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(RESEARCH ARTICLE)

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# Evaluation of the quality of antibiotics sold in Lubumbashi (DR Congo) by MIC and MBC

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## Abstract

**Introduction:** Antibiotics play a crucial role in reducing morbidity and mortality from infectious diseases worldwide. The objective of this study was to evaluate the MIC of beta-lactams and fluoroquinolones marketed in pharmacies in the city of Lubumbashi.

**Material and methods:** This is a descriptive cross-sectional study conducted from December 22, 2024 to March 10, 2025. The study involved community-acquired *Escherichia coli* strains isolated from urinary tract infections; as well as 4 antibiotics from 3 different pharmaceutical companies operating in Lubumbashi: ciprofloxacin; norfloxacin; amoxicillin + clavulanic acid and ceftriaxone.

**Results:** The pharmaceutical firm 1 has revealed that the *Escherichia coli* strains had MICs within the normal range for amoxicillin + clavulanic acid (5 strains/5); norfloxacin (3 strains/2).

For company 2, amoxicillin + clavulanic acid and norfloxacin had MICs within the normal range for all 5 strains. And for company 3, all 5 strains had MICs within the normal range for amoxicillin + clavulanic acid. The MBC/MIC report of antibiotics from different pharmaceutical firms, for which the MICs were within CLSI standards, revealed that the CMIs were bactericidal.

**Conclusion:** The antibiotics from pharmaceutical company 2 performed well compared to those from other companies; followed by the antibiotics from pharmaceutical company 1 and those from pharmaceutical company 3.

**Keywords:** Evaluation; Quality; Antibiotics; MIC; Lubumbashi

## 1. Introduction

Antibiotics play a crucial role in reducing morbidity and mortality from infectious diseases worldwide [1]. Their misuse and inappropriate use has led to the selection of multidrug-resistant bacteria. This is a growing global public health problem. The O'Neill report estimated that by 2050, 10 million deaths per year could be linked to antibiotic-resistant bacteria. This is a problem that affects all regions of the world, but it is most significant in sub-Saharan African countries [2,3].

The emergence and spread of antibiotic resistance expose patients to an increased risk of treatment failure. This leads to longer hospital stays, higher treatment costs, and increased morbidity and mortality, thus compromising the fight

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against infectious diseases [4]. One recognized reason for therapy failure is the pressure on drug selection, particularly when drugs are poorly chosen and administered at doses that are too low, leading to the survival of resistant bacterial populations or inducing antibiotic resistance mechanisms [5,6]. The ineffectiveness of antibacterial therapies necessitates not only the active search for new therapeutic strategies, but above all, the judicious selection of antibiotics based on various parameters, including microbiological ones [7].

The minimum inhibitory concentration (MIC) defines the in vitro levels of sensitivity or resistance of specific bacterial strains to the applied antibiotic [8]. A reliable MIC assessment significantly impacts the choice of a therapeutic strategy, which in turn affects the efficacy of anti-infective treatment [9]. To obtain a credible MIC, numerous factors must be considered, such as the appropriate choice of method, adherence to labeling guidelines, and a relevant interpretation of the results [10].

In this article, we wish to evaluate the MIC of beta-lactams and fluoroquinolones marketed in pharmacies in the city of Lubumbashi using the dilution method.

## 2. Material and methods

This is a descriptive cross-sectional study to evaluate the quality of antibiotics used in the treatment of bacteria isolated from community-acquired urinary tract infections in Lubumbashi; completion from December 22, 2024 to March 10, 2025. The study focused on community-acquired *Escherichia coli* (*E. coli*) strains isolated from urinary tract infections in patients seen at the Bacteriology Laboratory of the Higher Institute of Medical Techniques of Lubumbashi (ISTM/Lubumbashi) during the study period. It also examined four antibiotics from three different pharmaceutical companies operating in Lubumbashi: ciprofloxacin (500 mg tablet); norfloxacin (400 mg tablet); amoxicillin + clavulanic acid (500 mg/62.5 mg tablet); and ceftriaxone (1 g injectable).

