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Post-marketing surveillance of doxycycline hyclate capsules used in self-medication in the Maluku I Health Zone, Kinshasa, Democratic Republic of the Congo

Muya, C. B.[1,4], Ntambwe, N. M.[2], Bisuta, L. B.[2], Miyila, M. B.[2], Sita, N. G.[2], Mafuta, K. D.[2], Masansa, V.[2], & Mbinze, K. J.[3]

[1]*Faculty of Pharmaceutical Sciences, Official University of Mbujimayi, Democratic Republic of the Congo*
[2]*Congolese Pharmaceutical Regulatory Authority, National Quality Control Laboratory Directorate, Kinshasa, Democratic Republic of the Congo*
[3]*Drug Analysis Laboratory, Faculty of Pharmaceutical Sciences, University of Kinshasa, Kinshasa XI, Democratic Republic of the Congo*
[4]*Department of Galenic Pharmacy and Drug Analysis, Faculty of Pharmaceutical Sciences, University of Kinshasa, Kinshasa XI, Democratic Republic of the Congo*

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Correspondence to:
Bony Muya Cidingi
bmuya70@gmail.com

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ABSTRACT

Introduction
In the Democratic Republic of Congo, self-medication is a common practice, particularly with antibiotics such as doxycycline hyclate. This raises concerns about safety and efficacy in the absence of medical prescriptions and therapeutic monitoring.

Purpose
The purpose of this study was to survey pharmacy sellers regarding the most requested antibiotics for self-medication, according to the WHO AWaRe classification, and to evaluate the quality of the most commonly used antibiotic for self-medication in the Maluku I Health Zone. This zone was chosen because it is a border and porous area with potential for smuggling and illicit drug sales, as part of post-marketing surveillance.

Methods
A descriptive cross-sectional study was conducted among sellers in 101 of 116 pharmacies in a peri-urban area of Kinshasa. The study focused on antibiotics used in self-medication, followed by quality control tests conducted according to the USP–NF 2024 pharmacopoeial standards on 12 different batches of doxycycline hyclate.

Results
The results showed that 87.06% of vendors participated in the survey, including 84.2% males and 15.8% females, with a mean age of 39.51 ± 9.84 years. Regarding educational level, 47.5% had Bac+0, 40.6% Bac+3, 7.9% Bac+5, and 4.0% other qualifications. In terms of training, 59.4% had studied nursing, while only 2% had studied pharmaceutical sciences. Doxycycline capsules were the most requested antibiotic in the Access category (89.1%), while chloramphenicol capsules were the least used (26.7%). Of the analysed batches, 41.7% had compliant marketing authorisations, 16.7% were unregistered, and 41.7% had non-compliant authorisations. All (100%) batches passed the identification and dissolution tests. However, 25% failed the mass uniformity test, while 58.3% passed the assay test and 41.7% failed.

Conclusion
Regular post-marketing surveillance is necessary to protect consumers from substandard products, given the high rate of under-dosed medicines found in circulation.

INTRODUCTION

Self-medication, defined as the use of medications without a prescription or medical supervision, is an increasingly widespread practice in many low- or middle-income countries, particularly in the Democratic Republic of the Congo (DRC). This trend is especially concerning when it involves antibiotics, owing to the high risks of misuse, the development of bacterial resistance, unreported adverse effects, and serious clinical complications (Bagheri & Giroud, 2022).

Post-marketing surveillance studies often provide crucial information about the quality of medicines available to the public (World Health Organization [WHO], 2015). This approach arose in response to the existence of substandard medicines circulating in both developed and developing countries. The WHO defines such products as authorised medicines that fail to meet quality standards, specifications, or both (WHO, 2017).

These substandard or falsified products account for an estimated 10–15% of the global pharmaceutical market (Voice of America/Afrique, 2018). Furthermore, it has been reported that 42% of counterfeit medicines seized between 2013 and 2017 originated from sub-Saharan Africa (BBC News Africa, 2020).

