were present in all AWaRe groups, whereas in Ukraine they were limited to two Watch-group products and absent from the Access and Reserve categories.

Conclusions. The Polish antibiotic portfolio demonstrates greater balance and diversification, with predominance of oral and patient-adapted dosage forms supporting outpatient treatment and antimicrobial stewardship. In contrast, the Ukrainian market is hospital-oriented, with reliance on parenteral formulations and limited availability of patient-adapted antibiotics. Expansion of oral and pediatric-oriented dosage forms in Ukraine is required to improve access to first-line therapy and alignment with WHO AWaRe principles.

Introduction. The increasing prevalence of antimicrobial resistance and the limited availability of antibacterial medicinal products in optimal dosage forms necessitate an assessment of the structure of national pharmaceutical registers. Particular importance is attached to the analysis of antibiotic portfolios with regard to dosage form diversity and age-specific orientation, as these factors critically determine the feasibility of rational use of antibacterial agents in both outpatient and inpatient settings. Comparative analysis of the pharmaceutical markets of Ukraine and European Union countries enables the identification of structural imbalances and potential directions for optimizing pharmaceutical provision.

Antimicrobial resistance remains one of the most pressing global public health challenges, largely driven by inappropriate and excessive antibiotic use, with significant clinical and economic consequences, as described by Ventola et al. [1].

Dosage form characteristics play a critical role in ensuring effective and safe pharmacotherapy, particularly in pediatric populations. Comprehensive reviews by Al-Japairai et al. and Strickley et al. have demonstrated that inappropriate oral dosage forms may negatively affect treatment adherence, dosing accuracy, and therapeutic outcomes in children [2–3]. As discussed by Al-Japairai et al., factors such as unpleasant taste, difficulties in swallowing solid forms, and the lack of age-adapted formulations frequently lead to therapy refusal, manipulation of dosage forms, or incorrect dosing, thereby limiting the real-world effectiveness of antibacterial treatment [2].

In the context of the global fight against antimicrobial resistance (AMR), the AWaRe classification developed by the World Health Organization (WHO) has become an effective tool for monitoring antibiotic use and shaping rational prescribing policies [4]. This system categorizes antibacterial agents into three groups – Access, Watch, and Reserve, which differ in terms of efficacy, safety, resistance potential, and recommended availability, as summarized in WHO regulatory frameworks and national stewardship adaptations, including the UK experience reported by Bou-Antoun et al. [4–5]. According to this classification, Access antibiotics should be made widely available as first-line agents with a low risk of resistance development, in line with WHO guidance referenced [4; 6]. The share of antibiotics from this group should account for at least 60% in hospital settings and 95% in outpatient care, as reported in WHO AWaRe monitoring frameworks and stewardship analyses [4–5; 7]. However, in Ukraine in 2024, the proportion of Access antibiotics did not exceed 59.1% in the outpatient sector and 39.8% in hospitals, indicating a significant deviation from global benchmarks [8–9].

The dosage form (DF) is one of the key factors determining the accessibility of antibiotics across different levels of healthcare delivery. In Poland, equitable distribution of antibiotic dosage forms within the framework of combating antimicrobial resistance has been achieved through systematic support of national pharmaceutical production and regulatory policies harmonized with European Union standards, particularly with regard to compliance with Good Manufacturing Practice principles, as reflected in regulatory and pharmaceutical frameworks of the European Medicines Agency and WHO manufacturing guidance [10–11]. Issues related to dosage-form subdivision and pharmaceutical quality are discussed in technological studies by Cunha-Filho et al. [12]. Polish drug registries record a broad range of antibiotic DF, including oral suspensions, powders for solutions, and parenteral DF, ensuring an adequate therapeutic choice depending on the severity of the clinical case, as documented in registry-based and stability analyses by Perks et al. [13] and sensory-evaluation studies by Zhang et al. [14].

In the Ukrainian pharmaceutical market, the main dosage forms remain solid oral medicines (tablets and capsules), which are convenient for outpatient use, as noted in stability and dosage-form studies. According to the study by Stechyshyn et al. [15], oral dosage forms predominate among Access antibiotics, while parenteral DF are mainly represented in the Watch and Reserve categories. The situation in Ukraine remains challenging due to excessive and irrational antibiotic use: according to national and international monitoring data, the share of Watch antibiotics in 2024 reached 32.4% in primary care (target value <5%) and 29.0% in specialized institutions. In contrast, the use of Access antibiotics remains below the recommended levels according to national monitoring and strategic documents [8–9].

A major step toward strengthening AMR control in Ukraine was the implementation of Order No. 1513 of the Ministry of Health, which regulates the rational use of antibiotics in accordance with the AWaRe classification and national regulatory standards [16], supported by established pharmacodynamic principles [17].

Studies conducted in low- and middle-income countries, including market analyses by Rani et al. and multicenter dispensing studies by Khan et al., have demonstrated that deviations from the recommended AWaRe distribution are a common challenge, often reflecting structural characteristics of national pharmaceutical markets rather than purely clinical decision-making [18–19].

Similar patterns have been reported in hospital- and system-level analyses, where antibiotic prescribing practices were shown to be influenced by availability constraints and market structure, as demonstrated by Nguyen et al. and Prajapati et al. [20–21].

It is evident that the effective implementation of the AWaRe classification principles is impossible without adequate development of the national pharmaceutical sector, particularly in the field of producing dosage forms that meet the needs of all three AWaRe categories. The availability of antibiotics in formulations optimal for different patient groups (oral, parenteral, pediatric, etc.) is a critical prerequisite for ensuring effective, safe, and convenient therapy in both outpatient and inpatient settings. In particular, the absence of oral forms of Access antibiotics may lead to the prescription of Watch or Reserve agents, which contradicts the principles of rational antibiotic use and contributes to the escalation

of resistance, as emphasized in WHO essential medicines frameworks for children [22].

In addition, the availability of appropriate oral dosage forms is a key prerequisite for the safe and timely transition from parenteral to oral antibiotic therapy. Clinical pharmacological analyses by Landersdorfer et al. indicate that an early intravenous-to-oral switch is feasible and clinically justified for many antibacterial agents, provided that suitable oral formulations with adequate bioavailability are available [23].

Previous comparative analyses by Semenchuk et al. have identified significant differences in the structure and availability of antibacterial medicinal products between the Ukrainian and Polish pharmaceutical markets, highlighting the need for a more detailed assessment of dosage form distribution within the AWaRe framework [24].

To better understand existing gaps and potential areas for improvement, a comparative analysis of the Ukrainian pharmaceutical market with that of EU countries – particularly Poland – is warranted. This approach enables the identification of differences in dosage form availability, structural barriers, and key priorities for optimizing antibiotic use in Ukraine.

The aim of this study was to conduct a comprehensive comparative analysis of registered antibacterial medicinal products in Poland and Ukraine as of early 2025 according to the AWaRe classification criteria, with a focus on dosage forms, age-specific availability, and alignment with the WHO-defined principles of rational antibiotic use.

