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# Contents of Amoxicillin Drugs Dispensed in Goma, Democratic Republic of Congo

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## Abstract

We studied 15 specimens of amoxicillin and 9 specimens of amoxicillin-clavulanic acid collected from pharmacies in Goma, DR Congo. Their claimed origin was India (n=11), DR Congo (n=5), France (n=4), Kenya (n=1), China (n=1), Germany(n=1), and Switzerland (n=1). The specimens were checked for falsifications following the WHO checklist. Content identity and amount of antibiotics in the specimens was investigated by Ultra High Performance Liquid Chromatography coupled with tandem mass spectrophotometry (UHPLC-MS/MS) and diode array detection (UHPLC-DAD). Nine of the 24 samples fulfilled the WHO criteria of counterfeit drugs, but all samples contained the active ingredients as claimed on the packages. We found under dosage of 90% and less in 3 of the 15 amoxicillin samples and in none of the 9 combined specimens. Amoxicillin over dosage (defined as 110% or more of indicated content) was found in 3 of the amoxicillin and in 1 of the combined specimens. Clavulanic acid was underdosed in none but overdosed in 5 of the 9 combined specimens. Our results highlight the need for drug quality control through inspection and specific analytical methods such as spectrophotometry and chromatography to reduce the public health challenge of illegal and substandard medicines in sub-Saharan Africa.

***Keywords:*** *Content of Amoxicillin, Drugs dispensed in Goma, Quality of amoxicillin in DRC*



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## 1. Introduction

Counterfeit and substandard medicines are a worldwide problem. According to WHO, they represent more than 50% of the world drug market (WHO, 2018; Delepierre *et al.*, 2012). The circulation of counterfeit medicines is higher in low-resource countries due to lack of pharmaceutical regulation (Almuzaini *et al.*, 2013). The most targeted classes of medicines in low resource countries are antibiotics, anti-malaria drugs and anti-tuberculosis drugs (Awad *et al.*, 2005; Mhando *et al.*, 2016). According to the United States Food and Drug Administration, between 10 and 30% of the illegal and substandard medicines are consumed in developing countries, including South-East Asia, Latin America and sub-Saharan Africa (Delepierre *et al.*, 2012). In such a context, the question of quality and conformity arises (Kelesidis and Falad, 2015; Nebot *et al.*, 2017). While there is a wealth of literature on counterfeit and substandard medicines in developed countries (Fleming-Dutra *et al.*, 2016; and Mc Donagh *et al.*,2018), there are few published data and studies on this phenomenon in Africa. In the Democratic Republic of Congo (DRC), regulation of pharmaceuticals are weak. The pharmaceutical profile survey shows that medicines are still a commodity in general trade (Ministère de santé publique, 2011). Among antibiotics, amoxicillin and amoxicillin-clavulanic acid are the most consumed ones (Ministère de santé publique, 2011; Busha *et al.*, 2020).

The aim of this study was to analyze the quality and to determine the amounts of amoxicillin and amoxicillin clavulanic acid in drugs dispensed in the pharmacies of the city of Goma where antibiotics are easily accessible without medical prescription.

## 2. Materials and Methods

15 specimens containing amoxicillin and 9 specimens containing amoxicillin-clavulanic acid (amoxiclav) were collected randomly according to the WHO sampling procedure (OMS, 1999) in different dispensaries and pharmacies of the city of Goma, Democratic Republic of Congo, between July 1, and November 31, 2019. The ambient temperature varied between 19 °C and 24 °C during this time of the year. The packages were carefully inspected and classified in accordance with the WHO checklist (WHO, 1999; Hollein *et al.*, 2016; Schiavetti *et al.*, 2020). The samples were then sent to the Faculty of Pharmacy of the Université Libre de Bruxelles and analyzed by the laboratory of medicines and health products of Sciensano. Identification was done using Ultra High Performance Liquid Chromatography coupled with tandem mass spectrophotometry (UHPLC-MS /MS) (Schiavetti *et al.*, 2020). Quantification was performed using diode array detection (UHPLC-DAD) following methods, described by Tie *et al* (2019).