To determine MIC values, we used Mueller-Hinton broth. Antibiotics were diluted in sterile distilled water to obtain an appropriate starting concentration, and the dissolved and diluted antibiotics were used to prepare working solutions in Mueller-Hinton broth [11,12]. The working solutions must contain double dilutions of antibiotics, with the range of concentrations used for testing depending on the specific drug and taking into account the critical MIC values for the reference strains. Subsequent double dilutions of the antibiotic should be performed using the schemes available in the literature [11] and proposed by EUCAST [13]. In the broth microdilution method, working solutions prepared with double dilutions of antibiotics are dispensed into appropriate wells of microtiter plates and, in this form, can be used directly for MIC determinations or stored in plastic bags for up to three months at a temperature ≤ −60 °C [11]. The inoculum to be treated with further dilutions of antibiotics up to final values of $5 \times 10^5$ CFU (colony forming units)/ml [11] from one of the bacterial suspensions of 0.5 McFarland units corresponds approximately to a culture density of $1.5 \times 10^8$ cells/ml and proceed with dilutions of the order of 100× up to a density of $10^6$ CFU/ml (9.9 ml of broth + 0.1 ml of 0.5 McFarland suspension) then distribution into wells containing the appropriate concentrations of antibiotics in the broth (50 µL of bacterial inoculum + 50 µL of liquid medium with antibiotic or 10 µL of inoculum for 100 µL of diluted antibiotic). If commercial assays with a lyophilized antibiotic are used in the wells, a $5 \times 10^5$ suspension should be obtained immediately by adding 50 µL of 0.5 McFarland suspension to 10 mL of broth [14]. Obtaining a 0.5 McFarland suspension is verified by measurements in a densitometer or spectrophotometer, where the absorbance at a wavelength of 625 nm should be between 0.08 and 0.13 [15,16]. The inoculum obtained in the microtiter plate wells should also be monitored. For this purpose, when using broth microdilution, 10 µL should be taken from the growth control well (Mueller-Hinton broth with bacterial suspension and without antibiotic). Obtaining a growth of 20 to 80 colonies of a given bacterial strain proves the density of 5 × 105 CFU/ml [11].

The MIC value is the lowest concentration of an antibiotic at which bacterial growth is completely inhibited. In the broth microdilution method, for some antibiotics, separate rules for reading the MIC value are used [15], including the use of resazurin (a weakly fluorescent blue dye), which is reduced by active bacteria to fluorescent resorufin (pink) [17].

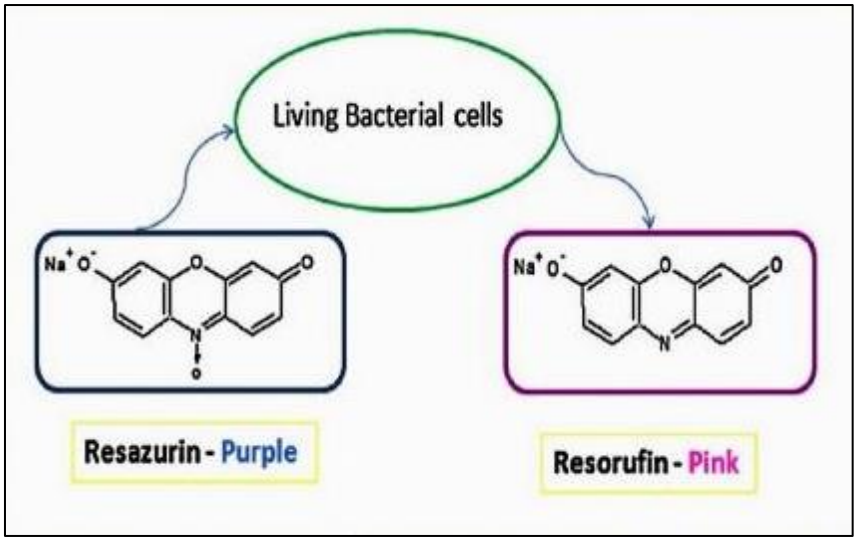


**Figure 1** Reaction of the transformation of resazurine into resorufin [18]

CMI according to CLSI standards [19]: Ciprofloxacin: 0.004-0.016 µg/ml; Norfloxacin: 0.03-0.12 µg/ml; Amoxicillin + clavulanic acid: 1-8 µg/ml; Ceftriaxone: 0.03-0.12 µg/ml.