Some antibiotics—owing to their accessibility and affordability—are commonly used without medical supervision. This practice is encouraged by factors such as poverty, low education levels, and limited awareness among patients about the potential consequences of self-medication (Karungamye, 2023; Mboni et al., 2023; Raynaud, 2008). Doxycycline hyclate, one of the antibiotics recommended by the WHO as a first-line option for empirical treatment of infections in healthcare settings (Zanichelli et al., 2023), is among the drugs frequently misused. This situation raises major concerns about the quality of medicines available in the Congolese market, the absence of therapeutic monitoring, and insufficient pharmacovigilance.

In the context of misuse of substandard antibiotics—leading to risks of therapeutic failure and antimicrobial resistance—post-marketing surveillance is essential. Such monitoring enables the assessment of socio-behavioural factors contributing to inappropriate antibiotic use and evaluates the extent of substandard drug circulation. It also provides a foundation for recommendations aimed at improving product quality and regulatory systems. Similar studies have been conducted in comparable contexts but remain insufficient (Denekew et al., 2024).

The objective of this study was to survey pharmacy vendors on the most requested antibiotics for self-medication, based on the WHO AWaRe classification, and to evaluate in the laboratory the quality of the most commonly used antibiotic for self-medication in the Maluku I Health Zone as part of post-marketing surveillance.

METHODS

Study Design and Site

This was a descriptive cross-sectional study conducted in the urban–rural Health Zone of Maluku I, Kinshasa. The area was chosen because it is a border and porous zone, with potential for smuggling and illicit sales of medicines. The estimated population was 304,556 in 2024. The study focused on antibiotics. The survey period extended from 15 September 2024 to 15 January 2025, while quality control analyses were conducted at the National Quality Control Laboratory in Kinshasa from 4 February to 28 March 2025.

Materials

Chemicals and Reagents

Doxycycline hyclate (100.0%) was sourced from the U.S. Pharmacopeia (Washington, USA). HPLC-grade methanol, potassium dihydrogen phosphate (lot 2319134), disodium edetate, 1N hydrochloric acid, and triethylamine were obtained from MERCK (Darmstadt, Germany).

Sampling of vendors and drug batches was performed using a non-probability convenience method. On average, three batches were collected per manufacturer registered in the DRC, with 100 units per batch. Inclusion criteria for vendors required that they be of legal age, employed at a pharmacy within the study area, and available and willing to participate. Vendors who did not meet these criteria were excluded.

Samples were required to meet the following criteria: inclusion in the national medicines list as an antibiotic in the Access category; manufacture in the DRC or another low-income country; and a remaining shelf life of at least one year at the time of collection. Ethical approval was obtained

under reference N°693/BN/PMMF/2024 from the National Health Ethics Committee granted in accordance with DRC Health Ministerial Decree No.1250/CAB/MIN/S/ZKM/043/MC/2006, December 18,2006, and informed consent forms—translated into the local language—were provided to all participants.

Equipment

The following equipment was used: Agilent 1290 Infinity II HPLC (California, USA), Mettler ME204TE/00 analytical balance (Ohio, USA), XPR6UD microbalance (Greifensee, Switzerland), METROHM 913 PH meter (Herisau, Switzerland), CARY 60 G6860A/60UV-VIS UV-visible spectrophotometer (California, USA), and AGILENT G7910A/G7911A Dissolutest 708-DS (California, USA).

Methods

A post-marketing surveillance plan was developed in accordance with WHO recommendations (WHO, 2015). The census of pharmacies was followed by investigator briefings and a structured survey conducted using an Android-based digital questionnaire. Data were collected via **Kobo Collect** (version 2024), processed using **IBM SPSS** (version 2018) and **Microsoft Excel** (version 2016), and analysed using descriptive statistics.

Assay and identification analyses were performed using a high-performance liquid chromatography (HPLC) system, chosen for its flexibility, high sensitivity, and superior resolution.

The analytical method was verified for trueness, precision, accuracy, and linearity in accordance with USP–NF (2024) requirements before application. The verification results indicated acceptable bias values (≤2%), recovery rates ranging from 95% to 106%, and a determination coefficient (R^2) of 0.9932, demonstrating that the method was reliable within the concentration range of 0.24–0.42 mg/ml. Detailed verification data are available upon request.