Materials and methods. This study was designed as a descriptive and comparative analysis of antibacterial medicinal products registered in Ukraine and Poland. Data were obtained from official regulatory sources, including the State Register of Medicinal Products of Ukraine and the Polish Medical Product Register, as of early 2025 [25–26].

The analytical dataset included 904 antibacterial medicinal products registered in Ukraine and 737 products authorized in Poland at the time of data extraction [25–26]. Each registered product was considered an independent analytical unit, irrespective of active pharmaceutical ingredient, dosage strength, or manufacturer, allowing a comprehensive structural assessment of national antibiotic assortments.

All antibacterial medicinal products were classified according to the World Health Organization AWaRe framework into Access, Watch, and Reserve categories [4]. Within each AWaRe group, products were further categorized by dosage form as specified in the registration records. More than 20 distinct dosage-form types were identified, encompassing oral, parenteral, inhalation, and other dosage forms.

A quantitative structural analysis was conducted to determine the absolute number and proportional representation of each dosage form within individual AWaRe groups and across both national markets. Special attention was paid to dosage forms adapted for pediatric use and for patients with swallowing difficulties, including liquid oral preparations, dispersible tablets, sachets, and unit-dose formulations.

Data processing involved systematic grouping, calculation of percentage indicators, and construction of comparative structural diagrams. The results were interpreted in the context of rational antibiotic use and antimicrobial resistance containment strategies.

As the dosage-form structure of antibacterial medicinal products in the Ukrainian market according to the AWaRe classification has been comprehensively described in a previous publication, the present study focuses primarily on comparative analysis with the Polish pharmaceutical market [15].

Results and discussion. The obtained data made it possible to identify the specific distribution of dosage forms within each of the three AWaRe groups (Access, Watch, Reserve), to determine their orientation toward different patient categories, and to assess their potential alignment with the principles of rational antibiotic use in clinical practice.

These results are shown as part of a comparative analysis with Polish data, with emphasis on the most significant differences (Figure 1).

The results indicate that in both Poland and Ukraine, registered antibacterial medicines are available in a variety of dosage forms intended for different routes of administration. In some cases, individual antibiotics are available simultaneously in both oral and parenteral (injectable) DF. This situation may lead to discrepancies between absolute counts and percentage values, as the same medicinal product can be classified under multiple administration-route categories.

In Poland, the Access group includes 252 registered medicinal products (Figure 2), of which the majority – 71.41% are represented by oral dosage forms. In Ukraine, this share is slightly lower, accounting for 64.77% of 176 formulations. The Polish pharmaceutical market demonstrates a broader range of formulations suitable for children and patients with dysphagia. The proportion of such dosage forms in Poland reaches 19.04%, whereas in Ukraine it is 17.61%. Importantly, 70 parenteral formulations are registered in Poland, representing 27.78% of all Access medicines, while 62 parenteral forms are available in Ukraine (35.23%).

Analysis of the Watch group revealed that 381 antibacterial agents are registered in Poland (Figure 2), of which 66.66% are oral formulations. The most common among them are film-coated tablets (FCT), accounting for 40.16% of all oral forms. In Ukraine, the Watch group comprises 541 dosage forms, with oral formulations constituting only 44.18%. Similarly, film-coated tablets (FCT) dominate this category, representing 29.39% of the total. Within the Polish Watch group, the largest proportion of parenteral formulations consists of powders for solution for injection/infusion (PII, 14.70%), making them the leading dosage type in this category. A considerable share also includes powders for solution for infusion (PSInf, 11.55%), while powders for injectable suspension (PIS) account for 2.89%. In the Ukrainian Watch group, there are 298 parenteral formulations (55.08% of the total), dominated by powders for solution for injection (PSI) – 221 products, or 40.85%. Other parenteral forms are less common: powders for

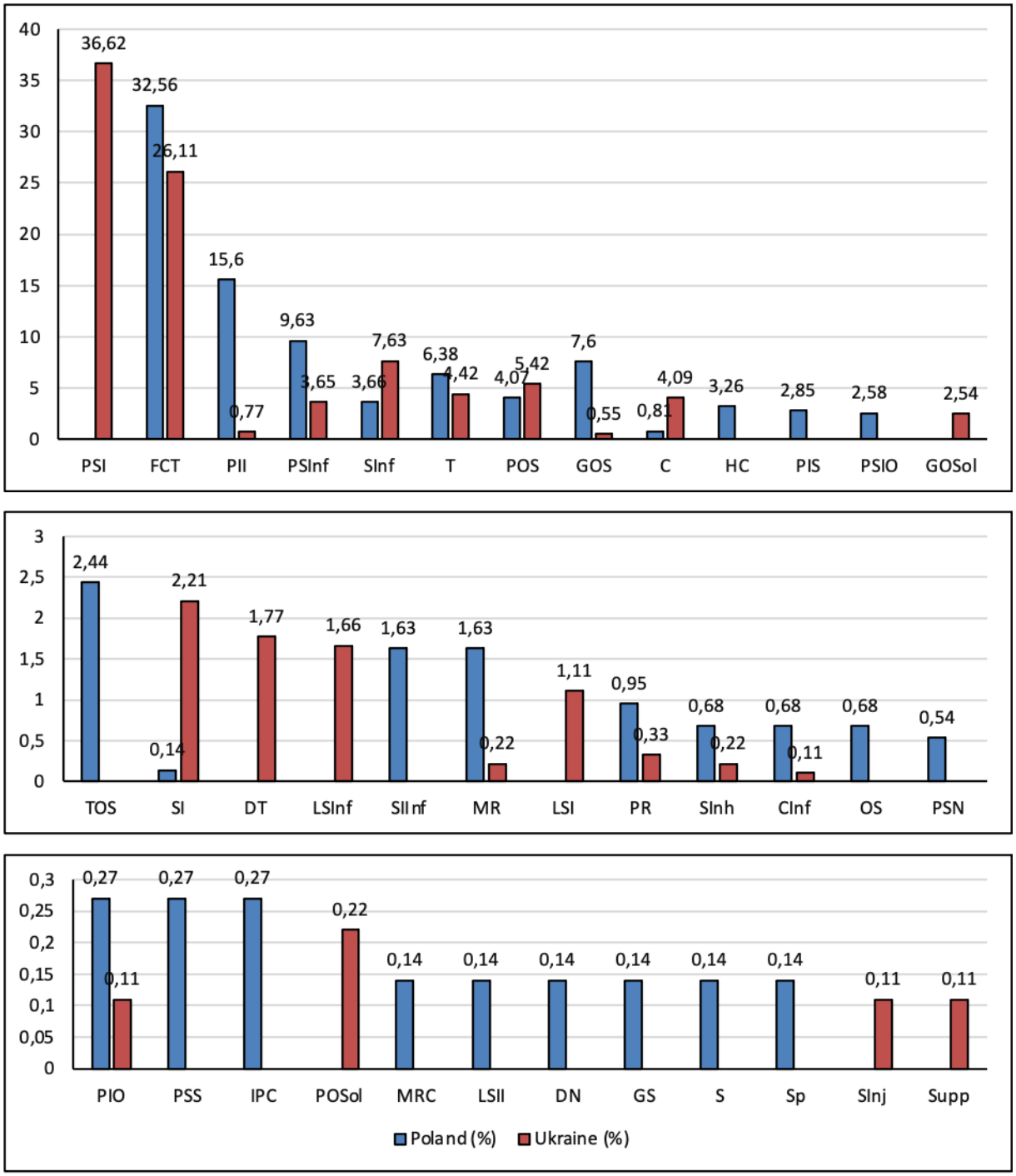

Figure 1. Structural characteristics of dosage forms of antibacterial agents included in the AWaRe classification and represented in the pharmaceutical markets of Ukraine and Poland