The minimum bactericidal concentration (MBC), This is the lowest concentration of an agent capable of causing the death of at least 99.99% of the bacteria in an inoculum (< 0.01% survivors) [19]. For his determination, the broth dilution method was used to calculate the minimum biological concentration (MBC) of the antimicrobials. 0.1 mL aliquot was taken from the wells of microtiter plates where no growth was observed after 18–24 h of incubation at 37 °C and then inoculated on to the surface of Trypticase Soy Agar. The plates were incubated for 18–24 h at 37 °C. Since the detection limit of this technique is 10 CFU/mL, the absence of growth on Trypticase Soy Agar indicated that the concentration was below this value. The initial concentration of $10^5$ CFU/mL had thus been reduced to less than 10 CFU/mL. Therefore, the MBC was effectively considered to be activity involved of an antibiotic is defined by the ratio: MBC / MIC:

- MBC / MIC ≤ 4 Bactericidal antibiotics
- MBC / MIC = 4–32 Bacteriostatic antibiotic
- MBC / MIC => 32 Antibiotic tolerant bacteria

The sample size was convenient, consisting of 5 community-acquired *E. coli* strains and 5 batches of the same antibiotic for the 4 antibiotics mentioned above, from 3 different pharmaceutical companies operating in Lubumbashi. This study was approved by the medical ethics committee of the University of Lubumbashi under number UNILU/CEM/008/2025. Verbal consent was obtained from the respondents and their anonymity was guaranteed in the processing of the data. The data was entered and processed using Excel 2016.

## 3. Results

The results in Figure 2, concerning company 1, demonstrate that all 5 *E. coli* strains had MICs within the normal range for amoxicillin + clavulanic acid. However, not all strains were within the normal range for ceftriaxone. 3/2 strains had MICs within the normal range for norfloxacin, and finally, 4/1 strains did not have MICs within the normal range for ciprofloxacin.

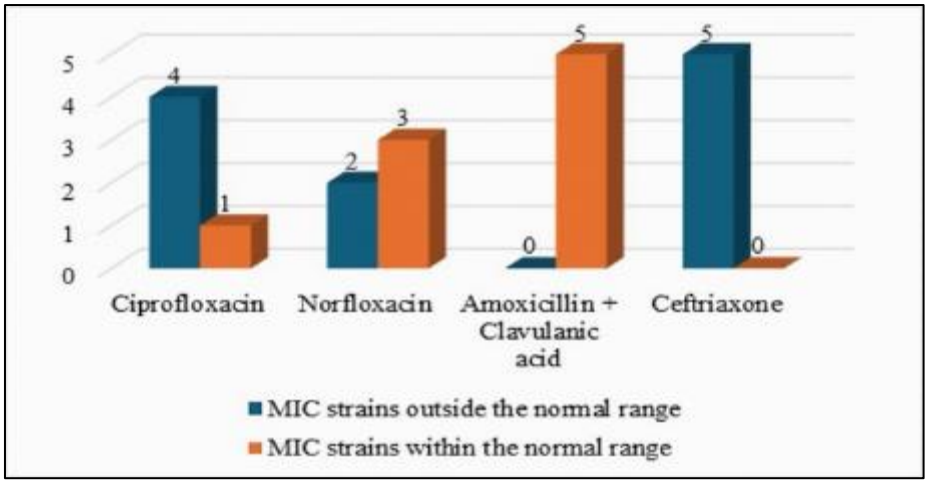


**Figure 2** MIC distribution of 5 *E. coli* strains according to CLSI standards for antibiotics from company 1

The results in Figure 3, concerning firm 2, demonstrate that all 5 *E. coli* strains had MICs within the normal range for amoxicillin + clavulanic acid and norfloxacin. However, not all strains had MICs within the normal range for ceftriaxone, and finally, 4 out of 1 strains had MICs outside the normal range for ciprofloxacin.

