

**A Catch-22? An Exploration of the Domestic Production of
Antiretroviral Drugs in Uganda**

By

Margo E. Warren

A Thesis Submitted in Partial Fulfillment of the Requirements
For the Degree of Master of Arts in International Development Studies

Saint Mary's University, Halifax, Nova Scotia

© Margo E. Warren, 2012

Approved:
Dr. Robert Huish Ph.D.
Supervisor

Approved:
Dr. Joseph Tharamangalam Ph.D.
Reader

Approved:
Dr. Matthew Schnurr Ph.D.
External Examiner

Date: July 31st, 2012



Library and Archives
Canada

Published Heritage
Branch

395 Wellington Street
Ottawa ON K1A 0N4
Canada

Bibliothèque et
Archives Canada

Direction du
Patrimoine de l'édition

395, rue Wellington
Ottawa ON K1A 0N4
Canada

Your file Votre référence

ISBN: 978-0-494-89994-6

Our file Notre référence

ISBN: 978-0-494-89994-6

NOTICE:

The author has granted a non-exclusive license allowing Library and Archives Canada to reproduce, publish, archive, preserve, conserve, communicate to the public by telecommunication or on the Internet, loan, distribute and sell theses worldwide, for commercial or non-commercial purposes, in microform, paper, electronic and/or any other formats.

The author retains copyright ownership and moral rights in this thesis. Neither the thesis nor substantial extracts from it may be printed or otherwise reproduced without the author's permission.

AVIS:

L'auteur a accordé une licence non exclusive permettant à la Bibliothèque et Archives Canada de reproduire, publier, archiver, sauvegarder, conserver, transmettre au public par télécommunication ou par l'Internet, prêter, distribuer et vendre des thèses partout dans le monde, à des fins commerciales ou autres, sur support microforme, papier, électronique et/ou autres formats.

L'auteur conserve la propriété du droit d'auteur et des droits moraux qui protège cette thèse. Ni la thèse ni des extraits substantiels de celle-ci ne doivent être imprimés ou autrement reproduits sans son autorisation.

In compliance with the Canadian Privacy Act some supporting forms may have been removed from this thesis.

While these forms may be included in the document page count, their removal does not represent any loss of content from the thesis.

Conformément à la loi canadienne sur la protection de la vie privée, quelques formulaires secondaires ont été enlevés de cette thèse.

Bien que ces formulaires aient inclus dans la pagination, il n'y aura aucun contenu manquant.

Canada

A Catch-22? An Exploration of the Domestic Production of Antiretroviral Drugs in Uganda

Margo E. Warren, Master of Arts

Abstract

This research focuses on analyzing the potential of the domestic production of antiretrovirals (ARVs) to be used as a means of increasing access to medications for Acute Immune Deficiency Syndrome (AIDS) patients requiring treatment in Uganda. The case study of the South-South partnership between the Ugandan pharmaceutical company, Quality Chemical Industries Limited (QCIL), and the Indian drug-manufacturing corporation, Cipla, looks at the development of a local pharmaceutical industry for the production of ARV drugs. The research notably explores the issues that can impede the success of the endeavor. I argue that currently the operation has not led to a significant increase in access to the medications primarily due to market entry restrictions. However, it does have the ability to amplify long-term access to affordable ARV drugs in the country in the future if a variety of factors are met at both the local and international level.

July 2012

Acknowledgments

First and foremost, I must thank my thesis supervisor Dr. Robert Huish. This thesis would not have been made possible without his guidance, encouragement, and suggestions. I came to him with an idea and he believed that we could turn it into a great topic. For that I am forever grateful, as he has provided me with years of inspiration. I would also like to thank my First Reader Dr. Joseph Tharamangalam for taking on my work despite the large geographically distance between us. His knowledge and expertise on the Indian side of the research helped me to better comprehend the critical issues at hand. In his course and through his work with me on this research project I have learned a great deal. As well, I am thankful to my External Examiner Dr. Matthew Schnurr for agreeing to take the time to read my thesis. Coincidentally, he also fueled my desire to study African development, many years ago as an undergraduate student in his modern African history course.

I would also like to acknowledge the help of my fellow classmates, in my graduate program. Their kind words of encouragement, important critiques, and positive attitudes helped me along the way and up until the final days of writing. I cannot thank them enough for the articles they brought to my attention and for helping me with the process of my research.

I am thankful to my family who have supported this research from day one and who have always taught me to keep going even when obstacles present themselves. Constant phone calls to discuss my research helped me wrap my head around some of the important elements of my research.

I must also thank all of the people I met in Uganda, who assisted with my research. By sharing their stories, both hardships and successes, it provided me with the motivation to keep writing. Their kindness and generosity will always be appreciated. A special thanks goes out to my American friends in Uganda who helped to uncover the mystery of the Ugandan drug industry, and who knew that secrets could be unlocked over tea and chapatti.

Lastly, I am thankful to Nathan for believing in me even when he didn't always agree with me.

Table of Contents

Abstract.....	ii
Acknowledgments	iii
List of Figures	vi
List of Acronyms and Abbreviations	vii
Dedication	ix
Chapter 1:.....	1
Introduction to the Topic	1
Background	4
The issue at hand	6
Research questions	9
Main argument	10
Justification of study	12
Outline of the thesis	14
Chapter 2:.....	16
Literature Review	16
Health and development.....	16
The intrinsic and instrumental value of health	16
AIDS and development.....	21
The impact of the epidemic on the Global South	21
Antiretroviral medications and the fight against AIDS:	23
The global ARV scale up and the debate about the benefits of foreign aid	23
Factors influencing the production and distribution of ARVs:	25
The effect of TRIPS on the provision of ARVs	25
South-South trading partnerships for health related products	33
The Production of generic drugs	36
India's pharmaceutical industry and its ability to produce ARV drugs	36
The importance of the Doha Declaration and its impact on generic drug production ...	38
The domestic production of ARVs	39
Chapter 3:.....	42
Methodology	42
Justification of the study	42
Limitations to the scope of the study	45
Required information	47
Data collection techniques	48
Policy discussions	48
Key informant interviews	50
Documents	53
Analysis of findings	54
Chapter 4:.....	57
ARV Provision and Distribution in Uganda	57

Treatment as prevention	73
Factors preventing universal ARV distribution in Uganda	78
The role of NGOs in the distribution of ARVs in Uganda	81
Chapter 5:.....	86
India's Foreign Direct Investment in Uganda	86
Pharmaceutical sector development in India: The origins of Cipla	86
Quality Chemical Industries Limited: History and current operations.....	96
Foreign direct investment for the production of pharmaceuticals	98
The Politics of TRIPS and its influence on generic pharmaceutical production	102
Chapter 6:.....	117
Key Findings.....	117
Operational costs and the process of cost recovery	118
Strategies for cost reduction.....	123
Issues with entry into the market for ARVs.....	128
The Significance of the South-South partnership	133
Supply chains and market competition	135
The implications of the TRIPS Agreement	142
Closing remarks	146
Chapter 7:.....	148
Conclusion and Recommendations	148
Suggestions for the future.....	150
NGO collaborations with the Government	157
Long-term access to care.....	159
Outlook on the future	160
Bibliography:	163
Appendix 1: Interview Guide.....	178
Appendix 2: Informed Consent Form	182
Appendix 3: Partner Organization Support Letter	185
Appendix 4: Government Research Permit.....	186
Appendix 5: Research Ethics Certificate.....	187

List of Figures

Figure 1: The Scale up of ARVs.....	63
Figure 2: The Distribution of Financing for ARVs	66
Figure 3: ARV Donor Funding Distribution:.....	130
Figure 4: ARV Supply Chain Flow Chart.....	136

List of Acronyms and Abbreviations

Abuja Declaration: The 2001 Abuja Declaration on HIV/AIDS, Tuberculosis, and Other Infectious Diseases

ACP: AIDS Control Program

AIDS: Acute Immune Deficiency Syndrome

APIs: Active pharmaceutical ingredients

ART: Antiretroviral therapy

ARV: Antiretroviral

BRICS: Brazil, Russia, India, China, and South Africa

BIPAI: Baylor International Pediatric AIDS Initiative

CA: Crown Agents

CapitalWorks: CapitalWorks International Partnership Fund

CCO: Chief Commercial Officer

CDC: Centre for Disease Control

CHAI: Clinton Health Access Initiative

CSIR: The Indian Council of Scientific and Industrial Research

CSR: Catholic Relief Services

Doha Declaration: The Doha Declaration on the Trade Related Aspects of Intellectual Property Rights Agreement and Public Health

d4T: Duovir-N

EFV: Efavirenz

FDA: Federal Drug Authority

FDI: Foreign Direct Investment

GATT: General Agreement on Tariffs and Trade

Global Fund: The Global Fund for AIDS, Tuberculosis, and Malaria

HAART: Highly Active Antiretroviral Therapy

HIV: Human Immunodeficiency Virus

HSHASP: Health Sector HIV/AIDS Strategic Plan

IDCs: Innovative Developing Countries

IDI: Infectious Disease Institute

JCRC: Joint Clinical Research Centre

LDC: Lesser Developed Country

3TC: Lamivudine

MAP: World Bank Multi Country AIDS Program

MoH: Ministry of Health

MeTA: Medicines Transparency Alliance

Mulago: Mulago National Hospital

MSF: Médecins Sans Frontières

NDA: National Drug Authority

NMS: National Medical Stores

NGO: Non-Governmental Organization

NVP: Nevirapine

Paris Convention: Paris Convention for the Protection of Industrial Property
PEPFAR: The US President's Emergency Plan for AIDS Relief
PEA: Private Equity Africa
PhRMA: Pharmaceutical Research and Manufactures of America
QCL: Quality Chemicals Limited (formally known as)
QCIL: Quality Chemical Industries Limited
RoU: Republic of Uganda
SAPs: Structural Adjustment Programs
SCMS: Supply Chain Management System
STD: Sexually Transmitted Disease
TASO: The AIDS Support Organization
TB: Tuberculosis
TLG: TLG Capital Fund
TPI: Tanzanian Pharmaceutical Industry Limited
TRIPS: Trade Related Aspects of Intellectual Property Rights
UAC: Uganda AIDS Commission
UK: United Kingdom
UNAIDS: The Joint United Nations Programme on HIV/AIDS
UNGASS: United Nations General Assembly Special Session
UPMA: The Ugandan Pharmaceutical Manufactures' Association
US: United States
USAID: United States Agency for International Development
USD: United States Dollars
US FDA: United States Food and Drug Administration
WHO: World Health Organization
WTO: World Trade Organization
AZT: Zidovudine

Dedication

To the children at Mulago who could brighten
even the gloomiest of days with their smiles.
May you always receive the medication you need.

Chapter 1:

Introduction to the Topic

For over thirty years Acute Immune Deficiency Syndrome (AIDS) has plagued countries, predominately those in Sub-Saharan Africa. While great strides have been made since the onset of the epidemic, in terms of treatment and prevention, over 22.5 million people are currently living with human immunodeficiency virus (HIV) in the region (United Nations Programme on HIV/AIDS [UNAIDS], 2010). The disease has crippled the health care systems of already resource-deprived countries, only further accentuating the problem. Governments struggle to provide care to patients, despite the strong presence of international aid agencies and non-governmental organizations (NGOs) that are contributing to the fight against AIDS. It is clear that long term, sustainable measures to treat patients and to prevent the spread of the disease are necessary and that these solutions must come from within those countries most greatly affected by the disease. However, due to the high cost of the necessary medications to treat AIDS, many governments have grappled with how to best address the issue given their limited resources.

When HIV was first viewed in patients in the early 1980s, treatment programs did not exist. At this time doctors and researchers had never seen AIDS, which is the advanced acute syndrome that develops from the HIV virus. Thirty years ago there was no cure nor were there therapeutic medicines available for patients identified with the disease. In the early stages of the history of HIV/AIDS, doctors focused on dealing with

the many opportunistic infections that occur as a result of the virus' breakdown of the host's immune system. Patient care was centered on treatment of the symptoms of AIDS, as opposed to the root cause.

It was not until 1987, that any drug focusing directly on the HIV virus was approved (Konopnicki & Clumeck, 2004). By this time, HIV/AIDS had spread to a global epidemic. By 1988 AIDS rates had skyrocketed specifically, in Sub-Saharan Africa, where the disease is believed to have originated (Avert, 2012a). Adult prevalence rates in Africa were upwards of 30% of the population, particularly in the great lakes region (2012a). Significant gains in the effectiveness of the drugs were later made with the introduction of Highly Active Antiretroviral Therapy (HAART) (2004). The new treatment program consisted of a triple combination of antiretroviral medications. This development proved to be successful in suppressing the viral load of human immunodeficiency virus found in a patient suffering from AIDS (2004). While the discovery of HAART was a critical step in the provision of treatment to those in desperate need, the creation of the medication did not transfer into immediate relief for all patients on a global scale. The cost of the antiretroviral drug therapy (ART) was extremely high, and ranged from \$7,944 USD to \$20,224 USD per person per year depending on the type of drug required and the specific brand¹ (Floyd & Gilks, 1998). The exorbitant price of the treatment made the medicines nearly impossible to obtain for the HIV positive population living in poverty. For those surviving on less than one dollar

¹ Many different types of drug combinations are available for the treatment of HIV/AIDS. Adult first line drugs primarily consist of a combination of three different antiretrovirals. First line drugs are used most predominantly for patients that have recently begun treatment or those who have successfully adhered to the initial treatment regime presented by his or her physician. For the purpose of this research I will be referring primarily to adult first line drugs, as they are the most commonly used ARVs in Uganda and what are being produced in Uganda.

a day, a year's supply of antiretroviral (ARV) drugs at even the lowest price available would be equivalent to the entire daily expenditure of one person every day for approximately twenty-two years (author's own calculations).

Fisher (2005) explains that the cost of drug therapy continues to act as a significant factor affecting the provision of ARVs. In recent years, the prices have fallen to as low as \$64 USD per person per year for the most popular first line combination drug therapy (World Health Organization [WHO], 2010). While efforts to reduce the cost of ARVs have been relatively successful through multilateral organization subsidies, lobbying, and the introduction of generic versions of the drugs, it is important to recognize that the medicine still remains out of reach for millions of people worldwide (UNAIDS, 2012b). For those living below the poverty line purchasing ARV drugs out of one's own pocket is an unrealistic expectation that would lead to crippling economic loss. Many patients in the Global South are forced to rely on the support of weak government services to gain access to the medications. However, due to the overwhelming number of patients requiring the drugs, the governments of economically hobbled countries are primarily unable to provide ARVs to their citizens or to reach the entire population in need (Pogge, 2008). These countries must, therefore, rely extensively on the help, and outreach of multilateral and NGOs.

Recent studies have proven that by taking antiretroviral drugs, one can significantly reduce his or her transmission rate, by upwards of 96% (WHO/UNAIDS, 2011). As well, starting treatment early can decrease the incidence of developing tuberculosis (TB) by 90% (UNAIDS, 2012b). This is a significant factor in preventing AIDS deaths as TB is

listed as the technical cause of death for the largest amount of AIDS patients (Médecins Sans Frontières [MSF], 2011).

According to UNAIDS, if combined efforts to increase treatment and prevention are heightened with continued financial support 12 million infections and over 7 million deaths can be avoided by 2020, with new infections halved by 2015 (2011). Now the need to provide ARV drugs is of even greater importance, as treatment of the sick leads to prevention for the population.

Background

The international community viewed Uganda early on as a leader amongst African countries for its recognition of the human and development consequences of HIV/AIDS (Kinsman, 2010). By 1986 the country already formulated an action plan to combat the disease, and took an open and honest approach towards discussing prevention methods (2010). Uganda's approach to dealing with the devastating epidemic in its early years was praised, as many other nations at the time had not acknowledged the impact of the disease (2010). The country became known as a success story for Africa in the way it addressed and dealt with the issue of HIV/AIDS (2010).

Yet, at the beginning of the 1990's Uganda's HIV/AIDS rate was the worst in the world (AVERT, 2012b). Unfortunately, the country continued to be in desperate need of treatment programs (Haakonsson & Richey, 2007). Furthermore, within the country only an elite group of citizens had access to ARV drugs, as few could afford the expensive patented versions (O'Manique, 2004). While it was evident that the average HIV positive Ugandan could not afford to pay the enormous price tag for the medications, the problem

was exacerbated by the public health system's lack of resources required to treat and care for the growing number of AIDS patients. International organizations recognized the urgency of this issue and provided HIV testing, implemented prevention programs, and rolled out ARVs for treatment of the disease.

Despite the country's proposed achievements in fighting HIV/AIDS, the prevalence rate of the virus in Uganda has continued to result in significant challenges to development. The gravity of the HIV emergency in the country remains enormous. The disease has caused extensive suffering for a substantial proportion of the population, as AIDS not only affects the patients but their family members and loved ones, who must care for them. Over 1 million people are living with the disease in Uganda and more than 100,000 new infections occur each year (UNAIDS, 2012a). The high volume of HIV positive people in Uganda has led to a situation in which an overwhelming number of patients require immediate treatment in order to survive. The National AIDS Program remains highly dependent on the provision of foreign aid to maintain and enhance treatment plans (Ministry of Health [MoH], 2011a). This situation poses a threat to the continuation of the Program in the event of reductions in donor funding.

ART is proven to be successful in increasing the quality of life for patients. The drugs allow those who are HIV positive to live healthy lives, suppressing the progression of the virus into AIDS. As well, for those patients who are already suffering with symptoms from AIDS, drug therapy can help them to recover, to maintain their livelihoods, and to enable them to participate in everyday life activities as they would otherwise. The drugs are essential in protecting the capabilities of HIV/AIDS patients. Access to the medications, is therefore, not only crucial for patients to remain in good

health but necessary to aid in the intrinsic and instrumental development efforts of the country.

Although these drugs are attainable for the affluent members of the global society, for those where AIDS rates are the highest, and whose governments cannot provide universal access, ARVs remain unaffordable and inaccessible. The Government, multilateral organizations, and NGOs support treatment programs in Uganda. Nevertheless, for the majority, acquiring these medications is still extremely difficult, as less than 50% of the Ugandan population with HIV/AIDS has access to the drugs (Ministry of Health [MofH], 2011). In order to protect the human right to health for HIV positive patients it is critical for Uganda to improve treatment for those suffering from HIV/AIDS by finding a sustainable method of accumulating ARVs through which the country can become self-reliant.

The issue at hand

The focus on manufacturing generic versions of ARVs has increased their affordability and accessibility. However, due to the 1994 agreement on the Trade Related Aspects of Intellectual Property Rights (TRIPS), which is enforced by the World Trade Organization (WTO), many countries are now prohibited by international law from creating and manufacturing generic versions of patented brand name drugs.

The Doha Declaration on the TRIPS Agreement and Public Health (The Doha Declaration) was settled on in November 2001, allowing countries to manufacture less expensive versions of crucial drugs in the name of public health emergencies, as defined by the governments of the states themselves (Haakonsson & Richey, 2007). Previously,

the TRIPS Agreement prevented the replication of any patented drug, which posed major risks to the health of billions who could not afford to pay the expensive prices for brand name Western products. The Doha Declaration temporarily paved the way for governments to produce generic forms of otherwise patented and out of reach drugs to attempt to account for the issue of health epidemics.

As a result of the Doha Declaration, select Lesser Developed Countries (LDCs), as defined by the WTO, are now legally able to produce generic versions of patented essential medicines until 2016 when they will no longer be exempt from the regulations of the Agreement. The World Health Organization (WHO) (2010a) defines ‘essential medicines’ as “those that satisfy the priority health care needs of the population” (p.1). In practice, the clause does not necessarily equate to increased access to these medicines, as many countries lack resources and infrastructure to produce the medications on their own.

For lower-middle income countries excluded from the Doha Declaration, patents act as barriers for the continued production of new generic pharmaceutical products (MSF, 2011). These countries must either rely on the medications that were developed prior to the TRIPS Agreement or depend on ‘discounted’ price systems from brand name companies, which can amount to six times the cost of the generic equivalent (2011).

Prior to the TRIPS Agreement countries in the Global South, most predominantly Brazil and India were successful in developing profitable pharmaceutical industries. Pharmaceutical companies were able to produce and sell drugs for more locally affordable prices than patented versions sold at inflated Western prices. These countries introduced generic versions of antiretroviral medications early on, as both had pre-established facilities for the production of generic pharmaceuticals. These lower middle-

income countries remain huge exporters of generic ARVs to other areas in the Global South. Most notably, India is the primary supplier of ARV drug imports in Africa (UNAIDS, 2012b). Only a select few countries included under the LDC category of the TRIPS Agreement have been able to utilize the amendments made to the Agreement to manufacture generic versions themselves.

Domestically producing drugs can significantly reduce their costs by eliminating expensive transportation costs. As well, countries can maintain more control over the pricing to provide locally affordable prices in conjunction with a constant supply of ARVs within the country (Aginam, 2010). UNAIDS (2012b) advocates for increased FDI to produce ARVs, as such initiatives will, “play a major role in not only ensuring long – term access to HIV medicines but in developing an industry manufacturing other medicines particularly suited to the African context” (p.21).

While governments and NGOs strive to provide ARVs to patients, based on the findings of this research, for many the drugs are still very difficult to obtain. Providing a steady domestic supply of the drugs can also decrease the instances of stockpile shortages when the drugs ordered from abroad fail to arrive on time. It is extremely problematic both practically and morally speaking when supplies of ARVs run out, as government services, and NGOs and can no longer provide patients with the proper medications. This poses an enormous risk to the HIV population, as ARV drugs must be taken daily in order to be effective. Otherwise, patients are put at risk for developing a lifelong resistance to the drugs, rendering the medicine ineffective. Increasing national supplies of ARV drugs and lowering the costs of medications to treat HIV/AIDS are important steps in enhancing

coverage. Albeit, there are many issues involved with the local production of antiretrovirals that will be explored through this thesis.

In 2007, a partnership was formed between the Government of Uganda, the Ugandan pharmaceutical company, Quality Chemical Industries Limited (QCIL), and the Indian generic drug-manufacturing corporation, Cipla. The drug factory in Luzira, a suburb outside of the capital Kampala, began to produce generic ARVs in 2007, with support from Cipla. The focus on the domestic production of ARVs in Uganda is an issue that necessitates the focus of this research. There is great potential, through the creation of the factory, to lower the price of the drugs and increase the amount of medicine existing within country. By eliminating the transportation costs of imported drugs, and ensuring that generic versions are made readily available companies producing ARV drugs domestically could, in theory, provide generic drugs for prices lower than those of imported versions. If price reductions are achieved through local production access to the medications could be increased by enabling the procurement of larger quantities of the drugs despite price ceilings for funding. The strategy seeks to enhance treatment numbers with the hope of eventually creating a self-sustaining system for the provision of ARVs, although many factors impact its ability to do so.

Research questions

As the number of patients requiring antiretroviral medicine continues to grow each year countries must look towards more long-term solutions in order to facilitate the treatment of these patients in need. This thesis specifically explores the viability of the domestic production of ARV drugs to increase access to the medication in Uganda. For

the purpose of this thesis increasing access is defined in terms of heightened affordability resulting in the augmentation of the procurement capacities for agencies supplying ARVs. Specifically, the thesis intends to answer two main questions with regard to foreign direct investment (FDI) for the production of ARV drugs in Uganda. The research questions posed are as follows:

- 1) Can the domestic production of ARVs in Uganda increase maintainable access to medicine for HIV positive patients in the country?
- 2) What factors influence the potential success of this particular FDI operation?

Main argument

I argue that currently the production of ARV drugs in Uganda has not led to a significant increase in access to the medications due to barriers of entering the ARV market. However, the operation has the potential to do so in the future if particular cost reduction strategies and policy changes are met at both the local and international level. The empirical evidence collected through field research completed in Uganda demonstrates that several factors, including increased entry to the donor market, further price reductions, and the significance of the company's South-South partnership with Cipla shape the joint venture's capability of increasing access to affordable ARV drugs. The key findings are as follows:

1) The need for entry into the donor market for ARVs.

All ARVs purchased with government funding for supply in public clinics and institutions are procured directly from QCIL. However, presently all multilateral and non-

governmental organizations in Uganda are not purchasing ARVs from the factory.

Particularly, the organizations receiving funding from the United States (US) Government are restricted from procuring any medicine produced at the factory based on the organization's official policy. Since many government clinics and hospital wings partner with and receive funding from American organizations, they are unable to buy drugs produced within Uganda. This factor acts as a substantial barrier to entry into the market for ARVs for QCIL, and impacts its cost recovery phase as well as its ability to achieve economies of scale by increasing the productive capacity of the plant.

2) The necessity of further price reductions

A situation known as a 'Catch-22' presents itself. For organizations to procure from QCIL price reductions must occur, while for the costs of the drugs to be reduced more buyers must in turn purchase the drugs. Currently, while the generics produced at the plant are lower in cost than brand name versions, they do not match the prices of the lowest imported generics. In order for the factory to facilitate an increase in access to the ARV medications further price reductions must therefore occur. The 'Catch-22' situation and be resolved through several cost reduction strategies.

3) The significance of QCIL's South-South partnership with Cipla

The South-South partnership plays a vital role in the ability for operation to survive, as it increases the potential for the plant to obtain more cost effective pricing while ensuring the high caliber of the factory. If completed through assistance from Cipla the final phases of the operation could decrease the price of the drugs produced within the country enough to be cost competitive. This could provide ARV drug prices that are lower than those of imported versions.

Along with backing from the donor community to purchase the drugs produced at the plant further reductions in pricing could lead to an increase in the amount of drugs procured by both the public and donor financed not for profit sector. The results of this study support the viewpoint that the domestic production of ARVs can increase access to the medications, while raising important concerns with regard to the factors necessary for the particular operation to be successful in doing so.

Justification of study

The number of patients requiring ARV medicine only continues to rise as approximately 124,000 people are infected with HIV each year in Uganda (Ministry of Health [MofH], 2011). As infection rates increase the need for a feasible means of providing these medications becomes even more critical. New ways of procuring ARVs in countries with high HIV/AIDS rates must be further explored in order to develop a sustainable solution to treat the growing number of patients. Providing relatively inexpensive generic drugs to treat HIV/AIDS, contributes to the enhancement of the health of entire populations that are burdened with their struggle to cope with the disease. However, a reliance on external actors to procure and distribute such drugs can hinder the capability of a country to advance its own long-term solution to the problem at hand.

This research is necessary to investigate the issues surrounding the development of profitable pharmaceutical sectors for generic ARV drugs in economically marginalized countries. Pharmaceutical industries in countries with significant HIV/AIDS rates could, in theory, help increase access to the essential medications needed to treat the epidemic

and improve the ability for citizens to obtain an integral aspect of the human right to health. In the case of Uganda, FDI for the production of ARVs could boost access to the drugs, although the ability to do so is influenced by a variety of factors. Exploring the research questions (1) and (2) will contribute to important dialogue in both global health and development literature. While case studies (Cohen *et al.*, 2005; Wilson, 2009; Guimier, Lee, and Grupper, 2004) have looked at the challenges to the domestic production of ARV drugs in various countries in Sub-Saharan Africa, to date, no extensive studies have focused on the specific operations in Uganda.

This research specifically uses the case of Uganda to exemplify the challenges new pharmaceutical companies may face when attempting to enter the market for the sale of generic ARV drugs to government and NGO purchasers. The study analyzes the ability for Uganda to increase affordable access to antiretroviral drugs through the construction of the QCIL drug factory. It will examine the drug procurement and distribution methods of various NGOs in the region and the impacts their presence has on the generic drug factory's successful entry into the pharmaceutical market for ARVs. This information will help shed light on the potential challenges that other emerging pharmaceutical operations for the production of generic ARVs may also face. Specifically, this study will advance knowledge on the impact that the presence of foreign donors has on ARV pharmaceutical sector development and the significance of the role of the South-South partnership between Uganda and India.