Note: ***C*** *– capsules;* ***CInf*** *– concentrate for solution for infusion;* ***DN*** *– dispersion for nebuliser;* ***DT*** *– dispersible tablets;* ***FCT*** *– film-coated tablets;* ***GOS*** *– granules for oral suspension;* ***GOSol*** *– granules for oral solution;* ***GS*** *– granulate for syrup;* ***HC*** *– hard capsules;* ***IPC*** *– inhalation powder in capsules;* ***LSI*** *– lyophilisate for solution for injection;* ***LSII*** *– lyophilisate for injection/infusion and inhalation;* ***LSInf*** *– lyophilisate for solution for infusion;* ***MR*** *– modified-release tablets;* ***MRC*** *– modified-release capsules;* ***OS*** *– oral suspension;* ***PII*** *– powder for injection/infusion;* ***PIO*** *– powder for iv and oral use;* ***PIS*** *– powder for injectable suspension;* ***POS*** *– powder for oral suspension;* ***POSol*** *– powder for oral solution;* ***PR*** *– prolonged-release tablets;* ***PSI*** *– powder for solution for injection;* ***PSInf*** *– powder for solution for infusion;* ***PSIO*** *– powder + solvent for injection/ infusion/oral;* ***PSN*** *– powder + solvent for nebuliser;* ***PSS*** *– powder for suspension in sachet;* ***S*** *– syrup;* ***SI*** *– solution for injection;* ***SIInf*** *– solution for injection and infusion;* ***SInf*** *– solution for infusion;* ***SInh*** *– inhalation / nebuliser solution;* ***SInj*** *– suspension for injection;* ***Sp*** *– sponge;* ***Supp*** *– suppositories;* ***T*** *– tablets;* ***TOS*** *– tablets for oral suspension*

solution for infusion (PSInf, 5.55%), solutions for infusion (SInf, 5.18%), lyophilisates for solution for infusion (LSInf, 2.77%), lyophilisates for solution for injection (LSI, 0.55%), and solutions for injection (SI, 0.18%). Regarding pediatric-oriented formulations, there are 68 such products in Poland (17.85%), compared with 52 in Ukraine. However, the proportion of pediatric formulations among oral medicines in Ukraine is markedly lower – only 9.61%. Notably, within the structure of parenteral products, substantial differences are observed: their share in Ukraine reaches 55.08%, while in Poland it is 37.54%.

The Reserve group comprises 104 products in Poland (Figure 2) and 187 in Ukraine. In both countries, the share of oral formulations is comparable, around 35%. Specifically, Poland has 37 oral medicines (35.58%), mainly film-coated tablets (FCT, 18.27%) and granules for oral suspension (GOS, 17.31%). In Ukraine, oral formulations represent 32.09%, with film-coated tablets (FCT, 25.67%) and granules for oral solution (GOSol, 6.42%) being the most prevalent. Parenteral formulations hold a leading position in both markets. In Poland, there are 61 such products (58.66%), primarily powders for solution for infusion (PSInf, 23.08%) and powders for injection/infusion (PII, 23.08%). In Ukraine, the proportion of parenteral agents is even higher, reaching 67.91% of the total Reserve group, with powders for solution for injection (PSI) predominating (42.78%). A notable share also includes solutions for infusion (SInf, 18.18%; 34 positions). Less common but still present in the Ukrainian register are lyophilized forms for injection (LSI), powders for injection/infusion (PII), and powders for solution for infusion (PSInf). Inhalation dosage forms among antibacterial medicines were identified predominantly in Poland, where 13 products (1.76% of the total) were registered: one in the Access group, five in the Watch group, and seven in the Reserve group (Figure 2). In contrast, the Ukrainian market is considerably narrower, with only two inhalation solutions (SInh) registered in the Watch group and none in the Reserve group. In addition, several atypical dosage forms were identified. In Ukraine, these include suppositories (Supp, Watch group) (pipemidic acid suppositories), while in Poland a sponge (Sp, Access group) was registered – each represented by a single product (gentamicin-impregnated collagen sponge).

A comparative analysis of registered antibacterial medicinal products in Poland and Ukraine according to the WHO AWaRe classification revealed significant differences in the structure of dosage forms and their targeting toward different patient groups.

Within the Access group, 252 antibacterial medicinal products were registered in Poland, of which 71.41% were oral formulations (Figure 2). In Ukraine, the corresponding indicator was lower – 64.77% out of 176 positions. Although oral dosage forms predominate in the Access group in both countries, their range, structure, and patient-oriented design reveal both common and divergent features. In both markets, a substantial share consists of film-coated tablets and hard capsules, which are typical formulations for adult patients. Powders and granules for oral suspensions, traditionally used in pediatric practice, are also represented.

The Polish market demonstrates greater pharmaceutical diversity and a pronounced focus on the needs of pediatric patients and individuals with dysphagia. According to Bou-Antoun et al. [5], diversification of oral antibiotic dosage forms within the Access group is a key prerequisite for effective implementation of the WHO AWaRe strategy, particularly in outpatient and pediatric practice. This tendency is clearly observed in the present study, where the Polish market demonstrates greater pharmaceutical diversity and a pronounced focus on the needs of pediatric patients and individuals with dysphagia. It includes formulations such as sachets, suspensions, syrups, and tablets for preparation of oral suspensions, providing high ease of administration and the possibility of individualized dosing across age groups. These forms constitute 19.04% of the total Access segment, indicating a deliberate pharmaceutical policy aimed at addressing the specific needs of vulnerable populations. Similar patterns of prioritizing pediatric-adapted oral formulations have been reported by Proud et al. [27] in national hospital and outpatient datasets in Scotland, where Access antibiotics were intentionally formulated to support step-down therapy and reduce hospitalization. In contrast, in the Ukrainian market such formulations constitute only 17.61%, indicating a structural limitation in pediatric and dysphagia-adapted provision.

