

TABLE OF CONTENTS

Table of contents	i
Copyright	v
Abbreviations.....	vi
Abstract	vii
Dedication	ix
Acknowledgements	x

CHAPTER ONE

Introduction	1
Background	4
Quality, safety and efficacy of drugs	5
Associated factors of counterfeit and substandard drugs	6
German Pharma Health Fund (GPHF) Minilab	6
Effects of counterfeit and substandard drugs.....	6
Statement of the Problem	7
Problem analysis diagram	8
Rationale of the study	9
Study objectives	9
Research question	10
Operational definitions	10

CHAPTER TWO

Literature review	11
-------------------------	----

CHAPTER THREE

Research methodology	13
Study setting	13
Study population	13
Study design	13
Variables	14
Inclusion criteria	14
Exclusion criteria	14
Sampling method	14

Sample size determination	15
Data collection technique	15
Validity of the results	16
Reliability of the results	16
Data quality control checks	16
Ethical consideration	16
Data analysis	17
Materials and methods	17
Drugs and formulations chosen for the study	18
Artemether/Lumefantrine tablets quality analysis	19
Sulphadoxine/Pyrimethamine tablets quality analysis	24
Quinine sulphate tablets quality analysis	29

CHAPTER FOUR

Data presentation	35
Analytical results	35
Discussion	48
Conclusion	50
Recommendations	51
Study limitations	51
References	52
Appendices	55
Appendix I: Drug collection sheet	55
Appendix II: Gant chart	56
Appendix III: Study budget	57
Appendix IV: Consent form	58
Appendix V: Letter for permission to carry out the study	59
Appendix IV: Letter for permission to collect drug samples from public health institutions	60

List of figures:

Figure 1: Picture of all antimalarial drugs collected for quality analysis ... 18

Figure 2: Picture of Artemether/Lumefantrine tablets collected for quality analysis
..... 19

Figure 3: Picture of Sulphadoxine/Pyrimethamine tablets collected for quality analysis
..... 24

Figure 4: Picture of Quinine sulphate tablets collected for quality analysis.. 29

List of tables:

Table 4.2.1: Results of the verification of active ingredients contained in
Artemether/Lumefantrine tablets analysed 36

Table 4.2.2: Results of the percentage content of active ingredients contained in
Artemether/Lumefantrine tablets analysed 37

Table 4.2.3: Results of the assessment of packaging and labelling of
Artemether/Lumefantrine tablets for quality 38

Table 4.2.4: Results of ascertaining the proportion of Artemether/Lumefantrine tablets
that were substandard 39

Table 4.2.1.1: Results of the verification of the active ingredients contained in
Sulphadoxine/Pyrimethamine tablets analysed 40

Table 4.2.1.2: Results of the percentage content of the active ingredients contained in
Sulphadoxine/Pyrimethamine tablets analysed 41

Table 4.2.1.3: Results of the assessment of packaging and labelling of
Sulphadoxine/Pyrimethamine tablets for quality 42

Table 4.2.1.4 Results of ascertaining the proportion of Sulphadoxine/Pyrimethamine
tablets that were substandard 43

Table 4.2.1.1.1: Results of the verification of active ingredient contained in Quinine
sulphate tablets analysed 44

Table 4.2.1.1.2: Results of the percentage content of active ingredient contained in
Quinine sulphate tablets analysed 45

Table 4.2.1.1.3: Results of the assessment of packaging and labelling of Quinine sulphate
tablets for quality 46

Table 4.2.1.1.4: Results of ascertaining the proportion of Quinine sulphate tablets that were substandard 47

COPYRIGHT

All rights reserved. No part of this study may be reproduced or stored in any form either electronically, mechanically, photocopying, recording or otherwise without prior written permission from the author or the University of Zambia.

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.

To all my brothers and sisters, and all my in laws for the support and prayers to enable me accomplish my research.

ACKNOWLEDGEMENTS

This research could not have been successfully completed without the invaluable support and guidance of the so many people I am highly indebted to.

To my supervisors, Dr. C.C. Michelo and Mr. O. Mweemba, especially Dr. C.C. Michelo, thank you very much for finding time from your busy schedule to guide me, read my numerous revisions, encourage me and ensuring that this study succeeds.

I would also like to recognise the support rendered to me by Professor S. Siziya, Dr. S. Nzala, Dr. W. Mutale, and Mr. R. Zyambo for reading through my proposal and rendering me valuable guidance and encouragement.

My profound gratitude goes to the Pharmaceutical Regulatory Authority staff, especially the Director General, Ms.E. Mwape and the inspectorate staff, and the Quality Control Laboratory Manager, Mr. Mainga for the support they rendered to me by authorising to buy drug samples from private health institutions in Lusaka, and also for allowing me use their quality control laboratory at no cost.

I also wish to thank the Permanent Secretary- Ministry of Health, the Deputy Director Pharmaceutical Services, Mr. Nanduba, and Lusaka District Health Management Team for the supporting they render to me as my sponsors and authorising me to collect drug samples from public health institutions in Lusaka District.

I am also indebted to the entire department of Community Medicine staff for the knowledge they imparted in me which enabled me to write the proposal and finally come up with this piece of research work.

To God is the glory for the good health I enjoyed during the period of my research work.

Finally my profound thanks go to my dear wife, children, brothers and sisters, in laws and friends for the support and tolerance for being away from them for a long time as I spent long hours working on my research.