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Determination of the Prevalence of Different Brands of Fixed Dose Artemether/Lumefantrine Tablets Sold in Pharmacies in Uganda

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ABSTRACT

Substandard, counterfeit and falsified antimalarial agents are a big challenge to effective malaria elimination interventions mainly in developing countries. In low-and middle-income countries (LMICs), the quality of antimalarial agents inclusive of AL is affected by several factors including insufficient regulation porous borders and limited funds. This study therefore focused evaluation of quality of different brands of fixed dose artemether/ lumefantrine tablets sold in Ugandan Pharmacies. This was an experimental study conducted using AL tablets obtained from different pharmacies in the different cities of Uganda purchased using mystery shopper method. The samples were screened for quality using visual inspection, assessed different physical quality parameters like weight variation, friability, disintegration and dissolution and content assay tests were also done both for the brands from the pharmacies and their correspondent LTR. The assay test was done using HPLC technique USP method. The samples were considered substandard if the API content was outside 90-110% range of the label claim. Data was analysed using descriptive statistics and presented as means with standard deviations and frequencies. 400 AL samples were collected from the different Pharmacies in the different cities and the corresponding LTRs in the strengths of 20/120, 60/360 and 80/480 with commonest brands Lumartem, Lumaren and Artefan. The presence of A/L brands that are unregistered and the total assay failure of the brands of 18% for the AL tablets purchased causes alarm.

Keywords: Artemether lumefantrine, quality, tablets, prevalence

INTRODUCTION

Artemether Lumefantrine (AL) is the most commonly used Artemesinin Combination Therapy (ACT) in the management of uncomplicated *P. falciparum* malaria [1]. Both artemether and lumefantrine are blood schizontocides [2]. However, artemisinin also has some gametocytocidal activity resulting in a decrease in malarial parasite transmission [2]. Food enhances the absorption of both Artemether and Lumefantrine however, this effect is more pronounced for lumefantrine [3]. Therefore, there is a necessity for a standard African diet is adequate to ensure optimal efficacy for Artemether lumefantrine [3].

Artemether is a herbal remedy anciently used in Chinese for relapsing fever from *Artemisia annua*, alternatively called sweet *wormwood* [4]. Lumefantrine on the other hand is not from nature rather formed by chemical synthesis following research carried out in 1967 by the academy of Military Medical Sciences in Beijing China [5] The initial approval of AL as an ACT to the market dates back to 1999 and has been used ever since then in the management of un complicated malaria worldwide [5]. The presence of unregistered antimalarial agents on the market has been reported in different parts of the world and the quality of these agents remains in question causing a great risk to the general population taking these agents [5].

Substandard and falsified antimalarials are very prevalent in countries considered as low and middle income (LMICS) at a rate of 19.1% [6] and have significant negative health and economic effect, with a high deaths burden, disability and wastage of money on cost-ineffective antimalarials leading to health inequities in Uganda [7]. Developing countries including Uganda have over 25% of their medicines reported as counterfeit and substandard, these medicines lead to around 0.25 million deaths per year. However, treatment with good quality medicines can help reduce all these deaths [8].

Treating malaria with good quality antimalarials (artemether-lumefantrine) instead of counterfeits and substandard drugs can help to prevent the high death rates, morbidity due to consumption of poor-quality drugs [9]. The recommended first-line treatment for management of uncomplicated falciparum malaria a species that causes the most severe forms of malaria and subsequent deaths is fixed dose artemether lumefantrine [10]. AL is used in management of uncomplicated plasmodium falciparum malaria in Uganda however due to the presence of porous

borders and unregulated private sector drug procurement, there may be poor quality artemether-lumefantrine on the market. Therefore, this study will focus on evaluating the quality of different brands of fixed-dose artemether-lumefantrine tablets on the Ugandan market.

METHODOLOGY

Study design

This was an experimental study which involved use of pharmacopoeias, compendia and non-compendia tests.