Preparation of Solutions for HPLC-UV Analysis

Standard Solutions

In a 100 ml volumetric flask, 42.0350 mg of doxycycline hyclate RS USP was dissolved in 100 ml of 0.01 N HCl solution, sonicated for 5 minutes, and diluted to volume with the same solution to obtain a 140% doxycycline hyclate solution (0.42 mg/ml), labelled S1.

From S1, two 50 ml volumetric flasks were prepared: 36 ml and 29 ml of S1 were diluted with 0.01 N HCl and sonicated for 5 minutes to obtain 100% (0.3 mg/ml) and 80% (0.24 mg/ml) doxycycline hyclate RS USP solutions, respectively.

A 100 ml volumetric flask containing 30.0465 mg of doxycycline hyclate RS USP was similarly prepared to obtain a 100% control standard solution (0.3 mg/ml). Approximately 1.5 ml of each standard solution was injected into the HPLC system for single and triplicate analyses.

Sample Solutions

Twenty capsules from each batch were weighed individually, emptied, and reweighed to determine the average content weight. The contents were homogenised, and an amount equivalent to 6.25 mg of doxycycline hyclate was dissolved in a 25 ml volumetric flask with 0.01 N HCl solution, sonicated for 5 minutes, filtered, and analysed using HPLC in triplicate for each batch.

Phosphate Buffer Solution

A phosphate buffer was prepared by dissolving 3.1028 g of KH_2PO_4, 0.5022 g of disodium edetate, and 0.5 ml of triethylamine in 850 ml of distilled water, sonicated for 5 minutes, diluted to 1000 ml, and adjusted to pH 8.5 ± 0.2 with 1N NaOH.

Dissolution Test

Standard Solution

Two 100 ml volumetric flasks containing 2.0155 mg and 2.0355 mg of doxycycline RS USP were dissolved in distilled water to obtain standard solutions of 0.020 mg/ml.

Sample Solution

One capsule was placed in each of six dissolution containers containing 900 ml of distilled water at 37°C. After 30 minutes (with one-minute intervals between containers), 20 ml aliquots were collected, filtered, and diluted to obtain a 0.0222 mg/ml solution of doxycycline hyclate.

Chromatographic Conditions

The column used was C18 (100 mm × 4.6 mm, 3.5 µm). The oven temperature was 60°C. The mobile phase consisted of phosphate buffer (pH 8.5) and methanol in gradient mode.

Table 1:
Conditions for using gradient mode

Time (min)	Solution A (%)	Solution B (%)
0.0	90	10
2.0	90	10
4.0	60	40
6.0	90	10
9.0	90	10

Injection volume: 5 µl; **Flow rate:** 0.6 ml/min; **Resolution:** 1.5; **Analytical wavelength:** 276 nm (UV-Vis mode).

In Vitro Dissolution Test Conditions

Table 2:
Parameters and operating conditions for the in vitro dissolution test

Parameter	Condition
Medium	*Water*
Volume	900 ml
Rotation speed	75 rpm
Temperature	37 ± 0.5°C
Analysis time	30 minutes
Analytical wavelength	276 nm
Paddle distance	4.5 ± 0.5 cm
Apparatus	Apparatus 2 (Paddle)

RESULTS

Census

Among the 15 health areas in the zone, 11 were included in the study. A total of 116 pharmacies were identified in October 2024, and 101 of them participated in the survey, representing an 87.06% participation rate.