## 3. Sample Processing

All suspension and syrup samples have been analyzed. For tablets and capsules, the number of units to be analyzed was determined as follows: (i) if the number of units available was less than or equal to 3, one unit was analyzed; (ii) if the number of units available was greater than 3 but less than or equal to 11, half of the units was used for analysis; (iii) if the number of units was greater than 11, the number of units to be analyzed was a quarter of the total number of units with a maximum of 20 units. Samples were accurately weighed (Tie *et al.*, 2019). To 25 mg of the pulverized substance, approximately 20 mL of methanol / $H_2O$ (50:50, v/v) solvent was added followed by ultra-sonication for 15 min. The resulting solution was made up to 25.0 mL and diluted 10 times with methanol / $H_2O$ (50:50, v/v). The solution was filtered through a 0.2 µm polytetrafluoroethylene (PTFE) filter before the injection step.

## 4. Screening for Content

Screening was performed by UHPLC-MS/MS on a Dionex UltiMate 3000 Rapid Separation LC (RSLC) system (Thermo Scientific, Sunnyvale, CA, USA) connected to an amaZon™ speed ETD mass spectrometer (Bruker Daltonics, Bremen, Germany). The chromatographic separation was carried out at 25 °C on a Waters Acquity BEH shield RP18 column (150 mm × 2.1 mm, 1.7µm). The flow rate was 0.3 mL/min and the injection volume was 2 µL. Mobile phases A and B consisted respectively of 0.1% formic acid in water and 0.1% formic acid in acetonitrile. The total run time was 18 minutes. The mass spectrometer settings were based on those described by Tie *et al.* (2019).

## 5. Quantification

Calibration standards were prepared by diluting a stock solution of amoxicillin and/or clavulanic acid of 1 mg/mL in methanol/$H_2O$ (50:50, v/v). The solutions were filtered through 0.2 µm PTFE filters before injection. Sample were

quantified using an Acquity UHPLC system (Waters, Milford, MA, USA) equipped with a binary solvent manager, a sample manager and a DAD detector. Optimal separation was achieved on a Waters Acquity BEH shield RP18 column (150 mm × 2.1 mm, 1.7 µm). Column and sample temperatures were maintained at 25 °C and 15 °C respectively. The injection rate was 0.2 mL/min and the injection volume was 5 µL. The gradient consisted of 0.01% formic acid in water as phase A and acetonitrile as phase B. The gradient started with an isocratic elution of 99% of phase A over 5 min, followed by a linear dilution to 85% over 10 min. Then the percentage of phase A decreased linearly to 25% in 15 min and a return to the initial composition in 2 min. A wavelength scan with the diode array detector was performed for all samples in the range of 190-400 nm for identification of each sample. Screening and quantification method were validated according to ISO:17025 as described by Tie *et al.* (2019) (SISO/IEC17025, 2007; Feinberg, 2007; and European Commission, 2018). Under dosing was defined as a drug content of 90% or less, overdosing as a drug content of 110% or more of the labeled amount (Roumeliotis *et al.*, 2020).

## 6. Results

### *6.1. Visual Counterfeit Indicators*

Of a total of 15 samples of amoxicillin and 9 samples of amoxicillin-clavulanic acid, 11 claimed to be from India, 5 from DR Congo, 4 from France, and 1 each from Kenya, China, Germany, and Switzerland. However, a close examination of all the labels of samples purporting to come from DR Congo pointed towards a source in India. On close visual observation of their labeling, some samples showed evidence of counterfeiting or sub-standard quality. The Cemoxil boxes and vials differed in the labeling and color (Appendix 1). The visual WHO criteria of suspected falsification are given in column 8 of Table 1. Most frequent were lacking information on storage (2, 3, 6, 14, 15, 16), lacking expiratory date (1, 2, 3, 5, 6, 14, 15, 16), absent batch number (1, 2, 3, 5, 6, 14, 15, 16), and absent address of manufacturer or responsible person (1, 2, 3, 6, 12, 14, 15, 16).