Study area

The study focussed on all the different brands of fixed dose artemether/ lumefantrine on the Ugandan market obtained from all the different ten cities that is Kampala the capital city, Jinja, Mbaale, Soroti, Lira, Gulu, Arua, Hoima, Mbarara, Masaka and Fortportal.

Study setting

The experimental procedures were carried out at the KIU-WC Pharmaceutics Laboratory that is for disintegration, thickness, friability, hardness and weight uniformity. Not only was the research done at KIU-WC pharmaceutics Laboratory but also at the analytical Research laboratory of Mbarara University of Science and Technology.

Inclusion criteria

All tablets claimed having artemether and lumefantrine were obtained from NDA licenced Pharmacies as well as batches of AL tablets left with at least three months to their expiry date were purchased reason aligned to avoid those with near expiry from expiring during storage before analysis. Sample with different products names at the same licenced drug outlet were obtained.

Exclusion criteria

Drug outlets with less or equal to 48 tablets of a batch of AL tablets were not purchased as these were the number of tablets needed for the study catering for all the involved tests and Samples of short expiry were not included also.

Sampling procedure

In this study, two aspects of sampling were involved, namely sampling pharmacies and sampling of tablets from different AL batches for laboratory testing.

Sample size determination of drug outlets

The formula for sample size determination for drug quality studies provided by [11] was used to calculate the number of private pharmacies to be sampled. WHO recommends that for a drug survey to be done across the country, the lowest number of Pharmacies from which drugs are to be obtained should be twenty (20). For this study, the following formula for sample size calculation was used:

The formula $sa = Px20$ was used [11].

Where;

Sa is the number of the private drug outlets sampled in the capital city

$P = n1/n$

where n is the total number of private drug outlets in the country.

$n1$ is the list of private drug outlets in the capital city (Kampala) and 20 is the lowest number of private drug outlets to be selected.

The number of private drug outlets sampled in the selected geographical unit region (sb) =20- sa

Total number of private drug outlets in Kampala is 1106

Total number of private drug outlets in Uganda is 2193

$Sa = (1106/2193) \times 20$

$Sb = 20 - ((1152/2055) \times 20) = 10$ pharmacies.

Sb is the number of pharmacies from which the AL tablets were obtained from from a given city other than the capital city Kampala.

Using the above formula, samples were collected from 10 pharmacies from each of the Cities NDA regions of Uganda cities that is Kampala the capital city, Jinja, Mbaale, Soroti, Lira, Gulu, Arua, Hoima, Mbarara, Masaka and Fortportal. Therefore, based on the calculation 110 Pharmacies were considered in the study.

Selection procedure for drug outlets

A stratified random method of sampling was used to select the various Pharmacies following calculation of the required sample size of drug outlets. This involved assigning random numbers to the Pharmacies in the City and these numbers were noted on small pieces of paper. The papers were then folded, placed in two different baskets, and shaken. One piece of paper was randomly taken at a time out of the basket and the number was written without replacement. In the basket private pharmacies 10 papers would be taken at random without replacing and these were representative of be the Pharmacies that were considered in the study and it is from these Pharmacies that the drugs were bought.

Replacing of a Pharmacy was only to be done in a scenario where if during the time of data collection, it is found out that the Pharmacy is non-existent and the next on the list was to be selected.

Collection of AL tablets from the drug outlets

In order to reduce bias during sampling, mystery shoppers were used to purchase the AL tablets. The mystery shoppers were not informed of the study main goal and only instructed to collect samples. Different batches from different brands of tablets claimed to be containing artemether and lumefantrine were purchased from selected private pharmacies. 48 tablets of each batch and brand were bought. All brands were collected in cases where a drug outlet had more than one brand and/ or batch of AL tablets. The following information was written in a sampling form (Appendix I) upon drug buying, the facility code and type of the drug outlet, date of sampling, brand/ trade name and batch number of the sampled AL tablets, manufacturing date, expiry date country of

origin, manufacturing company, will all be documented in a drug sampling form(appendix1). To ensure that drugs collected are protected from sunlight and moisture, all AL samples collected were packed and sealed in a well labelled envelope that was later packed in a polythene bag that is dark and water proof. The samples were transferred to Kampala International University Western Campus Pharmaceutics and Pharmaceutical Technology Laboratory where they had to be stored according to manufacturers' storage conditions stated on package pending laboratory analysis.