Socio-Demographic Characteristics of Pharmacy Sellers

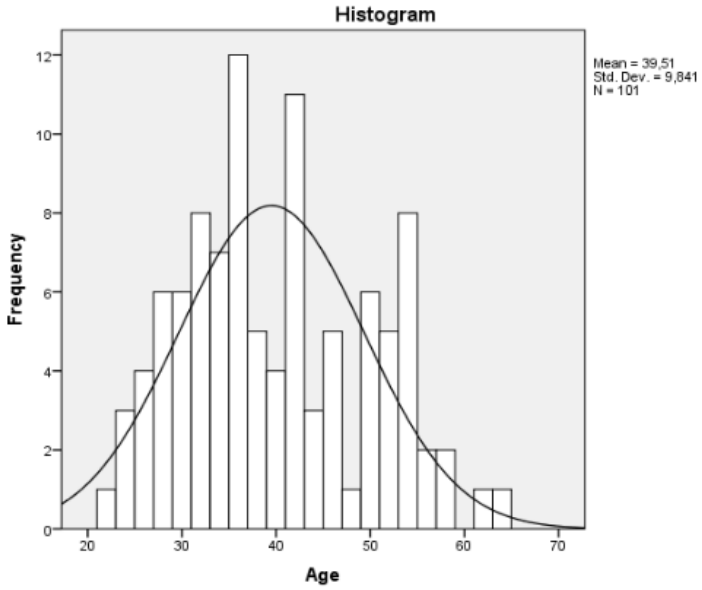
Table 3 presents the distribution of sellers according to gender and age.

Table 3:
Distribution of Sellers by Gender and Age

Socio-demographic characteristics	Frequency (n = 101)	Percentage (%)
Sex		
Male	85	84.2
Female	16	15.8
(Sex ratio: 5.3)		
Age (years)		
22–28	14	13.9
29–35	26	25.7
36–42	27	26.7
43–49	13	12.9
50–56	17	16.8
57–64	4	4.0
(Mean age: 39.51 ± 9.84 years; range: 22–64 years)		

Figure 1 shows the distribution of pharmacy sellers by age group.

Figure 1:
Distribution of Pharmacy Sellers by Age Group



Level of Education and Training Completed

Table 4 summarises the educational levels and professional training of the pharmacy sellers.

Table 4:
Distribution of Sellers by Level of Education and Field of Training

Variables	Frequency (n = 101)	Percentage (%)
Level of Education		
Bac+0	48	47.5
Bac+3	41	40.6
Bac+5	8	7.9
Other Training	4	4.0
Field of Training		
Nursing	60	59.4
Other Fields*	32	31.7
Pharmaceutical Techniques	7	6.9
Pharmaceutical Sciences	2	2.0

Use of Different Antibiotics According to the AWaRe Classification

Table 5 presents the frequency of use of each antibiotic by AWaRe category.

The results show that *doxycycline capsules* (89.1%) were the most frequently requested in the Access category, followed by *metronidazole tablets* (84.2%) and *cotrimoxazole tablets* (83.2%).

Table 5:
Frequency of Use of Different Antibiotics by AWaRe Categories

Antibiotic	Frequency (n = 101)	Percentage (%)
Categories AWaRe - Access		
Doxycycline capsule	90	89.1
Metronidazole tablet	85	84.2
Cotrimoxazole tablet	84	83.2
Amoxicillin capsule	75	74.3
Phenoxymethylpenicillin tablet	69	68.3
Nitrofurantoin tablet	56	55.4
Amoxicillin tablet	47	46.5
Doxycycline tablet	40	39.6
Amoxicillin + clavulanic acid tablet	39	38.6
Clindamycin capsule	37	36.6
Chloramphenicol capsule	27	26.7
Categories AWaRe - Watch		
Ciprofloxacin tablet	89	88.1
Cefixime tablet	69	68.3
Cefuroxime tablet	39	38.6
Clarithromycin tablet	34	33.7
Azithromycin tablet	24	23.8
Azithromycin (duplicate entry)	12	11.9

Note: No oral products are currently included in the Democratic Republic of the Congo's National List of Essential Medicines under the Reserve category (World Health Organization, 2021).

Results of the Collection of Different Batches of Doxycycline Hyclate

Table 6 presents the batches analysed in this study and their origins.