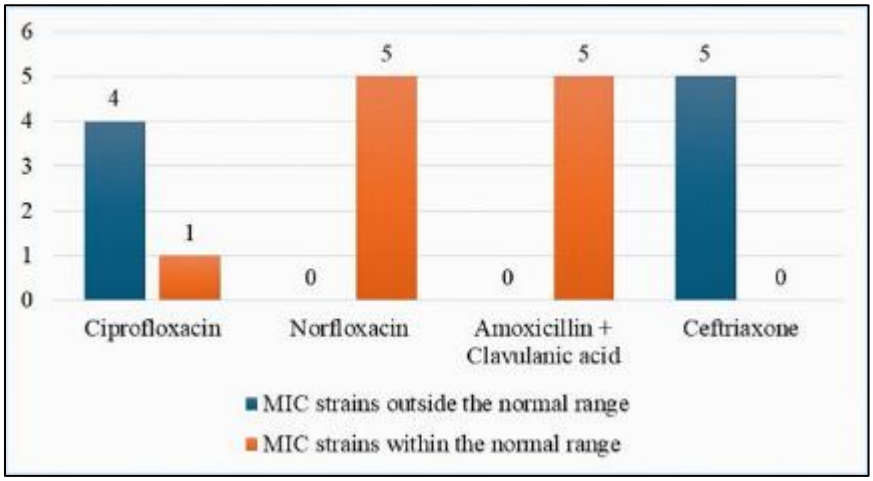


**Figure 3** MIC distribution of 5 *E. coli* strains according to CLSI standards for antibiotics from company 2

The results in Figure 4 for company 3 confirm that all 5 *E. coli* strains had MICs within the normal range for amoxicillin + clavulanic acid. However, not all strains had MICs within the normal range for ciprofloxacin and ceftriaxone, and finally, 3 out of 2 strains did not have MICs within the normal range for norfloxacin.