Materials used in weight uniformity determination

To determine the weight uniformity of the different brands of fixed dose AL, equipment like an analytical balance, weighting boats. The analytical balance was not only applied for weight uniformity determination but also to weigh solutes for the preparation of the mobile phase.

Materials used in content analysis and assay

The equipment in the analysis of uniformity of content were stainless steel HPLC Column,

pH meter to be used to determine the pH of the mobile phase. Sonicator, Millipore apparatus for water filtration, Nylon membrane filters, filter paper, beakers, pipettes, spatulas, measuring cylinders, Vortexer, motor, and pestle.

Not only equipment was needed, several reagents were used inclusive of acetonitrile HPLC grade that was used as mobile phase A in assay and dissolution test. Hexane sulphonic acid sodium salt and sodium dihydrogen phosphate monohydrate (analytical grade) used to prepare the ion pair reagent (B-phase). Orthophosphoric acid (85%w/v) for pH adjustment of the ion pair reagent, 2-propanol (HPLC grade), and filtered distilled water as a solvent.

The artemether and lumefantrine reference standards (RS) were obtained from CIPLA Quality Chemical Industries Limited (Cipla QCIL), Uganda which was kept under the required storage condition that is temperature 2-8^{o}C and in a dark waterproof container with silica beads to absorb the moisture. These were applied in determination of the standard curves and calculating the quantity of artemether and lumefantrine in each batch.

Data management analysis

The generated laboratory results were kept in hard copies for safety and reference. Following HPLC analyses, resultant chromatograms generated were printed and filed. Data from chromatograms was entered in Microsoft excel before analysis.

For the data of the different physicochemical parameters that is from weight uniformity, average weight, standard deviation, and percentage relative standard deviations was calculated for each brand using standard formulae in Microsoft Excel. Not only for weight uniformity but also for friability, disintegration, hardness, thickness and dissolution was analysed using a standard formula in Microsoft excel.

Following assay, the area under the curve (AUC) obtained in the chromatograms of the samples and standard solutions during the assay of content was employed to auto-calculate the percentage amount of APIs

The amount of API in both the artemether and lumefantrine test assays was acceptable if the result was in the range of 90-110% of the declared amount as per international pharmacopeia.

To compare the assay results of both the Brand obtained from the general market and that obtained from the respective LTR, this was based on the difference or the similarity in the content following assay and a table showing the consistency (similarity of content) and inconsistency (difference in content) was obtained from the data set. Two pie charts showing the frequencies of occurrence of consistency or inconsistency were drawn from the data set for both Artemether AND Lumefantrine assays.

Ethical considerations

Ethical approval and clearance was obtained from Kampala international University Research and Ethics Committee. The identity of the drug outlets from which the drugs were obtained was protected by coding like A, B, C, D, E, F and so on. The different brands identity too was protected by use of codes BAL1, BAL2, BAL3, BAL4 and so on. To minimise bias, mystery shoppers who were used in the study were not be from the same location of tablet collection. During running of the different laboratory experiments, protective gears were put on to avoid any direct exposure of the reagents and the body. After the experiment, the wastes from the experiment were disposed off as per the NDA guidelines of pharmaceutical waste disposal. Data obtained from the research will be published but the identity of the brands and the drug outlets will be protected by coding and this is how the data will be published.

RESULTS

A total of 105 licensed drug out lets (Local Technical Representatives, wholesale and retail pharmacies) across the country from different regions were considered in this study (n=105) that is 14% local technical representatives for the different brands used in the study, and 86 percent general community retail and wholesale pharmacies. The proportion of wholesale to retail pharmacies used in the study is 82% retail (n=70) to 18% (n=10).