This disproportion reflects structural differences in the pharmaceutical approaches of the two countries: while the Polish model prioritizes improved accessibility for patients with swallowing disorders and young children, the domestic market remains less flexible in forming a pediatric-adapted portfolio. Comparable disparities between high-income EU countries and resource-constrained systems were described by Rani et al. [18], who demonstrated that limited availability of child-friendly oral antibiotics constrains rational Access-group utilization. These observations are consistent with the findings of the present study for Ukraine.

The absence of certain formulations such as syrups, sachets, or dispersible tablets for suspension preparation in the Ukrainian portfolio may limit the clinical variability of antibacterial therapy and reduce convenience and compliance among pediatric patients and those with swallowing impairment [11]. According to Abu-Ajaleh et al. [7], inadequate availability of patient-adapted oral antibiotic formulations directly affects treatment adherence and increases inappropriate antibiotic use. This phenomenon is also observed in the present study, where the absence of syrups, sachets, and dispersible tablets in the Ukrainian Access portfolio may limit compliance among pediatric and dysphagic patients.

It should be emphasized that the expanded spectrum of oral dosage forms is crucial not only for pediatric practice but also for adapting therapy to the functional needs of adult patients [1; 28]. Similar conclusions were reached by Adekoya et al. [6], who emphasized that formulation diversity is as important as molecule selection for rational antibiotic use. In the present

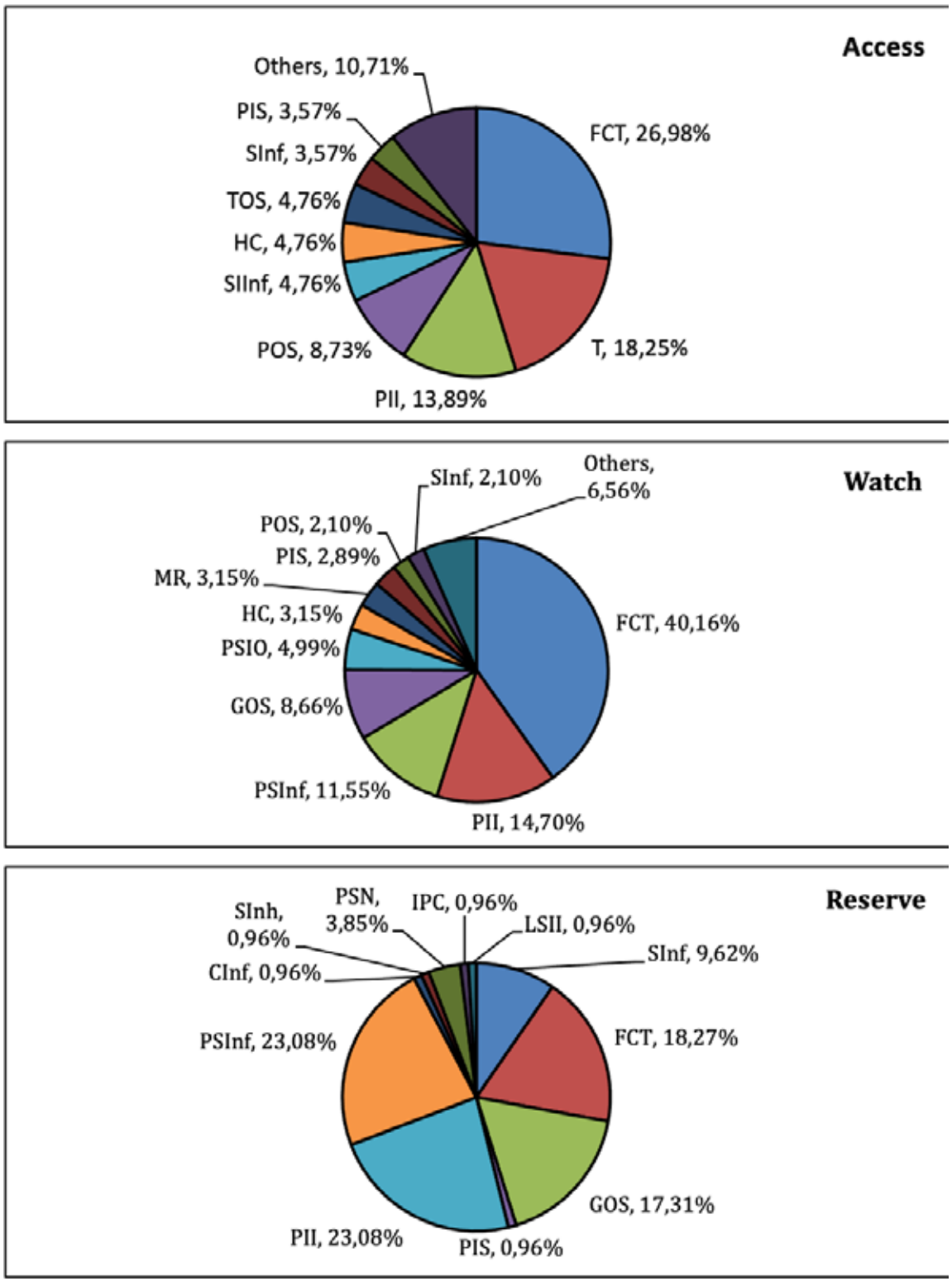

Figure 2. Distribution of antibacterial medicinal products in Poland by AWaRe group (Access, Watch, Reserve) and dosage form

Note: Abbreviations: ***CInf*** *– concentrate for solution for infusion;* ***FCT*** *– film-coated tablets;* ***GOS*** *– granules for oral suspension;* ***HC*** *– hard capsules;* ***IPC*** *– inhalation powder in capsules;* ***LSII*** *– lyophilisate for injection/infusion and inhalation;* ***MR*** *– modified-release tablets;* ***PII*** *– powder for injection/infusion;* ***PIS*** *– powder for injectable suspension;* ***POS*** *– powder for oral suspension;* ***PSInf*** *– powder for solution for infusion;* ***PSIO*** *– powder + solvent for injection/infusion/ oral;* ***PSN*** *– powder + solvent for nebuliser;* ***SIInf*** *– solution for injection and infusion;* ***SInf*** *– solution for infusion;* ***SInh*** *– inhalation / nebuliser solution;* ***T*** *– tablets;* ***TOS*** *– tablets for oral suspension.*

study, expanded oral-form availability in Poland supports improved adherence, reduced medication errors, and safer first-line antibiotic utilization. This enhances treatment adherence, improves therapeutic outcomes, and reduces the risk of medication errors – especially for first-line antibiotics characterized by a low resistance potential [2]. Moreover, the use of oral forms decreases the need for injectable interventions, thereby reducing healthcare-staff involvement [8]. Consequently, it helps shorten hospital stay duration and frequency, which is particularly important under resource-limited healthcare conditions [22].