### *6.2. Content Analysis*

All investigated samples contain the labeled substances, no additional peaks could be identified in the chromatograms (Figures 1 and 2).

**Table 1: Profile of Amoxicillin and Amoxicillin-Clavulanic Acid Specialties Collected From Pharmacies in Goma, Dr Congo. Counterfeit Code Gives The Number of Who-counterfeit Criteria Not Med By the Product (Packaging, Storage Conditions, Identification, Expiry Date Outside And Inside, Address of Responsible Person, Batch Number). Content Indicates Percentage of the Compounds Actually Measured in Relation to the Amount Labeled on the Product**

| | Specialty | Form | Compound | Producer | Batch number | Origin claimed | Counter-feit code | Content In % |
|---|---|---|---|---|---|---|---|---|
| 1 | Cemoxil 250mg/5ml | Syrup | A | Aura Pharmaceuticals PVT/New cesamex | KD-2660-A | Inde | 4 | 101.3 |
| 2 | Cemoxil 250mg/5ml | Syrup | A | New cesamex | 663218 | DRC | 5 | 91.7 |
| 3 | Amoxy 125/5ml | Syrup | A | Momax Labo Pharma | NA | DRC | 6 | 70.7 |
| 4 | Moxacil 250mg/5ml | Syrup | A | Dawa | 1712047 | Kenya | 0 | 116.0 |
| 5 | Hipen 125mg/5ml | Syrup | A | Zydus Cadila | G/1174 | Indc | 2 | 110.5 |
| 6 | Amoxin250mg | Syrup | A | Phatkin | 59D18 | DRC | 6 | 95.3 |
| 7 | Amoxy 250 mg | Syrup | A | Shalina | P7507 | Inde | 0 | 99.3 |
| 8 | Clamoxyl 250mg/5ml | Syrup | A | GSK | SK3M | France | 0 | 100.9 |
| 9 | Clavuzam 400/57mg | Syrup | A/C | ALISON | ED18E002-1 | Inde | 0 | 102.9 105.0 |

Table 1 (Cont.)

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 10 | Dafraclav 200/28mg | Syrup | A/C | Dafra pharma | 18141034A | Suisse | 0 | 110.4<br>120.7 |
| 11 | Moxiclav DUO 457mg/5ml | Syrup | A/C | Shalina | M8004 | Inde | 0 | 102.3<br>116.8 |
| 12 | Amoclav 400 +57mg/5ml | Syrup | A/C | HEXAL | HE1661 | ND | 2 | 105.1<br>126.4 |
| 13 | Auroclav 250+31.25 | Powder for suspension | A/C | Medicef Pharma | 1800365-1 | India | 0 | 108.1<br>122.7 |
| 14 | Amoxicillina 500mg | Capsule | A | REYOUNG PHARMA | NA | Chine | 6 | 98.0 |
| 15 | Zenoxyl 500mg | Capsule | A | ZENUFA | 16C-27 | DRC | 6 | 89.8 |
| 16 | Caisamox 500 | Capsule | A | CAISA PHARMA INTERNATIONAL | NA | DRC | 6 | 82.7 |
| 17 | Amoxy 500 | Capsule | A | Shalina | P8050 | India | 0 | 97.8 |
| 18 | Augmentin 500/62.5mg | Tablet | A/C | GSK | 3,40094E+12 | France | 0 | 100.3<br>101.6 |
| 19 | Auroclav 562.5 mg | Tablet | A/C | Medicef Pharma | MB/09/775 | Inde | 0 | 100.3<br>97.8 |
| 20 | Amoxiclav Denk 1000/125 | Powder for susspension | A/C | Denk Pharma | 21885 | Germany | 0 | 93.8<br>109.6 |
| 21 | Hinconcil 250/5ml | syrup | A | - | - | France | 0 | 95.8 |
| 22 | Curam | syrup | A/C | Sandoz | KD5594 | France | 0 | 105.7<br>125.7 |
| 23 | Uniclav DUO 565.5 | Tablet | A/C | Unique Pharma | 2000586-1 | India | 0 | 103.4 |
| 24 | ACLAV 1000/125mg | Powder for suspension | A/C | Pharmas | 9762 | India | 0 | 98.5 |

