Quality control of anti-infective medicines : case of ciprofloxacin and metronidazole formulations in Butembo

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1. Introduction

The substandard or falsified medicines have increased around the world and have become one of the biggest health crimes when you consider the potential harm. Democratic Republic of Congo (DRC) is not spared by this scourge; with an almost non-existent quality assurance and quality control system and a drug logistics circuit not well mastered [1]. Anti-infective drugs are of great concern: their use can lead to treatment failures, microbial resistance to drugs, increased morbidity and mortality.

2. Objective

We aim to evaluate the quality of ciprofloxacin (CIP) and metronidazole (MET) based formulations marketed in Butembo (see Fig. 1), specifically, verifying parameters based on the WHO check list of visual inspection.

3. Material and Methods

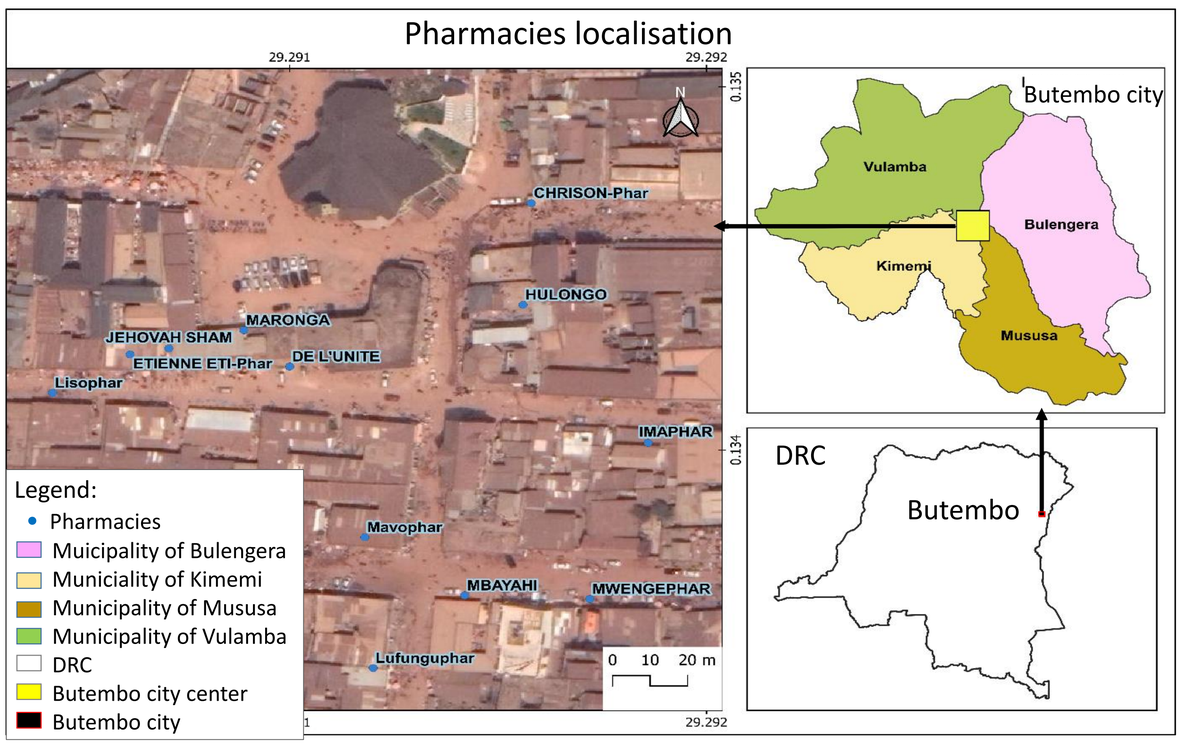

Fig. 1. Sampling area

3.1. Material

The pre-survey and the collection of samples (24 August – 01 September 2021) were limited to 12 pharmacies known as wholesalers in the town. Tablets, oral suspensions and solutions for injection containing MET or CIP, with at least 6 months validity were included in this study.

Table 1. Description of samples.