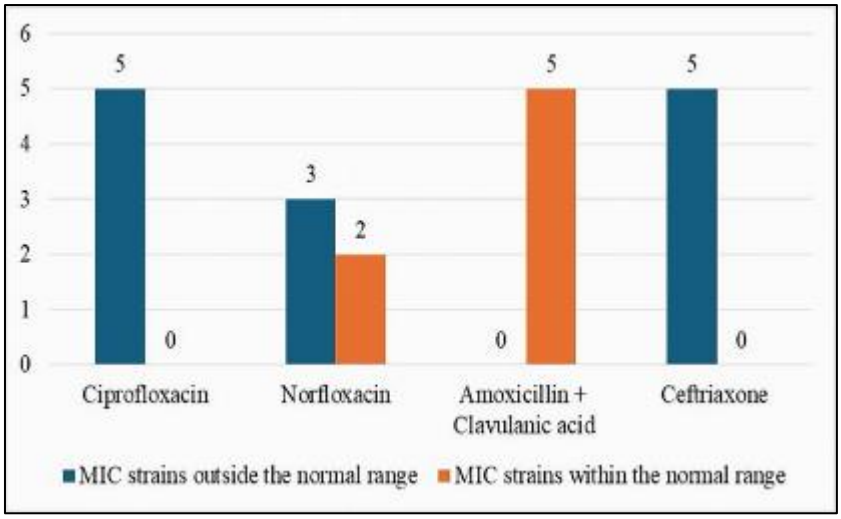


**Figure 4** MIC distribution of 5 *E. coli* strains according to CLSI standards for antibiotics from company 3

**Table 1** MICs of antibiotics from different pharmaceutical companies

| **ANTIBIOTICS** | ***MIC OF THE PHARMACEUTICAL FIRM 1*** | | | | | **CLSI STANDARD (µg/ml)** |
|---|---|---|---|---|---|---|
| | ***Strain E. coli 1*** | ***Strain E. coli 2*** | ***Strain E. coli 3*** | ***Strain E. coli 4*** | ***Strain E. coli 5*** | |
| Ciprofloxacin | - | - | - | - | 0,01234 | 0,004-0,016 |
| Norfloxacin | 0,08889 | - | - | 0,02963 | 0,02963 | 0,03-0,12 |
| Amoxicillin + Clavulanic acid | 0,140625 | 0,0703125 | 0,140625 | 0,140625 | 0,28125 | 1-8 |
| Ceftriaxone | - | - | - | - | - | 0,03-0,12 |
| ANTIBIOTICS | *MIC OF THE PHARMACEUTICAL FIRM 2* | | | | | CLSI STANDARD (µg/ml) |
| | *Strain E. coli 1* | *Strain E. coli 2* | *Strain E. coli 3* | *Strain E. coli 4* | *Strain E. coli 5* | |
| Ciprofloxacin | 0,01234 | - | - | - | - | 0,004-0,016 |
| Norfloxacin | 0,018 | 0,01481 | 0,01 | 0,04443 | 0,018 | 0,03-0,12 |
| Amoxicillin + Clavulanic acid | 0,28125 | 0,140625 | 0,0703125 | 0,140625 | 0,0703125 | 1-8 |
| Ceftriaxone | - | - | - | - | - | 0,03-0,12 |
| ANTIBIOTICS | *MIC OF THE PHARMACEUTICAL FIRM 3* | | | | | CLSI STANDARD (µg/ml) |
| | *Strain E. coli 1* | *Strain E. coli 2* | *Strain E. coli 3* | *Strain E. coli 4* | *Strain E. coli 5* | |
| Ciprofloxacin | - | - | - | - | - | 0,004-0,016 |
| Norfloxacin | 0,0987 | - | 0,011 | - | - | 0,03-0,12 |
| Amoxicillin + Clavulanic acid | 0,140625 | 0,140625 | 0,140625 | 0,28125 | 0,28125 | 1-8 |
| Ceftriaxone | - | - | - | - | - | 0,03-0,12 |

The results in Table 1 show the MICs of different antibiotics from various pharmaceutical companies compared to the MICs of CLSI standards. The numerical values in bold are for different strains of *E. coli* that meet these standards.

**Table 2** CMBs of antibiotics from different pharmaceutical companies

| **ANTIBIOTICS** | ***MBC OF THE PHARMACEUTICAL FIRM 1*** | | | | |
|---|---|---|---|---|---|
| | ***Strain E. coli 1*** | ***Strain E. coli 2*** | ***Strain E. coli 3*** | ***Strain E. coli 4*** | ***Strain E. coli 5*** |
| Ciprofloxacin | - | - | - | - | 0,01234 |
| Norfloxacin | 0,08889 | - | - | 0,02963 | 0,02963 |
| Amoxicillin + Clavulanic acid | 0,140625 | 0,0703125 | 0,140625 | 0,28125 | 0,28125 |
| Ceftriaxone | - | - | - | - | - |
| | *MBC OF THE PHARMACEUTICAL FIRM 2* | | | | |
| ANTIBIOTICS | *Strain E. coli 1* | *Strain E. coli 2* | *Strain E. coli 3* | *Strain E. coli 4* | *Strain E. coli 5* |
| Ciprofloxacin | 0,0411 | - | - | - | - |
| Norfloxacin | 0,018 | 0,04443 | 0,01 | 0,04443 | 0,018 |
| Amoxicillin + Clavulanic acid | 0,5625 | 0,28125 | 0,0703125 | 0,140625 | 0,0703125 |
| Ceftriaxone | - | - | - | - | - |
| | *MBC OF THE PHARMACEUTICAL FIRM 3* | | | | |
| ANTIBIOTICS | *Strain E. coli 1* | *Strain E. coli 2* | *Strain E. coli 3* | *Strain E. coli 4* | *Strain E. coli 5* |
| Ciprofloxacin | - | - | - | - | - |
| Norfloxacin | 0,329 | - | 0,011 | - | - |
| Amoxicillin + Clavulanic acid | 0,140625 | 0,140625 | 0,140625 | 0,28125 | 0,28125 |
| Ceftriaxone | - | - | - | - | - |

The results in Table 2 demonstrate the MBCs of the different antibiotics for different pharmaceutical firms for which the MICs were within the CLSI standards.