**Note:** A = Amoxicillin; A/C = Amoxicillin and Clavulanic acid; NA = Not Available.

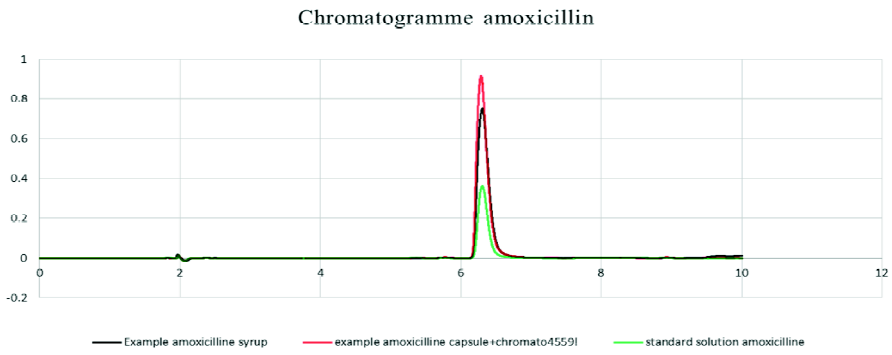


**Figure 1: Chromatogram of Amoxicillin Preparations. Black: Amoxicillin Syrup; Red: Amoxicillin Capsule; Grey: Amoxicillin Standard Solution. X-axis (AU) Y-axis: Time (min)**

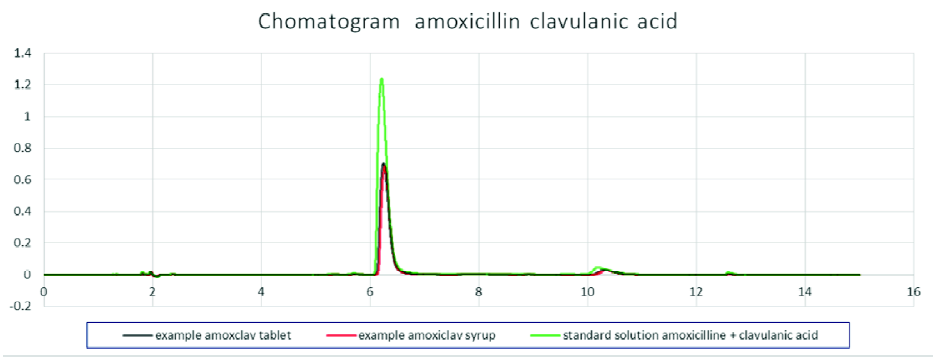


**Figure 2: Chromatogram Amoxicillin Clavulanic Acid. Black: Amoxyclav Tablet; Red: Amoxyclav Syrup; Grey: Standard Solution Amoxicillin + Clavulanic Acid. X-axis (AU)…. Y-axis: Time (min)**

### *6.3. Underdosing*

In the amoxicillin group, 3 of the 15 samples had less than 90% of the labeled content (samples 3, 15, 16). Of note, these 3 samples had the highest score of the WHO-falsification suspect. In the amoxicillin-clavulanic acid group, no underdosing of 90% or less was observed.

### *6.4. Overdosing*

In the amoxicillin group, the labeled content was exceeded by 110% in 2 of the 15 samples (4, 5). In the combined group, 1 of the 9 samples showed an amoxicillin content of 110.4% (10), and 5 showed clavulanic acid contents exceeding 110% (10, 11, 12, 13, 22).