Analysis of parenteral dosage forms within the Access group first-line antibacterials with a low risk of resistance development – revealed that they constitute 27.78% of the Polish assortment and 35.23% of the Ukrainian one. Both countries exhibit common and distinctive characteristics reflecting global trends and national approaches to clinical needs. In both, powders for solution for injection or infusion predominate, owing to their storage stability, transportability without quality loss, and flexibility for inpatient use.

Parenteral forms are primarily used in severe infections, emergency conditions, or when oral administration is impossible or provides insufficient bioavailability, which explains their prevalence in hospital practice despite the overall dominance of oral medicines within the Access group. According to Nguyen et al. [20], parenteral Access antibiotics remain indispensable for severe infections but should be progressively replaced by oral forms when clinically feasible. This principle is partially reflected in the present study, where Poland demonstrates a broader range of adaptable parenteral formulations enabling individualized administration strategies. Detailed analysis, however, shows differences in variability, specialization level, and clinical adaptability.

According to Landersdorfer et al. [23], early transition from intravenous to oral antibiotic therapy is pharmacologically justified and clinically safe for a wide range of antibacterial agents, particularly within the Access and Watch groups, provided that appropriate oral dosage forms are available. This principle is clearly reflected in the present study, where the Polish pharmaceutical market demonstrates a higher availability and diversity of oral formulations, enabling step-down therapy and outpatient continuation of treatment. In contrast, the limited oral assortment in Ukraine may represent a structural barrier to early IV-to-oral switching and prolong hospital-centered antibiotic use.

The Polish market exhibits a higher degree of specialization and clinical adaptability, demonstrated by the presence of combined formulations with extended administration flexibility. Notably, powders for preparing injection/infusion solutions (PII, 13.89%) and ready solutions for injection/infusion (SII, 4.76%) belong to combined forms suitable for both intravenous and intramuscular administration, with variable infusion duration depending on clinical context. Such pharmaceutical flexibility enables optimization of therapeutic strategies considering patient status, infection characteristics, and resource availability.

Additionally, powders for injectable suspensions (PIS, 3.57%) are represented in the Polish portfolio, expanding technologically adapted forms and providing controlled release or reduced tissue irritation at the injection site. In general, the diversity of combined forms in the Polish Access segment indicates a strategic effort toward individualization of treatment while adhering to rational antibiotic-use standards. Although ready-to-use infusion solutions (SInf) are represented by only three products (3.66%), this suggests a preference for stable formulations requiring reconstitution before administration, which are more logistically advantageous.

Conversely, the Ukrainian market is less variable and represented exclusively by powders for solution for injection (PSI, 17.05%), limited to bolus administration without infusion flexibility, thereby narrowing clinical applicability. In contrast, Saleem et al. [29] reported that limited variability of injectable formulations in resource-constrained healthcare systems leads to prolonged parenteral therapy and delayed switch to oral treatment. This observation corresponds with the Ukrainian pattern identified in the present study. However, the higher proportion of ready-to-use injectable solutions (SI, 10.80%) in Ukraine may reflect the need for rapid administration under resource constraints or emergency conditions where minimizing preparation time is critical.

Thus, while both countries demonstrate a general tendency toward reliable, evidence-based parenteral formulations aligned with principles of logistical efficiency, the Polish Access segment shows a greater degree of pharmaceutical specialization, reflected in a broader representation of functionalized forms adaptable to diverse clinical scenarios. In turn, the Ukrainian approach appears more pragmatic, focusing on simple, readily available formulations consistent with current national healthcare challenges.

Within the Watch group (Figure 2) antibacterials with higher resistance potential requiring controlled use – the analysis of dosage forms in Poland indicates a focus on ambulatory treatment. According to Proud et al. [27], high proportions of oral Watch antibiotics are a marker of mature antimicrobial stewardship systems aimed at reducing hospital burden. This tendency is clearly demonstrated in the present study for Poland, where oral formulations account for 66.66% (n = 254 of 381) of the Watch group. This distribution aligns with principles of clinical rationality and addresses the needs of children and dysphagic patients. Although pharmacoeconomic evaluations were not performed in this study, the predominance of oral forms likely correlates with improved cost-effectiveness through reduced hospitalization [8; 16]. Such a model supports global strategies aimed at reducing hospital load and expanding access to primary-care treatment under professional supervision [9; 22].

The Polish oral portfolio is dominated by film-coated tablets (FCT, 153 units) and includes pediatric-oriented formulations (17.85% of total). In contrast, in Ukraine, oral forms account for 44.18% (n = 239 of 541) in the same group, primarily film-coated tablets (FCT, 29.39%), while potentially pediatric formulations comprise only

9.61%, indicating limited access for children and patients with dysphagia. However, Khan et al. [19] reported that in systems with limited outpatient infrastructure, Watch antibiotics are predominantly administered parenterally, reinforcing hospital-centered care. This pattern closely mirrors the Ukrainian Watch-group structure identified in the present analysis.

Modified-release formulations (prolonged-release tablets (PR), standard tablets (T), modified-release tablets (MR), and capsules (C)) are considerably less frequent in Ukraine [15], whereas Poland shows a higher diversity, expanding options for personalized therapy [24]. Despite these differences, both countries retain a baseline presence of film-coated tablets, ensuring stability, dosing control, and pharmacoeconomic suitability for outpatient use. The importance of formulation technology for rational antibiotic use has been emphasized by Gujral et al. [30], who reported that modified-release dosage forms contribute to improved pharmacokinetic stability, reduced dosing frequency, and enhanced patient adherence. These findings correspond with the present study, where modified and technologically advanced oral formulations are more frequently represented in the Polish Watch group, while their scarcity in the Ukrainian market restricts opportunities for individualized outpatient therapy.

Analysis of parenteral forms within the Watch group highlights both commonalities and divergences reflecting national approaches to treating severe infections requiring systemic antibacterial therapy. Ukraine demonstrates a hospital-oriented pattern, with parenteral forms constituting 55.08% of the total, whereas Poland presents a balanced model (37.54% parenteral, 58.03% oral), favoring outpatient therapy under supervision. This aligns with modern antimicrobial-policy principles – ensuring effective ambulatory access to Watch antibiotics while preserving hospital resources for severe or complicated cases – thus supporting rational antibiotic use and clinical flexibility [31].

In Poland, powders for preparing solutions for injection/infusion (PII) are the predominant parenteral forms, providing flexibility for bolus or prolonged infusion use. Powders for solution for infusion (PSInf) and powders for injectable suspensions (PIS) are also represented, indicating a hospital orientation with adaptable administration modes. A notable advantage of the Polish market is the availability of ready-to-use infusion solutions (SInf) and concentrates for solution for infusion (CInf) for rapid therapy initiation in emergencies. Combined forms with a solvent (PSIO) and dual-use powders for infusion or oral solution (PIO) further enhance therapeutic flexibility and enable switch strategies [15]. According to Bou-Antoun et al. [5], the availability of dual-route or combined formulations is a cornerstone of modern AWaRe-aligned switch therapy. This is also observed in the present study for Poland, where combined parenteral forms facilitate transition from inpatient to outpatient care.

