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ABBREVIATIONS

ADRs	-	Adverse Drug Reactions
AIDS	-	Acquired Immuno Deficiency Syndrome
CDC	-	Centre for infectious Diseases Control
CSO	-	Central Statistical Office
DEC	-	Drug Enforcement Commission
DRC	-	Democratic Republic of Congo
GPHF	-	German Pharma Health Fund
HIMS	-	Health Management Information System
HIV	-	Human Immunodeficiency Virus
LUD	-	Lusaka Urban District
MDGs	-	Millennium Development Goals
MOH	-	Ministry Of Health
PHC	-	Primary Health Care
PRA	-	Pharmaceutical Regulatory Authority
UN	-	United Nations
UV	-	Ultra Violet
UNZA	-	University of Zambia
UNZA REC	-	University of Zambia Research Ethics Committee.
USP	-	United States Pharmacopoeia
WHO	-	World Health Organization
ZDHS	-	Zambia Demographic Health Survey

ABSTRACT

The problem of counterfeiting of drugs presents an enormous public health challenge. No area of the world is unaffected, but mounting evidence shows that the problem is disproportionately severe in developing and emerging market countries, which also have a high burden of infectious diseases such as tuberculosis and malaria. Since no area of the world is unaffected, it is obvious that Zambia is no spared, although there is almost complete absence of both qualitative and quantitative data on the prevalence of counterfeit and substandard drugs in the country.

The purpose of the study was to evaluate the quality of Artemether/Lumefantrine, Sulphadoxine/Pyrimethamine and Quinine tablets in selected Public and Private Health Institutions in Lusaka District.

A cross sectional design study was conducted using quantitative research method. 20 Public and Private Health Institutions were randomly selected, and 430 tablets of each drug type were selected using convenient sampling method. The quality of the drugs was ascertained using the GPHF-Minilab at Pharmaceutical Regulatory Authority, and data were entered in Epidata and analysed, and presented in cross tabulations.

This study provides objective evidence to answer speculations whether or not substandard antimalarial drugs exist in Lusaka. The study has revealed that substandard antimalarial drugs exist in Lusaka as evidenced by the 6.98% of Sulphadoxine/Pyrimethamine tablets that failed to comply with the required active ingredients and their percentage content. The substandard drugs could not have been counterfeited but could have been as a result of non adherence to Good Manufacturing Practice. The study shows that the antimalarial drugs conformed to the official monographs requirements in ascertaining the quality of the pharmaceutical products in terms of packaging and labelling. The existence of substandard antimalarial drugs in Lusaka, and their final use in prevention and treatment of malaria could have detrimental clinical consequences and implications to the patient, as substandard drugs unsafe and inefficacious.

The revelation of the existence of substandard drugs by this study poses a challenge to the Pharmaceutical Regulatory Authority to enhance its Post-marketing surveillance

programme to ensure and assure constant quality monitoring of drugs that are found on the Zambian market, as quality, safety and efficacy are the tenets of every pharmaceutical product.

DEDICATION

This research is dedicated to my beloved and dear wife, MISOZI NGOMA ALUTULI, who has always been supportive and inspiring to me and at the same time who was my course mate for the Masters of Public Health programme.

I also dedicate this research to my late parents, Mr. and Mrs. Alutuli, and my beloved children, Clara, Junior Luke, Joseph, Neketela, Nana Njamba, Hope and Grace Lormuthunzi Chisomo for the support and encouragement they rendered to me during my research.

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