In the wake of ongoing debates over the injustice of TRIPS in regards to its hindrances on human capabilities, the research exhibits the necessity of obtaining and producing generic versions of ARVs for countries burdened with the disease. The thesis

considers the benefits and cost effectiveness of the proposed mode of procuring the medications, while reflecting on the moral significance of increasing lifelong access to ARV drugs for those in need.

Outline of the thesis

The first three chapters of this thesis provide information on the nature of the study along with significant background to the area of research. Chapter 2 discusses the conceptual framework of the thesis through a literature review. Chapter 3 provides the methodology, which frames the scope of the study and addresses the issues of the data collection techniques.

Chapter 4 looks at the role of the Government of Uganda in the provision of ARVs to those living in the country that must acquire the drugs to maintain their human right to health. A history of AIDS policy in Uganda is provided, as the country has a unique past with regard to the virus. The chapter explains the historical significance of AIDS in Uganda, which set the stage for international presence in the form of an extensive amount international funding for HIV/AIDS treatment and prevention programs. The section also outlines the current ARV drug distribution methods used by the Government of Uganda, along with how these methods are facilitated. The chapter sheds light on the factors that prevent the Government from being able to provide ARVs to all Ugandans in need. Lastly, it addresses the gaps in public health coverage and highlights the organizations that have stepped in to fill these holes and provide ARVs to those who are unable to obtain them from government services. The complex system of

foreign aid for ARV drug procurement and distribution is explained, as it directly pertains to the accessibility of ARV drugs in the country.

Chapter 5 focuses on QCIL's partnership with Cipla. The chapter contains insight into the development of the Indian pharmaceutical industry. Particular attention is paid to its foundations, successes, limitations, and current operations in Uganda. This chapter also includes information on the QCIL drug manufacturing plant. It is in this section that a detailed overview of the operation is provided.

Chapter 6 presents the key findings of the research. The chapter focuses on a discussion of the potential for FDI in the production of ARVs in Uganda to increase access to drugs. As well, the chapter looks specifically at how organizations on the ground in Uganda influence the country's ability to develop a self-sustaining pharmaceutical sector for ARV drugs. The section includes an outline of the different distribution systems for ARV drugs. The supply chains of the government services, NGOs, and QCIL are explained. The data collected provides an analysis of the operations at QCIL and a discussion of the factors necessary to expand market shares and lower prices to increase the accessibility of the medications for Ugandans in need. This portion of the chapter includes findings from the fieldwork completed in Uganda.

Lastly, the conclusion summarizes the main points and arguments of the thesis and illuminates the broader significance and relevance of the topic to international development and global health. Suggestions are also made with regard to policy recommendations and further academic study and advocacy.

Chapter 2:

Literature Review

Health and development

The intrinsic and instrumental value of health

Health pertains to development in two principal ways. Health is commonly believed to hold both instrumental and intrinsic value in contributing to the well-being of a population, as it is both a principle goal of development in addition to being a means of achieving it.

The intrinsic value of health can be defined as having value in and of itself, as it is an essential component of human life. Improvements in the health of those who live in poverty help contribute towards the ability of said population to secure the fundamental human right to life and self-determination. Health is one of the “entitlements that belong to all human beings by virtue of their being humans” (Cullet, 2003, p. 140). Health is recognized in the Universal Declaration of Human Rights in Article 25 where it is stated that all individuals should have the right to the health and well-being of one’s self and one’s family, which is inclusive of medical care (United Nations [UN], 2012). The most significant element of the declaration is that these rights are to be encompassing of all individuals regardless of their sex, religion, language, race, or country of origin (Uvin, 2004). However, the extent of what is to be considered a universal human right continues to be contested (2004). Specifically, states have “sought to use the parts of the declaration that they felt supported their ideological vision of the world and to ignore the rest” (2004, p. 10). Most notably, the US limits their use of the definition of human rights to include

only civil and political rights, integral aspects of liberal market economies, and refrains from acknowledging the universality of economic and social rights, which specifically recognize health as a human right (2004). Most other countries have acknowledged the significance of the right to health and signed the UN Covenant on Economic, Social and Cultural Rights (2004).

The intrinsic value of health in itself was notably highlighted on the world stage in 1978, when the Alma Ata Declaration was signed with the goal of “Health for All” by the year 2000 (WHO, 1977). The Alma Ata Declaration specifies the importance of primary health care on a global level. The concept of health as an intrinsic human right thus became important for all members of the global society and was recognized as necessary in maintaining one’s livelihood.

Amartya Sen (1999) and Martha Nussbaum (1997) both argue that the language of human rights is limited in that it does not ensure the ability for citizens to fulfill such rights. Instead, they emphasize the significance of human capabilities and the role of governments in providing such liberties to their citizens (Nussbaum 1997; Sen, 1999). Nussbaum provides an extensive list of the substantive freedoms that are required for all citizens in order for human dignity to be respected with specific reference to life, and bodily health, and integrity (Nussbaum, 1997). Sen also attests to the requirement of increasing human capabilities. He explains that these capabilities fall under interconnected categories pertaining to politics, economics, social services, transparency, and security (1999). He argues that these freedoms are an integral aspect of development (1999). Both academics provide concepts of essential universal principles that should be guaranteed to all human beings (Uvin, 2004).

Paul Farmer suggests that health is not only a fundamental human right but also that it is the most basic right, the integral right to life (2005). He explains that violations of human rights are reflective of the social conditions that populations are restricted to, thereby subjecting them to discrimination (2005). He refers to this phenomenon as ‘structural violence’, and advocates for the improvement of health services to aid in ending such extreme human suffering (2005). He states that this dilemma is a consequence of low socioeconomic status in conjunction with the failures of a government to provide its citizens with public health care, adequate nutrition, and social security (2005). Access to medications is a vital component of reducing the anguish caused by a government’s inability or unwillingness to take responsibility for the well-being of its people (2005). Patients are subjected to structural violence through a life of poverty in countries where essential medicines are unavailable on the basis of their cost combined with a lack of available government health services.

A healthy population tends to act as a primary indicator of a developed nation.² Agbonifo describes a healthy nation as one where, “the mental and physical needs of the generality of its citizens are adequately met” (Agbonifo, 1983, p. 2003). These needs refer to strong levels of nutrition; proper hygiene, not only on an individual basis but in reference also to the environment one lives in; sufficient infrastructure including water facilities and shelter; and adequate health care services (1983). Thus, the good health of a nation can be reflective of its development achievements.

² However, the economic prosperity of a country does not always equate to the best standard of health for all citizens. The United States is one such case where in some areas of the country, primarily among economically marginalized communities, health standards and life expectancy are below those of severely resource-deprived countries in the Global South. For example, in Washington D.C. AIDS rates are higher than those in many West African countries, a result blamed on a lack of resources for health (Vargas, & Fears, 2009).

Instrumentally, health is a critical aspect of development. Those plagued with disease and physical pain struggle to provide for their families and will likely be trapped in cycles of poverty in the absence of access to medical care and treatment.

While economic prosperity in development theory is repeatedly equated with the result of poverty alleviation,³ this notion is often heavily contested, particularly by the theory of human development (Sen, 1999).

Sen suggests that the development of a country must be focused on increasing capabilities, or liberties, for citizens and that economic growth does not necessitate the creation of these freedoms (1999). He explains that these freedoms are not only the ends of development but that expanding the capabilities societies possess also acts as the means of development (1999). These capabilities are significantly constrained when individuals are burdened with disease and ill health. Sen states that the absence of such freedoms can lead to extreme poverty, which prevents individuals from accessing clean water, sufficient nutrition, and essential medicines, among other necessities (1999). As well, a lack of capabilities for citizens is closely linked with inadequate government provisioning for social services including public health centers (1999). According to Sen, the achievements of societies are subject to the available opportunities and freedoms with reference to the “enabling conditions of good health, basic education, and the encouragement and cultivation of initiatives” (1999, p.5). Achieving higher standards of health for the citizens of a nation is thus a critical component of increasing their quality of life.

³ For further reference on development theories focusing on the gains of economic growth, see the work of Milton Friedman (1962) and Martin Wolf (2005).

The good health of a population heightens the ability for citizens to better practise their liberties. Without disease and suffering, members of a society can reach their full potential and flourish in a society of innovation, and increased economic output. Berg (1973) contends that health also contributes to children's ability to develop both mentally and physically, which in turn, creates an educated population. Finally, a healthy society is one in which families are also able to thrive, as they are not forced to care for their sick and dying family members. Berg (1973) outlines the instrumental value of health when he explains that good health can increase one's ability to contribute to society. Good health enables workers who previously suffered from debilitating poor health to regain their livelihoods.

The presence of disease can play a critical role in the ability of a population to remain in good health. The health of a population can be substantially impacted by the occurrence of an epidemic, which can, in turn, act as a barrier to development and human flourishing. Citizens burdened with disease are unable to reach their full potential in society. Pogge (2008) explains that a way to decrease the prevalence of completely avoidable premature deaths and morbidity is by enabling patients to gain access to the necessary treatment, vaccines, or cures. With regard to HIV/AIDS this ability is severely restricted, as the required medicine to treat the disease remains out of the financial reach of the citizens and their governments most in need (2008). Hence, this limits their intrinsic right to health and its instrumental role in development.

AIDS and development

The impact of the epidemic on the Global South

The high prevalence rate of HIV/AIDS in Sub-Saharan Africa acts as an overwhelming challenge to development in the region. The virus not only causes immense physical and emotional suffering but exacerbates issues that threaten livelihoods across the African continent. Lewis (2006) maintains that the impact of the disease has created a pressing moral demand to find solutions to improve access to treatment and care.

The virus puts an enormous burden on the economies of the countries faced with the highest rates. Academics have noted that many countries with already weakened economies, and equally frail resources, face the struggle of attempting to support the large population of HIV positive patients through costly treatment and drug therapies (Sachs, 2005). The weight of the epidemic has further drained the preexisting minimal government resources available to deal with the breath of such costly emergencies.

From an economic standpoint, high AIDS rates have contributed to a significant decrease in the productive workforce as many labourers are simply too sick to attend their jobs. As well, many family members are forced to forgo their livelihoods in order to take care of their ill relatives. In particular, AIDS has led to a decline in the agricultural productivity levels of many countries in Sub-Saharan Africa (International Labour Organization [ILO], 2000). The loss in productivity within the agricultural sector has even resulted in the occurrence of AIDS induced famines, and in 2002 14 million were at risk of starvation (UNAIDS, 2002). UNAIDS explains that due to the effects of the

disease, farming skills, rural livelihoods, productive capacity to work on farms, and household earnings have all deteriorated (2002). AIDS not only threatens the ability for citizens to obtain their fundamental human right to health but it further impacts food security and their capability of maintaining their livelihoods.

The massive increase in orphans due to AIDS, and the inability for parents to care for their children can subject them to volatile situations including lives as street children, trafficked prostitutes, or drug addicts. O'Manique (2004) argues that the increase in orphans as a result of AIDS also makes children significantly more vulnerable to be conscripted as child soldiers or join rebel forces. These orphaned or uncared for children are typically unable to attend school or reach their full potential and remain trapped in the cycle of poverty.

What's more, AIDS puts a tremendous strain on the health care delivery systems of already underfunded and understaffed hospitals (Lewis, 2006). Other life threatening diseases are neglected as a result and often basic health issues are ignored, as the resources required to deal with the patients' needs are unavailable (2006). The ability to maintain in good health is then even further obstructed for other patients burdened by disease and injury, as resources for health diminish.

Pogge (2008) states that the health systems of most countries suffering from diseases exacerbated by poverty, particularly HIV/AIDS, struggle to provide citizens with essential medicines, even when the costs are relatively low or when the medicine is donated. This aspect of a global dearth of health care development has effected access to ARVs and intensified the crisis of HIV/AIDS in the Global South, as sites for treatment and testing are few and far between. He also states that the strategies to alleviate

injustices through increasing access to medicine are complimentary, as reducing poverty would lessen the global burden of disease and in turn, decreasing the incidence of disease would reduce poverty (2008). Improving the ability for populations to access essential medication, would expand the capability for economically marginalized citizens to work, self-organize, and contribute to their economic progression (2008). These freedoms are again a central component of development.

The destructive capacity of AIDS has deepened barriers to development and reduced the quality of life for millions. The capabilities of those already adversely affected by the disease have been severely constrained. The disease substantially increases human suffering in the Global South, while patients with access to ARVs, predominantly in the Western world are able to maintain relatively healthy lives. Due to the high price of the drugs, governments of resource-constrained countries have become dependent on foreign aid to help relieve such suffering.

Antiretroviral medications and the fight against AIDS:

The global ARV scale up and the debate about the benefits of foreign aid

The topic of foreign aid is one that has sparked great debate in recent years in reference to the significance it has on the development of the nations it intends to help. Numerous scholars have heavily contested the accomplishments that NGOs and other donor agencies have made through aid to the developing world. Notably, Dambisa Moyo has put forth the idea that all aid to Africa should be cut by the year 2013 (2009). She argues that Western aid is prohibiting African governments from being held accountable for their problems, and that much of the donor funding is lost to corruption within the

system (2009). She suggests that in its place, market based solutions should be introduced.

Moyo's counterpart William Easterly, has also criticized Western aid for failing to adequately reach the poor (2006). Easterly presents the theory that there are two methods of looking at foreign aid. The first approach describes foreign aid projects that are top down. He names these donors "planners" and suggests that they have an overly optimistic and "utopian" view of foreign aid (2006). The second group of donors he illustrates is the "searchers" that look for more bottom-up solutions to the specific problems commonly found in the Global South (2006). He identifies this as the more realistic approach (2006). While his approach to foreign aid and the suggestions he puts forward are less radical than those proposed by Moyo, both scholars believe that foreign aid has essentially failed to create significant improvements in standards of living particularly for those in Sub-Saharan Africa.

Others strongly disagree with these views. Jeffery Sachs argues that foreign aid should instead be increased for the poorest members of the Global South (2005). He has an optimistic approach towards developmental aid and believes that with the right implementation financial contributions from donors can be extremely beneficial for the deeply impoverished. He proposes that significant gains can be made in regard to solving problems common to the developing world and can eventually eradicate poverty (2005). Stephen Lewis also agrees that Western governments should amplify the yearly pledge of foreign aid, specifically, lobbying for increased funding to fight HIV/AIDS in Africa (2006). However, unlike Sachs, Lewis sees a need for aid at all levels of development and not only for the poorest of populations (Sachs, 2005; Lewis, 2006).

Lewis and Sachs continue to be key players in the international procurement of funding for ARV projects worldwide. Moreover, Sachs maintains that scaling up the amount of ARVs available to AIDS patients through foreign assistance is a vital issue (Sachs, 2001). Given the high price of the patented medications, the governments of countries laden with the disease, with much of their populations living in poverty, continue to struggle to provide ARVs to patients. By approaching the initial concern through an economic standpoint, Sachs developed systematic calculations of the amount needed from 2007-2015 to provide care and treatment programs for HIV/AIDS patients (2001). He proposed an increase in funding for ARVs on a multinational scope (Sachs, 2005). International organizations have contributed to an increase in the antiretroviral medications available to those in need. However, due to the high cost of the drugs primarily as a result of private control over patents, governments and citizens continue to struggle to gain access to the medicine.

Factors influencing the production and distribution of ARVs:

The effect of TRIPS on the provision of ARVs

The creation of the TRIPS Agreement generated extreme controversy. The Agreement is believed to particularly limit access to medications at locally affordable prices by preventing the reproduction and sale of patented medicines at lower costs (Aginam, 2010). The WTO's mission is the establishment of specific and legally binding rules and regulations to facilitate and mediate international trade (WTO, 2012). Several academics dispute the validity of the WTO's claims that its intentions are to improve the

welfare of citizens in its member countries, as many trade deals have, in actually, adversely affected populations (O'Manique, 2010; Pogge, 2008; Cullet, 2003).

Initiated and enforced by the WTO, the TRIPS Agreement attempts to protect intellectual property rights, which are described as “rights given to people over the creations of their minds. They usually give the creator an exclusive right over the use of his or her creation for a certain period of time” (WTO, 2011). Some argue that intellectual property rights are important to permit ownership of creative material and prevent others from reproducing their work without first paying royalties to the original creator (Nozick, 1974). Unlike other types of property, intellectual property is not a substantial entity that can be fought over, as more than one person can benefit from its use at a time (Stiglitz, 2006). Restricting its use is inefficient as it results in non-rivalrous consumption or zero marginal costs in economic terms (2006). Thomas Jefferson famously compared knowledge to a candlewick in that “when one candle is used to light another it does not diminish the light of the first” (2006, p.1279). The very idea of knowledge as ‘property’ remains a topic of contention to this day.

More controversially, the TRIPS agreement awards intellectual property rights in the form of monopoly patents over biological organisms including seeds found in nature, molecules, human genes, and tools required for medical innovations (Pogge, 2008; Stiglitz, 2006). This type of patenting is frequently disputed; as it provides individuals with the rights to matter and knowledge many believe to be the common property of humankind (Seeratan, 2001). To exemplify this fact, patents were filed in the US to own the rights of the healing properties of turmeric, which has been common knowledge for hundreds of years in India (Stiglitz, 2006). Furthermore, Carlos Correa (2002) argues that

intellectual property rights “erect barriers to the diffusion and use of knowledge” (p. 261). Paul David (1992) also confers that the patenting of knowledge reduces the societal benefits that could result from new findings as well as the useful application of better scientific understanding for further innovation. An individual’s proposed right to restrict the use of such knowledge, by appropriating it as private property, negatively impacts the well-being of entire populations unable to benefit from it.

Heavily challenged is the notion that the rights of inventors should come before the right to life for the poor (Joseph, 2003; Correa, 2002; Pogge, 2008). Specifically, Robert Nozick (1974) supports the use of medical patents, as he claims they are necessary to protect individual property rights. He suggests that they do not result in detriment to patients unable to access the medication, as they would have been equally worse off without such an invention in the first place (1974). However, Nozick’s theory fails to adequately justify the patenting of not only a specific product, but the type of product as well, by limiting the right for others to create their own medications that would have the same effect (Pogge, 2008). Patent legislation is supposedly intended to reflect liberal economic theory promoting individual property rights (Nozick, 1974). Instead, it accomplishes the reverse, as it impacts the natural right for others to make use of their own property to create any product with the same effect, and is thus by nature in violation with the principles of neoliberal theory (Pogge, 2008). The legally binding rules behind the Agreement, therefore, restrict the very freedoms it seeks to protect.

Furthermore, the notion of the monopolistic practices of pharmaceutical companies conflicts with the free-market principles of the WTO. Stiglitz argues that intellectual property rights permit exclusive control over knowledge, thereby distorting

free market practices through the creation of monopoly power (2006). Patents limit competition and produce prices far above marginal costs, which the market does not create (Correa, 2002). Therefore consumer spending is restricted resulting in economic inefficiency caused by artificial scarcity, commonly referred to as deadweight loss (2002). Stiglitz states that by restraining the use of medical knowledge through patents, “it not only affects market efficiency but life itself” (Stiglitz, 2006, p. 1279). The patent system not only jeopardizes the human right to health in favour of individual property rights but it is also hypocritical in nature, as it deviates from the proposed resolutions of the WTO. These resolutions claim to be, “aimed at reducing obstacles to international trade and ensuring a level playing field for all” (WTO, 2012). However, the patent system only increases such obstacles.

Pogge (2008) states that, in relation to pharmaceutical products the intellectual property law imposed by the TRIPS Agreement is, “morally deeply problematic” (p. 223). He explains that these types of patents act as impediments to the accessibility of essential medicines for much of the population of the Global South (2008). The Agreement was formulated by a small interest group, without consultation from public health experts and failed to assess the implications the Agreement would have on the health of the poor (Correa, 2002). In fact, Global health authorities acknowledged early on the ethical implications of restricting access to medications through patents (Pogge, 2008). The AIDS crisis further demonstrates the negative consequences of the Agreement, as lifesaving medication has been rendered unaffordable (Correa, 2002). Haakonsson and Richey also argue that the Agreement significantly hindered the health

of entire populations who could not afford to pay for medications due to the high prices of patented drugs, with specific reference to the AIDS pandemic (2007).

Cullet (2003) states that prior to the signing of TRIPS many countries neglected to provide patent protection for pharmaceutical products due to their belief in health as a basic need and focused on manufacturing more affordable generic versions of essential medications. However, Hellerstein (2004) explains that due to the TRIPS Agreement, many ARV drugs are under patent which gives pharmaceutical companies the sole rights to manufacture the drugs and sell them on the market at inflated prices despite low production costs. TRIPS is argued to have only exacerbated the inequity of global health in that the expensive medications prohibit economically marginalized populations in the South from obtaining the drugs, while those in the affluent Western world are able to benefit from them (Heywood, 2002).

Many countries burdened with disease in the Global South suffer as a result of the newly enforced patent regulation that hinders the ability for governments to manufacture generic versions of the drugs. However, for some actors the benefits of TRIPS are immense. TRIPS created a system that undermines the production of generic drugs by WTO member states. Heywood (2002) infers that by preventing access to patents and prohibiting the reproduction of drugs the Agreement enabled pharmaceutical companies to expand their power and substantially increase profits. Since patent holding companies could legally own the rights to a type of drug, the prevention of the production of generic replications would eliminate all market competition. This factor would thereby allow the pharmaceutical company owning the patent to have complete control over pricing. TRIPS is also said to have augmented government revenue in the developed countries that

control the rights to produce the products, through taxation (Agrawal & Saibaba, 2001). As well, it is presumed that job creation in the West increased as a result of the manufacturing of patented products (2001).

Increased pharmaceutical research is proposed as a leading factor in the creation of TRIPS and the argument in favor of its passing, heavily lobbied for by the Pharmaceutical Research and Manufactures of America (PhRMA) (Seeratan, 2001). While the notion of the high cost of research and development for new drugs is frequently used to support necessity of drug patents, numerous scholars dispute the legitimacy behind this claim (Thomas, 2002; O'Manique, 2010; Challu, 1991). Challu argues that the pharmaceutical industry developed prior to the enforcement of patent laws and that it is a false assumption that innovation within the drug-manufacturing sector is dependent on increasing patent protection (1991). Those in opposition to TRIPS state that imitation is an integral part of development and that all fully developed countries have taken advantage of the achievements of others to better society (Agrawal & Saibaba, 2001). Agrawal and Saibaba (2001) illustrate this point through the example of Switzerland and its lack of product patent implementation until the 1970's as an attempt to replicate patented drugs and develop its pharmaceutical industry.

Pharmaceutical companies are also known to invest much more in the marketing of their products than in the research and development of new drugs. Marcia Angell (2004) says that the Western drug industry spends significantly more on marketing and administrative costs than any other aspect of the drug production. She adds to her argument by stating that specifically, in 2002 the top ten US pharmaceutical companies spent \$67 billion dollars on marketing and administration equating to 31% of their yearly

expenditures whereas merely 14% was allocated to research and development (2004).

The claim is often made that that product prices are justifiably high in order to account for research and development costs (Vernon, 2004). However, Angell (2004) argues that the drug prices are more reflective of marketing expenditures, and the enormous profit margins. As well, the budgets allocated to marketing alone, show that the major pharmaceutical companies in the US, nicknamed, 'Big Pharma' could certainly afford to reduce prices of ARVs without losing research and development costs (Joseph, 2003). Based on such statistics, the idea that such high drug prices are necessary for the continuation of new drug innovation is flawed.

Western pharmaceutical companies have also greatly benefited from publically funded research findings. Correa (2002) attests that universities or public research institutes make the majority of important drug innovations, which then license their findings to private companies for production. To further illustrate this point, government funding is said to contribute to the discovery of 70% of the drugs proven to produce therapeutic results (United Nations Development Programme [UNDP], 1999). Particularly publically funded research is believed to have led to breakthroughs in the creation of ARV drugs (Correa, 2002).

Another important factor to note is that public expenditure is the most significant contributor to the purchase of patented pharmaceuticals (Joseph, 2003). Government hospitals provide medications to patients based on tax revenues (2003). Taxpayer money thus makes up the majority of pharmaceutical profits from patented medicines, essentially subsidizing the costs of research and development, marketing, and the extensive profits made by Big Pharma (2003). The same premise is also true for insurance companies

where clients buy into plans to help cover the cost of medications they may require (2003). Essentially, this also enables drug companies to charge higher prices than the market value without risking a loss of buyers.

It is suggested that pharmaceutical companies will invest more in research for currently incurable diseases if they have an increased financial incentive and profits to reinvest into further research (Agrawal & Saibaba, 2001). Conversely, profit driven markets, including the global pharmaceutical industry, primarily focus on consumer interests. Thomas (2002) points out that the Global South is hardly a lucrative market for pharmaceutical companies to invest in. Diseases associated with poverty typically do not bring about substantial profits and are, therefore, not reflective of consumer interests, as those living in poverty have virtually no purchasing power on a global level (2002). To exemplify this argument the WHO stated that, between 1975 and 1996 only 11 new chemical products were invented for tropical diseases, out of the total 1,223 (WHO, 2001). As well, the grossly disproportionate amount of research and development allocated to diseases common in the developing world demonstrates that market incentives in the form of patents are ineffective in regions where the majority of buyers cannot afford to pay for their medications (Troullier, *et al.*, 2002). The patent system typically fails to attract research and development attention to diseases of poverty and thus the justification for the TRIPS Agreement is questionable, as those in the Global South face high drug prices and yet see minimal relevant drug innovation.

The creation of TRIPS has been a topic of contention in the realm of global health, as it has directly affected access to life saving medications. Fink (2000) argues that the welfare of the drug dependent population is negatively correlated with an increase in

pricing due to the enforcement of patent protections for pharmaceutical products. The imposed patent regime has cut off poor patients from obtaining the essential medicines they need (Cullet, 2003). TRIPS renders lifesaving drugs inaccessible due to their price and drastically reduces the means of government health services, agencies for international development, and NGOs to provide the drugs to patients (Pogge, 2008). Pogge states that, “millions of deaths from AIDS and other treatable and curable disease are due to the suppression of manufacture and trading of generic drugs” (p. 232). Correa (2002) argues the patents for pharmaceutical products have an “asymmetric effect in the North- South context” (p. 272). He explains that for the North, patents enhance the creation of new drugs, which contributes to the generation of wealth and health care breakthroughs, while for the South patents prohibit access to previously developed medications, and are unsuccessful in initiating drug innovation for poverty related diseases (2002). While the debates between the rights of the pharmaceutical companies and those of the patients in resource-deprived countries continue, it is evident that global health equity has seen a definitive decline in large part due to the TRIPS Agreement. Therefore, it is necessary to examine alternative options available to countries with regards to generic drug production that could ensure a viable long-term strategy to treat HIV/AIDS patients in the Global South.

South-South trading partnerships for health related products

South-South trading partnerships can play a vital role in increasing access to essential medicines. Pécoul, (2004) explains that diseases prevalent primarily among poverty stricken communities, including tuberculosis, malaria, and HIV/AIDS have a

greater research priority in the countries plagued by them than such illnesses would have in more affluent countries. This is an important aspect of South-South trading partnerships within the realm of medical developments, as the technological innovation of one developing country can greatly contribute to the medical advancements of another.