In Ukraine, parenteral forms dominate the Watch group – 298 products (55.08%), primarily powders for solution for injection (PSI, 40.85%), reflecting a preference for short-term intramuscular or intravenous administration with good stability and shelf-life. Other parenteral types constitute less than 5.55%. As in Poland, there is growing interest in flexible dual-route forms; in Ukraine, these are represented by dual-purpose powders (PIO, 0.18%), suitable for both injectable and oral use – indicating institutional interest in step-down (switch) therapy to transition from inpatient to outpatient treatment. Although Nguyen et al. [20] identified early adoption of step-down strategies in selected LMIC hospitals, such approaches remain limited. This is consistent with the marginal representation of dual-route formulations in the Ukrainian Watch segment identified in the present study.

Hence, flexible therapy forms are a shared trend, though the scale and form of implementation differ between systems.

The Reserve group, encompassing antibiotics for multidrug-resistant infections refractory to first- or second-line agents, warrants special attention. These drugs represent “last-resort therapy” and are used predominantly in hospital settings under strict authorization, ensuring appropriateness, safety, and efficacy [17]. According to Prajapati et al. [21], Reserve antibiotics should be tightly regulated and predominantly administered in inpatient settings to prevent resistance amplification. This stewardship-oriented approach is reflected in both national portfolios analyzed in the present study. Their registration profile allows assessment of national healthcare readiness to combat antimicrobial resistance and integration of stewardship principles into pharmaceutical policy.

Oral formulations are not predominant in this group, consistent with international practice: their share remains limited (~30% in both countries). In Poland, 37 oral forms (35.58%) were identified, primarily film-coated tablets (FCT) and granules for oral suspension (GOS) – the latter designed for pediatric, geriatric, and dysphagic patients [11]. In Ukraine, oral formulations comprise 32.09%, mainly film-coated tablets (FCT) and granules for oral solution (GOSol), also targeting special-needs populations. Other oral types – uncoated tablets, capsules, or dispersible forms – are absent, limiting dosing flexibility. Notably, Ukraine lacks additional pediatric formulations beyond granules for oral solution, constraining effective pediatric therapy for severe infections and complicating oral step-down transition after discharge [8; 25]. Similar constraints in pediatric access to Reserve antibiotics were described by Rani et al. [18], who reported limited child-friendly formulations for multidrug-resistant infections. This challenge is equally evident in the Ukrainian Reserve group identified in the present analysis.

The overall scarcity of oral forms in the Reserve group reflects its clinical specificity. Nonetheless, even a limited presence of specialized oral options enables therapy de-escalation and continuation of outpatient care following intensive parenteral courses, supporting treatment continuity and indicating partial integration of stewardship and patient-oriented approaches into national pharmaceutical policies.

Within the parenteral segment of the Reserve group, which dominates both national portfolios, Poland lists 61 products, mainly powders for solution for infusion (PSInf) and powders for preparing solutions for injection/infusion (PII) – each 23.08%. This pattern reflects a focus on formulations with high bioavailability and maximal therapeutic efficacy, typically used in hospital settings for severe clinical conditions. Dual-purpose powders (PII) provide flexibility between injection and infusion routes and support controlled, prolonged administration critical in multidrug-resistant infections. Other forms – powders for solution for injection (PSI) and concentrates for solution for infusion (CInf) – are rare, indicating their narrow or specialized use. Notably, combined parenteral-oral formulations (PIO) are absent, confirming Poland's hospital-oriented strategy without integrated de-escalation schemes.

In Ukraine, parenteral forms represent 67.91% of the Reserve group, confirming their key role in managing resistant infections. Powders for solution for injection (PSI, 42.78%) dominate, illustrating a pragmatic approach emphasizing simplicity, stability, and transportability – critical under resource constraints [26]. Infusion solutions (SInf, 18.18%) are also significant, mainly for supportive or prolonged therapy. Less common but present are lyophilisates for solution for injection (LSI), powders for injection/infusion (PII), and powders for solution for infusion (PSInf), providing supplementary options to enhance dosing flexibility.

Both countries share the predominance of parenteral forms in the Reserve group, consistent with the high pharmacological risk and need for intensive monitoring. However, structural differences highlight divergent pharmaceutical policies: Poland favors technologically advanced standardized infusion forms ensuring controlled pharmacokinetics, whereas Ukraine relies on injectable powders balancing efficacy, practicality, and pharmacoeconomic feasibility.

Thus, analysis of parenteral segments in both countries reveals not only a high level of therapeutic adequacy but also varying degrees of technological integration, resource planning, and individualization. The Polish system demonstrates stronger structural organization and focus on standardized inpatient infusion therapy, whereas the Ukrainian approach is more adaptable to real-world constraints yet potentially less robust for prolonged controlled regimens. Both models, despite differences, contribute to addressing global antimicrobial-resistance challenges, though further harmonization with principles of controlled, evidence-based, and patient-oriented antimicrobial use remains essential.

Finally, consideration of inhalation and non-typical dosage forms – although quantitatively minor in both national registers – is warranted due to their clinical relevance, targeted action, non-invasiveness, and contribution to individualized therapy.

In the Polish register, inhalation, combined, and non-standard forms occupy a distinct niche – only 1.76% (13 products) overall – but are crucial for conditions requiring localized delivery with reduced systemic exposure. Their presence indicates targeted use in respiratory infections where high local antibiotic concentrations are desired with minimal systemic toxicity.

Within the Access group, only one inhalation form (DN) was identified. No other inhalation variants (solutions, powders, or solvent-combination forms such as SInh, PSN, IPC) were found, indicating limited development or demand for localized therapy in low-resistance-risk infections.

In the Watch group, five inhalation medicines were registered – four nebulizer solutions (SInh) and one inhalation powder in capsules (IPC) – consistent with their use in complicated respiratory infections requiring targeted pulmonary delivery with reduced systemic load. The Ukrainian Watch subset includes two inhalation solutions (SInh), showing methodological similarity though smaller scale.

The Reserve group contains the largest number of inhalation products – seven – indicating high specialization for treating multidrug-resistant pulmonary infections demanding localized therapy. These include mainly powders with solvent for inhalation (PSN), as well as isolated nebulizer solutions (SInh), inhalation powders (IPC), and long-acting inhalation solutions (LSII). Their concentration underscores clinical selectivity for cases where standard oral or parenteral forms are ineffective or excessively invasive. In contrast, no inhalation forms are present in the Ukrainian Reserve segment, creating a gap in access to non-invasive targeted therapy for critical cases.