## 7. Discussion

The aim of this study was to analyze the quality and to determine the amounts of amoxicillin and amoxicillin clavulanic acid in drugs dispensed in the pharmacies of the city of Goma where antibiotics are easily accessible without medical prescription. Initial visual observations revealed some evidence of counterfeiting or sub-standard quality by referring to the WHO standardized visual inspection checklists. Screening results showed that all samples contained the active ingredients as claimed on their packaging, overall 46% of the samples analyzed were not conform to what they were claimed. The analysis of different samples of amoxicillin and clavulanic acid in amoxi -clav (quantification by UHPLC) (Tie *et al.*, 2019) shows that one out of five amoxicillin samples are under dosed while more than half of the amoxicillin clavulanic acid samples are overdosed in clavulanic acid. In a context where counterfeiting and sub-standard drugs represent 50% of the world drug market (Delepierre *et al.*, 2012; WHO, 2018), these results highlight the importance of analyzing the physical and chemical quality of drugs in countries with little pharmaceutical regulation (Ministère de santé publique, 2011; Hollein *et al.*, 2016).

Our study is limited by the small number of samples studied. Moreover, it is limited to amoxicillin and amoxicillin-clavulanic acid, the most frequently used antibiotics in Congo. However, it is one of the few studies in DR Congo that has looked at the quality and compliance of medicines dispensed in its pharmacies.

The overdose observed in more than half of the samples of Amoxicillin and clavulanic acid in this study, raises the question of the adverse effects of this molecule amongst which we can mention in particular, the digestive disorder, but also the hepatotoxicity although often not documented.

The results obtained in this study raised questions about the origin of the products and the control and regulation of pharmaceutical products. Regardless of the origin of the samples, in 30% of the amoxicillin samples a net under dose, and in 80% of the amoxicillin clavulanic acid samples an overdose of clavulanic acid can be observed. It should be noted that an excessive dose of an active ingredient in a low quality drug can be toxic in humans, especially children. Similarly, under-dosed antibiotics can lead to therapeutic failure with the risk of increased mortality in children. Another

consequence of counterfeit or substandard medicines, especially antibiotics, is the emergence of multi-resistant strains that can be disseminated worldwide (WHO, 2014; Fleming-Dutra *et al.*, 2016; Mc Donagh *et al.*, 2018; and European Commission, 2018). Many sub-standard or counterfeit medicines escape control in resource-limited countries including the DR Congo. In sub-Saharan Africa and South East Asian countries, many drugs including antibiotics contain incorrect ingredients (Awad *et al.*, 2005; Delepierre *et al.*, 2012; and Mhando *et al.*, 2016). In some cases, they contain more active ingredient than indicated on the package as in our study. The consequence of this overdose is the increase of potential of adverse effects that can be fatal, as in the case of hepatotoxicity. This constitutes a major challenge in pharmacotherapy and pharmacy vigilance. Recent data report 1.7 cases of hepatotoxicity per 10,000 prescriptions (Hubert *et al.*, 2004). The clavulanic acid molecule in these studies seems to be the main factor responsible for liver injury.

This is a major public health challenge gives the high burden of infectious diseases and poverty, which account for 50% of deaths (WHO, 2014). Given the scale of this problem, government initiatives, such as, in Nigeria, Rwanda, Cambodia and Thailand (Hita *et al.*, 2012; Glass, 2014; Attaran *et al.*, 2012; Binagwaho *et al.*, 2013; Lamy *et al.*, 2015; and Cartwright and Baric, 2018) to combat counterfeit and substandard medicines should be undertaken and imposed on low-resource countries. Awareness campaigns using the media, mass education on the risk should be undertaken and generalized to sensitize the public on the risk incurred by this phenomenon.

## 8. Conclusion

Counterfeit or substandard medicines represent a serious problem in all resource-limited countries with considerable public health consequences. Most often, under-dosing of the active ingredient is the main problem with low quality medicines. This study highlights the importance of drug quality control. Strict regulation combined with inspection and chemical quality analysis is a prerequisite to counter this phenomenon and protect public health. Better monitoring of distributed antibiotics will benefit the populations of the low-resource countries and will add to the efforts against multi resistant strains worldwide.

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# Appendix 1

**Example of Counterfeit Amoxicillin Produced New Cesamex**


**Figure 3: Two Purported Amoxicillin Samples Produced by New Cesamex**


**Figure 4: Amoxicillin Produced by New Cesamex**

Appendix 1 (Cont.)


**Figure 5: Amoxicillin with Counterfeit Stigma**

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