Stewart (1987) suggests that trade between countries in the South can be mutually beneficial for several reasons. Countries can benefit from comparative advantage, the acquirement of knowledge, the ability to maintain protection against competition from larger more developed external players, and the power to take advantage of economies of scale through foreign direct investment (1987). For countries that are unable to purchase goods from the West, partially due to poor exchange rates, South-South trade can act as a viable means of attaining such imports (1987). As well, trading partnerships can be beneficial in the event of a world economic crisis, as North-South trade may be rendered unstable (1987). Furthermore, the North continues to maintain power over international trade through preferential free trade agreements and thus countries in the South often lack economic agency with regard to trading practices on a global level (Pogge, 2008). For this reason South-South trading policies can be more advantageous.

Lastly, South-South trade, as exemplified by the Bolivarian Alliance for the Peoples of Our America (ALBA), may not necessarily follow the prototypical capitalist free trade principles of the Western world, and may instead encourage trade policies that seek to primarily benefit social welfare. As in the case of India, its trading partnerships have also reflected a more self-made path to development, through the promotion of family and government run businesses, in addition to private enterprises (Economist,

2011). Such trading partnerships could facilitate more country specific economically beneficial trading principles.

Many countries in the Global South are becoming increasingly capable of contributing to health innovation and are referred to as Innovative Developing Countries (IDCs) (Morel *et al*, 2005). These IDCs have the capacity to create and manufacture safe health products while at the same time introducing new strategies for improvements in health care (2005). South-South trade plays a vital role in transferring the benefits of affordable products produced in an IDC to other developing nations. Trading partnerships revolving around newly developed pharmaceutical products have an important role in improving access to such drugs for economically marginalized populations (2005).

Dionisio, Fabbri, and Messeri (2008), explain that South-South partnerships are becoming a growing occurrence for ARV production and procurement. Pharmaceutical industries in Sub-Saharan Africa, made possible through trading partnerships with other drug producing countries in the Global South, help reinforce the competitive advantage of the generic drug companies against multinational brand name pharmaceuticals (2008). Such cooperation can also provide influence and authority in terms of the control over global ARV drug pricing (2008). Moreover, South-South trading partnerships can threaten the pricing systems of major brand name corporations forcing them to lower drug costs or risk losing the market to companies from the South that can offer locally appropriate prices for their products (2008).

Aginam (2010) highlights the fact that South- South partnerships for the increased provision of ARVs are likely the way forward, as similar North-South trade relations have in large part failed to produce significant results in terms of increasing access. While

compulsory licenses for the generic production of essential medicines are permitted, they are rarely utilized. He states that due to lengthy and difficult negotiation processes, combined with administrative blocks and holdups, only one Western country issued a compulsory license from a Western pharmaceutical company to produce generic ARVs still under patent (2010). Canada amended its patent laws, to include the ability to produce generic ARVs to be exported to LDCs in emergency situations, a clause included in the TRIPS Agreement. However, Aginam (2010) explains that when the time came to apply the compulsory license to produce ARVs for export to Rwanda, the procedure was so time consuming and challenging that the Canadian company stated it would not go through the process again. He argues it is highly likely, due to bureaucracy involved with the issue of obtaining a compulsory license, that Canada's effort to produce generic ARVs for a resource constrained country will be the last from a Western nation (2010). South-South partnerships for pharmaceutical development may be a better approach to obtaining ARVs.

The Production of generic drugs

India's pharmaceutical industry and its ability to produce ARV drugs

Pharmaceutical companies and foreign governments have criticized the development of India's pharmaceutical industry, as it is based on the generic reproduction of brand name products (Koshy, 1995). The Indian Patent Act, created in 1970, accounted for process patents although it did not include the patenting of products, which is said to have been controversial as this type of patenting was rare (Agrawal & Saibaba, 2001). This Act enabled Indian companies to replicate drugs that had recently begun to be sold

in international markets and sell them domestically at a significantly lower cost than patented drugs sold in the developed world. Indian generic drugs usually entered the market shortly after the patented versions through a process of reverse engineering rather than innovation (2001). Koshy (1995) states this to be an infringement on the rights of the pharmaceutical companies who were credited to creating the drugs. He also claims that the Indian Patent Act was created in the 1970's to ensure that the country could profit from its own domestic market at the expense of the pharmaceutical companies who had originally invested in the development of the products (1995).

Following the introduction of the Indian Patent Act, Indian pharmaceutical companies saw an increase in profits and they emerged, within the global pharmaceutical industry as leaders due to the low price of the drugs. The nature of their success sparked great debate internationally (Agrawal & Saibaba, 2001). Koshy claims that the India Patent Law enforced an artificial price ceiling for royalties, which contributed to an unfair advantage in the pharmaceutical industry, as the UK and the US were forced to pay much higher royalties to manufacture similar pharmaceutical products (1995). It is also suggested that these supposed unequal trading practices have deterred large Western pharmaceutical companies from continuing to operate in the Indian pharmaceutical market and, some have withdrawn their presence entirely (1995). However, others suggest Western pharmaceutical companies are the ones guilty of unequal trading practices, through their own use of tariffs, and anti-dumping regulations to prevent inexpensive products from entering the market (Pogge, 2008).

Agrawal and Saibaba (2001) view the institution of the Indian Patent Act as being largely beneficial to the Indian society, as many expensive medications patented in the

Western world became more affordable and accessible to economical marginalized populations. In 2005, the WTO enforced the restrictions of TRIPS, as the 10-year grace period for countries defined as ‘developing’ to amend their laws regarding patented products came to an end. Many view these enforced implementations as having devastating consequences on the health of the Global South (Aginam, 2010; Fink, 2000; ‘t Hoen, 2006). India, among other nations in the South, was forced to make amendments to the Indian Patent Act and add the protection of product patents despite international protest (Agrawal & Saibaba, 2001). However, by this time India had already created a successful drug manufacturing industry and one that other Western countries specializing in drug manufacturing would view as significant competition (Koshy, 1995).

The importance of the Doha Declaration and its impact on generic drug production

The Doha Declaration, agreed upon in November 2001, intended to effectively allow countries to legally manufacture drugs in spite of the Agreement in the name of public health emergencies, although its passing faced great opposition from pharmaceutical companies (Haakonsson & Richey, 2007). Prior to the creation of TRIPS, India had legally produced generic forms of drugs for many decades. With the enforcement of the Agreement, many of these production measures were halted as it was reasoned that this served as an infringement on the intellectual property rights of the pharmaceutical companies (2007). The creation of the Doha Declaration allowed for governments of LDCs to produce generic forms of patented brand name drugs, which TRIPS had previously prohibited them from manufacturing. The provision of compulsory licenses for drug production permitted countries in a declared health emergency to

produce generic versions of patented medicines or import them from preexisting pharmaceutical companies. Aginam (2010) explains that the Doha Declaration initially contributed to India's ability to continue to manufacture its own generic medications, which resulted in drastic cost reductions.

Others dispute the power of the Declaration suggesting it lacks significance in its ability to increase access to essential medications (Cullet, 2003; Pogge, 2008; Abbott, 2002). Abbott (2002) argues that, in practice, the effectiveness of this clause is contested as compulsory licenses have failed to be granted and, instead, the amendments have acted as simply a bargaining tool for negotiating price concessions with pharmaceutical companies. Cullet (2003) suggests that the Doha Declaration is "inadequate in so far as it merely extends the possibilities of granting a compulsory license and does not amend the TRIPS Agreement" (p.155). Haakonsson and Richey (2007) agree that the benefits of the Declaration were minimal, as it did not act as an enabling body for all countries to manufacture crucial medications.

Many states also faced issues of political pressure from large Western aid donors to abide by the original TRIPS Agreement in order to maintain foreign aid despite the clauses stated in the Doha Declaration (2007). International pressure continues to impact plans to produce generic drugs throughout the Global South.

The domestic production of ARVs

In recent years, in part due to the exemptions made by the Doha Declaration, several countries in Sub-Saharan Africa have begun to locally manufacture ARVs. These efforts reflect an attempt to lower the costs associated with importing the drugs and to

ensure a continuous in-country supply. Aginam suggests that foreign direct investment for pharmaceuticals can be beneficial in increasing access to ARVs, although he explains that such trade does not innately ensure the sustainability of drug supplies and that the drugs must be competitively priced in relation to imported versions circulating within the country (2010). He also suggests that partnerships among countries for generic drug manufacturing can be beneficial in increasing health equity (2010). Enhancing political alliances to push for changes to global policies may help influence the production and trade of generic drugs (2010).

Guimier, Lee, and Grupper (2004) argue that the domestic production of ARVs can be an economically viable strategy of procuring the medications. They explain that if a variety of factors are met, particularly with reference to extensive funding, and the ability to produce other medicines in addition to ARVs domestic pharmaceutical industries can be successful in lowering drug costs. However, Kaplan and Laing (2005) caution that the method is not cost-effective. They suggest that it is difficult for new industries to achieve greater economies of scale than larger established companies and that many countries lack the pharmaceutical expertise and infrastructure required to produce the drugs (2005). Instead they promote the importation of medicines over local manufacturing (2005).

It is clear that there are many problems involved with Uganda's ability to supply its citizens with ARVs and to protect the right to health for a significant portion of its population. Specifically, short-term practical challenges exist within the country, which limit the capacity of the health care system. Furthermore, there is a lack of engagement and commitment to health aid as an integral right at both the local and global level. This

thesis will further explore these themes to illustrate the variety of issues surrounding the domestic production of ARVs and to determine whether the method could be used as a mode of increasing access to essential medicines in Uganda.

Chapter 3:

Methodology

The research questions this thesis proposes were addressed by using a variety of methods. First, the research explored the question of whether the domestic production of ARVs in Uganda can lead to heightened drug accessibility. Second, the factors influencing the potential success of the drug production initiative were also uncovered by using a multiple method approach. A qualitative field study in and around Kampala, Uganda facilitated the completion of the research. The research analyzed the South- South partnership's potential to decrease drug prices in the future and work towards a self-sustaining supply of ARVs to reduce the country's dependency on foreign aid. Finally, the research investigated the factors influencing the ability of the factory to increase access to the medications. By illustrating these factors, the research illuminates similar issues that may arise for other pharmaceutical industries in the Global South. The methods engage diverse sources, both through review of existing literature and information retrieved through the field study.

Justification of the study

The broader research question seeks to determine if domestically producing ARV drugs can act as a method of enhancing the permanency of ARV treatment programs by increasing a more renewable supply of drugs within a given region or country. Several domestic manufacturing sites have been created in various countries throughout Sub-Saharan Africa in recent years. While South Africa is home to the largest pharmaceutical

sector for the production of ARV medications, other countries including Zambia, Zimbabwe, Tanzania, Kenya, and Ghana have also begun to develop manufacturing centers to produce ARVs (Wilson, 2009). These countries could have made for interesting studies individually or as a cross-sectional analysis. However, such a comprehensive comparative study of the domestic production of ARVs across several countries surpasses the scope of a Master's thesis. By focusing this study on one country and a particular situation, I could thoroughly analyze the specific operation. Through the case study, I could also illustrate the dynamics of Uganda's joint venture with India and the significance of the partnership.

Berg (2009) highlights the fact that by using an instrumental case study approach, research can provide greater insight into a more generalized topic or theory. Uganda was chosen for the study for several reasons. Primarily, Uganda represents an example of an African country that has recently begun producing its own ARVs through a joint venture with an accredited pharmaceutical company from the Global South, Cipla. Since QCIL in Uganda does not involve external financial support from foreign donors, the research findings exemplify the case of an African nation that has taken its own initiative to produce medicines for its people. Also, while several countries have only begun to develop plans to start manufacturing ARVs, Uganda is already distributing the ARVs in government hospitals and clinics and thus the operation could be appropriately analyzed by viewing the full scope of the development.

Given the relative democratic stability in the Uganda, its free press, and the reputation of being open to foreign research projects, the country made for an appropriate place to do research in. The aforementioned factors are important when attempting to

retrieve national documents and valid newspaper articles to confirm sources, which is a vital component of the multiple methods approach.

The country has also received substantial foreign aid for ARV drug procurement since the early years of the epidemic, and continues to remain heavily reliant on donor funding to support its ARV treatment programs. This is also true for many other countries facing issues of high HIV/AIDS rates with a lack of government resources to sufficiently treat the vast number of patients. However, Uganda also holds a particularly strong history of government response to the epidemic. Furthermore, the Government offers free ARV treatment to patients requiring it, although the service is far from universal. Given the combination of strong donor presence combined with the existence of public provisioning for ARVs, both the country's public health system and AIDS based NGOs may experience greater ARV procurement capabilities if the operations at QCIL can create more cost efficient medications.

Researchers have examined the successes and failures of current ARV domestic production efforts in various countries in the Global South. However, the domestic manufacturing of ARVs remains a relatively new initiative. This research is critical to outline the specific issues that Uganda faces as it implements a strategy for ARV drug production. This thesis is necessary to help determine whether the method of domestic production could be used as a viable means of increasing the provision of ARVs to patients in a particular case. However, this research only begins to address these issues. Further research is needed in order to illustrate the variety of socio-economic issues that may arise, to determine if similar methods of drug procurement could be a beneficial means of increasing access to ARVs in other countries.

To date, no extensive studies focusing on the case of Uganda have been published, and there is little research pertaining to case studies of South-South partnerships for pharmaceutical development. There is a gap in the body of research on FDI for ARVs in Sub-Saharan Africa. It is for these aforementioned reasons that a case study approach on the domestic production of ARV drugs in Uganda was selected.

Qualitative fieldwork was used for the study. The fieldwork consisted of data collection combined with data analysis and iteration, resulting in the completion of follow up interviews, as discussed by Mikkelsen (2005). The field study was the best choice for the research as it encompassed, “theoretical studies, and a variety of relevant data sources, documentary studies, theoretical interpretation, and final analysis” (Mikkelsen, 2005, p. 49). The case specific field study was, therefore, well suited to answer the research questions.

Limitations to the scope of the study

A case study approach may affect the generalizability of the research when compared to cross-sectional studies, as each country encounters unique issues with regard to the successful development of a generic drug producing facility. However, this thesis will contribute to the current body of related research, as similarities can be drawn across different country cases in order to highlight reoccurring issues.

As well, given that the QCIL is still in its infancy, as it only started to produce ARVs in 2007, the current operations may not necessarily reflect those of the future, or the exact trajectory of all FDI for the production of ARVs. However, this study provides valuable insight into the early operations. A longitudinal study of Uganda’s ARV

production efforts over a lengthier period of time would allow for larger conclusions to be drawn regarding the success of the operation. Such a study would also increase the research's accuracy, in relation to whether the endeavor led to sustainable access to ARV medications for patients in Uganda. While this type of study could not be completed given the limitations of a Master's thesis, the research findings were beneficial in providing an analysis of the current operations as well as the factors impeding its potential future success.

As the research was primarily facilitated in the capital city of Kampala the findings may appear limited to urban care centers, and neglectful of those living in rural areas. Patients residing in rural areas are typically vulnerable to unequal access to medications, particularly when compared to those living in urban areas. Yet, in this study geographic location did not play a significant role in the provision of ARVs from QCIL. The reason for this is twofold. First, patients requiring ARVs from government services in rural areas must travel to the government hospitals for their medications and thus the distribution of drugs purchased from QCIL does not impact geographic accessibility. Guimier, Lee and Grupper (2004) also state that geographic accessibility is not linked to the origins of drug production, but instead for those in rural areas treatment is indicative of the presence of clinics and treatment centers within their close proximity. Second, with this in mind, access to care in rural areas is primarily provided by various NGOs and the donor country procurement policies do not vary across regions. By focusing the research on the major drug suppliers and distribution centers for ARVs in the country, and highlighting the main donor country policies, the findings were able to provide clear

insight into both the national and the externally funded systems of drug procurement, at the highest level.

Required information

In order to analyze the capability for QCIL to increase access to ARVs, information was obtained from a variety of different sources, and the operation was explored from various viewpoints. To answer the research questions, information was required on past and current government strategies for providing ARV treatment to patients in Uganda. As well, it was necessary to access information on the origins of generic drug production and how Uganda generated the ability to produce its own supply of medications, despite international patent laws attempting to prohibit their reproduction. In particular, research on the present and historical operations of the partnering company Cipla was essential to understand how it functions as a generic producer. Also, by obtaining information on the limitations and flexibilities in the TRIPS Agreement, the legal aspects of the generic manufacturing of ARVs in Uganda could be outlined. Data was also required on the current operations of the drug-manufacturing center in Uganda to assess whether the plant succeeded in enhancing access to the drugs for its population in need. Direct information was required on the goals and objectives of the operation; the amount of drugs that is being produced and the pricing; which parties are purchasing the drugs; and the distribution methods currently used.

Information on the existing various supply chains for ARV drugs imported into the country was also of significant importance. The study required such material to

outline the distribution methods used by both NGOs and the Government along with the issues in relation to the large influx of ARV medication from various external sources.

Data collection techniques

In order to acquire the information it was important to use multiple methods, through which I could examine the issue of access to ARVs from a variety of different viewpoints and thereby confirm findings through various sources. Berg (2009) describes the importance of using multiple methods in qualitative research and explains that, “by combining several lines of sight, researchers obtain a better, more substantive picture of reality; a richer, more complete array of symbols and theoretical concepts; as a means of verifying many of these elements” (p.5). To facilitate the confirmation of sources, several different research methods were utilized including policy discussions, document research, key informant interviews, and a literature review.

Policy discussions

Discussions took place in Uganda with selected individuals who were able to attest to the policies and goals of the Government, a particular company, or an organization, by which they were employed. The discussions filled the gaps in the available written documentation regarding government and NGO policies for ARV drug procurement. According to Claire Mercer (2006), “NGOs are a fount of local knowledge” and thus they can be a valuable source to obtain information from (p. 98). The discussions also served the purpose of outlining the general aspects of the public and private supply chain systems for ARV drugs and to establish the methods various NGOs use to procure and receive the ARVs they distribute. Information was collected from

QCIL, as well as from the Ministry of Health, private ARV procurement companies, and several AIDS based NGOs.

By interviewing representatives from NGOs, valuable information was retrieved concerning the effectiveness of the operations from a third party not directly involved in the functions of the factory, as was the case of QCIL executives and government officials.

For the discussions, the informants must have worked or lived in Uganda for an extended period of time in order to provide the researcher with viable and reliable information. Katie Willis (2006) highlights the relevance of such discussions when she explains that they can be, “an excellent way of gaining factual information such as details of NGO policies and government initiatives” (p. 146). The discussions also highlighted new information that should be incorporated into key informant interviews at a later date.

Snowball sampling, also called chain referral sampling, was used to select personnel for the discussions, as the initial sample of people was chosen based on their specific jobs with preferred organizations or within the Government (Biernacki & Waldorf, 1981). These people then recommended other potential candidates for interviews with similar research relevant characteristics and the process was continued until no new information was being retrieved. (1981). Biernacki and Waldorf (1981) explain that the method is particularly useful when the research is based on a topic that may require insiders to suggest other people who might have valuable information. Many AIDS based NGOs in Uganda work closely or partner with other similar organizations or the Government, and directly with the supply chain systems. It is for this reason that the snowball sampling technique was useful. The method uncovered many excellent sources required to outline the complex system of ARV procurement in Uganda.

Key informant interviews

A series of key informant semi-standardized interviews was necessary to acquire specific information on particular dimensions related to Cipla's FDI, and the logistics of the supply chain for ARVs in Uganda. The interview guide approach to semi-standardized interviews was used to increase the participatory nature of the interviews and to close gaps in the research that arose during the interviews (Patton, 2002). The interviews were completed via email or by phone and each participant was sent an informed consent form, or read one over the phone, respectively. Rubin and Rubin (1997) state that phone interviews are a good method to use if previous face-to-face contact has already been established, as is the case of the follow up interviews for this study. If participants agreed to partake in the study their response to the email or verbal statement acted as acknowledgement of their informed consent. By using follow up key informant interviews, it enabled the collection of more specific data, which could include personal opinions deviating from the strict policies outlined in the policy discussions.

I gathered enough information to synthesize themes of the proposed research questions and help increase data triangulation through the use of connecting information found via multiple methods, as described by Willis (2006). By interviewing a variety of different contacts whose opinions and viewpoints varied depending on their context, I increased the objectivity of the research. The key informants were chosen based on their unique knowledge on a given topic within the realm of the research (Mikkelsen, 2005). An important aspect of the semi-standardized interview is that the questions can exhibit the manner in which individuals view the world and particular situations in differing ways

(Berg, 2009, p.107). This was pertinent to the research as opinions and statements on issues varied between interviewees.

The key informants included personnel from the Government of Uganda, NGOs operating in the country, private procurement agencies, and QCIL, all of who were able to provide unique perspectives on the functioning of the QCIL plant and its impact on increasing access to ARVs in the country. Willis (2006) draws attention to the fact that such interviews can enable the researcher to accumulate more information on the formation of certain policies and, “can examine the processes, motivations and reasons for successes and failures” (p. 146). This aspect of key informant interviews was particularly relevant to this research, as it illustrated deeper more reflective responses than those retrieved through the policy discussions.

The interviews also acted a way to reconfirm the information that was gathered through policy discussions in the initial visit to Uganda, to maintain that it was up to date, as six months’ time had passed. The interview process also allowed for contemplation and reflection to occur following the initial policy discussions raising new questions that could then be answered in key informant interviews, which is an important aspect of qualitative research (Mikkelsen, 2005). Since QCIL is an emerging industry, this follow up stage was an important aspect of the research, as specific information regarding quality assurance certificates and purchasers could have changed. Interviewing key informants important aspects of the policy discussions could also be clarified. Specific questions that were formulated after an initial analysis of the general findings could be answered. The responses in the key informant interviews allowed for the interviewees to express more opinion based responses than in the policy discussions. To account for this, the key

informant interviews required an informed consent form. The informed consent form allowed for the informants to speak more openly about ARV procurement in Uganda, to not be confined to discussing the policies of the organization they represented, and to protect their identity if they wished.

A key informant interview with a NGO leader, whose organization deals with the distribution of ARVs was necessary. This interview helped to determine if the particular NGO's procurement policy had changed based on bilateral funding policies since the initial policy discussion. It also helped to determine whether the interviewee felt that the construction of the plant had impacted the organization's supply of drugs.

As well, information was obtained from QCIL regarding the partnership with Cipla, the current operations, and the accomplishments of the joint venture. During a tour of the plant, six months prior to the key informant interview, many questions were answered regarding quality assurance techniques, international accreditation from various sources, and the factory's distribution methods. Similar, albeit more in depth questions were also posed in the key informant interview to determine if any new certifications had been granted since the initial tour and to discuss the future of the operation.

Furthermore, a government representative was contacted to provide information on access to ARVs in the public sector, and the relationship between the Government of Uganda and QCIL. Finally, a private drug distributor offered insight regarding procurement and distribution logistics with regard to supply chains and the functioning of government services. The key informant interviews added to the multiple methods approach to the study as information that surfaced in policy discussions and through documentary research and literature review was solidified.

Documents

By retrieving government and NGO documents I found information on national AIDS statistics; present government policies and future strategies for the provision of ARV treatment; and NGO official policy statements. The data was collected through a review of various official Ministry of Health reports regarding HIV/AIDS treatment measures, Global Fund grant application forms and agreements, PEPFAR's most recent five-year strategic plan, official NGO progress reports, and country reports. As well, legal documents regarding Uganda's patent legislation helped to outline the specifics of the country's lawful ability to produce generic drugs.

Specific information regarding the past procurement methods of the Ministry of Health prior to the establishment of the QCIL drug manufacturing center was obtained through previous official government reports. Furthermore, similar information was retrieved from past yearly progress reports published by multilateral, and bilateral organizations found in the Makerere University library in Kampala. Mikkelsen (2005) explains that secondary data in the form of published reports can be a significant source of reliable information. These documents illuminated the origins of ARV procurement and distribution in Uganda and the key players involved in the gradual scale up of treatment. The documents also outlined the current policies in place and plans for the future. This type of research was able to reaffirm statements made in policy discussions thus enhancing data accuracy, and justifying the use of multiple methods.

News sources from prior to the construction of the plant were retrieved from both local Uganda papers, and foreign papers. These sources were helpful in finding information on the origins of the QCIL drug plant, updates on the current expansions of

the industry, information on the public health system and its distribution of ARVs, along with issues of access to essential medicines in the country. Useful quotes and opinions from bureaucrats, country leaders, and QCIL personal were also accessed through the retrieval of newspaper articles. Information obtained from newspaper articles contributed to the multiple method approach of the research thus aiding in the confirmation of findings.

Analysis of findings

After carefully reviewing all policy discussions, interviews, and retrieved documents, content analysis was used to group the findings (Corbin & Strauss, 2008). The analysis was done through a process of open coding, by searching the gathered information for reoccurring themes in the data. The transcribed interviews permitted multiple reviews of the data, which helped to recognize and connect similar statements from various sources. This process allowed for certain factors to be highlighted across different sources, increasing the accuracy of individual statements. Reoccurring themes were brought out through open coding of the transcribed manuscripts of the policy discussions and key informant interviews. Reflexivity was used to ensure awareness of the potential biases in the responses from participants (Mikkelsen, 2005).

Selective coding was then used to organize the information based on central statements and themes. This process facilitated the categorization of information into groups based on corresponding opinions and statements (Corbin & Strauss, 2008). The grouping of the information into categories enabled the dominant ideas to become more apparent and for any outlier statements to be drawn out. As well, information regarding

specific policies and methods of drug accumulation was confirmed through the selective coding process in conjunction with information found through academic and documentary research. The validity of statements was enhanced by confirmation through multiple sources to verify and substantiate the assessment (2005).

When the coding was complete the data was analyzed with specific regard to answering the research questions. Reoccurring themes and statements backed up by multiple sources were used to determine a consensus among those interviewed with regard to whether the factory has led to an increase in access to ARVs.

The research faced some limitations in relation to the amount of documents that were publicly available and to those who were willing and available for interviews or policy discussions. Specifically, government documents outlining ARV policies and national plans may be inaccurate representations of what government services were actually able to accomplish in the allocated period of time. However, this is balanced by the use of multiple methodologies. For example, policy discussions confirmed the validity of the functioning of previously published plans for ARV distribution, while offering insight as to the likelihood of future proposals meeting the desired outcomes as stated.

It is also possible that key informant interviewees may not have revealed the whole truth or may have been deceitful in their responses. To help ensure that informants did not feel pressure to answer the questions in a certain way all of the key informants were notified that their identities would be kept confidential if they wished. As well, all key informants had the opportunity to answer the questions at their own convenience, through their personal email accounts, or via phone when they were not at their respective

workplace. This aspect of the interviews reduced the participant's risk of feeling pressure to make statements, which favored his or her organization, company, or government.

Through the use of multiple methods the research could confirm findings and ensure the reliability and validity of the information that was retrieved. The findings from the field study in Uganda, when combined with information found in academic literature, were able to answer the research questions and provide unique information in addition to that which could be reaffirmed through similar studies.

Chapter 4:

ARV Provision and Distribution in Uganda

The current distribution of free ARVs through the AIDS Control Plan (ACP) is deeply rooted in the Ugandan Government's early recognition of the disease and its strategy to address the problem of HIV/AIDS. This chapter provides a historical context of HIV/AIDS in Uganda, to examine the factors that have led the country to produce ARVs locally, and the limitations of the strategy with regard to its ability to provide patients with the medicine they need. The information provided in this chapter is composed of a compilation of data obtained through pre-existing literature, field discussions, documents from government and NGO reports, and official company statements. The various research sources help to accurately outline both the past and present functioning of the national AIDS plan as well as the contributions foreign donors have made to it.