Table 6:
Batches Collected and Their Origins

Code	Brand Name	Manufacturer/ Distributor	Batch No.	Country of Origin	Manufacturing Date	Expiry Date	Marketing Authorisation Validity
A	Doxycycline capsule 100 mg	Norrie Pharmaceutical Co. Ltd / MEDICO PLUS	231208	China	Dec 2023	Dec 2026	20/01/2026
B	Doxycycline capsule 100 mg	Yangzhou No. 3 Pharmaceutical Co. Ltd / MEDICO PLUS	231208	China	Dec 2023	Dec 2026	20/01/2026
C	Doxycycline capsule 100 mg	Caisa Pharma	4D0X03	DRC	Sept 2024	Mar 2027	Not registered
D	Doxycycline capsule 100 mg	Caisa Pharma	4D0X04	DRC	Nov 2024	Oct 2027	Not registered
E	DOXY-100	Phatkin	09_24	DRC	Aug 2024	Jul 2027	08/03/2029
F	DOXY-100	Phatkin	08_24	DRC	Jul 2024	Jun 2027	08/03/2029
G	DOXY-100	Phatkin	10_24	DRC	Aug 2024	Jul 2027	08/03/2029
H	Doxycycline capsule	Prashi Pharma Pvt. Ltd / Prince Pharma	DC_49	India	Dec 2023	Nov 2026	Not declared
I	Doxycycline capsule	Prashi Pharma Pvt. Ltd / Prince Pharma	DC_53	India	Feb 2024	Jan 2027	Not declared
J	Doxycycline capsule	Prashi Pharma Pvt. Ltd / Prince Pharma	DC_54	India	Feb 2024	Jan 2027	Not declared
K	Doxycycline 100 mg capsule	Yangzhou No. 3 Pharmaceutical Co. Ltd / Unique Pharma	240128	China	Jan 2024	Jan 2027	Not declared
L	Doxycycline 100 mg capsule	Yangzhou No. 3 Pharmaceutical Co. Ltd / Unique Pharma	230966	China	Sept 2023	Aug 2026	Not declared

Results of Physicochemical Analyses

Identification of Doxycycline in Batches

Table 7 shows the retention times obtained for each batch compared with the standard reference.

Table 7:
Results of the Identification Test for the Different Batches

Date	Product Code	Average Retention Time ± SD	RSD (≤ 2%)
25/02/2025	Standard	6.4 ± 0.00	0.00
	A	6.3 ± 0.01	0.022
	B	6.3 ± 0.05	0.078
	C	6.3 ± 0.02	0.034
	D	6.2 ± 0.021	0.325
	E	6.2 ± 0.011	0.170
05/03/2025	Standard	6.9 ± 0.00	0.00
	F	6.9 ± 0.007	0.102
	G	6.9 ± 0.009	0.133
	H	6.9 ± 0.045	0.648
06/03/2025	Standard	6.9 ± 0.000	0.000
	I	6.9 ± 0.042	0.606

Date	Product Code	Average Retention Time ± SD	RSD (≤ 2%)
	J	6.8 ± 0.018	0.260
	K	6.8 ± 0.013	0.198
	L	6.7 ± 0.010	0.147

Assay Results by HPLC

Table 8 presents the proportion of compliant and non-compliant batches following assay analysis.

Table 8:
Proportion of Compliant vs. Non-Compliant Batches After Assay

Batch Code	Specification	Concentration Obtained (% ± SD)	Compliant	Non-Compliant
A	90.0–120.0	81.6 ± 0.022		✓
B		91.7 ± 0.052	✓	
C		101.3 ± 0.077	✓	
D		109.0 ± 0.027	✓	
E		92.2 ± 0.013	✓	
F		77.0 ± 0.223		✓
G		75.7 ± 0.001		✓
H		79.5 ± 0.028	✓	
I		88.7 ± 0.026		✓
J		85.0 ± 0.005		✓
K		92.5 ± 0.192	✓	
L		104.0 ± 0.223	✓	

In Vitro Dissolution Test

The difference between the working standard response factor (29.747024) and the control standard response factor (29.744597) was 0.01%, within the acceptable limit of ≤ 2.0%, confirming system suitability.

Table 9 shows the amount of doxycycline hyclate dissolved in Stage 1.