Inhalation dosage forms of antibacterial agents within the Watch and Reserve groups demonstrate high clinical relevance, particularly in the treatment of respiratory tract infections. However, they remain narrowly specialized and have not achieved widespread clinical application. Their absence within the Access group indicates limited integration of inhalation-based approaches into standard treatment protocols. Poland exhibits a more diversified portfolio of inhalation DF, especially within the Reserve group, whereas in Ukraine such products are represented only marginally and exclusively within the Watch category. According to Bou-Antoun et al. [5], inhalation antibiotics play a strategic role in managing resistant respiratory infections while minimizing systemic exposure. This is consistent with the present study, where Poland demonstrates a more diversified inhalation portfolio, particularly within the Reserve group. However, Saleem et al. [29] highlighted that limited access to inhalation DF in resource-constrained systems restricts targeted respiratory therapy. This observation aligns with the absence of Reserve-group inhalation antibiotics in Ukraine identified in the present study. This asymmetry reflects heterogeneity in pharmacotherapeutic strategies and highlights potential avenues for improving access to inhalation dosage forms – particularly in outpatient and pediatric practice, where non-invasiveness is of paramount importance.

Overall, although quantitatively limited, inhalation forms play a crucial role in targeted therapy of respiratory infections, especially where bacterial sensitivity to narrow-spectrum antibiotics is preserved. Their greatest concentration in the Reserve group may indicate a trend

toward the adoption of innovative delivery systems designed for complex clinical cases.

Within the Ukrainian Watch segment, the presence of a single suppository formulation (Supp) distinguishes it from the Polish portfolio and reflects a somewhat broader range of dosage forms adapted to individual patient needs – particularly where access to traditional administration routes is restricted or physiological limitations exist. Such a dosage form may be valuable in pediatric, geriatric, or palliative care, where non-invasiveness and ease of administration are of critical significance.

Another noteworthy finding is the inclusion of an unconventional dosage form – a sponge (Sp) – within the Access group of the Polish pharmaceutical market. Its registration likely corresponds to specialized surgical applications, primarily for localized antibiotic delivery to infected sites or for the management of superficial and deep skin infections. This example illustrates a multidirectional pharmaceutical approach, oriented not only toward systemic therapy but also toward localized targeted intervention, in line with modern principles of rational antimicrobial use.

Analysis of dosage-form structures for antibacterial medicines registered in both countries reveals a predominance of DF intended primarily for the adult population (Figure 1). This pattern is typical of markets oriented toward standardized production, fixed dosing, and mass consumption, which reduce logistic costs and manufacturing expenditures [12]. However, such an approach does not fully account for the therapeutic needs of vulnerable age groups, notably children and older adults [10; 11; 31].

Pediatric-adapted DF and dosage forms suitable for geriatric patients and individuals with dysphagia on the Polish market amount to approximately 134 products, including combination formulations, representing 18.19% of the total. According to Adekoya et al. [6], neglect of pediatric and geriatric formulation needs represents a systemic barrier to rational antibiotic use. This issue is clearly demonstrated in the present study, particularly in Ukraine, where pediatric-adapted formulations account for only 10.61%. Considering the substantial epidemiological burden of bacterial infections among children, as reported by WHO, pediatric antibiotic therapy requires individualized dosage forms – featuring pleasant organoleptic properties, flexible dosing options, and user-friendly administration routes (e.g., suspensions, sachets, dispersible tablets) [1; 32]. The limited availability of such formulations' points to an insufficient focus on pediatric needs during the development and registration of antibacterial products [11; 33].

Regulatory authorities have highlighted pediatric formulation development as a cornerstone of rational medicine use. According to the European Medicines Agency [34], the absence of age-appropriate dosage forms leads to dosing inaccuracies and irrational antibiotic exposure in children. This regulatory perspective is consistent with the present findings, which demonstrate a higher proportion of pediatric-adapted oral formulations in Poland compared with Ukraine, indicating better alignment with European stewardship and regulatory principles.

The lack of medicines tailored for geriatric use and for patients with swallowing disorders is equally concerning. Similar concerns were raised by Abu-Ajaleh et al. [7], who emphasized that dysphagia and polypharmacy in older adults require formulation-sensitive prescribing. The limited availability of such formulations identified in the present study confirms this gap. Elderly individuals frequently present polymorbidity, dysphagia, age-related pharmacokinetic and pharmacodynamic changes, and are subject to polypharmacy, which necessitates particular attention to formulation compatibility and administration convenience. The low representation of specialized formulations for this demographic indicates a structural deficit that should be addressed through formulary policy reform and state pharmaceutical-supply programs [8].

Swallowing dysfunction represents a significant but often overlooked barrier to effective oral pharmacotherapy. As reported by Stegemann et al. [35], the lack of dysphagia-adapted dosage forms frequently results in inappropriate tablet manipulation and reduced treatment safety. This issue is also evident in the present study, where the limited availability of liquid and dispersible antibiotics in Ukraine may compromise treatment adherence among pediatric, geriatric, and dysphagic patients, reinforcing reliance on parenteral therapy.

To improve the accessibility, safety, and efficacy of antibiotic therapy in vulnerable age groups, it is advisable to expand the range of dispersible tablets, chewable forms, ready-to-use liquids, inhalation suspensions, and unit-dose formulations (Figure 1). Such adaptation to patients' physiological characteristics would enhance treatment adherence, clinical outcomes, and reduce antimicrobial resistance risks.

Therefore, efforts should focus not only on expanding the diversity of dosage forms but also on ensuring equitable access across AWaRe groups. If user-friendly formulations are available for Watch antibiotics but not for Access agents, this may distort prescribers' choices even when clinical protocols are properly followed. Consequently, dosage-form analysis helps identify systemic barriers to the implementation of AWaRe principles, which hold direct implications for pharmacoeconomics and healthcare policy.

The analysis of the national structure of antibacterial dosage forms in Ukraine according to the WHO AWaRe classification (Access, Watch, Reserve) revealed a number of systemic barriers that complicate the realization of rational-use principles and directly affect the adaptability of clinical protocols, especially in primary care, pediatrics, and geriatrics. These barriers have both clinical and pharmacoeconomic significance, influencing physicians' prescribing decisions, therapeutic accessibility, and the overall effectiveness of the healthcare system.

Based on the analysis of antibacterial dosage forms in Ukraine, the following priority directions are recommended to strengthen the national healthcare system – particularly under wartime conditions:

Limited representation of specialized oral formulations for vulnerable groups (children, patients with dysphagia) underscores the need to expand domestic production or import of syrups, sachets, unit-dose powders, and tablets for suspension preparation. Compared with Poland, where 18.19% of oral antibiotics are pediatric-adapted, in Ukraine this share is only 10.61%. The Ministry of Health should prioritize these formulations for procurement and incentivize local production taking into account the needs of internally displaced persons and children in settings with restricted medical access.

The high share of ready-to-use injectable solutions (10.8% within the Access group) highlights their critical importance in emergency situations – particularly on the front line, in mobile hospitals, or in areas with limited infrastructure. These forms require no reconstitution and allow rapid administration. The Ministry should therefore support or stimulate production of such forms, especially for infusion therapy in sepsis, pneumonia, and severe trauma.