At the time President Museveni came to power, AIDS was still a highly stigmatized disease across the world and particularly in Sub-Saharan Africa. His open and active approach to dealing with the epidemic was regarded by many as groundbreaking for the time (Kinsman, 2010). The implementation of the ACP would later set the stage for the introduction of ARV medication to treat the large population that was suffering from AIDS.

The first cases of AIDS in Uganda were recognized in 1983 (Ministry of Health [MoH], 2011b). By 1986, upwards of 900 cases had already been reported, and rose to 6000 in just two years (2011b). The Government of Uganda officially recognized AIDS

as a significant issue in 1986 with the creation of the AIDS Control Plan (ACP) in an attempt to provide a solution to the escalating problem (Kinsman, 2010).

The idea is put forth that President Museveni himself, while fighting in the Ugandan civil war, first predicted that AIDS would become a serious issue for his people (Allen and Heald, 2004). However, Kinsman (2010) proposes that instead Museveni's interest in the disease was politically motivated and reflected his desire to maintain healthy military troops to assure his own electoral stability. She also suggests that Fidel Castro played a significant role in drawing to Museveni's attention the problem of HIV/AIDS (2010). She explains that Castro, who had previously recognized the impact of the disease in Cuba, had supported Museveni's army and realized that the disease was evidently present amongst the Ugandan troops (2010).

Putzel alternatively argues that AIDS research in Uganda in the early 1980's was a contributing factor in the creation of the ACP (2004). He explains that scientists researching the disease in Uganda helped bring its status as an epidemic into the limelight, as well as, to the attention of President Museveni, who listened to the concerns and acted accordingly (Putzel, 2004).

Initially, the ACP focused primarily on prevention through education campaigns about the disease to help Ugandans comprehend its destructive capabilities and how it is spread (Kinsman, 2010). By partnering with the WHO for financial and technical support, the ACP facilitated a large-scale campaign to educate Ugandans on HIV/AIDS via a vast array of prevention messages throughout the country (MoH, 2011a). In the 1990s the Ugandan Ministry of Health oversaw the creation of AIDS prevention and treatment services including a safe blood transfusion service; confidential counseling and testing; an

HIV/AIDS care and support organization; and a national STD Control Program (2011a). While the founding principles of the program did not include the provision of ARVs, eventually the Government facilitated the procurement and distribution of medications with donor funding as generic versions were introduced.

The Government's continued attention to the health crisis of HIV/AIDS ultimately led to the provision of the drugs required to treat the growing amount of AIDS patients. However, in 1987 when the first ARV drugs were introduced on global markets the prices were beyond the reach of most citizens in Uganda as treatment per person per year cost upwards of approximately \$20,000 USD (Floyd & Ginks, 1998). Therefore, it was primarily only a small percentage of the Ugandan elite who were able to purchase the drugs out of pocket, as the annual government expenditure on health did not include ARV treatment for patients in national hospitals and clinics until 2004 (MoH, 2011a).

Antiretroviral drug treatment became available to the general public in Uganda in 1998 through the Joint Clinical Research Center of Uganda (JCRC) (MoH, 2003). The JCRC was the first research center and remains the largest of its kind in Sub-Saharan Africa (Whyte *et al.*, 2004). The institute stemmed from the Ministry of Defense through partnership with the Ministry of Health, and Makerere University, with the intention of providing a research institute to focus on the study of the AIDS epidemic and the distribution of medication (2004). The research center initially provided ARVs to study participants along with those able to pay for the drugs (2004). The JCRC has since continued to carry out research studies and offers medication to HIV patients through partnership with various international research institutes and funding organizations (2004). In 2000, ART was still not available in public health centers, and thus patients

who could not afford to purchase the drugs out of pocket depended on research institutes and private donor funded clinics for the provision of the medications (Republic of Uganda [RoU], 2000). It was not until the introduction of generic drugs that the Ministry of Health would begin to supply ARVs to patients in public hospitals and clinics with the support of foreign donors.

Since the country faced serious infrastructural restraints as a result of the civil war, attempting to rebuild a weakened economy proved to be a difficult task for Museveni (O'Manique, 2004). The effects were seen throughout many sectors, and specifically, in the health system. The country's health care system faced major structural problems relating to funding and Uganda was already burdened with huge debts to the World Bank, as it had borrowed extensively to rebuild the country after the war (2004). Neoliberal economic structural adjustment policies (SAPs) were implemented, and the Ugandan health care system was increasingly privatized (Poku, 2005). The privatization measures prevented testing and access to care for the rapidly growing HIV positive population, due to prohibitive fees for service (2005). Many Ugandans were unable to afford to pay for their hospital visits which created an influx of AIDS based NGOs to fill the gaps in the public healthcare system (2005).

Uganda's AIDS policy was affected by neoliberal ideology through the greater impending operational issues for health systems resulting from the implementation of SAPs in the country (Poku, 2005). The SAPs also contributed to the Government's inability to take significant action slowing the spread of the disease, due to a lack of resources for health and specifically for testing of the disease (2005). The destruction of the health care system left a significant void that would be filled with foreign aid.

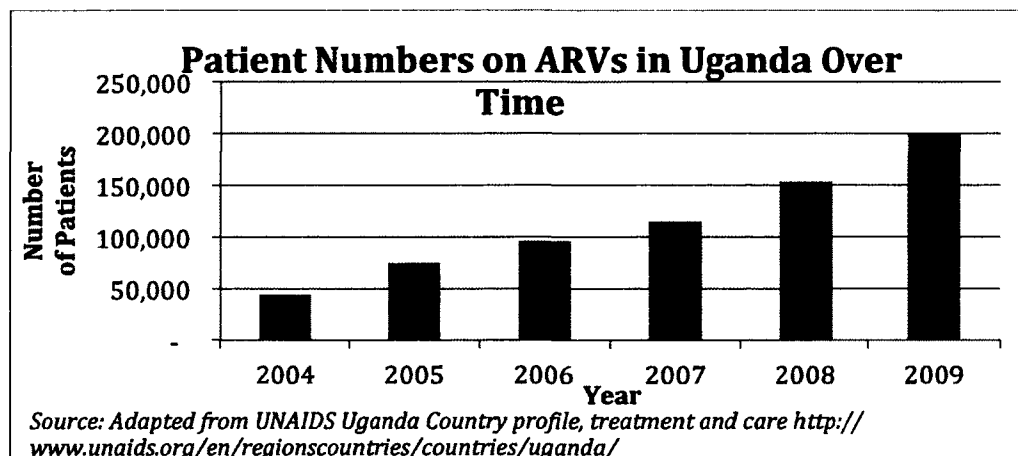
Uganda had been forced to rely on outside sources to fund its AIDS policies in the past but in 1992, the World Bank was said to have taken precedence amongst the international community responding to Uganda's AIDS epidemic (O'Manique, 2004). It was at this time that the World Bank facilitated the creation of the Uganda AIDS Commission's (UAC) 'multisectorial strategy' in 1992 to oversee and control AIDS prevention measures and policies in Uganda (Uganda AIDS Commission [UAC], 1992). This strategy was a result of the Bank's belief that the Government alone could not handle the epidemic (1992). With a \$3 million USD grant from the World Bank Multi Country AIDS Program (MAP), the Government of Uganda started to procure ARVs for the public sector in 2003 (MoH, 2003b). Kinsman (2010) suggests that the strategy lacked any significant measures to address the spread of the disease and the health care system remained significantly restrained resulting in extremely limited access to treatment.

At this time, Uganda also submitted an application to the Global Fund to receive an additional grant intended to help sustain a proposed ARV program (2003b). As generic versions became available in 2003, the prices of ARVs were drastically reduced, enabling the Government to begin to import the drugs from Cipla for use in their national ARV programs (Whyte et al., 2004).

Just prior to the introduction of generic ARVs, the cost of triple combination brand name drug therapy was approximately \$500 USD per month, whereas when Cipla released a generic equivalent the cost dropped to only \$28 USD per month (2004). The substantial decrease in pricing enabled the Government to launch a universal free ARV country-wide program ARVs for public health centers in 2004 (MoH, 2009). However, the yearly government health expenditure per capita for 2006 was merely \$7.84 UDS

(UNIDO, 2010). This number was a far cry from the estimated \$336 USD per person per year required for even generic antiretroviral treatment (White *et al.*, 2004). The price of ARV treatment also excluded the costs associated with testing, treatment for opportunistic infections, and hospital care for critical cases, even further emphasizing the minimal resources available from the public sector (MoH, 2003b). Despite the increase in drug procurement, financial restraints still plagued the public sector, and for most, access to ARVs remained a significant problem. Government resources for health care were minimal at best, and issues with overcrowding and underfunding of public system continued. To make matters worse, an influx of terminally ill AIDS patients who had been unable to seek treatment flooded the hospitals, only accentuating the burden on the already strained health care services.

By 2004, only 45,000 AIDS patients had access to ARVs in Uganda (WHO, 2008). While the number increased to 121,200 by 2007, NGOs maintained a stronghold on Uganda's AIDS program and the Government relied extensively on foreign contributions to provide ARVs to patients (2008). The following chart provides an overview of the scale up of ARVs since they first became largely available to the general public.

Figure 1: The Scale up of ARVs

In 2007, many NGOs were prohibited from purchasing the generic versions of ARVs since the newly created drugs had not received approval from donor country drug regulation boards (National Academy of Sciences [NAS], 2007). In particular, official PEPFAR policy prevented the procurement of even WHO prequalified ARVs, procured by the Global Fund and MSF on the basis that they did not have United States Food and Drug Administration Authority (US FDA) approval (Dietrich, 2007).

Initially, as generic ARVs entered the market many did not have US FDA approval and were deemed unacceptable, thus prohibiting their procurement for use in donor funded clinics (National Academy of Sciences [NAS], 2007). The policy in effect limited the numbers of patients able to receive drug therapy from PEPFAR programs, as the prices for brand name ARVs were substantially higher than those of the available generic equivalents. While PEPFAR eventually accepted generic ARVs, it took two years of international pressure to change the policy and yet still only 27% of the drugs procured with PEPFAR funding came from generic manufactures (Dietrich, 2007). Western

resistance to the promotion of generic drug production is also reflected in the struggle Uganda faced to begin to manufacture ARVs.

In 2005, the Ugandan Minister of Health announced a plan to manufacture ARVs within the country through a joint partnership with the Indian pharmaceutical company, Cipla. The initiative sparked great debate, as the creation of the plant was significantly delayed, due to influence from Western aid agencies supporting the HIV/AIDS programs in the country (Haakonsson & Richey, 2007). The operation held off on its efforts to begin to manufacture the drugs as a result of attempting to meet the desires of many Western donors who disapproved with the generic production of the medications, in that it did not align with the principles of the TRIPS Agreement (2007). The production of generic versions of the drugs was seen as an infringement on the intellectual property rights of the major American pharmaceutical companies, who were also large suppliers for PEPFAR funded programs, as they would lose profits with the generic manufacturing of their products (2007). In actuality, as a result of its qualification as an LDC, Uganda did not need to conform to the TRIPS Agreement since it was still in the approved transitional period to amend its patent laws. Through support from Cipla Uganda possessed the ability to produce generic drugs. Due to the dependence on Western funding, the Government of Uganda lacked agency in the face of US pharmaceutical companies, which led to further delays in the creation of the factory.

The production of the drug manufacturing plant finally began in 2007 despite the previous disapproval from Western donors. The Government of Uganda inaugurated a plan to explore the potential for a more long-term approach to ARV drug procurement in the country, through its support given to the construction of the QCIL drug manufacturing

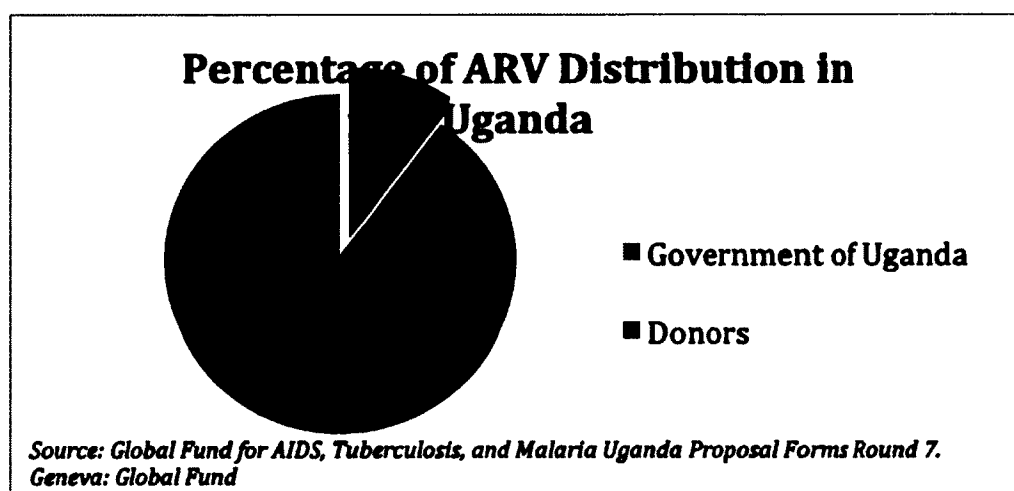
plant. The AIDS Control Program Manager for the Ministry of Health, Dr. Zainab Akol explains that while the Government no longer maintains its initial shares in the company, the procurement of ARV drugs from the factory remains a large component of the current ACP (Z. Akol, personal communication, July 6th, 2011). She states that the Government will continue to purchase the drugs produced at QCIL until 2015, under contract with the company. The government funding allocated to the purchase of ARV and antimalarial drugs from QCIL is said to be 60 billion Ugandan shillings, equivalent to approximately \$23.9 million USD as of currency conversions on April 11th, 2012 (United Nations Industrial Development Organization [UNIDO], 2010). The drugs purchased through the agreement by the Government of Uganda are for distribution in public hospitals and are intended to be free to all patients, as stated directly on the packages produced at QCIL. This system is to help ensure that the drugs produced at the plant are of no cost to patients in Uganda and to prevent their sale on the black market.

While the Government of Uganda attempts to provide free ARVs to patients in clinics and hospitals, services are limited as they are unable to supply medication to the vast majority of those in need. As of 2009, the public health sector funding for essential medicines per capita was estimated to be \$0.93 USD (UNIDO, 2010). This amount is dismal in comparison to the cost of ARV treatment per person per year. The Government, therefore, must use various mechanisms, in order to provide a greater number of patients with the medications.

First, funding from the national health budget, contributed by the Government of Uganda is used to purchase drugs from QCIL for distribution in public facilities (Z. Akol, personal communication, July 6th, 2010). These drugs are distributed to a limited number

of patients in government hospitals and clinics and account for approximately 10% of the ARVs distributed in Uganda. The figure illustrates the significance of such an enormous donor supply of donor funded ARVs.

Figure 2: The Distribution of Financing for ARVs



Second, the Government receives substantial funding from multilateral and bilateral agencies that provide financial support for the provision of ARVs (Z. Akol, personal communication, July 6th, 2010). The Global Fund supports the public health systems by providing grants that are released directly to the Ministry of Finance. These grants are intended to support national AIDS treatment programs, and to provide treatment to patients in public sector hospitals and some NGO supported clinics partnering with the Government. However, the portion of funding allocated to the purchase of ARVs is disbursed through the third party private drug procurement company Crown Agents (CA), which currently only procures WHO accredited imported versions and does not purchase drugs from QCIL.

PEPFAR funding for ARVs is intended to provide medication to private not-for-profit clinics and research centers. This funding is entirely channeled through private third party procurement and distribution agents before reaching the care centres. The funding does not contribute to the enhancement of the public system.

The reproduction of generic versions of most second line and pediatric medications is prohibited, as the drugs were primarily patented after the imposition of the TRIPS Agreement. UNITAID provides funding specifically for second line and pediatric medication. The international funding body supports the Clinton Health Access Initiative (CHAI), which is responsible for purchasing and obtaining the drugs (UNITAID, 2012). The procurement options of these types of drugs are primarily limited to price negotiations with Western pharmaceutical companies, or by the obtainment of a compulsory license to have generic versions produced (Dionisio, Fabbri, & Messeri, 2008).

All drugs purchased with the donor money, whether it be by NGOs or the Government, must meet the appropriate quality assurance standards of the particular organization (MoH, 2011a). In the case of PEPFAR, this means all drugs procured with funding from the organization must be US FDA approved and in the case of the Global Fund, all ARVs procured must first receive WHO prequalification (National Academy of Sciences [NAS], 2007). The organizations are consequently restricted from purchasing drugs that may be more readily available or at a lower cost due to the aforementioned policies.

Several donor-funded centers operate out of the largest public hospital, Mulago National Hospital in Kampala. These centers partner with the Ministry of Health to help

facilitate research, testing, and care for patients requiring treatment for AIDS.

However, the funding for drug procurement is handled independently of the Ugandan government. The Infectious Disease Institute (IDI), the Center for Disease Control (CDC), the Baylor International Pediatric AIDS Initiative (BIPAI), The AIDS Support Organization (TASO) are all institutions are situated on the grounds of Mulago to help provide treatment, and counseling to patients. All of the aforementioned centers are supported by foreign donor programs and most predominantly by PEPFAR. While these institutes operate in conjunction with the Ministry of Health, given that they receive funding from external sources the drugs provided in the centers are also subjected to donor country regulation standards.

The third method the Government relies on for the provision for ARVs is the help of NGOs, which distribute the drugs for free in clinics run by private donors or the NGOs themselves (Z. Akol, personal communication, July 6th, 2011). These organizations may work entirely independently from the Government or may coordinate to run clinics. These NGOs typically receive funding from multilateral or bilateral organizations. The NGOs operating in Uganda primarily attempt to fill the gaps in the public health coverage or to provide special medicines, in particular pediatrics and second line medications, which are not covered by government services.

Lastly, a very small number of patients choose to purchase the drugs on their own through private clinics although this is a rare occurrence due to the pricing (Z. Akol, personal communication, July 6th, 2011). The Government provides a small amount of ARVs to private clinics so that patients who are willing to pay service fees to avoid waitlists need not pay for the ARV medications they receive but only the cost of the visit.

However, the Government support is only enough for 5,000 patients to receive free ARVs from private clinics (Z. Akol, personal communication, July 6th, 2011). This study's primary focus is to evaluate whether access has been increased, in terms of the country's universal free ARV program and thus does not discuss the private system at length.

Care centers tend to be located primarily in urban areas. Therefore, treatment is inaccessible for those unable to reach the services and particularly for some of the most at risk groups, including migrant labourers, sex workers, and soldiers (MoH, 2011a). The critical issue of access to medications for those living in rural or isolated areas, or in mobile professions is a vital component of a lack of resources needed to adequately distribute medications. While some NGOs run clinics in rural areas to provide treatment, those who are unable to obtain ARVs from these services, due to limitations in resources, are forced to travel to national clinics in more populated regions to receive treatment. This is a process that requires frequent and costly travel. A fifteen-kilometer ride to a clinic via *matatu* (shared taxi) would cost approximately Sh2,000 equivalent to \$0.80 USD, as of currency conversions on April 11th, 2012 (Sserwanga, 2008). This figure consumes the weekly expenditure required for a rural family to purchase basic essentials such as salt and soap (2008). It is evident that gaps in coverage are significant issues with regard to access to medications. Nevertheless, despite these shortcomings in the public health system, Uganda can still be credited with attempting to make ARVs more readily accessible, and for free to patients.

The Ministry of Health created the first Health Sector HIV/AIDS Strategic Plan (HSHASP) in 2005 with a grant from the Global Fund in the hopes of increasing access to

care (MoH, 2011a). ARV drug therapy became available through government services at 380 sites (2011a). As of June 2010, ARV drugs were available in all federal hospitals and primary clinics, although resources and access to treatment remain severely limited (2011a). For patients in need of ARVs gaining access to the medication is a difficult process.

According to the Ministry of Health, the success rate of patients adhering to ART remains over 90% in Uganda (2011a). This statistic insinuates that the majority of patients have been successful in following the treatment regimen and taking the medicine at the proper time. These patients can continue on with first line treatment medications, as they have properly adhered to the medicine and not developed a resistance to the drugs (MoH, 2011a). Currently of the patients receiving ARV care, 97% are on first line medications, although the specific drug combinations vary (2011a). The drug factory in Uganda is in theory able to supply the vast majority of HIV/AIDS patients with drug combinations intended for first line treatment. This is an important factor when considering the potential for the domestic production of drugs to increase access, as the drugs produced are relevant to patient needs.

Although ARVs are distributed in government-run hospitals in clinics, the service is limited. Over 50% of adults and 70% of children currently do not have access to ARVs in the country (2011a). These statistics exhibit the necessity of further improving access to ARVs within the country and highlight the fact that while Uganda provides treatment to patients, it is far from achieving universal coverage. The WHO suggests that Uganda's proposal for universal ARV treatment will only be possible if the Government can obtain affordable drugs, since over 50% of Uganda's health budget is already allocated to AIDS

and Malaria (WHO, 2008). Médecins Sans Frontières (MSF) defines universal access to ARVs as “reaching 80% of people in need of HIV/AIDS treatment” (MSF, 2011, p. 3). According to informants, currently government services for ARV treatment only permit a new pre-registered patient to begin treatment when another dies, due to a severe lack of resources.

A patient may travel for days to reach a national health site only to wait in the corridors of the hospital without a bed for many more days on end before he or she is even able to see a doctor. Once admitted into the hospital, a patient desperately requiring ARV treatment would be subjected to a waitlist, given the scarce resources for pre-forecasted amounts of ARVs available for distribution in government services. Despite being in dire need of the medication, patients must wait to gain access to treatment, and in many cases are left with no other choice but to return home without medicine. Informants confirm that government services remain drastically underfunded and understaffed and many HIV positive patients instead are reliant on NGOs for the provision of their treatment.

Even those that do receive ARVs from the public system the process of obtaining the drugs can be significantly challenging. Gladys Bambola, a forty-four-year-old HIV positive Ugandan, lost her husband to AIDS in 1994 and explains that accessing medication “is not easy, because you have to undergo a number of tests and counseling before you qualify for ARVs” (Sserwanga, 2008. p.2). She also clarifies that “the testing itself is expensive” and that it can cost Sh23,000, equivalent to approximately \$9.26 USD as of currency conversions on April 11th 2012 (2008, p.2) This is a price which is an entire month’s wages for some (2008). Many patients who cannot afford to pay user fees

for government services must rely on donor- funded clinics for treatment, as they typically cover the cost of testing.

Uganda faces the challenge of extreme dependence on external financial support. The country's ARV program is 90% donor funded (refer to figures 1 and 2) by various development partners providing the resources necessary to maintain ARV services (Republic of Uganda [RoU], 2010). As well, many NGOs established care centers for the treatment of HIV/AIDS primarily as emergency services in the absence of strengthening government health services to provide long term support (MoH, 2011a). The system of donor funded sites has led to a weakening of the public health sector given that many health professionals previously employed in government run hospitals and clinics were lost to privately funded hospitals and clinics (2011a). The Ministry of Health (2011a) notes that the system of donor funded not-for profit clinics has created, "an uphill challenge for the sustainability and further expansion of the national ART program" (p. 24). With such an extreme reliance on donor agencies for the continuation of treatment programs comes instability and concerns with regard to how long they will remain present in the country and whether their financial resources will eventually run dry or be drastically reduced.

As previously outlined, the Government must use various mechanisms to sustain ARV distribution throughout the country. These mechanisms can be difficult to coordinate resulting in frequent ARV stockpile shortages and a lack of supplies (MoH, 2011a). Resource restraints and coordination errors can lead to problems with heightened drug resistance hindering the continued success of the program. Increased efficiency in the system of ARV drug procurement is required to improve the functioning of the

Ugandan ART program (2011a). Expanding access to drugs for HIV positive patients is a multifaceted problem. Challenges with the provision of ARVs remain ominous. The public health sector severely lacks resources and instability in the donor system is a threat to the continuation of ART programs. A scale up of ARV distribution is desperately needed in the country, in spite of the fact that the resources currently available remain minimal and have faced severe cutbacks.

The Government has recognized the importance of increasing treatment coverage, despite retractions in funding. In the HSHASP for 2010-2015, the focus on expanding treatment for HIV positive patients is highlighted as a key component of the plan (MoH, 2011a). As well, the plan proposes to strengthen the forecasting systems required to determine the amount of ARV drugs needed at a given center for a certain period of time. The plan is intended to simultaneously work towards increasing the procurement capacities for centers distributing the drugs while improving the functioning of the flow of medicines for government services. Unfortunately, funding restrictions at both the national and international level impede the Government's success rate of achieving these goals.

Treatment as prevention

While many methods of drug procurement have helped expand the number of patients on ARVs, it is important to acknowledge the significance of a constant and continued decrease in AIDS rates in Uganda, in order to reduce the total number of patients requiring treatment. The Ministry of Health recognizes that in the wake of emerging of new studies proving that by taking ARV medication one can reduce his or

her rate of transferring the disease by 96%, treatment is now also prevention (Z. Akol, personal communication, July 6th, 2011). Given the fact that treatment and prevention are no longer considered mutually exclusive, the ACP has begun to focus more heavily on the combined efforts of providing medicine to patients while simultaneously preventing the disease from spreading, although finding the resources to do so remains a significant challenge (Z. Akol, personal communication, July 6th, 2011).

With the new discovery of the preventative qualities of ARV drugs that are already being used to treat the disease, public health measures to heighten treatment numbers can also contribute to preventing the further spread of the disease. Increasing treatment numbers could also help to lower new infection rates. In order to facilitate the expansion of care as a form of prevention a scale up of ARVs is required to ensure that a greater percentage of the HIV positive population is able to receive treatment. However, currently access to the drugs remains restricted for the majority of the HIV positive population in Uganda (Ssenkibirwa, 2011).

The HIV prevalence rate on average for Uganda is approximately 6.4% of the population considered to be sexually active between ages 15 and 49 (MoH, 2011). The rate is lower than in the early years of the epidemic although it is on the rise again. The overall amount of new infections has doubled since 2005 and in 2009 alone over 124,000 new infections were reported (2011). What's more, experts are predicting that in the next year the new infection rates will rise to over 140,000 (York, 2011). Raymond Byaruhanga, director the AIDS Information Center states that, every year new infection rates rises "by [another] 10,000 or 15,000 and soon it will be 20,000 or 30,000" (2011).

Despite the amount of new infections the prevalence rate is distorted due to the rapid increase in population in recent years (MoH, 2011a).

According to the Ministry of Health (2011a) the prevalence rates also, “masks the heterogeneity of the disease across different regions, sex, age and marital status” (p.1). In the Central and Northern regions of Uganda the rates were as high as 8.5% and 8.2% of the population, which speaks to a lack of attention and inclusion in AIDS education programs for more rural areas (2011a). Denis Kibira, a health researcher in Uganda explains that the rise in HIV prevalence is “very worrying” and that, “in the next five or ten years we are going to face a real crisis” (York, 2011, p.1). It is imperative that improved action be taken in order to slow the rate of new infections, while continuing to increase the number of patients on ARVs. Such action would necessitate more substantial and realistic education programs for prevention from the Government and NGOs to reach those living in rural areas. These types of programs must also target marginalized populations, including sex workers, and migrant laborers.

It is also important to acknowledge that the official HIV prevalence statistics do not include those who have neglected to get tested or those unaware of his or her HIV positive status. Currently only 40% of Ugandans have been tested for HIV, a fact that hinders the potential for counseling to facilitate behavioral changes (York, 2011). Since the disease has an incubation period of ten years, most people do not experience any symptoms, until the end of the incubation period, and may not be tested until that point. Evidently, throughout this ten-year period they may infect numerous sexual partners, unknowingly. This factor combined with a lack of resources to treat the growing number HIV positive patients, results in significant delays from the time one is infected with the

disease and when they start treatment. A patient typically does not start to take ARVs until he or she begins to show signs of the disease, or when his or her CD4 count² is low enough to require the medication for immediate survival (WHO, 2011). Prior to receiving treatment, HIV positive patients are significantly more likely to infect their sexual partners with the disease.