Table 9:
In Vitro Dissolution Test Results for Batches

Batch Code	Average Concentration (% ± SD)	Specification (80.0–120.0%)
A	99.98 ± 0.18	✓
B	99.99 ± 0.12	✓
C	99.91 ± 0.10	✓
D	99.98 ± 0.11	✓
E	100.10 ± 0.14	✓
F	99.97 ± 0.25	✓
G	99.97 ± 0.17	✓
H	99.99 ± 0.21	✓
I	99.93 ± 0.11	✓
J	99.87 ± 0.15	✓
K	99.99 ± 0.17	✓
L	99.94 ± 0.17	✓

Mass Uniformity Test of Batches

Table 10 presents the results of mass uniformity. Batches A, D, and F were non-compliant with the standard acceptance range (90–110%).

Table 10:
Results of Mass Uniformity

Batch	Average Weight (g)	SD	Average Weight ± SD (g)	Decision
A	0.1425	0.0229	0.1425 ± 0.0229	Non-compliant
B	0.1599	0.0043	0.1599 ± 0.0043	Compliant
C	0.2380	0.0163	0.2380 ± 0.0163	Compliant
D	0.2503	0.0166	0.2503 ± 0.0166	Non-compliant
E	0.3208	0.0162	0.3208 ± 0.0162	Compliant
F	0.2654	0.0268	0.2654 ± 0.0268	Non-compliant
G	0.3173	0.0166	0.3173 ± 0.0166	Compliant
H	0.2927	0.0156	0.2927 ± 0.0156	Compliant
I	0.2917	0.0148	0.2917 ± 0.0148	Compliant
J	0.2795	0.0133	0.2795 ± 0.0133	Compliant
K	0.1596	0.0143	0.1596 ± 0.0143	Compliant
L	0.1919	0.0031	0.1919 ± 0.0031	Compliant

Acceptance criteria:

- No more than two units may deviate from the average mass by more than 10%.
- No unit may deviate by more than twice that percentage (European Pharmacopoeia 6.0, 2007).

DISCUSSION

The results of this study reveal that patients in the Maluku I Health Zone freely obtain antibiotics from pharmacies, most of which are operated by men with limited qualifications (see **Tables 3** and **4**). This situation poses a danger to the rational use of medicines. Doxycycline hyclate was the most widely used antibiotic for self-medication in the Access category (see **Table 5**). Of the 12 batches collected and analysed, the majority were manufactured in the Democratic Republic of the Congo (DRC), followed by China and India. Among these, 16.6% were unlicensed, and 41.7% were sold with non-compliant marketing authorisations. In total, 58.3% were of substandard quality (see **Table 6**), reflecting a failure in the regulation of the pharmaceutical sector in the DRC.

All batches passed the identification and *in vitro* dissolution tests at Stage 1 (see **Tables 7** and **9**). However, 41.7% were under-dosed, highlighting the danger of consuming substandard products when self-medicating. These results corroborate findings from other studies that have reported high levels of self-medication and weak pharmaceutical regulation in low-income countries (Karungamye, 2023; Raynaud, 2008). Similarly, the circulation of substandard antibiotics persists despite efforts by national pharmaceutical regulatory authorities, as demonstrated by the high rate of under-dosed batches found (41.7%)—a figure consistent with those reported by Denekew et al. (2024) in Ethiopia, where 60% of doxycycline batches were under-dosed.

These results have certain limitations, particularly due to the use of non-probability sampling (for convenience), which is a less representative technique. Other limitations include the small number of batches collected, the selection of only one pharmaceutical form, and the limited number of collection sites—one health zone out of 516 available in the DRC. Consequently, the findings cannot be generalised to the entire country.

CONCLUSION

Despite the existence of a national pharmaceutical regulatory authority in the DRC, substandard drugs continue to circulate in the market, as demonstrated by the 41.6% of under-dosed and 58.3% of substandard batches identified. This finding underscores the urgent need to strengthen pharmaceutical regulation.