**Table 3** Interpretation of the CMB/CMI ratio according to the CLSI standard

| **ANTIBIOTICS** | ***RAPORT MBC/MIC OF THE PHARMACEUTICAL FIRM 1*** | | | | | **Interpretation criteria** |
|---|---|---|---|---|---|---|
| | ***Souche E. coli 1*** | ***Souche E. coli 2*** | ***Souche E. coli 3*** | ***Souche E. coli 4*** | ***Souche E. coli 5*** | |
| Ciprofloxacin | - | - | - | - | 1 | MBC MIC ≤ 4: Bactericidal antibiotics<br>MBC / MIC = 4–32 Bacteriostatic antibiotic<br>CMB / CMI ≥ 32 Antibiotic tolerant bacteria |
| Norfloxacin | 1 | - | - | 1 | 1 | |
| Amoxicillin + Clavulanic acid | 1 | 1 | 1 | 2 | 1 | |
| Ceftriaxone | - | - | - | - | - | |
| *RAPORT MBC/MIC OF THE PHARMACEUTICAL FIRM 2* | | | | | | |

| | | | | | |
|---|---|---|---|---|---|
| Ciprofloxacin | 1 | - | - | - | - |
| Norfloxacin | 3,3 | 3 | 1 | 1 | 1 |
| Amoxicillin + Clavulanic acid | 1 | 2 | 1 | 1 | 1 |
| Ceftriaxone | - | - | - | - | - |
| *RAPORT CMB/CMI OF THE PHARMACEUTICAL FIRM 3* | | | | | |
| Ciprofloxacin | - | - | - | - | - |
| Norfloxacin | 1 | - | 1 | - | - |
| Amoxicillin + Clavulanic acid | 1 | 1 | 1 | 1 | 1 |
| Ceftriaxone | - | - | - | - | - |

The results in Table 3 interpret the MBC/MIC ratio values of antibiotics from different pharmaceutical companies, for which the MICs were within CLSI standards. They represent the activity of an antibiotic based on the MBC/MIC ratio, according to whether it is ≤ 4: bactericidal antibiotic; 8–16: bacteriostatic antibiotic; and ≥ 32: antibiotic-tolerant bacteria.[19].

## 4. Discussion

The results found in this study share several points of agreement with other researchers who have worked on antibiotic use and *E. coli* strains. Our research reveals both strengths and weaknesses. Among the strengths is the marketing in Lubumbashi of antibiotics that did not produce MICs standardized according to CLSI standards. However, the small sample size of the antibiotics and pharmaceutical companies selected, as well as the lack of typing of the tested *Escherichia coli* strains, constitute the weaknesses of this study.

The determination of the quality of community-use antibiotics by the MIC of ciprofloxacin, norfloxacin, amoxicillin + clavulanic acid and ceftriaxone for different pharmaceutical firms tested against the 5 strains of community *E. coli* was carried out according to the CLSI reference standard.MICs address the clinical threshold, the antibiotic concentration used to indicate whether an infection with a particular bacterial isolate is treatable in a patient. Clinical thresholds are used by clinical microbiology laboratories to define patient isolates as susceptible (S), intermediate (I), or resistant (R) to a panel of antibiotics. Thus, the MIC test is the absolute reference for guiding physicians' treatment practices. Referring to the Clinical and Laboratory Standards Institutes (CLSI) tables, which address the standard performance of antimicrobials, notably through the determination of the MIC applied in mg/L or µg/mL [19].