The Ministry of Health (2011a) names several possible reasons for the increase in the new infections including; the sero-discordant prevalence of HIV among couples in a committed relationship; multiple sexual partners, and low condom usage amongst the sexually active population. New infections are also increasing in married and common law couples, as over 40% of those who are HIV positive have a HIV negative spouse (2011a). Due to the long incubation period of HIV, a spouse may have been unaware of his or her HIV positive status prior to marriage but fortunately did not infect his or her partner. Statistics also show that 76% of all new infections are sexually transmitted (2011a). Therefore, with a scale up of the number of patients on ART, infection rates could see a definitive decline based on the aforementioned factors, as sexually active people on ARV drugs can drastically reduce rates of transmission (National Institutes of Health, 2011).

The low the utilization of prevention measures due to an increase in access to AVR drugs is also noted as a factor fueling the epidemic (MoH, 2011). While this factor

¹ The CD4 count refers to the amount of T-helper cells in an HIV positive patient's blood stream. T-helper cells are important immune system cells, which are attacked by the HIV virus making the patient more susceptible to contracting other illnesses. CD4 tests measure the amount of T-helper cells still left in the body. The WHO ARV guidelines for 2010 advocate that patients with HIV/AIDS should begin ARV treatment immediately if they have been diagnosed with TB. Otherwise, a patient should begin treatment when their CD4 count drops below 350 cells per cubic millimeter of blood, an update from the 2006 WHO guidelines, which quoted the number as fewer than 200 cells per cubic millimeter of blood (WHO, 2010).

should be recognized when discussing the potential for an ARV treatment scale-up, it is merely one of several potential reasons behind the increase in the HIV incidence in Uganda. What's more, given that ARV treatment in Uganda is far from universal, complacency in the presence of access to medication should not be seen as significant factor effecting AIDS rates or as a deterrent for increasing the amount of ARV drugs available within the country.

Of greater significance is the decline in education campaigns for condom usage from the early days of prevention advertising (York, 2011). The promotion of abstinence only campaigns by PEPFAR programs implemented under George Bush is also heavily criticized for leading to a rise in AIDS rates and recent years (Kinsman, 2010). As well, religious lobbying led to a ban on the promotion of condoms on Ugandan billboards and on television commercials, before 9pm (2010). Asuman Lukwago, the permanent secretary in the department of health states that HIV rates, "have stagnated, and there's evidence of increasing infections. There is a new generation of young people who are unaware of the dangers of not using condoms" (York, 2011, p.1). Greater awareness and more effective educational campaigns are important aspects of lowering new infection rates.

Together the aforementioned strategies and programs may be effective in lowering the rates of transmission for HIV/AIDS in Uganda. However, when combined with increased ARV treatment, official infection rates may see an even greater decline. Ideally, given the results of the new studies, patients should start on ARVs as soon as they are diagnosed to avoid transmission to others, which could significantly aid in reducing the rate of new infections. However, due to limited resources, both the Government and

NGOs currently struggle to provide treatment to even half of the patients requiring immediate treatment for their survival, let alone the 1.2 million HIV positive people in the country (UNAIDS, 2012a). HIV treatment policies will, therefore, most likely continue to be based on the provision of medication to only those in dire need of ARVs, despite the preventative capabilities of the drugs.

Factors preventing universal ARV distribution in Uganda

While Uganda initiated the distribution of ARV drugs and facilitated strategies to enhance treatment, there are many issues surrounding the potential for universal coverage. As stated in the previous section, prevention measures to halt the spread of the disease are necessary in order to decrease the number of patients requiring ARV treatment. The large quantity of new infections restricts the capability of obtaining universal ARV coverage in Uganda.

The management of ART programs can be very complicated and requires significant human resources to guarantee the availability of a continued supply of medications. As well, monitoring the treatment programs of individual patients is essential to ensure their effectiveness. There are many challenges associated with the provision of ART that may be exacerbated in the absence of adequate resources. The Ministry of Health highlights these issues as:

- Complications with the administration of ARV medications including the necessity of compliance to treatment programs for the continued duration of one's life;
- The danger of patients developing a resistance to the drugs;
- Difficulty in monitoring treatment as continued testing is required;

- The prerequisite for patients to be counseled on how to accurately take the medication and on the necessary behavioral changes that must take place. (MoH, 2003a)

These points are critical to the successful implementation of ART programs and are closely related to issues of funding pertaining to ill equipped hospitals and a lack of human resources for health in the country. The physician ratio in Uganda as of 2005 equated to merely 0.117 per 1000 people, a number drastically below the minimum 2.3 health workers needed to suffice a country's primary healthcare requirements (Central Intelligence Agency [CIA], 2012). In the absence of medical personnel to aid patients in adhering to treatment, and without the proper diagnostic tools to determine one's status and CD4 count, ARV treatment programs could be unsuccessful in increasing treatment numbers despite an influx of ARVs.

The Ugandan Ministry of Health states that the ACP is not functioning efficiently and has issues with the quality delivery of HIV/AIDS services (MoH, 2011a). Although the Ministry put standards in place for appropriate guidance of the delivery of HIV/AIDS services, a lack of infrastructure, equipment, and funding, and human resources prevent the full implementation of such standards (2011a). Specifically, health centers in rural areas are frequently under staffed with a severe lack of resources as they have difficulty attracting human resources and funding (2011a). Treatment centers in Uganda are limited in their operational capacities, which inherently affects the quality of service delivery of ARV treatment programs.

Uganda's Gross Domestic Product (GDP) as of 2012 is \$45.9 billion USD when adjusted for purchasing power parity (CIA, 2012). In relation to the country's GDP, it is considered to be among the world's low-income countries (UNIDO, 2010). The most

recent statistics for 2009 indicate that 8.2% of the GDP is allocated to health expenditure (CIA, 2012). This statistic exemplifies the failure to reach the proposed 15% of the GDP of African nations that is to be reserved for health expenditure, as outlined in the 2001 Abuja Declaration on HIV/AIDS, Tuberculosis, and Other Infectious Diseases (Abuja Declaration) (UN, 2002). As well, when compared to the overall Ugandan budget, the actual percentage of health sector funding from the Government saw a nearly 10% decline from 2006/2007- 2008/2009 (UNIDO, 2010). Unfortunately, the outflow of funding does not stretch far, as the health care system is crippled by diseases prevalent in the country, and particularly by AIDS. The Ugandan government spends over 50% of its national health budget on AIDS and malaria treatment and patient care alone, which absorbs the majority of the resources for health care and forces the treatment of other health problems to the bottom of the list of the national health priorities (WHO, 2008). Issues of financial resources for the improvement of HIV/AIDS services remain a problem, as the actual amount received remains below what is to be expected (MoH, 2011a). The resources for health sector HIV/AIDS activities are predominately donor funded, and are primarily channeled through the private not-for profit sector (2011a). Hence, despite the past influx of financial resources for HIV/AIDS services, government centers do not necessarily see a benefit to the quality of care and improvements to the system and have even seen a decline in some instances.

Of the Government's total yearly expenditure, the portion allocated to funding for health has not seen a substantial increase over the years, raising questions of the sustainability of the Government's ability to provide services for HIV/AIDS (MoH, 2011b). If funding for the public health sector continues to remain constant while the

number of patients rises, health facilities will inevitably become further strained and less capable of providing access to medications for those in need. It is evident that Government services have, thus far, failed to meet the needs of the HIV population in Uganda. The parliamentary leader of the opposition in Uganda, Nandala Mafabi states that, “funding of the health sector should be the priority duty of the Government whose constitutional responsibility is to provide health to its citizens and should not be left to the donors” (Mafabi, 2011, p.1). As foreign donors continue to dominate the system of ARV procurement and distribution in the country, it only further perpetuates the issue of dependence on foreign aid to attempt to fill the gaps in government coverage.

The role of NGOs in the distribution of ARVs in Uganda

NGOs have undoubtedly played a significant part in the shaping of Uganda’s AIDS program. Foreign aid is often tied to a political or social agenda, and is exemplified through the case of Uganda. Some AIDS education programs implemented by major foreign donors in Uganda are arguably politically motivated and negatively affect the impact of the epidemic (Kinsman, 2010). Most notably PEPFAR’s infamous Abstinence, Be Faithful, and use a Condom (ABC) strategy is criticized for being a disguise for an ‘abstinence-only’ campaign (2010). The program is also critiqued for being primarily motivated to preach an abstinence-only agenda that is deeply rooted in the Christian values of the American Republican Party (2010). While it is important to recognize that some aspects of donor programs may be attributed to the spread of the disease, it is also imperative to recognize the weight of their presence with regard to ARV procurement. The negative implications included in the scope of such multifaceted programs should not

be neglected or undervalued, as it is critical that such programs are evaluated for the entirety of their value. However, in order to answer the research questions outlined in chapter 1, this thesis will primarily focus on the issues with the procurement of ARV drugs by NGOs and multilateral organizations in Uganda, rather than the broader list of issues associated with their presence in the country.

Uganda's ARV program is funded primarily through the support of PEPFAR, the Global Fund, and MSF, which the WHO highlights as an issue in regards to the sustainability of the program (WHO, 2008). While efforts by NGOs, bilateral, and multilateral organizations to increase the amount of Ugandans on ARVs have been relatively successful, the sustainability of donor funded ART programs is questionable, as it is evident that the provision of ARVs continues to remain extremely dependent on donor funding. The WHO suggests that stability and consistency are both issues that must be overcome within the Ugandan AIDS program, as stockpile shortages can result in major treatment problems (2008).

In the wake of the current global economic crisis international funding sources for ARVs have seen a definitive decline. Given that Uganda's ARV program is so heavily reliant on contributions from foreign agencies and donors, halts or reductions in funding poses serious issues for the permanency of the program. In the spring of 2010 MSF published a report illustrating the cutbacks made to donor programs for ARVs and particularly reductions in the budget for PEPFAR (MSF, 2010b). The report stated that PEPFAR's budget for ARVs was significantly reduced for the 2009-2010 year and that the organization implemented an overall freeze on the funding allocated for HIV/AIDS (2010b).

Specifically, the funding for ARVS in Uganda was cut six-fold, ultimately leading to a drastic decline in the amount of HIV positive Ugandans who would have been able to start treatment (2010b). In the absence of ARV treatment the severity of patients' conditions increases, putting an enormous strain on already weakened medical systems, as critical and palliative patients fill the beds (2010b). Dr. Mit Philips, Health Policy Analyst for MFS states that, "the current donor retreat will prevent more people from accessing treatment and will threaten to undermine all the progress made since the introduction of ARVs" (MSF, 2010a, p.1). Others have also expressed their concern over a lack of funding to sustain ARV treatment programs. Dr. Peter Muganyizi founding director of the Ugandan JCRC states that a withdrawal in PEPFAR funding is of great concern and that he foresees, "the return of catastrophic times of the 90's, when everything in Africa came to standstill and the hospitals couldn't function and the staff fled the health service- and many of them died. They couldn't get access to treatment and had nothing to offer their patients" (Boseley, 2010, p.1). The reoccurrence of such a situation would defeat much of the progress already made in the fight against HIV/AIDS.

The Global Fund has also experienced recent financial cutbacks, resulting in the cancellation of the next round of funding for grant programs intended to provide treatment to patients suffering with HIV/AIDS in the Global South (Heilprin, 2011). While the preexisting programs receiving grants from the Global Fund will continue to be funded, no new projects will be implemented (AIDS Span, 2011). The cancellation of grants for the 11th round of funding means that there will be no financial aid for grants to scale up the number of new patients receiving ARVs, until 2014 at the earliest (2011). The Global Fund cites the global economic downturn, as the primary reason behind the

lack of funding (2011). Since the Global Fund relies largely on funding from governments in the G8, the debt crisis in Europe and the US has led to reductions in their yearly contributions to the organization (2011). Cutbacks in funding only further restrict patient numbers.

Jeffery Sachs (2011) also discusses the dangers of financial cutbacks to programs facilitating the distribution of ARVs, specifically in regard to the Global Fund. He argues that the current US Government initially pledged \$4 billion USD for the period of 2011-13 but retracted the funding, while continuing to spend \$1.9 billion USD each day on the military. He also describes Washington's decision to cut funding as "a new depth of cynicism and recklessness" (Sachs, 2011, p. 1). MSF states that in order to meet necessary treatment and prevention goals, as outlined by UNAIDS, countries must pledge an additional \$6 billion USD annually by 2015 (MSF, 2011). However, in 2009 and 2010 both the Global Fund and PEPFAR experienced cutbacks to financial resources, as funding from governments declined (2011). Whether Western donors decide to hold true to their pledges for funding does not change the fact that ultimately relying on the good will of donors to maintain ARV programs poses huge challenges to the stability of ARV distribution projects.

If a patient's treatment program does not remain constant, he or she may be unable to continue on with their treatment path, as the drugs become no longer effective. The TRIPS Agreement prevented the reproduction of all second line and pediatric medications developed after 2005, without first obtaining a compulsory license. These patients must rely on newer, patented, and more expensive drugs to maintain treatment (MSF, 2011). If vast numbers of patients do not receive the proper treatment on time

resulting in drug resistances, the necessary second line treatment may not be readily available, due to the high costs of the patented versions. Since most second line treatment drugs are still under patent in the West, the treatment costs of ARV programs could escalate while donor funding simultaneously decreases. As well, a possible third line drug regimen is nearly twenty times more expensive than the WHO recommended first line medications and more than six times more expensive than the least expensive second line regimen (2011). These second line and potential third line medications will likely remain at exorbitant prices, as their generic reproduction is prevented through patents enforced the TRIPS Agreement and thus no competition exists.

Currently, 1.2 million people in Uganda are HIV positive (UNAIDS, 2012a). However, as of 2009 only 200,400 patients were receiving ART (2012a). Dr. Kihumuro, the Ugandan AIDS Commission's director explains that the disparity in treatment would only increase due to the rising infection rates (Ssenkabirwa, 2011). Moreover, President Museveni acknowledges the growing issue of the sustainability of ART programs and states, "for every two people we put on treatment, five are being infected" and that "it will be unattainable to meet the demand" (2011, p.1). Treatment numbers remain low despite the fact that more patients receiving treatment could translate into reductions in the amount of new infections, as the spread of the virus would be restricted. It has become evident that maintaining an ARV program so heavily reliant on contributions from donors, poses great issues of sustainability, which is dangerous as the continuation of treatment for AIDS patients is critical for their survival. It is, therefore, imperative to examine other more long-term approaches of ARV drug procurement that may enhance the longevity of the ARV treatment programs.

Chapter 5:

India's Foreign Direct Investment in Uganda

This chapter outlines and analyzes the expansion of India's pharmaceutical industry and, in particular, Cipla. An overview of the history of the company is relative to the research as it highlights the key factors that enabled the country to create a successful and profitable domestic drug industry, which eventually led to its FDI in Uganda. A discussion of the history and current operations of QCIL is also essential to illustrate the establishment of the company and the goals behind its formation. It is also critical to draw attention to the future limitations of the production of generic drugs in India, in order to assess the issues surrounding the operations in Uganda. By understanding the origins of Cipla, and the elements behind its success, along with the obstacles it faced as a result of the TRIPS Agreement, similar factors pertaining to the production of generic medicines in Uganda can be emphasized. Field discussions accompany historical data and scholarly research to provide a thorough analysis of both QCIL and Cipla as well as the growth of their partnership.

Pharmaceutical sector development in India: The origins of Cipla

In 1935 Indian born chemist Dr. Khwaja Abdul Hamied founded Chemical, Industrial, and Pharmaceutical Laboratories, now commonly known as Cipla Limited (Cipla, 2011). His formulas were used for the creation of several medicines produced by the company when it officially opened in 1937 (2011). Cipla originated as a publicly limited company, meaning that under British colonial law shareholders and owners would

not be liable individually if the company were to be sued and, instead, Cipla at large would be held accountable in a legal battle (2011). This aspect of the company became very significant following the creation of the TRIPS Agreement, as Cipla encountered numerous legal issues with regard to the production of generic drugs. Given its status as a publically limited company, Cipla could apply for insurance to cover the costs of legal battles and protect against bankruptcy.

The late Dr. Hamied was said to have placed great value on the importance of improving the health of the Indian population (McNeil, 2000). Dr. Hamied's Indian nationalism is also reflected in his desire to host the 'Father of the Nation', Mahatma Gandhi, at his factory (McNeil, 2000). In 1939, Gandhi praised the company when he visited the original Bombay (Mumbai) based factory (Cipla, 2011). Even prior to the end of British colonial rule, Dr. Hamied focused on the importance of developing a successful Indian owned and operated company.

In the 1940's, the company emerged as a national pharmaceutical leader since the country relied on Cipla to produce essential medicines during the Second World War (Cipla, 2011). As well, the decade marked the creation of the Technical Industrial Research Institute founded by Dr. Hamied, which became the Indian Council of Scientific and Industrial Research (CSIR). The CSIR remains the main research centre in the country (2011). The company also instigated the manufacturing of the chemicals required in the production of the medications; to avoid issues with government imposed import restrictions (2011). In the decades following the 1940s many legislation changes in India would have a significant effect on the development of the pharmaceutical industry in its entirety.

At the time of Indian independence from the Great Britain, Cipla was a successful Indian owned and operated company. However, in 1947, India had control over a mere 10% of the national pharmaceutical industry, with the other 90% owned by foreign corporations (The Economist, 1997). It was also at this time that drug prices in the country were the highest in history (1997). To reverse this, the Government instated high tariffs and price controls on imported pharmaceuticals, while domestic industries were protected for newly developed drugs (1997). These protectionist policies reflected the political ideology of the time in India. Prime Minister Jawaharlal Nehru facilitated a type of state-led development, which was industry-oriented and focused on import substitution (Kohli, 2007). The policies implemented under Nehru's governance planted the seed for an industrial economy to grow (Rodrik & Subramanian, 2004).

Some academics dispute the economic success of India's state-led style of development in the years succeeding independence (Bhagwati & Desai, 1970; Myrdal, 1968). However, despite its criticisms Nehru's economic plan was shown to have led to significant industrial growth (Kohli, 2007). While some sectors were neglected due to Nehru's policies, in particular agriculture, other industries were able to benefit immensely (2007). The Indian pharmaceutical sector specifically profited as the economically protectionist policies prevented the domination of the industry by foreign multinational companies (Tomar, 1999). Without products from Western pharmaceutical companies flooding the market, Indian businesses gained control over the industry. This aspect of the Indian pharmaceutical sector development is of particular relevance, as foreign competition can hinder the success of newly introduced companies. Other developing pharmaceutical industries may not have the same type of market protection, making it

difficult to provide competitive pricing with larger foreign companies who can achieve greater economies of scale.

Indian pharmaceutical companies were able to continue to grow without fear of market infiltration from multinationals specializing in drug production. Nationalization of private industries continued and anti-monopoly laws were strengthened under Indira Gandhi's populist government that was in power in the late 60s to early 70s (Kohli, 2007). The Prime Minister also instigated a piece of critical legislation, the Indian Patent Act that would allow the pharmaceutical industry within the country to flourish. India used protectionist prescriptions in its Indian Patent Act to promote pharmaceutical sector development within the country (Kapczynski, 2009). The Act conforms to typically Western ideals of intellectual property rights for the majority of products such as computer software, although it does not hold the same position on chemicals for medicine or innovations in agriculture (McNeil, 2000). The same philosophy could be seen in the patent legislation of other countries in the South, prior to the imposition of the TRIPS Agreement and most notably in Brazil (2000).

Preceding the implementation of the TRIPS Agreement, Brazil's patent laws allowed for the replication of brand name medications, without consent from the patent holder (Brazilian Patent Law, 1996). While the country signed on to the 1883 Paris Convention for the Protection of Industrial Property (Paris Convention), the pharmaceutical and process patents expired in 1945 (McCabe, 2007). The expiration date of the previous patent legislation paved the way for legislation amendments eliminating patents for agricultural or pharmaceutical products (2007). In 1969, patents were completely removed for pharmaceuticals, with another amendment to the legislation

(2007). The amendments made, aided the country in developing a successful and profitable generic drug industry, as did the similar legislation changes in India.

Typically in many less developed countries, the concept of the ownership of knowledge is seen to be an unfair advantage, benefiting the already industrialized Western World while hindering the successful development of the Global South (Seeratan, 2001). Seeratan (2001) explains that frequently in the Global South, knowledge is regarded as “the common heritage of mankind” and is hence made available to all members of society (p.3). It is for this reason that many Southern countries have viewed the patenting of knowledge as unjust, and detrimental to development, particularly with regard to inventions that could be beneficial to health care and agricultural production (2007). This notion is present in the legislation changes implemented by both Brazil and India at the turn of the 1970s. The patenting of knowledge, through the imposition of pharmaceutical patents, is reflective of underpinnings of the TRIPS agreement. These ideals seek to push Western neoliberal thought and practice on the Global South, with particular regard to the importance of individual property rights.

The Indian Patent Act of 1970 enabled Indian pharmaceutical companies to produce generic drugs through the provisions made to the legislation, which permitted only process patents for pharmaceutical products and prohibited the use of product patents (Agrawal & Saibaba, 2001). This process of drug manufacturing created a large supply of reasonably priced medications within the country, described as a ‘Robin Hood’ style of producing drugs through which companies could provide drugs to the poor (Boseley, 2010). Cipla’s creator, Dr. Hamied, played a significant role in the creation of the act, as he is said to have lobbied Prime Minister Indira Gandhi for its finalization

(McNeil, 2000). The construction of the Indian Patent Act allowed for the production of generic drugs to flourish.

The Act was intended to allow for low-cost manufacturing competition enabling Indian firms to help develop a national pharmaceutical industry and provide affordable medicines (James, 2004). Without the costs of expensive patents or royalties, the price of the drugs could drastically decline. Given that the process keeps costs low, Indian pharmaceutical manufacturers could compete in markets both domestically and internationally (Kapczynski, 2009). The resulting success of the industry also increased economic independence for the country (Seeratan, 2001). In part, India's achievements in the pharmaceutical industry can be attributed to its resistance to strict patent laws. As well, the country's historically large population size created an enormous demand for generic drugs. To support the public health services, the Government required a vast amount of affordable medications for the growing number of citizens (Tomar, 1999). The refusal to enforce typical patent laws reflected devotion to the belief that the health priorities of the country should hold precedence over the rights of foreign corporations to maximize their profits through monopolistic practices (Seeratan, 2001). India found an advantageous method of producing low cost medications while simultaneously building a profitable pharmaceutical sector.

When Indira Gandhi returned to office in the 1980s, after regaining the power base she lost in the mid-70s, free-market economic growth became a priority reflecting a shift away from the state-led development policies of the past (Kohli, 2007). Restrictions on Indian businesses were removed, which facilitated corporate tax breaks and both public and private investments increased, as did industrial growth (2007). As well, the

Government of India now permitted technology imports, which increased productivity (Kohli, 2007). With the ability to import new technology, the manufacturing capabilities of Indian generic industries could be further enhanced. Increased efficiency in the industry enabled the price of domestically produced drugs to decrease even further. The import protected pharmaceutical industry could continue to grow, as it had been able to develop a specialized sector producing generic versions of medicines. Due to the existing patent laws abroad, other countries, most notably the US, were unable to produce these types of medicines, giving India a significant advantage in the market for affordable medications (Myers, 2007).

Public investment in India was not abandoned as it was in the US and the UK with the onset of neoliberal economic reforms (Harvey, 2005). In the absence of neoliberal style cutbacks to government services, investments in national health care continued. The Government also continued to preserve its stance on external trade liberalization as being detrimental for the development of Indian businesses (Kohli, 2007). Indian pharmaceutical industries could grow while still maintaining a form of market protection.

In 1992, Yusuf Hamied began to work on the reverse engineering of antiretroviral drugs required to treat AIDS patients (McNeil, 2000). He recognized that India would be severely affected by the pandemic and spent four years of his life developing a generic version of a common ARV drug, Lamivudine (2000). With the introduction of generic ARVs, the price dropped from upwards of \$20, 000 USD to only a few hundred USD annually per person per year (Hyman, 2005). The evident price differential between generic and brand name versions of ARVs exposed the actual operational costs of the drugs to the world (2005). The price distortions exhibited the immense profit made by

Western pharmaceutical companies, which continues to compromise the health and well-being of patients in need.

India lowered pharmaceutical prices while increasing the percentage of Indian owned firms leaving only 15% of its industry to Western pharmaceutical companies (Seeratan, 2001). Kawaja Abdul Hamied's son, Yusuf Hamied, Cipla's current managing director, explained that the company's "turnover is \$200 million USD, if we sold our products at American-originator prices, our turnover would be \$4 billion USD" (McNeil, 2000, p.1). By keeping operational costs down, and avoiding expensive royalties, Indian firms have been able to produce vital medicines at more locally affordable prices. They have also achieved this without cutting costs on labour, as even the lowest employee of Cipla is paid \$2,400 USD, a reasonable salary in India when accounting for purchasing power parity (2000). Hamied lists "social reasons" as the primary motivation for consistently lowering the price of drugs (2000). Cipla maintained its original focus on the production of low cost medications to help better the health of the Indian population.

Since its creation in 1935, Cipla has grown into one of the largest pharmaceutical companies in the world (Quality Chemical Industries Limited [QCIL], 2011). Cipla currently has forty manufacturing centres for drug production with quality assurance approval from various international bodies including the WHO, the Red Cross and eventually the US FDA (2011). However, obtaining approval from the US FDA was not an easy task, as it took two years and significant international pressure for Indian generic ARVs to be deemed acceptable by the US FDA for use in PEPFAR funded programs (Dietrich, 2007). The company succeeded in providing essential medicines at low costs to improve the health of the Indian population.

The generic industry in India is also praised for its provision of essential medicines to other countries in the South at locally affordable rates (MSF, 2007). Its focus, based on the production of generic forms of essential medicines, provides low cost versions of expensive brand name medications, thereby increasing affordability. The industry is even described as 'The Pharmacy of the Developing World', particularly with reference to the production and distribution of ARVs (2007).

India has also begun to export resources and knowledge capital to other countries in the Global South in order to aid in the creation of pharmaceutical developments for the local production of ARVs (Haakonsson & Richey, 2007). As well, the introduction of generic ARVs permitted the creation of fixed-dose combinations of various drugs, which increases adherence rates and simplifies treatment, acting as a critical component of the global ARV scale up (MSF, 2011). India's pharmaceutical sector has increased access to medications for millions living in the developing world. This factor has specifically enabled governments and NGOs to purchase larger quantities of ARV drugs for the same amount of funding. In 1999, prior to the introduction of generics, ARV treatment in Uganda per person per year equaled approximately \$7, 200 USD (Haakonsson & Richey, 2007). With the introduction of generic drugs, a year later, the price dropped to approximately \$480 USD (2007). This price differential would have permitted 15 new patients to start treatment for the price of one on the brand name medication (author's own calculations). In addition to contributing to improving the lives of citizens across the Southern Hemisphere, India has simultaneously constructed a highly lucrative and profitable industry from which the country benefited economically.