A total of 16 brands that had a claim of containing artemether-lumefantrine were obtained from the different selected cities and from the local technical representatives (LTR) except for one brand that wasn't at the LTR but on the general market. For each brand, packs of each available brand totaling to 48 tablets were bought. Out of the total brands (n=16) that were obtained, 81.0% (n=13) were

manufactured from India, 13.0% (n=2) from Uganda and 6.0% (n=1) from Switzerland as shown in table 3. All the sixteen collected brands had been registered for sale on Ugandan market evident from the latest updated Uganda Human drug register of September 2022 obtained from National Drug Authority website. Of the collected brands the two Uganda based manufactured brands that is Lumartem (20/120) from Cipla Quality Chemical Industries Limited and Lumaren (20/120) from Rene Pharmaceutical industries Limited had their registration details of Uganda put both on the pack where it was imprinted and on the insert. Other brands (6) that had this clear registration status as for the Ugandan based manufactured brands were from India and one brand coartem from Switzerland which is the innovator brand for this ACT. The batches of brands that were considered unregistered as of this study were those that had registration numbers from other countries like Tanzania, Ghana and Nigeria and had no Ugandan based registration status though were registered for sale on Ugandan Market by NDA. Of the sixteen collected brands, 13 (81%) had a strength of 20/120 (artemether/Lumefantrine) and one 6% had a strength of 60/360 and the final two 12% had a strength of 80/480 (Table 3).

Table 3: Collected brands and their general description

S/N	Brand name and strength	REG Status	Manufacturing date	Expiry date	Batch Number	LTR	Manufacturer	Country of origin
1	Lumartem 20/120	YES	05/2022	04/2025	QK20651	Quality chemical industries Ltd	CIPLA-QCIL	Uganda
2	Lartem	NO	04/2022	03/2025	LT12L	Abacus pharma(A) Ltd	Skant Healthcare Ltd	India
3	Artefan 60/360	NO	04/2021	03/2024	PA05831	Abacus pharma(A) Ltd	Ajanta pharma limited	India
4	Artefan 80/480	NO	11/2021	10/2024	PA19641	Abacus pharma(A) Ltd	Ajanta pharma limited	India
5	Artefan 20/120 Dispersible	NO	06/2022	05/2025	PA10152	Abacus pharma(A) Ltd	Ajanta pharma limited	India
6	Lonart 20/120	YES	11/2022	102025	B1AFJ147	Delmaw Enterprises Ltd	Bliss GVs pharma Ltd	India
7	Lonart DS 20/120	NO	6/2022	8/2025	BJBL19	Delmaw Enterprises Ltd	Bliss GVs pharma Ltd	India
8	Lariact 20/120	NO	12/2021	11/2024	L9856	Davimed Pharma Limited	Skant Healthcare Ltd	India
9	Lumaren 20/120	YES	09/2022	09/2025	07522	Rene industries Ltd	Rene Industries Ltd	Uganda
10	Lumiter 20/120	NO	08/2022	07/2025	L2756	Vitacare Limited	Macleods Pharmaceuticals Ltd	India
11	Comether 20/120	NO	09/2022	08/2025	T25005	Gittoes Pharmaceuticals Ltd	AGoG Pharma ltd	India
12	ROART 20/120	NO	11/2022	10/2025	R-86002	Royal Pharma 2011 (U) Ltd	Centurion laboratories PVT , LTD	India
13	Coartem 20/120	NO	2/2022	5/2025	HXL34	Surgipham(U)Ltd	Novartis Pharma Ag	Switzerland
14	Lumerex 80/480	NO	07/2021	11/2021	IGD031005	Medvin pharma	Ipca Laboratories Ltd	India
15	Komefan 140	NO	04/2022	03/2025	3149769	Delmaw Enterprises Ltd	Mylan Laboratories	India
16	Combiart	NO	06/2022	05/2025	VK1268	Delmaw Enterprises Ltd	Strides Shasun Limited	India