INN	Formulation	Dosage	Brands	Samples
MET	Oral suspension	125mg/5mL	Tricozole, Eflaron, Metazole	5
	Tablet	200mg	Tricozole, Flazole, Metrosim-200, Shelegyl	9
		250mg	Metazol	3
		500mg	Flagyl	1
	Solution for injection	500mg/100ml	Metro Inj, Abagyl, Nirmet	6
CIP	Tablet	250mg	Cipronat	3
		500mg	Ciprokin, Shalcip-500, Ecoflox-500, Zindolin, Cifin-500, Ciprofed, Cypro-Tro, Cipcina-500, Ciprolab-500, Cipro-Tro,	19
	Solution for Injection	200mg/100ml	Cifin, Shalcip, Ciprox, Goxin	5
			TOTAL	51

3.2. Methods

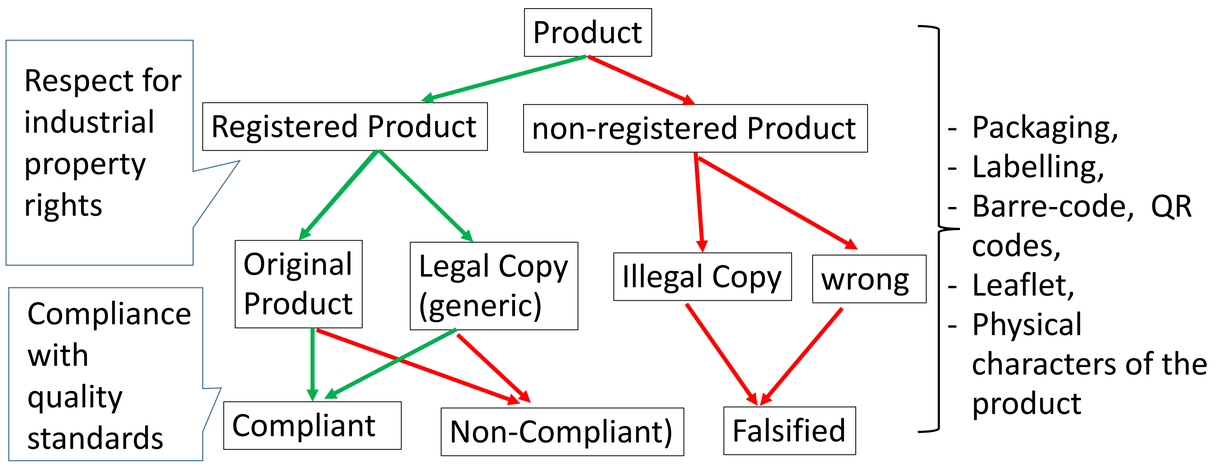

Fig.2. Medicines analytical strategy flowchart

4. Results and discussion

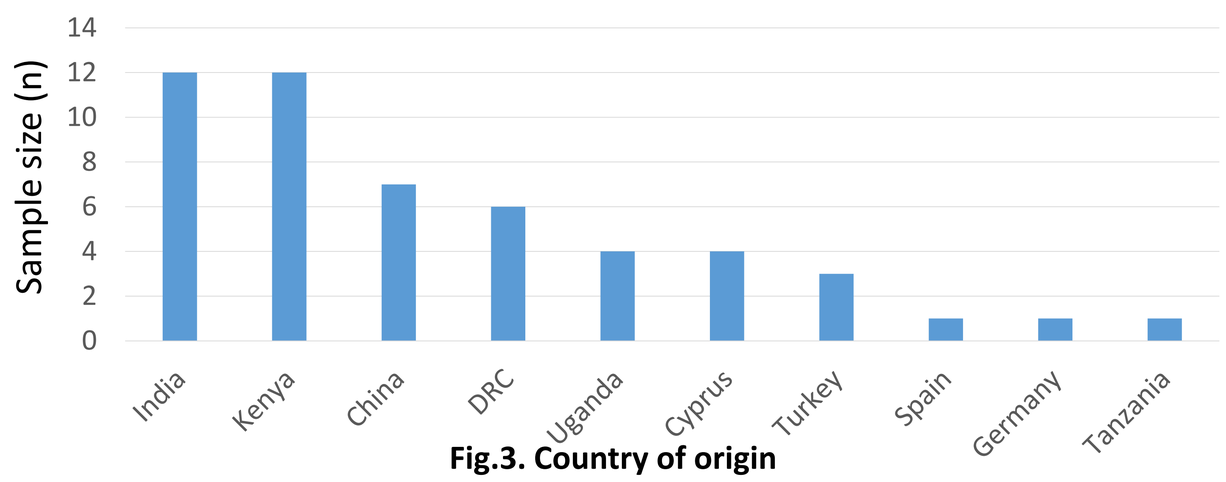

Fig.3. Country of origin

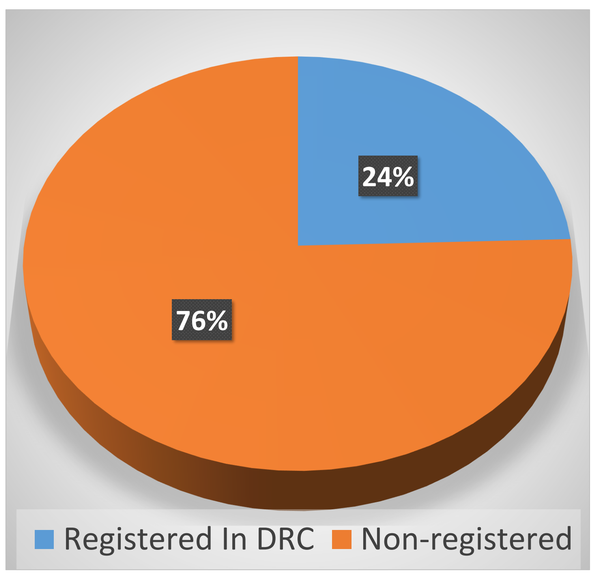

Fig.4. Licence status in DRC

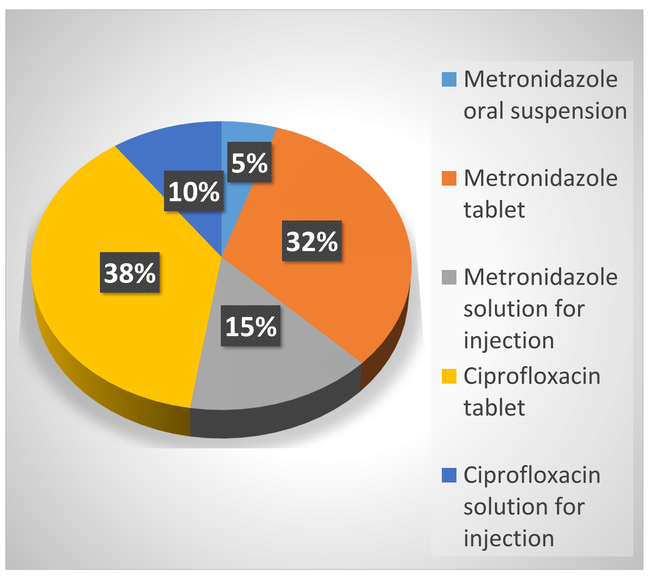

Fig.5. Distribution of non-compliant samples

Concerning the packaging and labelling, all the samples presented satisfactory results. Regarding physical characters of the product, only two tablet samples showed an integrity defect.

A total of 40 out of 51 samples constituted by 52,5% of MET samples and 47,5% of CIP ones, were found non-compliant to visual inspection specifications. The majority of non-compliance was due to the non-registration of samples in DRC [2].

For MET, 100% of tablet samples and injectable solutions and 40% of oral suspensions were not registered in DRC. For CIP, 68.2% of tablet samples and 80% of injectable solutions were not registered in DRC.

The majority of non-compliant products originated from Kenya, India and DRC. This situation shows that there is a major problem with the quality of medicines in Butembo.

5. Conclusion and perspectives

This work constituted the first step of the analytical approach of quality control of CIP and MET pharmaceutical formulations found on the Butembo market. Limited to visual inspection, it revealed some deficiency. This is why it is essential to continue the analyzes involving physicochemical tests for more precision.

The results obtained show a pharmaceutical regulation problem in DRC and an urgent need to develop a rapid and simple qualitative and quantitative screening methods for the quality control of MET and CIP based medicines.

References

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2. Direction de la Pharmacie et du Médicament (DPM), RDC, https://acorep-dpmrdc.org/Base/