It is therefore recommended to:

1. Systematically integrate post-marketing surveillance activities within the national pharmaceutical regulatory authority.
2. Advocate for the mobilisation of funds for the effective implementation of regulatory activities.
3. Continue public awareness campaigns on the dangers of self-medication and the risks associated with using substandard medicines.
4. Encourage researchers to extend this study by increasing the number of sites and pharmaceutical forms of doxycycline evaluated.

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Ethical Approval: Ethical approval was obtained under reference N°693/BN/PMMF/2024 from the National Health Ethics Committee granted in accordance with DRC Health Ministerial Decree No.1250/CAB/MIN/S/ZKM/043/MC/2006, December 18,2006.

Conflicts of Interest: None declared.

ORCID iDs:

Muya, C. B.[1,4]: https://orcid.org/0009-0006-6432-695X
Ntambwe, N. M.[2]: https://orcid.org/0009-0007-0496-499X
Bisuta, L. B.[2]: Nil identified.
Miyila, M. B.[2]: Nil identified.
Sita, N. G.[2]: Nil identified.
Mafuta, K. D.[2]: Nil identified.
Masansa, V.[2]: Nil identified.
Mbinze, K. J.[3]: Nil identified.

REFERENCES

Bagheri, H., & Giroud, J. P. (2023). Self-medication and drug misuse. *Bulletin of the National Academy of Medicine, 207*(2), 178–185. https://doi.org/10.1016/j.banm.2022.12.010

BBC News Africa. (2020, January 17). *How big is the problem of fake medicines in Africa?* https://www.bbc.com/afrique/region-51148173

Council of Europe (2007). *European Pharmacopoeia 6.0* Council of Europe

Denekew, T., Eticha, T., Teshome, Y., Endeshaw, S., & Ashenef, A. (2024). Post-marketing quality surveillance of selected antibacterial agents marketed in porous borders: The case of Ethiopia–Sudan–Eritrea border. *PLOS ONE, 19*(8), e0308223. https://doi.org/10.1371/journal.pone.0308223

Karungamye, P. (2023). Counterfeit and substandard drugs in Tanzania: A review. *Forensic Science International: Reports, 7*, 100302. https://doi.org/10.1016/j.fsir.2022.100302

Mboni, H. M., Tshikongo, A. K., Chirubagula, V. B., Shakalenga, C. M., Kanyegere, A. M., Rugema, B. B., Mushobekwa, S. S., Akiba, D. B., & Rusati, N. M. (2023). Evaluation of self-medication practices and their characteristics among students in Uvira in the Democratic Republic of Congo. *The Pan African*

Medical Journal, 45, 53. https://www.panafrican-med-journal.com/content/article/45/53/full

Raynaud, D. (2008). Determinants of recourse to self-medication. *French Review of Social Affairs, 1*, 81–94. https://doi.org/10.3917/rfas.081.0081

U.S. Pharmacopeia. (2024). *The USP approach for selecting columns of equivalence.* https://www.usp.org/resources/pqri-approach-column--equiv-tool

Vox of America/Africa. (2018, January 16). *Counterfeit medicines, a profitable and deadly trade in Africa.* https://www.voaafrique.com

World Health Organization. (2015). *Guidelines on medicines quality surveys (QAS15-630-30062015).* https://www.who.int/docs/default-source/medinines/norms-and-standards/current-projects/guidelines-on-medicines-quality-surveys-qas15-630-30062015.pdf

World Health Organization. (2017). *WHO global surveillance and monitoring system for substandard and falsified medical products.* World Health Organization. https://iris.who.int/handle/10665/326708

Zanichelli, V., Sharland, M., Cappello, B., Moja, L., Getahun, H., Pessoa-Silva, C., Sati, H., Van Weezenbeek, C., Balkhy, H., Simão, M., Gandra, S., & Huttner, B. (2023). The WHO AWaRe (Access, Watch, Reserve) antibiotic book and prevention of antimicrobial resistance. *Bulletin of the World Health Organization, 101*(4), 290–296. https://doi.org/10.2471/BLT.22.288614