The limited variability of injectable formulations, notably the scarcity of combined or universal forms suitable for both intramuscular and intravenous administration (unlike in Poland), reduces clinical flexibility. The Ministry should include such formulations in procurement strategies, since their versatility enhances therapeutic adaptability under constrained conditions.

The low availability of inhalation formulations (powders, nebulizer solutions) in the Watch group and their absence in Access and Reserve categories necessitate a revision of priorities – particularly considering the rising incidence of respiratory infections among displaced populations, civilians in shelters, and field conditions. Localization or import of these formulations could improve therapeutic outcomes while reducing systemic exposure.

Shelf-stable formulations that do not require cold-chain storage (e.g., powders for injection preparation) hold strategic importance during wartime. Their stability and logistical convenience make them suitable for reserve stockpiling and distribution to remote regions.

The limited variability of forms in the Access category in Ukraine may hinder effective implementation of the AWaRe approach, which aims to expand access to antimicrobials with a low resistance potential. The Ministry of Health should utilize such analyses as a tool to evaluate not only the quantitative but also the functional composition of national formularies, ensuring alignment with real-world conditions of medicine use.

Conclusions. A comparative analysis of antibacterial medicinal products registered in Poland and Ukraine as of early 2025 according to the WHO AWaRe classification revealed substantial structural differences in the composition and functional orientation of national antibiotic assortments.

In Poland, the antibiotic market demonstrates a more balanced and diversified structure across the Access, Watch, and Reserve groups, accompanied by a clear predominance of oral dosage forms and broader availability of pediatric- and patient-adapted formulations. Oral antibiotics account for 71.41% of Access-group products and 66.66% of Watch-group products, supporting outpatient-oriented treatment strategies and step-down therapy. Pediatric- and dysphagia-adapted formulations represent approximately 18.19% of the total Polish antibiotic assortment, while inhalation antibiotics – although limited in number (1.76% overall) – are present within the Watch and Reserve groups, enabling targeted therapy for respiratory infections. Collectively, these features reflect a pharmaceutical system aligned with antimicrobial stewardship principles and WHO recommendations for rational antibiotic use.

In contrast, the Ukrainian antibiotic portfolio is characterized by a pronounced predominance of parenteral dosage forms and a more hospital-centered orientation. Parenteral formulations constitute 35.23% of Access-group, 55.08% of Watch-group, and 67.91% of Reserve-group antibiotics, indicating a strong reliance on inpatient treatment modalities. Oral formulations are less prevalent, particularly within the Watch group (44.18%), and pediatric-adapted products account for only 10.61% of the total assortment, highlighting limited accessibility for vulnerable patient populations. Moreover, inhalation antibacterial medicines are entirely absent from the Reserve group and only marginally represented within the Watch category, restricting access to non-invasive targeted therapy options.

Overall, the findings indicate a higher degree of conformity of the Polish antibiotic assortment with WHO AWaRe principles, particularly regarding prioritization of Access antibiotics, diversification of oral dosage forms, and support for outpatient care. For Ukraine, the results underscore the need to expand the range of pediatric- and geriatric-adapted formulations, increase the availability of oral and flexible dual-route antibiotics, and introduce innovative dosage forms, including inhalation therapies. Such measures are essential to strengthen outpatient-oriented treatment strategies, reduce unnecessary hospitalizations, and improve adherence to rational antibiotic-use principles.

The study's findings may be applied to inform national formulary policy development, optimize public procurement strategies, and refine clinical treatment guidelines by aligning them with the real-world availability and functional diversity of antibacterial medicines. Future research should focus on longitudinal analyses of antibiotic registration trends in Poland and Ukraine, assessing the impact of regulatory reforms, European Union harmonization processes, and antimicrobial stewardship programs on the structure of national antibiotic assortments and resistance-containment efforts.

Conflict of interest: the authors have no conflict of interest to declare.

ПОРІВНЯННЯ ЛІКАРСЬКИХ ФОРМ АНТИБІОТИКІВ У ПОЛЬЩІ ТА УКРАЇНІ ЗА КЛАСИФІКАЦІЄЮ AWARE

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Метою роботи було проведення порівняльного аналізу антибактеріальних лікарських засобів, зареєстрованих у Польщі та Україні, відповідно до класифікації AWaRe Всесвітньої організації охорони здоров'я з урахуванням різноманітності лікарських форм, орієнтованості на вікові групи пацієнтів та принципів раціонального застосування антибіотиків.
Матеріали і методи. Проведено описове порівняльне дослідження з використанням офіційних даних Державного реєстру лікарських засобів України та Польського реєстру лікарських засобів станом на початок 2025 року. Суцільна вибірка охоплювала 904 антибактеріальні лікарські засоби, зареєстровані в Україні, та 737 – у Польщі. Застосовано кількісний і структурний аналіз асортименту лікарських форм у межах груп Access, Watch і Reserve, зокрема співвідношення пероральних, парентеральних та інгаляційних форм, а також наявність лікарських засобів, адаптованих для педіатричного застосування та для пацієнтів із порушеннями ковтання.
Результати й обговорення. Встановлено суттєві структурні відмінності між асортиментами антибактеріальних лікарських засобів двох країн. У Польщі переважали пероральні лікарські форми у групах Access (71,41%) та Watch (66,66%), тоді як в Україні їх частка була нижчою і становила відповідно 64,77% та 44,18%. Водночас в Україні домінували парентеральні лікарські форми, частка яких у групах Watch і Reserve досягала 55,08% та 67,91% відповідно, порівняно з 37,54% і 58,66% у Польщі. Педіатричні та адаптовані лікарські форми були більш представлені в Польщі (19,04% у групі Access та 17,85% у групі Watch), тоді як в Україні ці показники становили 17,61% та 9,61%. Інгаляційні антибактеріальні лікарські засоби переважно були представлені в Польщі (1,76% загального асортименту) та охоплювали всі групи AWaRe, тоді як в Україні вони обмежувалися двома лікарськими засобами групи Watch.
Висновки. Структура асортименту антибактеріальних лікарських засобів у Польщі є більш збалансованою та різноманітною з переважанням пероральних і пацієнт-орієнтованих лікарських форм, що сприяє амбулаторному лікуванню та реалізації принципів антимікробного стримування. Натомість український фармацевтичний ринок характеризується стаціонаро-орієнтованою моделлю з високою часткою парентеральних форм і обмеженою доступністю лікарських засобів, адаптованих для дітей та пацієнтів із порушеннями ковтання. Отримані результати свідчать про необхідність розширення асортименту пероральних і педіатрично орієнтованих антибіотиків в Україні з метою підвищення доступності препаратів першої лінії та узгодження з рекомендаціями ВООЗ щодо класифікації AWaRe.
Ключові слова: антибіотикорезистентність, асортиментний аналіз, міжнародний маркетинг, класифікація ВООЗ Access/Watch/Reserve, раціональне застосування антибіотиків, фармацевтична політика, порівняльний аналіз, система охорони здоров'я.

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