Another important factor that remains intact in India's patent law, despite the implications of the TRIPS Agreement, is that it reserves patents for only those drugs which prove to show actual therapeutic improvements over previous versions and does not grant patents to known combinations of molecules (MSF, 2011). This clause prevents evergreening, a process through which pharmaceutical companies alter drugs ever so slightly to reclaim patents on products approaching patent expiration dates. For example, the pharmaceutical company Merck first filed the patent on the ARV Efavirenz in 1993, which was set to expire in 2013 (2011). However, in an attempt to protect its monopoly on the product, Merck filed a new patent application for the crystallized form of the drug, expanding the original patent until 2018 (2011). Evergreening can continue to prevent the generic production of ARVs under patent, and is not recognized in the Indian Patent Act. Cipla is currently undergoing a lengthy legal battle with the Swiss pharmaceutical company Novartis, as it has accused the Indian generic drug producer of violating patent rules (Bajaj & Pollock, 2012). Cipla denied Novartis' patent application for the cancer drug Gleevec on the basis that it did not prove to be any more effective than an older version, and was a case of evergreening on the part of the Swiss pharmaceutical company (2012).

The international court case has AIDS activists greatly concerned, as the results of the case could affect Cipla's future ability to produce generic versions of brand name ARVs, which were previously denied patents based on the grounds of evergreening (2012). The Obama Administration in conjunction with PhRMA opposes the clause in the Indian Patent Act specifically intended to prevent evergreening (2012). Both parties are pushing for Indian companies to acknowledge extended patents in similar situations

through Pacific Rim Trade Agreements (2012). The future of the Indian generic industry would be significantly affected by the enforcement of such an agreement. This factor further necessitates the development of pharmaceutical industries in LDCs, which still have the legal ability to produce the generics that could be restricted from production in India.

Quality Chemical Industries Limited: History and current operations

Quality Chemicals Limited (QCL) was founded in 1997 to distribute primarily animal health products within Uganda (QCIL, 2011). QCL founding director and Chief Commercial Officer, George Baguma provides a historical overview of the operation and how its partnership formed with Cipla (personal communication, July 12th, 2011). Initially the company imported veterinary products from European companies, to treat livestock. However, it quickly became apparent to the owners of QCL that malaria was a major health risk for the Ugandan population in the rural areas of the country. With the realization that much of the rural population desperately required medicine to treat malaria, the company moved into the procurement of medications for human health issues and imported generic antimalarials from Cipla. Baguma states that once Cipla developed a generic antiretroviral for the treatment of HIV/AIDS and started to supply the medication to Uganda, QCL immediately imported ARVs in addition to antimalarials. With the mass influx of drugs being imported into Uganda, QCL recognized the need to start producing the medications within Uganda. The Ugandan owned and operated company Quality Chemicals Limited later evolved into what is now entitled, Quality Chemical Industries Limited (QCIL) with the formation of a partnership with the Indian

pharmaceutical giant, Cipla, who currently owns 42% of the company (Pharmaceutical Technology, 2011).

Baguma emphasizes that the primary motivation behind the creation of the company stems from the belief in the necessity of a homegrown solution to the global issue of HIV/AIDS. Furthermore, the provision of affordable ARVs for Ugandans is viewed as being best achieved through focusing on the domestic production of the drugs (G. Baguma, personal communication, July 12th, 2011). Uganda's decision to produce ARVs domestically also stems from the concern that, due to the restrictions of the TRIPS Agreement, relying on India for the importation of generic medicine may no longer be a sustainable method of procuring ARVs (Haakonsson & Richey, 2007).

By depending solely on pharmaceutical imports to treat endemic diseases, in particular HIV/AIDS, the Government must spend a significant amount of financial resources to purchase the medicines without any control over the pricing or benefit to the Ugandan economy (QCIL, 2011). QCIL believes that since Africa is home to over 60% of the world's HIV/AIDS patients, it is necessary for the continent to provide, "an African solution to an African problem" (2011). Baguma states that QCIL believes that the continent should not depend on the good will of the developed world to provide ARVs. QCIL puts great emphasis on the fact that relying on foreign donors and NGOs to supply medications to Ugandans is unsustainable. According to QCIL it is believed to be of great importance that countries in Sub-Saharan Africa, and Uganda in particular, develop industries that enable them to rely on the drugs they supply (G. Baguma, personal communication, July 12th, 2011).

Both the African Union and UNAIDS promote the local production of ARVs in Sub-Saharan Africa as a means of increasing access to the medications in addition to facilitating greater self-reliance, sustainable procurement practices, and job creation (African Union, 2007; UNAIDS, 2012b). As well, the recently announced East African Community Medicines Registration Harmonization Project calls for the encouragement of domestic manufacturing initiatives in the region for essential medicines and specifically, the production of ARVs through partnerships with Brazil, Russia, India, China, and South Africa (BRICS) (UNAIDS, 2012c).

In 2007, the drug factory began to produce generic versions of antiretroviral and antimalarial drugs. The plant currently produces 2 million tablets per day, which equates to approximately 600 million tablets a year (Pharmaceutical Technology, 2011). Generic first line adult ARV medications are manufactured and sold exclusively to the Government for use in public clinics and hospitals (G. Baguma, personal communication, July 12th, 2011). International agencies have approved the drugs produced at the Luzira drug factory for quality assurance purposes to make certain that they meet the appropriate standards (QCIL, 2011). Most notably, QCIL recently received certifications from the WHO as well as the International Red Cross, a very important step for the company (Pharmaceutical Technology, 2011).

Foreign direct investment for the production of pharmaceuticals

At the official request of President Museveni, Cipla agreed to the formulation of a joint venture with QCL, which would facilitate the transfer of technology and the

resources needed to create a drug-manufacturing center in Uganda licensed by Cipla (QCIL, 2011).

The foundation of the venture lies in the preexisting trading partnership between QCL and Cipla. While the inception of the idea came from QCL, the Government of Uganda played a significant role in the construction of the factory. As multiple informants confirm, when QCL approached Cipla with the idea of building a drug manufacturing plant in Uganda, the Indian company expressed interest but required a commitment from the Government of Uganda to purchase the drugs in order to ensure that there would be a reliable market and a guaranteed buyer for the ARVs. After careful review and consideration of the proposed project the Government gave its support to the initiative in the form of land to build the factory and a seven year contract to purchase the drugs. The Government's contract would ensure that all of the drugs purchased by the Government funding would come from the factory in Luzira. In reference to the creation of the factory, the Ministry of Health proclaimed "our position as the Ministry of Health of Uganda is that we are going to do everything to keep our people alive" (Haakonsson & Richey, 2007). The Government's commitment to purchase the drugs solidified the plans to construct the facility.

During the development of the plant the Government also bought shares in the company in the form of a \$5 million USD investment to aid in the completion of the factory. Two foreign private equity firms have since replaced the government investment in the industry, as the initial agreement was intended to be a temporary solution to an issue of funding (G. Baguma, personal communication, July 12th, 2011). Baguma elaborates that while the Government of Uganda is no longer directly financially involved

in the endeavor according to QCIL, it remains the main beneficiary. The drugs purchased with government funds are distributed in public hospitals and clinics to treat patients in need.

The private equity firms currently involved in the operations are CapitalWorks International Partnership Fund (CapitalWorks) and TLG Capital Fund (TLG). TLG was founded in 2009, with the goal of creating an industry that could facilitate commercial returns while enhancing social returns (TLG Capital Fund [TLG], 2011). Investments are intended to increase profits of indigenous businesses primarily in Sub-Saharan Africa that stand to benefit society (2011). TLG currently owns 12.5% of the company and recently increased its initial investment following QCIL's achievement of specific goals that were created prior to the finalization of the first investment (Private Equity Africa [PEA], 2011). TLG's Chief Operations Officer, Afsane Jentha, stated that the company is, "impressed by the management team's ability to execute on the growth and expansion strategy much earlier than expected and are confident that QCIL will continue to build on this success, including their plans for increased production capacity" (PEA, 2011). With the financial support from the investment firms the company can move forward with its strategy of expanding the industry.

The second installment of investment funds is expected to triple production by 2013 (2011). The investment is also intended to expand the factory to produce the active ingredients essential to drug formulas, with the goal of reducing imports and effectively lowering the price of the drugs (2011). Currently the operation imports the key components needed to manufacture the pharmaceuticals from Cipla. By manufacturing

the main ingredients of the drugs, QCIL could decrease operational costs by lowering the amount of imported substances and ensuring in-country supplies.

The second private equity firm investing in QCIL is the South African based, CapitalWorks. The company, created in 2006 focuses on generating increased returns on investments in industries based in Sub-Saharan Africa (CapitalWorks, 2011). The business owns a minority equity interest of 8.2% of the company shares (Pharmaceutical Technology, 2011). CapitalWorks' financial investment also contributed to QCIL's potential for the expansion of operations.

These two private firms were introduced to replace the Government's initial investment, as it was intended only to provide the finances required for the completion of the factory. The agreement between QCIL and the Government was that once the operation began to profit the investment would be immediately repaid, and thus the investment firms eventually bought out the Government's shares in the company (G. Baguma, personal communication, July 12th, 2011). Cipla, therefore, currently owns 42% of the company shares, with TLG and CapitalWorks owning 12.5% and 8.2% respectively and the remaining 37.3% of the shares belonging to the original Ugandan based company QCL (Pharmaceutical Technology, 2011; PEA, 2011). While the operation has acquired the financial assistance to expand operations, it is also of significant importance to outline the legal ability for the plant to produce generics.

The Ugandan patent legislation initially respected patents for UK products until 1991 when the legislation was amended in the Patents Act (Ugandan Law Reform Commission, 2004). The Patents Act recognizes domestic and regional patents registered under the African Regional Industrial Property Organization although it does not account

for international patents (2004). Uganda signed the TRIPS Agreement and became an official WTO member in 1995, although it has yet to amend its patent legislation to meet the requirements of the Agreement (UNIDO, 2010). A draft of the amended legislation was formulated in 2004, although it has not been approved by Parliament (2010). The cost of implementing new patent legislation can be equal to the development budget for an entire year for some low-income countries, posing significant issues for governments forced to adopt TRIPS (Economist, 1999). However, for Uganda the draft was funded by USAID, which provided a consultant to help with the process of revising the original Patents Act (Oxfam, 2002). It is not yet clear what influence the organization will have on the outcome of the newly revised Patents Act, or whether the suggestions will reflect the best interest of Uganda or those of the US. By using its status as an LDC, Uganda is exempt from the prescriptions of the TRIPS Agreement until 2015 when the transitional period for LDCs to amend their patent legislation comes to an end. The legal ability for Uganda to produce its own generic ARVs with support from India has not come easily, as the creation of the TRIPS Agreement is intended to halt these various types of endeavors.

The Politics of TRIPS and its influence on generic pharmaceutical production

In the early 80s, neoliberal economic thought emerged as the dominant political ideology in many Western countries, most notably in the US and the UK although the global trading policies would infiltrate the developing world as well (Harvey, 2005). The fundamental basis of neoliberalism lies in the belief that the well-being of humanity is best advanced through obtaining, “individual entrepreneurial freedoms and skills within an institutional framework characterized by strong private property rights, free markets,

and free trade” (2005, p. 2). The neoliberal theory challenged the belief in the importance of the public sector, and economic policies that distorted prices including tariffs, subsidies, and quotas (Willis, 2005). The creation of economic profits in the business sector was favored.

Governments throughout the world implemented capitalist policies. In particular, the UK under the leadership of Margaret Thatcher and the US under President Ronald Reagan, both imposed neoliberal economic policies in the countries they were governing (Harvey, 2002). These policies focused on trade liberalization, deregulation, and the privatization of government run entities. The market became a celebrated entity that was seen as the most appropriate tool for resource allocation, a belief that spread not only to the developing world but also to Western Europe and North America (Willis, 2005). In the countries housing the major brand name pharmaceutical companies, the economic policies adopted by the governments inherently clashed with the protectionist policies attributed to the foundation of the generic drug industry in India. Given that Indian legislation did not acknowledge individual property rights for health related products, the country failed to meet the desires of the countries promoting neoliberal economic globalization.

The creation of the TRIPS Agreement, negotiated in 1994 at the Uruguay round of the GATT, enhanced the practice of neoliberal values in many ways as it generated an international legal system in favor of individual intellectual property rights. The Agreement enabled major pharmaceutical companies in the West to profit immensely. The patent rights allocated to the drug companies for their products provides them with

the sole production rights and thus prices can be substantially inflated, as market competition is prevented.

When the WTO was created in 1995, replacing the GATT, it facilitated an international system of trade regulations. The system reflected the neoliberal values by emphasizing free trade between countries and binding the signature countries to its legislation (Harvey, 2002). This legislation included the regulations of the TRIPS Agreement, and countries were forced to adopt its policy prescriptions.

The TRIPS Agreement focuses on five main issues. These issues are as follows:

- “How basic principles of the trading system and other international intellectual property agreements should be applied;
- How to give adequate protection to intellectual property rights;
- How countries should enforce those rights adequately in their own territories;
- How to settle disputes on intellectual property between members of the WTO;
- And special transition arrangements during the period when the new system is being introduced” (WTO, 2011).

Specific rules and regulations are included in the Agreement to address each of the aforementioned points in order to ensure that all WTO member countries conform to the proposed prescriptions. The prescriptions coerce countries to meet the desired trade legislations or risk losing their status in the WTO.

Heywood (2004) notes that the creation of TRIPS is credited to two US-based companies, the pharmaceutical giant Pfizer and IBM, both of which had a vested interest in the outcome of the agreement, as it would certainly lead to an increase in profits. Following the creation of the Agreement, the US Government was responsible for accusations of patent ‘piracy’, in reference to claims that over \$2.5 billion USD had been

lost each year in royalties from imitative pharmaceutical drugs and pressured countries to conform quickly to the prescriptions of the Agreement (Mooney, 1996).

The TRIPS Agreement permits patents to be granted on newly developed products, protecting all inventions from being replicated by any other member state of the WTO, via international law. Patents enforce intellectual property rights, as they reward inventors with the sole rights to reproduce, and sell their products (Seeratan, 2001). However, a patent can also be viewed as a method of providing the patent holder with a monopoly on a given product, since patents stand to prevent the replication of an invention without permission from the original inventor (2001). The creation of the TRIPS Agreement, therefore, “presents the danger of legally sanctioned, price gouging, allowing for extreme prices, well above the cost of production” (2001, p.3). Such practices conflict with the WTO rules and regulations, as free competition and free trade practices are restricted. Furthermore, as outlined by Pogge (2008) and Correa (2002) the prices of pharmaceuticals under patent fail to meet the demands of the market, resulting in decreased economic efficiency, as they are set at substantially higher costs than the free market equilibrium.

Pharmaceutical products were certainly not excluded from goods that would have patent laws enforced through the TRIPS Agreement, permitting monopoly pricing to occur. The Agreement essentially reflects the prevailing political ideology at the time of its inception, as it enables big business to profit substantially, while protecting individual property rights. However, it is evident that TRIPS exposes several contradictions to neoliberal theory behind the WTO, in that the patent system distorts free trade practices by allowing corporations to set prices that should be naturally determined by the market.

The trade practices stand to benefit primarily the North, while the much of the South is prohibited from even entering the market, based on patent restrictions. These trade imbalances are further exemplified by the fact that Western markets continue to be protected by quotas, tariffs, subsidies, and anti- dumping regulations, while the WTO stands to abolish such practices in the Global South (Pogge, 2008). The Agreement only further enhances preexisting North- South power imbalances, as signatories to the WTO have no choice but to abide by the regulations of the Agreement despite its detriment to the development of pharmaceutical sectors in the South.

The justification of awarding patents to pharmaceutical companies resides in the belief that the research and development of the new medications is such a costly procedure, that in the absence of extensive profit margins for newly developed drugs, innovation would suffer (Vernon, 2005). However, with specific reference to ARVs, this argument falls short.

Many governments in the West provide tax incentives in addition to subsidies for pharmaceutical research and development (Correa, 2002). The US Government notably funded initial development, preclinical research, and clinical research for the creation of HIV drugs (2002). In one such case, with public finances, the Michigan Cancer Foundation developed the ARV Stavudine, which was later discovered by Yale University to be highly effective in the treatment of HIV/AIDS patients (2002). However, the drug is currently sold by the pharmaceutical company, Bristol-Myers Squibb for a significantly higher amount than its generic counterpart, despite the fact that the company did not invest in the research and development of the drug (2002). Furthermore, pharmaceutical companies in the US faced a nine-year legal battle to prevent revealing to

congressional investigators the actual research and development costs of the drugs they sell (Joseph, 2003). When Big Pharma won the case, it highlighted an important debate in terms of the true costs associated with research and development of new drugs (2003). The justification for the exorbitant price of all patented drugs as a reflection of the cost of research and development is an unsound argument and acts as a misleading rationalization for the necessity of the patent system.

Initially, India was strongly opposed to the TRIPS Agreement, as the country had successfully lowered prices for pharmaceutical products through its reluctant stance on patent enforcement (Kapczynski, 2009). As well, Indian-owned pharmaceutical manufacturers accounted for 85% of the domestic market, a drastic improvement from the mere 10% it held at independence (Seeratan, 2001). The industry had been able to grow substantially and prosper prior to the TRIPS Agreement, and thus the country's apprehension towards signing the agreement was obvious. Despite its initial disinclination to sign on to TRIPS, India would eventually accept the agreement as policies reflecting the neoliberal prescriptions were implemented in the country with the onset of the 1990s. At this time, India's economy was opened up to American products in an attempt to improve international trade relations, particularly with the US (Kohli, 2007). Since India had joined the WTO, increased trade liberalization in the country was promoted as the organization's inception lies in the aspiration to facilitate increased neoliberal globalization. Becoming a member of the WTO also put pressure on the country to adhere to its prescriptions, most particularly those of the TRIPS Agreement.

The creation of the TRIPS Agreement also created immense international pressure for countries to act quickly in amending their laws to meet the requirements of the

agreement. Previously created Acts that neglected the imposition of patents for pharmaceuticals, were to be adjusted to meet the requirements of the Agreement and to facilitate the protection of intellectual property rights.

In 1996, the US accused India of violating the conventions of the TRIPS Agreement and took the matter to the WTO dispute settlement body arguing that specific provisions of the TRIPS Agreement should be implemented without further notice (Tomar, 2007). The Indian Government heavily disputed the matter as it attested to the fact it had not failed to meet the proposed requirements, since the transitional period would not end until January 2005 (Seeratan, 2001). Although the panel had the ability to support India in its rebuttal the US was instead favored, which helped to win the case (2001). Most significantly, the US pushed for India to adhere to product patents in order to prevent the replication of pharmaceutical products protected in the West (2001). Tomar (2007) describes the US Government as a “bully” in the manner in which it pressured India to amend its legislation or risk losing its spot in the WTO. Tomar (2007) also explains that this behavior reflects the values of the US Government and its desire to facilitate free trade to suit its own best interests. By enforcing strict free trade regulations and patent protection on India, the US Government ensured the continuation of monopolistic tendencies of its pharmaceutical companies.

The 1990s marked a period of high economic growth for India, as many sectors focused on international trade. Maintaining membership of the WTO was critical for the country to sustain its high growth rates. Seeratan (2001) contends that the US Government is guilty of sanctioning countries, which do not meet their proposed level of intellectual property protection. The pressure from the US and the WTO to ensure that

India would immediately abide by the newly developing trading policies, reflected their desire to implement neoliberal economic regulations while simultaneously preventing the country from further utilizing the transfer of technology for generics. Large American pharmaceutical industries are losing their monopoly power with the growth of the generic manufacturing in India and huge incentives are apparent for the prescriptions of TRIPS to be enforced.

Seeratan (2001), states that the TRIPS Agreement essentially acts as a vector for Western imperialism over the developing world. She explains that the WTO forum enforces mandatory preferential trade agreements on countries and in India in particular, which faced no other option but to adopt the policies in order to remain part of the WTO, and participate in the global economy (2001).

Frederick Scherer, a professor of public policy at the Kennedy School of Government at Harvard explains that what the generic drug companies in India were doing at the time was, “perfectly legitimate, until 2005, under the Paris Convention and the Uruguay Round of trade talks”(McNeil, 2000, p.1). India had until 2005 to make changes to the patent legislation and to implement policies, which would prohibit the creation of new generic drugs. However, during this grace period India was not obliged to abide by the rules stated in the TRIPS Agreement. Scherer also states, “it is a marvelous piece of public relations to get these companies called pirates,” as generic drug producers are often referred to as by major Western pharmaceutical companies (2000, p.1). In 2000, the Indian Minister of health, Dr. Javid A. Chowdhury was quoted as saying, “we do not need to be apologetic about it (producing generics),” and went on to explain that if pharmaceutical companies in the West “can offer an 80% discount, there was something

wrong with the price they started off with” (2000, p.1). The evidently high profit margins of pharmaceutical companies exhibit the immense price distortions of patented medications.

When asked how he felt about being called a pirate, Yusuf Hamied explained that in the US the drug company Ciba-Geigy sold an arthritis medicine called Voltaren for \$2000 USD for 1000 tablets, whereas in India the identical product was sold by Ciba-Geigy for 5 cents a tablet, enabling someone to purchase the same quantity of the drug for only \$50 USD (2000). He went on to state that, due to competitive pricing from Indian generic pharmaceuticals, US companies drastically lower their prices to match those of the Indian companies (2000). ARV medications have been no exception to gross over pricing. A brand name triple therapy antiretroviral in the US can cost several times more than its generic counterpart. This fact is outlined by MSF in reference to the price of ARVs, as with the introduction of the generic fixed dose combination Zidovudine, Lamivudine, Nevirapine, the brand name equivalent prices dropped 56% (MSF, 2012). Mr. Hamied’s view is that those in the US who are forced to pay substantially higher prices for the same medications that are being sold in India are the ones who are really being pirated (2000). While Indian companies can produce medications at significantly lower prices than those produced by major pharmaceutical companies in the West, the prescriptions of the TRIPS Agreement have significantly impacted their ability to manufacture and sell generic products.

American pharmaceutical companies protect their rights to intellectual property even in the LDC markets (2000). When Cipla attempted to provide Duovir, a generic ARV, for free in Ghana Glaxo Wellcome, the maker of the brand name version,

Combivir, warned that they “reserve the right to enforce our patent rights against any further acts of infringement” (2000, p.1). The statement from Glaxo Wellcome exemplifies the unwillingness of major Western pharmaceutical companies to adjust their policies on intellectual property rights even in the face of public health emergencies, and where it is evident that a substantial market exists for the production of generic drugs.

In 2005, the WTO enforced the restrictions of TRIPS as the ten-year grace period for the developing countries to amend their patent laws came to an end. Many saw these changes as having devastating consequences on the health of those in the Global South (Pogge, 2008; Haakonsson & Richey, 2007; ‘t Hoen, 2006). India, among other countries, was forced to make amendments to its India Patent Act and add the protection of product patents despite international protest against the Agreement (2001).

While the Doha Declaration extends the deadline to enforce the regulations of the TRIPS Agreement until 2016, India was not included on the list of the 49 least developed countries (LDC), which were legally able to take advantage of the flexibilities (Hyman, 2005). The Doha Declaration prohibits any country with a population greater than 75 million, with the exception of Bangladesh, to be considered as a LDC under the prescriptions of the agreement (2005). This clause, therefore, also excludes Brazil and China (2005). The prescriptions stated in the Doha Declaration are intended to account for the provision of medicines for public health emergencies with particular regard to HIV/AIDS, malaria and tuberculosis (TB). However, the countries excluded from the TRIPS extension, particularly India, China, and Brazil are home to the largest generic ARV pharmaceutical producing and distributing companies in the world (2005). Their omission from the list limits the scope of the clause by deliberately prohibiting the largest

generic pharmaceutical companies from benefiting from it. Moreover, by preventing these major exporters of generic medications from providing newly developed essential medicines to LDCs, issues arise with sustaining the world's generic drug supply.

While TRIPS permits the LDCs included in the Doha Declaration to manufacture medication without permission from the patent holders, this is only to be done in the case of a self-declared national health emergency expiring in 2016 (Van Dyck, 2007). This clause sparked great debate as many argued that developing nations would likely lack the infrastructure or manufacturing capacity needed to produce drugs (2007). To account for this factor, the article was eventually altered to include compulsory licenses for parallel imports from other countries for necessary medications, enabling India to continue to provide ARVs to other resource-deprived countries (2007). However, a compulsory license must be first granted to the country exporting the drugs and only the required quantities must be produced (2007). This factor hinders the production of generic ARVs, as the industry must be heavily regulated. What's more, the national drug supplies become limited, as countries must first report the amount they will require in order for the generic medication to be produced and then wait for the medications to be delivered.

When asked, in 2005, about how the implementation of the TRIPS Agreement would affect Cipla's ability to produce ARVs, Dr. Hamied answered, "What can we do? What we are seriously contemplating is to set up a manufacturing base in one of these forty-nine countries, such as Bangladesh, and exporting from there... My main problem is that these countries might not have the money and resources to buy the drugs" (Hyman, 2005, p.1). The QCIL drug factory in Uganda can be considered a textbook example of the exportation of manufacturing centers Cipla was considering in 2005. The current

operations of the industry will be further explored in the remaining chapters. It is imperative to draw light on the importance of the creation of such industries, as India is limited in its ability to produce and export generic drugs as a direct result of the TRIPS Agreement. The South-South partnership stands to benefit both Uganda and India. Cipla is able to provide a vector for the continuation of its generic drug production, while QCIL obtains the support and assistance necessary to produce and supply ARVs to the country.

Indian legislation allowed for the development of generic products prior to signing the TRIPS Agreement, permitting the continued production of previously developed medicines (Van Dyck, 2007). While the country is prohibited from further utilizing innovative technology to reverse engineer new drugs, it is still able to benefit from earlier developments (2007). India not only specializes in providing generic pharmaceutical products to its own population, but also focuses on exporting generic drugs to other countries in the Global South, a factor that could change if further international trade restrictions are implemented. Of India's \$5 billion dollar pharmaceutical industry, 65% of the drugs produced are sold to countries in the South (Myers, 2008). This statistic exhibits how other resource-deprived nations are dependent on India for procuring inexpensive generic medicines. For many living in poverty, their fate lies in India's ability to produce and supply affordable medications.

Due to the signing and implementation of the policy implications of the TRIPS Agreement, Indian drug manufactures are no longer legally able to produce new generic versions of medications patented after 2005 (Van Dyck, 2007). This means that any medication developed post 2005 will be subject to both process and product patents and consequently generic versions cannot be recreated without permission from the patent

holder. Tomar (1999) states that, “the TRIPS Agreement is expected to negatively affect pharmaceutical producers and the Government’s ability to keep pharmaceutical costs down and supplies high” (p.2). As the Indian pharmaceutical industry is increasingly unable to continue to produce low cost generic medications, it is not merely the companies who will suffer but the populations in need of affordable essential medicines, and particularly ARVs.

India will, therefore, only continue to supply ARVs to the rest of the South for as long as the patients can adhere to the first line medications currently being produced (Van Dyck, 2007). With the high incidence of drug resistance, new combinations of second line drug therapies continue to be created. However, due to the prescriptions of the TRIPS Agreement, India is now unable to produce these generic versions, without being granted a compulsory license by the TRIPS Council or a voluntary license, by which the patent owner voluntarily gives a company the rights to produce a particular drug.