The results of pharmaceutical firm 1 have been revealed.The antibiotics for which the MICs were within CLSI standards for the 5 *Escherichia coli* strains tested were: amoxicillin + clavulanic acid (5/5 strains), norfloxacin (3/5 strains), and ciprofloxacin (1/5 strain). However, for ceftriaxone, no MICs were within the standards for any of the 5 strains (Figure 2). Pourpharmaceutical firm 2,Norfloxacin and amoxicillin + clavulanic acid yielded MICs within CLSI ranges for all 5 strains, and ciprofloxacin for 1 strain out of 5. However, for ceftriaxone, the MIC was not within ranges for any of the 5 strains (Figure 3). And finally, pourpharmaceutical firm 3,Amoxicillin + clavulanic acid yielded MICs within CLSI standards for all 5 strains, and norfloxacin for 2 out of 5 strains. However, for ceftriaxone and ciprofloxacin, none of the MICs were within CLSI standards for any of the 5 strains (Figure 4). We found that amoxicillin + clavulanic acid yielded MICs within CLSI standards for all 3 pharmaceutical companies and for all 5 *Escherichia coli* strains tested, followed by norfloxacin. In contrast, not all the MICs for the 5 *Escherichia coli* strains were within CLSI standards for ceftriaxone, and most were outside these ranges for ciprofloxacin. The antibiotic families tested in this study are mostly used in Lubumbashi, which is consistent with the results of Tshilumba in 2021 in Lubumbashi with the beta-lactam family at 49% followed by quinolones at 12% [20].

We highlight two realities in light of these results: firstly, the notion of resistance in community-acquired *E. coli* strains due to extended-spectrum beta-lactamases, as the amoxicillin + clavulanic acid molecule showed no problems against

these bacterial strains. This resistance of *Escherichia coli* strains to beta-lactams and fluoroquinolones was also found by Ndete et al., 2020 in Lubumbashi, with 50% resistance to ciprofloxacin [21]; KH Baka et al., in 2015, observed an average resistance rate to ciprofloxacin of 54% [22]; According to the first antibiotic resistance surveillance data published by the WHO, between 8% and 65% of *Escherichia coli* associated with urinary tract infections exhibited resistance to ciprofloxacin, an antibiotic commonly used against these infections [23]. Secondly, the issue of substandard or falsified medicines sold in pharmaceutical depots in Lubumbashi. This aspect was revealed by Tshilumba 2021 that in Lubumbashi, 43% (44/102) of the medicines collected were not registered and authorized for marketing in the DRC [20]; while the MA is the guarantor of the quality of medicines, it is likely that the high proportion of medicines without MA in the DRC is partly responsible for the cases of falsified and substandard medicines reported in this country [24,25].

Most studies to date have shown that the value of determining the MIC depends primarily on a "theoretical" MIC; generally, the highest MIC for the chosen antibiotic found in the species responsible for the infection. However, this carries a risk of individual carelessness and collective overuse of antibiotics [26]. Indeed, determining the MIC helps researchers and clinicians detect new resistance patterns and can therefore anticipate whether treatment needs to be modified or new antibiotics need to be developed [27]. The MIC can thus be an important surveillance tool for monitoring the spread of resistant pathogens and informing infection control strategies [28]. Although it is difficult to predict the clinical outcome of an infection based solely on the MIC value, it can help in choosing the most appropriate treatment. It defines in vitro the levels of sensitivity or resistance of specific bacterial strains to a targeted antibiotic [29].

## 5. Conclusion

Determining the quality of antibiotics used in the community revealed that antibiotics from pharmaceutical company 2 performed well compared to those from other companies; followed by antibiotics from pharmaceutical company 1 and those from pharmaceutical company 3. Amoxicillin + clavulanic acid from all 3 companies produced MICs that were within CLSI standards for all 5 strains of *E. coli*; followed by norfloxacin from company 2. However, ciprofloxacin and ceftriaxone did not perform well overall.

The interpretation of the MBC/MIC ratio values of antibiotics from different pharmaceutical firms, for which the MICs were within CLSI standards, revealed that the MICs were bactericidal.

## Compliance with ethical standards

### *Disclosure of conflict of interest*

No conflict of interest to declare.

### *Statement of ethical approval*

This study was approved by *the* medical ethics committee of the University of Lubumbashi under number UNILU/CEM/008/2025 after the study.

### *Statement of informed consent*

Informed consent was obtained from all individual participants included in the study.

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