The commonest brands obtained from the market with artemether and lumefantrine containing labelled claim that were purchased included; 100% prevalence for Lumartem, Lumaren and Artefan 20/120 which were collected from all the ten cities. Following Lumartem and Lumaren was Lumiter and ROART at 70% that is from 7 out of the ten cities then Artefan 20/120 dispersible and Artefan 60/360 which were

both at 60% from 6 six cities, lonart 20/120 and lonart DS followed with a prevalence rate of 50 % from five cities. The brands with very low prevalence included coartem 20/120 Lariacte 20/120 both at 30% meaning that both were from three cities only. Not only coartem and lariacte 20/20 but also komefan 140 that was 20 % that is only from two cities and finally lumerex 80/480 and combiart 20/120 at 10% meaning they were found only in one city (Table 4).

This data on prevalence considered the different brands collected from different cities and it was following this information that the different Local Technical Representatives were contacted and the corresponding brands they were dealing in collected too which were to be used in comparison with what had been collected from the cities.

For brands that are on the National Drugs Register and were not found anywhere during collection, the corresponding Local Technical Representatives were contacted to find out whether the brands in question were absolutely off market.

Table 4: Brands collected in different cities/NDA regions

KAMPALA	JINJA	MBARARA	MBALE	GULU	SOROTI	LIRA	ARUA	FORTPORTAL	HOIMA
Lumartem	Lumartem	Lumartem	Lumartem	Lumartem	Lumartem	Lumartem	Lumartem	Lumartem	Lumartem
Lumaren	Lumaren	Lumaren	Lumaren	Lumaren	Lumaren	Lumaren	Lumaren	Lumaren	Lumaren
Artefan 20/120	Artefan 20/120	Artefan 20/1202	Artefan 20/120	Artefan 20/120	Artefan 20/120	Artefan 20/120	Artefan 20/120	Artefan 20/120	Artefan 20/120
Artefan 20/120 Dispersible	Artefan 20/120 Dispersible	Artefan 20/120 Dispersible	Artefan 20/120 Dispersible	Artefan 20/120 Dispersible	Artefan 20/120 Dispersible				
Artefan 60/360	Artefan 60/360	Artefan 60/360		Artefan 60/360	Artefan 60/360				
Lonart 20/120	Lonart 20/120	Lonart 20/120	Lonart 20/120	Lonart 20/120	Lonart 20/120	Lonart 20/120	Lonart 20/120	Lonart 20/120	Lonart 20/120
Lumerex 80/480	Lumerex 80/480								
			Combiart 20/120						
Comether	Comether				Comether				
Coartem 20/120	Coartem 20/120	Coartem 20/120							
ROART	ROART	ROART			ROART				
	Komefan 140								
	Lariact 20/120				Lariact 20/120				

DISCUSSION

The different brands of AL obtained and used in this study were sourced from India, Uganda and Switzerland (Table 3) to reach the Ugandan Market. Though, findings from the study express that most of the imported brands were not having Ugandan registration numbers imprinted on the pack but were having registration numbers from other countries (Table 4). This brings out numerous concerns to National Drug Authority since the safety, effectiveness and quality of these medicines is not assured. The Ugandan registration status was written on the insert for some of the samples in this study but not on the packaging material where it was expected to be imprinted. This may be indicative of product falsification and also a manufacturer's gap to renew their registration status. The presence of unregistered AL brands on the market could be attributed to the porous borders presence that may have facilitated not just free entry but also un-monitored distribution of these products [12-15]. The registration process in the country can alternatively be weakened by inefficiency and ineffectiveness in the implementation of some policies set by National Drug Authority (NDA) especially due to insufficient funding [16-18]. Therefore, there is need for regulatory authorities to strengthen pre and post market surveillance for surety that all AL Brands in the market are licensed and registered.

CONCLUSION

The presence of A/L brands that are unregistered (without Ugandan registration number on insert and pack) causes alarm and this calls for NDA to intensify on its operations of Pharmacy supervisions to find out the conformity of the pharmacies to selling only registered medicines.

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