In order to facilitate the export of generic ARVs through a compulsory license significant government intervention is required (2007). Reports must first be submitted to the WTO Council by the developing country requesting the license to import a specific drug (2007). Following this request India must also apply for a compulsory license, and both parties are subjected to compensating the patent holder, thus raising the price of the drug (2007). Finally, the receiving country must ensure that the drugs will not leave its borders, a task, which can be very difficult to monitor for many nations lacking the resources to heighten border control (2007). The lengthy bureaucratic process deters governments from issuing compulsory licenses for the parallel importation of ARVs (Aginam, 2010). Hence, if a country has the capacity to manufacture the drugs

domestically, the costs can be lowered substantially while the availability of the medications can be increased. This factor has led Uganda to take advantage of the flexibilities of the TRIPS Agreement, as its status as an LDC permits the creation of a new industry for the production of generic ARVs until 2016. As of 2016, no new companies will be able to legally produce ARV medications, and only those drug combinations created prior to 2005 will be permissible.

Indian pharmaceutical companies continue to face problems with meeting the demands of the WTO while remaining a supplier of generic drugs to its own population and to other LDCs. As new trade deals are developed, India risks losing control over its pharmaceutical development strategy as it is feared that pressure to meet free trade agreements will coerce the country into meeting new intellectual property rights (Boseley, 2010). Large pharmaceutical companies in the US and Europe are said to be heightening pressure on politicians to insist that Indian firms conform to even stricter patent regulations (2010). TRIP-plus regulations are being enforced through regional or bilateral trade agreements, and include extensions to patents for greater than 20 years, restrictions to market entry for generics following patent expiration deadlines, and limitations to compulsory licensing (Cohen-Kohler, Forman, & Lipkus, 2008). These new regulations stand to exacerbate current issues of access to essential medications, as they will inherently even further limit the production of generic versions.

In particular, MSF has stated their opposition to a new free trade agreement between India and the European Union (EU) aimed at heightening the already existing limitations on the creation of generic products (2010). In 2010, protesters marched in

Delhi against the proposed free trade agreement (2010). President of the Delhi

Network of Positive People, Loon Gangte, explained that;

“Lifelong treatment for people living with HIV/AIDS depends on continued access to newer AIDS medicines. Because of international trade rules that India has already signed in the past, some of our newer AIDS medicines are already patented and completely unaffordable. We are protesting against India accepting terms that would further compromise access to life-saving medicine” (2010).

The present inequalities in the provision of ARV treatment have caused health as an intrinsic freedom to take a back seat. The supposed rights of major multinational corporations to increase profits have instead prevailed. Exploring the potential for domestic drug production to increase access to ARVs is critical for the continuation of affordable ARV medications. This is also a vital step in development as it exhibits the opportunities for collaboration between countries to utilize knowledge as a means of enhancing the health of entire populations and the economies of resource deprived countries.

This chapter has illustrated the development of both Cipla and QCIL, as generic drug producing companies, while illuminating the foundation of their relationship. As well, the chapter has explained the impact of the TRIPS Agreement in relation to the continued production of generic drugs and outlined the significance of the FDI for generic medicines in LDCs.

Chapter 6:

Key Findings

In light of the current restrictions of the TRIPS agreement, and the instability of the long-term presence of donor funding for ARVs, a self-sustaining method of procuring ARV medication is necessary. Through this chapter the domestic production of ARVs in Uganda is discussed as a means of increasing access to ARVs. The key findings shed light on the fact that the operation has not presently led to an increase in the accessibility of the drugs for Ugandans requiring ART and the reasons behind this. It assesses the necessary factors required for the operation to enhance the sustainability of the distribution of ARVs within the country for the future. The major findings presented in this chapter are confirmed through key informant interviews, policy discussions, previous academic research, official NGO and government documents, and contemporary news sources.

Through the use of multiple methods this qualitative study found that there are several factors impacting the success of the factory's ability to amplify access to ARVs in Uganda. It is important to acknowledge and explore these issues in order to comprehend the potential challenges associated with producing ARVs locally in Sub-Saharan African countries with particular regard to the case of Uganda. Research on other African countries also locally producing ARVs has previously cautioned that in particular cases the method may not be a viable means to increase access to the medication (Wilson, 2009; Govindaraj, Reich, & Cohen, 2000). Specifically, Wilson, Whiteside, and Cohen-Kohler (2008) highlight two important conditions required for the domestic production of

ARVs to lead to an increase access to the medications (2008). First, the drugs must be manufactured for less than the cost of importing them and second, WHO prequalification for the drugs must be achieved, as it is a necessity for entry into the donor financed market (2008). It is critical to recognize that while some domestic drug industries may experience difficulties attaining these critical aspects, such examples need not necessarily deter all efforts to locally produce ARVs. In the case of Uganda, the aforementioned requirements are significant factors in the success of the initiative. However, the research shows that the company has the potential to accomplish the necessary steps required to increase access to the medications.

A study of the domestic production of ARVs, in West Africa, provides an analytical framework for the necessary requirements for a newly developed generic drug factory to survive and prosper (Guimier, Lee, & Grupper, 2004). Guimier, Lee, and Grupper (2004) suggest that the local manufacturing of medications in Sub-Saharan Africa can be cost efficient and achieve the price reductions required in order to compete with the imported versions, if a variety of factors are met. This framework is used in the analysis of the key findings of this research.

Operational costs and the process of cost recovery

Startup costs for newly emerging pharmaceutical companies are typically very high, as new infrastructure must be built to suit the requirements of the operation. Interest on loans to build the facility can increase recovery costs, if they remain unpaid. This stage of the operations can also affect prices, as commonly the active pharmaceutical ingredients (APIs) required for the manufacturing of the products must be imported

(Guimier, Lee, & Grupper, 2004). Additionally, quality assurance standards must be achieved, and receiving internationally recognized certifications for medicines can be an expensive procedure (Wilson, 2010). During this period of time the prices may not be cost competitive with those of larger, more established pharmaceutical industries, as a new pharmaceutical company is still attempting to recover the costs associated with the development of the factory. This situation poses issues with the success of the initiative. In the absence of tariffs on foreign produced medications or government subsidies to decrease the selling price of the locally manufactured drugs, a company is often forced to either lose significant revenue or charge higher amounts for the drugs, than those imported. Guimier, Lee, and Grupper (2004) note the importance of the productive capacity of the plant as a key element affecting its ability to achieve competitive pricing, along with the necessary financial resources.

With reference to Uganda, QCIL is no exception to the process of cost recovery, as it began producing ARVs for sale to the Government in 2007 and is thus in the initial stages of the operation. Cipla agreed to provide assistance to QCIL for the production of ARVs on the condition that the Government of Uganda would purchase the drugs for at least seven years to ensure the existence of a guaranteed market (G. Baguma, personal communication, July 12th, 2011). The agreement between Cipla, QCIL, and the Government of Uganda was a necessary clause in the South-South partnership, which enabled QCIL to gain the financial support, resources, and pharmaceutical expertise from Cipla required for the construction of the factory.

Government involvement in pharmaceutical industrial developments is criticized in some academic studies. Govindaraj, Reich, and Cohen (2000) suggest that political

involvement in local drug manufacturing developments may contribute to the purchasing of domestically produced medicines for use in government hospitals and clinics despite the fact that the drugs may not be cost competitive with imported versions. Danzon (1997) also cautions that government policies pertaining to the domestic manufacturing of pharmaceuticals have in some cases sparked clashes between a country's industrial development objectives and the health policies. However, given the barriers to entry into the donor financed market for ARVs, an initial guaranteed buyer is necessary for the plant in Uganda to eventually reduce costs to below those of imported versions. This situation results in a monopsony, which, in theory, could enable the Government to demand price reductions, although the predetermined contract prevents this. However, should the factory also gain access to the donor market the situation could provide greater incentive to lower prices.

Informants confirmed, through key informant interviews that government involvement in the company has resulted in the purchase of drugs from the company for higher prices than those purchased from external sources. This is particularly due to the contracted procurement of all national ARVs from QCIL. It is important to note, however, that no patients have been taken off treatment as a result of the government's contract with QCIL. The funding allocated for the purchase of the drugs comes directly from government resources that were not previously used for the procurement of ARVs. Informants confirm that the Government had previously been relying on donor funding for its HIV/AIDS program. Although this contract may not initially be the most cost efficient strategy for the Ministry of Health to procure ARVs, a guaranteed market is a necessary step for the development of the local industry during the cost recovery phase. It

was also a conditionality of ensuring Cipla's role in the construction of the plant. This factor is often overlooked and undervalued by studies suggesting that governments should be absent from the functioning of developing pharmaceutical industries. Without the role of the Government the factory would be restricted from the entire market for ARVs, resulting in an impossible cost recovery situation.

The donor community present in Uganda thus exhibits a vast amount of control over the future of the pharmaceutical industry for ARVs in the country. Their decision of whether to procure drugs from QCIL or not will continue to be a determining factor in the success of the operation. Informants from various NGOs supplying ARVs and operating out of Kampala stated the higher cost of the drugs compared to imported versions, as a factor preventing them from procuring ARVs from QCIL. Multiple sources confirmed that since the official policies of their organizations focus on the most cost efficient means of providing the drugs, even a very marginal difference in price affects the NGO's desire and ability to purchase the drugs from QCIL. There was a strong consensus among informants from the public health sector and NGOs, that the drugs were not cheaper than the imported generic versions, and that there was little incentive to purchase the ARVs produced at the plant. In order for the drug prices to eventually be lowered the operation must achieve competitive prices and have a steady supply of buyers, which is difficult to achieve without the willingness of the donor community to purchase the drugs.

This situation resembles somewhat of a 'catch-22', as drug prices must be lowered in order to attract a larger amount of buyers, while for the cost of the drugs to be reduced the factory must draw in more purchasers. It is for this reason that the Government of Uganda and those of neighboring regions therefore currently play a vital role in the ability

for the venture to survive. The cost reduction strategies proposed in this section are essential to create incentive for donors to purchase drugs from the factory in order to significantly increase access to the medications.

Baguma explains that currently QCIL produces three antiretroviral products. The first is Duovir-N (d4T) a triple combination drug therapy consisting of Zidovudine (AZT) Lamivudine (3TC) and Nevirapine (NVP) tablets, currently selling for the price of \$198 USD per person per year. The second drug is Duovir (AZT/3TC), which consists of Zidovudine and Lamivudine, costing \$165.60 USD per person per year. Finally, Efavir is produced containing Efavirenz (EFV) and is sold for \$153.24 USD per person per year. Mr. Baguma states that these prices are within range of the guidelines for pricing of generic ARV drug therapy as proposed by a joint project, with UNITAID and MSF to regulate ARV drug prices. All three of the medications have obtained approval from the WHO as additional contract-manufacturing sites for the Cipla products, a beneficial aspect of the partnership between QCIL and Cipla (G. Baguma, Personal Communication, January 27th, 2012).

The triple combination drug d4T is a widely used regimen, as the lowest generic versions range from \$144 USD per person per year to \$101 USD per person per year (MSF, 2011). The second drug AZT/3TC ranges from \$123-101 USD per person per year in its generic form (2011). Lastly, the lowest EFV drugs vary from \$183 to as low as \$52 USD per person per year (2011). When compared, the price differentials between the drugs produced at QCIL and the lowest generic equivalents may appear to be substantial although it is important to note that the latter are not inclusive of transportation costs, and some prices are representative of discounts facilitated through CHAI. Depending on the

method of transportation and the allocated delivery time, the total price of the imported versions would likely be significantly higher than stated.

Emmanuel Katongole, Managing Director of QCIL, explained that the ARV drugs produced at the factory should eventually cost 30% less than the imported versions, which would provide a monthly dose of triple combination ARV drug therapy for approximately \$9 USD, an annual cost of \$108 USD (Vermulen, 2010). The pricing would then be cost competitive with the lowest imported versions. These prices range from \$183 - \$137 USD per person per year, not inclusive of transportation costs (MSF, 2010c). The proposed lower price of triple combination drug therapy, in relation to imported versions further exemplifies the potential for the domestic production of generic ARVs to substantially lower costs and increase the country's capability of enhancing access to those in need. The drugs would then be less expensive than those currently being procured through external sources by both the Government and donor organizations. This price differential could result in the potential for a countrywide ARV scale up as organizations bound to price ceilings in funding could treat more patients with the same amount of financial resources.

Strategies for cost reduction

In their study (Guimier, Lee, & Grupper, 2004) the authors point towards the necessity for smaller Sub-Saharan African countries to enter the regional market for ARVs, in order to increase profitability and to absorb production costs. As well, Guimier, Lee, and Grupper, (2004) note that, if traded regionally, exported drugs could increase foreign exchange. Given the substantial market for ARVs in the surrounding region,

QCIL has the ability to augment production to include the sale of the drugs to other neighbouring countries.

The factory also employs over two hundred staff members ranging from registered pharmacists; mechanical, civil and electrical engineers; as well as microbiologists, as described by Baguma. This aspect of the operation helps generate jobs and stimulate the local economy. The manufacturing center is host to Ugandan university student interns from a variety of different faculties who are able to gain much needed experience and training linking the company to institutions of higher learning. In addition to the potential for increased supplies of ARV drugs, the presence of the factory has the ability to also benefit Uganda economically.

The amount of jobs generated at the factory would continue to rise with the expansion of the factory and as more ARV orders begin to be placed. Increasing the productive capacity of the plant to amplify the amount of drugs purchased could also act as a stimulant to the Ugandan economy via job creation and increased government revenue through taxation. President Museveni acknowledges the significance of the plant's ability to generate job creation and states, "local ARVs give our children jobs on top of treating AIDS" (Kagolo, 2011). This factor is an important aspect of the local production of ARVs, as economic benefit to the country can be seen through the provision of drugs purchased from QCIL, as opposed to imported versions.

The expansion of the industry is already underway. The President of Rwanda, Paul Kagame promised that the Rwandan government would purchase ARV and antimalarial drugs from QCIL (Businge, 2012). The factory also received a pledge from the President of Eritrea, Isaias Afwerki to purchase ARVs from the plant and commended

President Museveni for supporting the plans for the construction of the factory (Mugisa, 2011b).

With regards to Rwanda, QCIL previously completed the process of country registration in order for the ARVs to be sold in Rwanda (Businge, 2012). Chief Executive Officer of QCIL, Emmanuel Katongole, stated that Uganda would provide “first world quality of drugs, at third-world price. Our prices are not the lowest, but are comparable to those recommended by the WHO” (2012). Mr. Katongole noted, “with Rwanda opening up its market for our products, it will greatly resonate Quality Chemicals in the rest of Africa and spur more investments” (2012). The promise of one country’s support may help legitimize the factory to other neighboring governments and help to justify their decisions to purchase ARVs from Uganda.

Guimier, Lee, and Grupper (2004) also propose that factories should invest in the production of several other drugs in order to maintain high profit margins. QCIL currently manufactures antimalarials, which can help aid in the cost recovery process, as the drugs begin to be sold more extensively in hospitals and clinics. Similar restrictions to the market are still applicable with regard to selling the antimalarials to donor agencies, although the antimalarials produced at QCIL have already achieved WHO prequalification. Furthermore, QCIL states that the company plans to diversify its range of products through the production of medications for hypertension, diabetes, and bacterial infections (G. Baguma, personal communication, January 27th, 2012). If successful in expanding its industries, QCIL will have met one of the major necessary conditions to help achieve cost competitive prices for ARVs, as outlined by Guimier, Lee, and Grupper (2004).

Baguma explains that currently the factory is only operating at 30-40% of its capacity. This factor also impedes the cost recovery process, as profits are not maximized. The first phase of the project was intended to focus on achieving the required quality assurance certifications to compete in both government and donor markets, while the second, and current phase is intended to augment production capacity through the sale of products across the East African region. The final stage of the project is to focus on achieving more competitive pricing to provide greater incentive for organizations and governments to procure from the factory. This phase intends to lower the prices of the medications through expanded markets and the production of APIs

The high cost of the imported APIs required during the manufacturing process of the drugs at QCIL is a contributing factor to the final price. As discussed by Wilson, Whiteside, and Cohen-Kohler (2008), the price of APIs in domestic manufacturing initiatives can be detrimental in the ability for a factory to achieve drug lower prices than imported versions. Guimier, Lee, and Grupper (2004) also highlight the impact that the high costs of APIs can have on decreasing the price of the finished manufactured medications in their analytical framework.

One method of reducing the production costs of ARVs, which can contribute to lower unit prices for medications, is for pharmaceutical industries to also produce the APIs involved in the drug recipes. By manufacturing the APIs required for a particular medication domestic manufactures can reduce drug prices, as APIs can account for 65%-90% of the production expenses (Pinheiro, Autunes, and Fortunak, 2008). QCIL recognizes the impact imported APIs can have on price fluctuations of the drugs and states the manufacturing of APIs as the final stage of the plan, although the factory

currently imports the ingredients from Cipla in India. Imported APIs are also subjected to fluctuations due to exchange rates, as materials are purchased from India in USD. Fluctuations in the Ugandan shilling when compared to the dollar can result in more expensive APIs and higher overall operational costs (G. Baguma, Personal Communication, January 27th, 2012). However, funding has already been accumulated for the expansion of the plant to manufacture APIs at QCIL through the investment from PEA (PEA, 2011).

By manufacturing all of the necessary ingredients within Uganda, the plant could also ensure the continuous and timely production of the ARVs produced at its facility, as potential issues with the delivery of APIs would be eliminated. Typically, importing APIs is a lengthy process, as it can take more than six months (UNIDO, 2010). Furthermore, pharmaceutical manufactures in Uganda stated that the price of APIs is subject to price variations as a result of the demand from other countries (UNIDO, 2011). Producing the APIs within Ugandan would decrease QCIL's reliance on Cipla for the production of the drugs.

In addition to producing APIs, some plant based pharmaceutical ingredients can also be grown locally. QCIL has formed a partnership with Rwanda to work together to promote the production of an API required for the antimalarial drugs produced at the factory (Businge, 2012). Specifically, *Artemisia annua* is key ingredient found in antimalarial drugs and is a crop that is now cultivated in Kenya, Tanzania, and Uganda (2012). Currently these plants are harvested in Uganda and exported to India where they are processed and resold in the form of API back to QCIL, for use in the production of its antimalarial drugs (2012). By also manufacturing the APIs within Uganda it would

augment agricultural jobs within the country. While it is unclear how long the completion of the expansion will take, beginning to produce the APIs required for antimalarials could help to drastically reduce the operational costs of the factory and contribute to lowering the price of the ARVs.

Issues with entry into the market for ARVs

Presently, due to the higher costs of the drugs produced at QCIL than those of imported versions the operation has not led to an increase in access to ARVs for NGOs. The Government of Uganda remains the sole purchaser of the drugs produced at the factory in Kampala. While the drugs circulating in government hospitals and clinics are procured through QCIL, they represent only 10% of the overall supply of ARVs in Uganda (Vermeulen, 2010). Informants stated that the prices of the ARVs produced at QCIL could be upwards of two to three times those of imported generic versions.

Given that PEPFAR funding is released through grants to local groups it does not serve to directly benefit the public health care system, contrary to the resources obtained through the Global Fund (Dietrich, 2007). While the Global Fund provides grants to the Government for the procurement of drugs for the public sector, the medicines remain subjected to donor country regulations, and particularly the necessity of obtaining WHO prequalification. These standards are important for maintaining quality assurance, but they can also impede the factory's ability to increase access to the medications.

The longevity of the factory in Uganda is highly dependent on whether it can gain access to the international donor ARV market. NGOs, multilateral, and bilateral organizations specializing in the procurement and distribution of ARVs typically focus

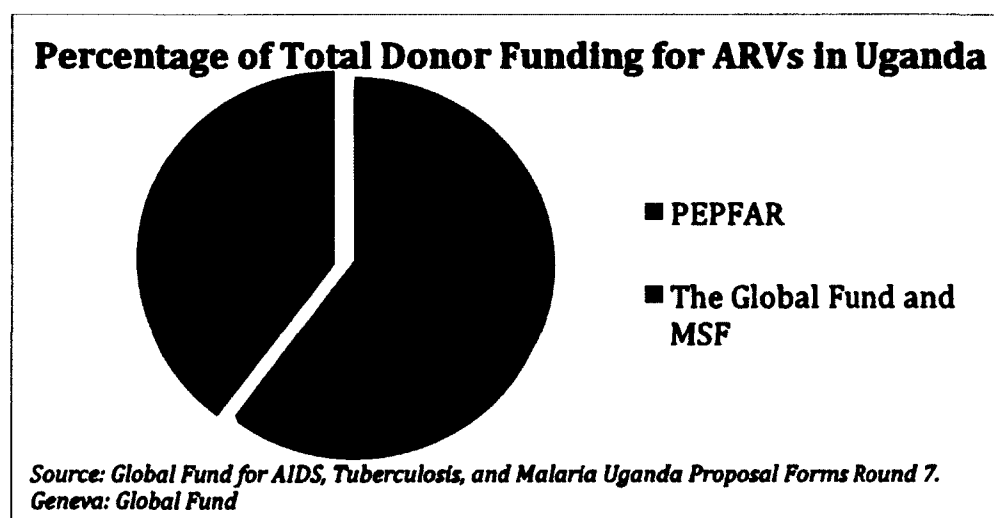
their fiscal plans on the provision of medicine to the greatest number of patients.

Therefore the pricing systems of the drugs play a vital role in their distribution particularly in countries, which are dependent on donor funding to provide medications to the large portion of their population suffering from AIDS. These organizations also remain bound to specific procurement policies, which enforce rules and regulations for the locations ARV drugs may come from. All programs receiving funding from foreign donors are subjected to procure only those drugs, which have obtained official certification from the given country's accredited drug authority. In the case of Uganda all ARVs purchased with funding from PEPFAR, or the Global Fund must have approval from the US FDA or the WHO, respectively. MSF also requires WHO prequalification for the drugs they supply. This factor significantly impacts the amount of buyers who are able and willing to purchase domestically produced drugs, and can act as an impediment to the cost recovery process of the newly developed factory.

In particular, PEPFAR's strong historic presence in Uganda has led many small Ugandan NGOs to seek funding from the bilateral organization. Since such a vast number of NGOs distributing ARVs in Uganda are PEPFAR funding recipients, the organizations are immediately restricted from purchasing drugs from QCIL, regardless of the drug pricing, as the factory has not yet received US FDA approval for its products (G. Baguma, personal communication, July 12th, 2011). Informants from various sectors made it clear that without US FDA approval, all centers receiving PEPFAR funding are prohibited from purchasing the drugs from QCIL. Therefore, despite the fact that QCIL has effectively obtained WHO prequalification for the ARVs it produces, the ARVs are still prohibited from procurement from NGOs receiving PEPFAR funding. PEPFAR

accounts for the largest percentage of the donor market as they provide approximately 60% of the ARVs distributed in Uganda, the other 40%, comprising primarily of funding from the Global Fund and MSF (Global Fund, 2007). The following pie graph illustrates the division of funding and the influence that PEPFAR has on the distribution of ARVs in Uganda.

Figure 3: ARV Donor Funding Distribution:



Obtaining approval for the use of generic drugs has long since been an issue for NGOs distributing ARVs and particularly those requiring US FDA approval. When PEPFAR originated, funding was solely allocated for the procurement of patent protected brand name medicines (Dietrich, 2007). The organization faced significant criticism, as generic ARVs already received WHO prequalification and were being distributed by UN affiliated organizations (2007). Dietrich (2007) argues that with reference to the restrictions it placed on the utilization of generics PEPFAR's procurement policy acted as a strategy to ensure that US pharmaceutical companies would continue to profit from the sale of ARV drugs, even if internationally accredited generic sources were available.

Presently, the US FDA has approved several Indian made generic ARVs for distribution in PEPFAR funded programs, although the majority of the financial resources are utilized for the purchase of patented medications (Wilson, 2010). Despite the enormous market for ARVs in Uganda, without US FDA approval, the drugs are prohibited from being sold to the majority of NGOs. This factor poses significant problems. Government resources allocated for ARV treatment contribute to a relatively small section of the overall funding for treatment programs in the country, as PEPFAR, the Global Fund, and MSF act as the primary supporters of these programs (Global Fund, 2007). The seemingly bountiful market for ARVs in Uganda is, in actuality, one that is highly limited due to technical restrictions.

Other countries producing ARVs locally in the region have also experienced issues with obtaining approval for their products, as research findings showed in a case study of Tanzania (Wilson, 2010). In light of the fact that the Tanzanian drug manufacturer, Tanzanian Pharmaceutical Industry Limited (TPI) has not received US FDA or WHO certification the company is restricted from entering the donor market for ARVs within the country, effectively impacting the success of the endeavor (Wilson, 2010). Obtaining internationally recognized quality assurance from accredited organizations is a necessary component of ensuring the safe provision of ARVs by NGOs. However, it is also critical to ensure that factories maintaining these quality assurance standards be rewarded with appropriate certifications, and not be excluded for reasons that stand to benefit donor country pharmaceutical companies, as suggested by Dietrich (2007).

QCIL faces a similar situation to that of Cipla the early days of PEPFAR implemented programs, where generic ARVs do not possess USFDA approval, despite receiving WHO prequalification, and reaching internationally recognized quality assurance standards. PEPFAR's position on ARV Procurement and distribution methods conflicts with the organizations proposed goals and objectives. As stated in the official executive summary of PEPFAR's Strategy for the fiscal years 2010-2014, the primary goals are as follows.

“Transition from an emergency response to promotion of sustainable country programs; Strengthen partner government capacity to lead the response to this epidemic and other health demands; Expand prevention, care, and treatment in both concentrated and generalized epidemics; Integrate and coordinate HIV/AIDS programs with broader global health and development programs to maximize impact on health systems; And to invest in innovation and operations research to evaluate impact, improve service delivery, and maximize outcomes” (PEPFAR, 2009, p.1).

While these strategies appear to promote new efforts to enhance sustainability through home grown inclusive efforts to increase access to ARVs, in practice such measures have both excluded and hindered the success of the very type of operation they propose to offer support to. In order for developing pharmaceutical companies to begin to recover their operational costs and effectively lower the drug prices they must first have access to open ARV markets. In the case of Uganda, this will require the manner in which the PEPFAR functions, to reflect the organization's proposed goals and objectives. Since PEPFAR is the largest financial supporter of Uganda's ARV program, its policies and practices have the most significant impact on the procurement of ARVs in the country.

Both the Global Fund and MSF are also key players as they primarily account for the remaining 40% of donor funding for ARVs (Global Fund, 2007). These organizations could procure medications from QCIL given that it has received official certification from

the WHO. QCIL is also said to be in negotiations with the Global Fund for the procurement of ARVs from QCIL (G. Baguma, Personal Communication, July 12th, 2011). However, these organizations must also permit entry into their donor markets as well, to help facilitate price reductions for the drugs at QCIL.

Obtaining WHO certification is an important step for the sale of ARVs to organizations such as the Global Fund and MSF, as well as achieving international accreditation that could persuade the US FDA to also certify the products. However, achieving WHO prequalification also adds to the expenses of a newly developed industry. The certification process usually takes 12-24 months costing upwards of \$200,000 USD (Kinsley, 2010). The certification application for ARV drugs must “include clinical data and bioequivalence studies” for individual drugs and fixed dosed combinations of previously certified ARV versions, a procedure that “requires not only the appropriate facility and equipment, but also the necessary trained human resources” to complete the testing (2010, p. 134). QCIL’s partnership with Cipla played a significant role in the obtainment of the certification, as the Indian pharmaceutical company offered technical expertise and necessary resources (Anderson, 2010).

The Significance of the South-South partnership

To date, South Africa notwithstanding, Uganda is the first country in Sub-Saharan Africa, as well as, the only country in its TRIPS defined category as a least developed country to achieve WHO prequalification for a domestic drug manufacturing centre (Anderson, 2010). Not only has the factory itself achieved WHO prequalification, but the ARV drugs have also been approved (G. Baguma, Personal Communication,

January 27th, 2012). Suerie Moon, local production expert at the Kennedy School of Government, at Harvard University explains that, “there is a lot of doubt in the global health community as to whether a firm in an LDC is capable of producing at WHO pre-qualification standards” and that the successful obtainment of such accreditation “sends a clear signal that its possible and is an important part of changing the way people think about local production” (Anderson, 2010, p.1597). Obtaining the prequalification is a very significant step for QCIL.

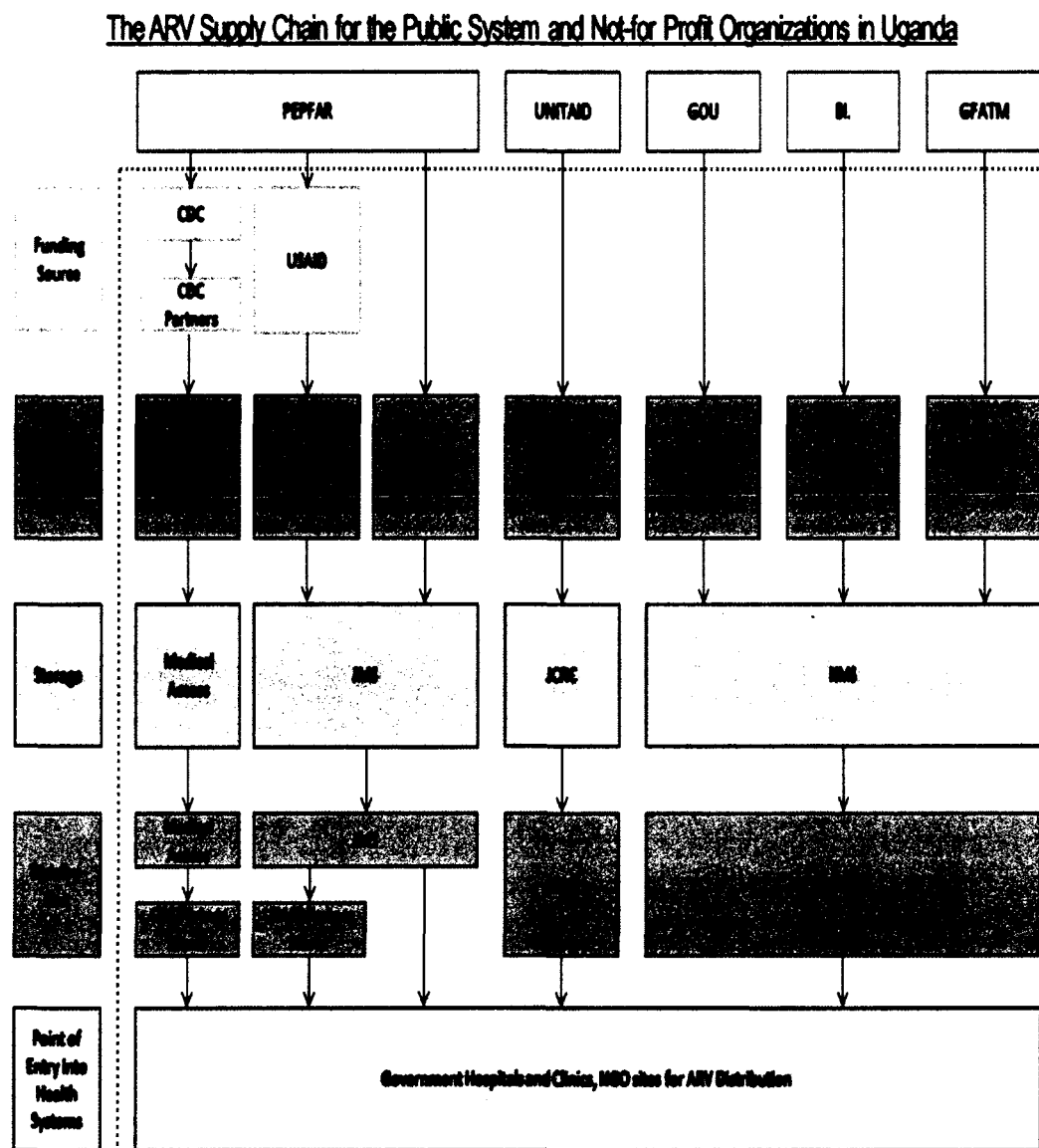
The South- South partnership between QCIL and Cipla is beneficial for the obtainment of the appropriate quality assurance for the drugs produced at the plant. Specialists from Cipla were able to provide assistance in completing the necessary steps to achieve WHO prequalification. Many attribute the quality assurance success of QCIL to its partnership with Cipla, as the Indian company modeled the plant after a pre-existing facility in Goa (Anderson, 2010) India also sent experts to train the Ugandan workers to appropriately administer important tasks (2010). Cipla has long since achieved the proper quality assurance standards necessary to receive WHO prequalification and help to create the high caliber of plant in Uganda. Additionally, the partnership enabled Cipla to apply for the prequalification of the plant as it helped QCIL overcome a series of issues and most notably the laboratory studies that could otherwise hold back an independent LDC firm from obtaining the WHO certification (2010). As well, Cipla factories in India received US FDA approval and thus have the ability to aid QCIL in effectively completing the process.

Donald Kaberuka, President of the African Development Bank explains the significance of such trading partnerships that are initiated from within African countries

to provide solutions to problems common to the Global South, particularly in reference to HIV/AIDS. He states, “African leaders must be in a position to define clearly what they want from this new South-South partnership. It certainly cannot be a replica of the traditional North-South relationship and that is for African leaders to decide -not China, Brazil, India or Malaysia” (UNAIDS, 2012b, p. 7). African initiated South-South partnerships for pharmaceutical development, as in the case of Uganda, exhibit the potential benefits to human capabilities via increased access to essential medications. The partnership also demonstrates that the South-South model for pharmaceutical development may aid countries in avoiding the neoliberal policy prescriptions of the TRIPS Agreement, which value individual property rights over the instrumental ability for one to practise his or her human right to health.

Supply chains and market competition

An important aspect of ARV drug procurement and distribution in Uganda is the complex system of supply chains. Two types of supply coordination mechanisms exist within the country. First, there is the public sector supply chain system, to which QCIL releases ARVs. Second, are the private systems, which procure and distribute ARVs for NGOs, private clinics, and public health centers receiving funding from multilateral and bilateral organizations. Both types of supply chains play a vital role in the distribution of pharmaceutical products across the country, and are critical components of access to ARVs. The following figure provides a flow chart for funding, procurement, and distribution of ARVs illustrating the complicated multiplayer system that exists within Uganda.

Figure 4: ARV Supply Chain Flow Chart

Source: Adapted from information retrieved from informants in the field

Legend:

BI: Boehringer Ingelheim- A German pharmaceutical company that supplies medication for the prevention of mother to child transmission of HIV/AIDS

CA: Crown Agents- A third party private procurement agent used by the Global Fund for the procurement of ARVs with funding from the organization

CDC: Centre for Disease Control- An American research institute that administers testing, and treatment for HIV/AIDS patients

CDC Partners: Centre for Disease Control Partner Organizations- Clinics directly partnering with CDC to facilitate the provision of ARVs to patients.

CRS: Catholic Relief Services – An American organization founded by Catholic Bishops to help provide aid to Europeans affected by World War Two, which is currently providing ARV treatment to HIV/AIDS patients through partnership with the Ugandan Catholic Church

GFATM: The Global Fund for AIDS, TB, and Malaria- A multilateral organization, which provides grants to local governments for the treatment and prevention of HIV/AIDS

GoU: Government of Uganda- Government funding allocated to the Ministry of Health for the provision of ARV treatment in government hospital and clinics

JCRC: Joint Clinical Research Centre- A research and treatment centre founded through a grant from the Government of Uganda, now partnering with NGOs, and foreign medical programs

JMS: Joint Medical Store- A private not- for profit organization founded by the Ugandan Catholic Medical Bureau and the Ugandan Protestant Medical Bureau that supplies ARVs to non-governmental organizations

Medical Access: Medical Access Uganda Limited- A third party private drug procurement agent, which originated under the United Nations AIDS Program Drug Access Initiative to negotiate prices for ARVs and provide the drugs to NGOs and the Government for the lowest possible cost

NMS: National Medical Stores- The national system for the importation and distribution of pharmaceutical products and medical supplies for government services and clinics

UNITAID: A multilateral organization that provides funding for second line and pediatric ARV medications through an international air transit tax, and by negotiating drug prices with major Western pharmaceutical companies

USAID: United States Agency for International Development- The United States Government international program for foreign development assistance

PEPFAR: The President's Emergency Plan for AIDS Relief – The United States Government initiative to provide support for treatment and prevention of HIV/AIDS in economically marginalized countries around the world

SCMS: The Supply Chain Management System- A private third party procurement agent operating under USAID to assist with the release of PEPFAR funding for the procurement and distribution of ARVs

The National Medical Stores (NMS), located outside of Kampala in Entebbe acts as a warehouse for all pharmaceutical products and medical supplies that are distributed to government hospitals and clinics. Imported medications typically arrive at the port of Entebbe via boat from the Kenyan side of Lake Victoria, or at the national airport, where the Federal Drug Authority of Uganda (FDA) tests the drugs for quality assurance. The drugs are then transported to NMS where they are sorted, stored, and later distributed to clinics and hospitals in the pre-forecasted required quantities. In the case of ARV drugs produced at QCIL, the Government places quarterly orders for ARVs, which are then produced at the factory to avoid the expiry of drugs that would be manufactured without a predetermined buyer. The ARVs are transported from the factory in Luzira, to NMS after being tested for quality assurance throughout several different production stages and as an end product by the NDA (G. Baguma, personal communication, July, 12, 2011).

Once the drugs are distributed to NMS, the warehouse is responsible for their proper storage and timely distribution to government clinics and hospitals, although Mulago National Hospital in Kampala remains the primary public center for the provision of ARVs, and many patients must travel great distances to receive their medications. At Mulago the necessary amount of ARVs for two months is forecasted by the hospital staff, ordered from NMS, and delivered to the hospital bimonthly. In the event that drugs are not received on time or an inaccurate forecast is made, a buffer stock is to be kept and replenished to avoid stock out shortages (Bugembe, 2009). However, disruptions in the supply chain or miscalculations in the quantity required can lead to stockpile shortages, or the expiry of drugs before they are distributed (Maseruka, 2009).

It is possible that management warehouses, of a similar nature to NMS may mark up drug prices once they are received prior to selling them to the Government, to intensify profits. This is an important consideration when evaluating the end price of the drugs once they reach the buyer. While there is potential that mishandling of funds and intentional mark ups on drugs may occur at NMS or through the sale of the drugs from QCIL to NMS, to date, there are no official reports to back up these types of allegations.

The second type of supply chain system procures stores, manages, and delivers ARVs through privately run operations. Private drug procurement systems operate completely independently from the Government of Uganda and have a significantly more complex procurement process, as the system rewards drug contracts to the company offering the lowest price through reverse bidding. As is the case with government supply chains, the ARV drugs procured by private supply chains for NGOs are intended to be free of charge to all patients.

The majority of patients in Uganda receive their medication predominantly from PEPFAR funding (Global Fund, 2007). These drugs are procured through private supply chain systems, which use various methods to obtain the medicines for the lowest costs possible. First line ARVs are purchased through a system reverse bidding. This type of system is commonly used by donors, and is recommended by the WHO to ensure the lowest possible prices for ARVs (Wilson, Whiteside, & Cohen-Kohler, 2008). Competitive pricing is facilitated as multiple tenders submit drug prices and the company offering the lowest price while still maintaining internationally accredited drug certification is rewarded with the sale. Once the drugs are purchased they are stored in a warehouse until they are distributed to NGOs and clinics in Uganda.

In order to compete in the market, in the case of PEPFAR, the pharmaceutical manufacturers must have already obtained US FDA certification for the products. Therefore, in addition to the procurement restrictions imposed on NGOs by donor country policies, it is also difficult for an emerging pharmaceutical industry from the South to enter the market for ARVs. This is in part due to the privately operated third party procurement systems including Crown Agents, which is used by the Global fund, and the Supply Chain Management System (SCMS), which is used by PEPFAR. These procurement agents select ARVs from only those companies permitted to enter into the bidding market and that can offer the lowest prices. These types of third party procurement systems, most notably the USAID operated Supply Chain Management System (SCMS) purchase and distribute the drugs that are eventually supplied in donor-funded clinics. While Crown Agents procures drugs, which are later transported to NMS and provide accounting, technical expertise, and training for the national drug distribution center, SCMS operates entirely independently from the government system.

SCMS was founded in 2005 under the operating body of USAID (Heavner, 2011). The operations at SCMS primarily focus on forecasting and quantification of the required amount of ARVs for use in PEPFAR funded clinics; storage and distribution of the medications; and quality assurance testing (2011). John Crowley, chief of the Supply Chain Management Division for USAID is critical of the public supply chain system and states that, “before PEPFAR, procurement of public health HIV commodities in targeted countries was a transactional, one-off event, with each purchase treated as a separate activity, with little or no connection to national health strategy and patient needs” (2011). In the public system of drug procurement, poor coordination has led to financial resources

being spent on priority shipping and high freight costs (Heavner, 2011). While these concerns may be valid, SCMS operates independently from the Government, and the coordination system does not serve to improve the quality of government supply chain logistics.

The work done by SCMS has led to millions of dollars in savings on transportation costs for PEPFAR, while government supply chains do not experience any such improvements. SCMS now ships approximately 65% of medications via ship and over land; a change, which saves 85% on shipping costs when compared to shipment by air (Heavner, 2011). SCMS states that since 2005 it has saved PEPFAR \$42 million USD in overall shipping costs and \$17.2 million USD in the year 2010 alone (2011). These savings on shipment methods highlight the large cost of pharmaceutical importation, resulting in more funding available for the procurement of ARVs. By providing an affordable source of accredited ARVs produced within Uganda, supply chain costs could be reduced even further, for both the public and private procurement systems. It is however, important to recognize the need to improve the quality and functioning of the public supply chain system in order to improve government health services.

Second line and pediatric medication distributed in Uganda are procured via the Clinton Health Access Initiative (CHAI). The market for second line and pediatric drugs is significantly smaller than for first line drugs due to treatment volumes. As well, most second line medications were developed after the TRIPS agreement, in 2005, which has prevented the further generation of generic counterparts. It is for these aforementioned reasons that the price of the drugs must be negotiated with major brand name pharmaceutical companies from the West. Since QCIL does not currently produce second

line drug combinations or pediatric drugs price negotiations for these products do not affect the market.

The coordination of the various supply chain procurement mechanisms is described by the Ministry of Health as “a challenge for the health sector resulting in persistent stock out of ARVs and other supplies that ultimately impacts adherence and the overall success of the program” (MoH, 2011, p. 24). The compartmentalization of the supply chains is thus an issue that can lead to organizational problems. NGOs typically receive ARVs from various sources each with a different forecasting and distribution cycle. As well, problems associated with the government procurement system could be minimized with more substantial monitoring and logistical support from multilateral and bilateral donors, as opposed to the promotion of privately run third party procurement agents.

The implications of the TRIPS Agreement

Another important consideration when evaluating the local production of ARVs is to take into account the growing restrictions for the production of generic medications due to the TRIPS Agreement, as outlined in chapter five of this thesis. Since India has now been excluded from the amendments made to the Agreement by the Doha Declaration, the country is restricted from replicating any patented drugs created after 2005. This factor prevents further reverse engineering of any newly introduced drugs and ultimately halts the continuation of new generic drug production. While India is currently excluded from the TRIPS exemptions, the LDCs, as defined by the Agreement, have only until 2016 to begin producing generic pharmaceutical products that are still under patent.

The repercussions of the Agreement will mean that as of 2016 no new industries will have the legal ability to produce generics patented after 2005 without first obtaining the proper licensees. These licenses may be issued voluntarily by a pharmaceutical company or in the form of a compulsory license if the request meets the proper qualifications outlined in the TRIPS Agreement. As previously discussed in this thesis, in practice it is an incredibly difficult task for countries to receive such licenses, which will undoubtedly limit access to the drugs (Dietrich, 2007). It is thus essential for emerging industries to be victorious in their current pharmaceutical development efforts in order for drug prices in the Global South to remain affordable for local governments and NGOs.

In the case of Brazil, the Government's total expenditure on all drugs doubled to \$414 million USD in the years from 2001 to 2005 (Dionisio, Fabbri, & Messeri, 2008). This growth in expenditure is attributed to the introduction of patented medications for ARVs as a result of the TRIPS agreement, despite the fact that Brazil has the industry and infrastructure to produce its own generic versions. Many countries may face a similar situation, where they possess the technical ability to produce ARV drugs and are legally able to issue a compulsory license for ARVs, although they do not for fear of harming international and predominately US trade relations (2008). Furthermore, major pharmaceutical companies, such as Abbott, may issue voluntary price discounts to countries facing health emergencies. However, these price discounts can act as binding contracts to force the country to purchase the drugs for a certain period of time. For example, Brazil made a price discount deal with Abbott for the purchase of ARV drugs (MSF, 2010c). This resulted in a situation where the country was bound to purchase the drugs for \$1000 USD per person per year, when it was eligible to receive the generic

version of the drug through the UNITAID-CHAI partnership for \$550 USD per person per year. (2010c) The situation speaks to the importance developing a domestic pharmaceutical industry and utilizing the capacity to produce the drugs, without facing pressure to instead import the drugs at brand name prices.

The Doha Declaration and the clauses outlined in the TRIPS flexibilities, were generated for the Agreement to provide extensions for countries deemed by the WTO as 'least developed' to establish industries for the creation of generic drugs (Van Dyck, 2007). However, these amendments have hardly been designed to promote the growth of a domestic drug industry in the Global South. The difficulties associated with the development of an infant industry, in the face of global competition are immense, notwithstanding one grown out of a country, which lacks substantial resources and is highly dependent on foreign aid. The TRIPS Agreement has halted the continuation of reverse engineering for the creation of generic products. The health of hundreds of millions living on less than one dollar a day will be directly affected in countries with governments that cannot afford to treat patients with costly Western medicines.

The Universal Declaration of Human Rights states in Article 25 that everyone should have the right to the health and wellbeing of one's self and of one's family, inclusive of medical care (UN, 2012). In Article 30 of the Declaration, it is proposed that, nothing outlined in the declaration should be interpreted to impact or destroy the rights and freedoms presented in the Declaration (2012). Furthermore, access to essential medication is also recognized by international law, as a critical component of right to human health (Committee on Economic, Social, and Cultural Rights, 2000; Commission on Human Rights, 2003). The interpretation of such agreements suggests that this right is

intended to take precedence, and that it should not be constrained by the interests of profit-making industries (Cohen-Kohler, Forman, & Lipkus, 2008). The TRIPS Agreement thereby is in direct violation of various human rights legislations, a matter that must not be overlooked in lieu of the rights regarding intellectual property. What's more, as previously outlined, the Agreement also infringes on the laws of the free market proposed by the WTO, creating unfair trade practices primarily benefiting the North.

Global citizens are entitled to the right to health through internationally recognized legislation. Although, in practice the right to treatment has not been met, thus limiting human capabilities in the South and failing to fulfill the promise of upholding health as a human right on a global scale. By enhancing provision of treatment, the domestic production of ARVs can help ensure that the medical needs of all citizens are met to increase human flourishing.

In spite of the Doha Declaration and the temporary flexibilities in the Agreement, few countries have been able to take advantage of the legal ability to produce generic medications. As the 2016 deadline approaches the Agreement will come into full effect primarily impacting those limited to lives in poverty in the Global South.

Devoid of assistance from India, the creation of the generic pharmaceutical industry in Uganda would not have been made possible; exhibiting the essential role South-South partnerships can have in aiding a country's home grown plans for development. It is through the joint venture, that Uganda is able to supply its own population with lifesaving medications, in spite of the major setbacks. While it may be viewed as a minor step away from the country's reliance on foreign aid for the provision of ARV drugs to its people, it is a significant step nonetheless. The issues involved with

the domestic production of ARVs must be acknowledged, but not overvalued. There is great potential to reduce drug prices while eventually creating a self-sustaining industry, for the delivery of ARVs at locally affordable prices for governments to purchase.

Closing remarks

The findings of this chapter illustrate that many issues are associated with the success of a profitable domestic drug industry for ARVs in Uganda. NGOs operating out of Kampala interviewed for the study did not feel that the production of the QCIL plant had affected their procurement capacities. It was evident that the price of the drugs is a significant factor hindering their distribution in donor funded clinics. It is also clear through the data collected, that many NGOs providing ARVs are restricted from purchasing the medicines produced at QCIL regardless of their price, due to donor country procurement policies. These policies have in effect hindered the immediate cost recovery phase of the operations at QCIL, along with the company's powerlessness to compete in closed markets. QCIL is unable to enter the majority of the market for ARVs in Uganda primarily as it is prevented from selling the drugs to the donor community despite its ability to achieve the appropriate internationally recognized quality assurance standards, from the WHO.

While the cost associated with importing the APIs from India and obtaining official certifications from the WHO and US FDA is expensive, barriers to entry in the market share of ARVs continue. These added costs hinder the profitability of the initiative and its ability to lower drug prices. However, it is pertinent to recognize that these factors

need not necessarily deter the expansion of similar joint ventures. With continued expansion of the industry combined with cost reduction strategies and support from international aid agencies, it is possible for the plant to lower costs and achieve the competitive pricing required to substantially increase access to the medications for those living with HIV/AIDS in Uganda.

The operation acts as an example of a country that used the flexibilities in the TRIPS Agreement to generate a local generic pharmaceutical industry. If Cipla and QCIL's joint venture can reduce the current prices of the ARVs it would help ensure a greater supply of generic drugs at affordable prices within the country. To date, such cases are few and far between, as the flexibilities outlined in the TRIPS Agreement serve to provide a LDC with nothing but the legal ability to produce generic ARVs, where what is needed are the resources, infrastructure, pharmaceutical expertise, and the willingness of the international aid community to open donor markets and begin to purchase the medicines in order to construct a fully functioning generic drug industry.

Chapter 7:

Conclusion and Recommendations

Given that HIV positive patients require continuous lifelong treatment for their disease, the provision of medications cannot be regarded as simply an emergency response to high AIDS rates, but instead must be recognized as a problem that requires a constant and sustainable supply of resources, as various organizations note (PEPFAR, 2012; UNAIDS, 2012b). Increasing permanent access to medication for HIV patients is a necessary element of alleviating human suffering and preventing millions of unwarranted deaths worldwide. This thesis has discussed the requisite component of expanding treatment to those in need, while highlighting the obstacles associated with such an enormous task. In response to the research questions, the findings show that it is possible for the domestic production of ARVs to increase a sustainable supply of the medicines within Uganda. However, several factors influence its ability to do so, including issues with obtaining donor country quality assurance certifications, the ability for the factory to lower its operational costs, and the significance of the factory's South-South partnership with Cipla. This thesis argues that while the joint partnership initiative has not yet led to an increase in access, it has the potential to do so provided that a variety of cost reduction strategies and policy changes are implemented at both the local and the international level.

This thesis examines the history of ARV distribution in Uganda to shed light on the limitations of the government health sector to provide treatment and care to the majority of those in need. Growing instability in the aid industry further emphasizes the

necessity for a reduction in Uganda's donor dependency, which is compulsory for the continuation of its ART programs.

I have also illustrated the development of India's generic drug industry, and the factors that contributed to its evolutionary pricing for ARV medicines. Specifically, Cipla's origins and growth as a company demonstrate the challenges associated with the creation of generic products in the South. Many of these obstacles are a result of insensitive international trade policies, which are neglectful of the negative repercussions to global health. As well, the section served to exemplify the implications of the TRIPS Agreement and the effect it has on increasing access to essential medicines globally.

The key findings of the thesis address the proposed research questions by establishing that access to treatment for those receiving drugs from NGOs and government services has not experienced a noticeable increase, primarily due to issues with cost reduction and donor market barriers. However, the factory's potential to enhance the supply of ARVs available to patients within Uganda on a long-term basis could occur, if it follows through with the continuation of proposed cost reduction strategies. The study outlines the key factors hindering the success of the initiative and highlights that if major donors refrain from procuring ARVs from QCIL the success of the project will be in jeopardy. As well, the findings discuss the importance of government policies to support the domestic drug industry in order to facilitate further price reductions for ARVs. Most significantly, the findings illuminate the significance of the unique South-South partnership and its impact on the past and future success of the domestic production of ARVs in Uganda.

While the study outlines the difficulties associated with achieving competitive pricing for ARVs produced within Uganda, several methods could be utilized to help create price reductions and gain access to the donor funded ARV market, in addition to those previously outlined in Chapter 6. Several higher-level policy implementations could also contribute to the ability for the plant to increase access to the drugs by providing NGOs with the legal ability and the incentive to procure ARVs from QCIL in the future.

Suggestions for the future

The issue of necessary price reductions is addressed with regard to national policy changes. Key players in support of the domestic drug industry in Uganda have mobilized to work towards achieving a strong and cohesive voice to help make more beneficial trading policies possible at the country level. The Ugandan Pharmaceutical Manufacturers' Association (UPMA) is a registered group of pharmaceutical companies in the country that are licensed to produce medications by the National Drug Authority (NDA) in Uganda. The pharmaceutical industry in Uganda is composed of a consortium of actors including domestic manufacturers, drug importers, wholesalers and retailers, and the regulatory aspect of the Government, which includes the NDA and NMS (Medicines Transparency Alliance [MeTA], 2009). Together these sectors, combined with backing from civil society organizations, comprise the Medicines Transparency Alliance Uganda (MeTA) (MeTA, 2009). Participation in MeTA enables local pharmaceutical companies to voice concerns and suggestions to a multi stakeholder council in order to work towards enhancing the successful development of a domestic pharmaceutical industry (2009). The

council aims to ultimately provide home-grown economic strategies to increase access to essential medicines for Ugandans

MeTA outlines several challenges to the growth of local pharmaceutical industries and suggests policy solutions for these issues. It is evident through this research that the production of locally manufactured ARVs in Uganda has undoubtedly been subjected to many of the challenges summarized by MeTA and thus aspects of the proposals for growth and profitability in the local pharmaceutical sector are directly applicable to the case of QCIL.

First, continued support of QCIL is required from the Ugandan Government, to improve its success rate. MeTA highlights the critical role of governments in purchasing domestically produced medications, as local manufactures are often excluded from private not-for profit tender markets (MeTA, 2009). Subsequent to the procurement policies of the particular organization, low pricing is the primary factor for the attainment of medications for NGOs. Local manufactures can have difficulty competing with the prices of products from larger established pharmaceutical companies, which can deter potential buyers. To account for this issue UPMA advocates for price differentials between the drugs available for purchase by international bidders and those produced locally (MeTA, 2009). Given that the Government remains the sole purchaser of the drugs produced at QCIL, imposed price differentials for the ARVs could impact the previous purchasing patterns of NGOs to encourage them to procure from QCIL. Entry into a pre-established market can be difficult for any emerging company that must achieve competitive pricing. However, government trade regulations to protect an infant

industry can aid in the growth of new industrial developments, as in case of the expansion of the generic drug industry in India.

The initial growth of India's pharmaceutical sector, as outlined in chapter two of this thesis, was largely based on the sale of the products to the Indian population. The industry also thrived on the support of the Indian government to enforce laws, which favored the growth of the sector within the nation. MeTA acknowledges the significance of the implementation of the trade regulations in India, which contributed to the profitability of the country's pharmaceutical sector through increasing the competitive advantage of locally, produced products (MeTA, 2009). Economic policies to prevent market entry from foreign companies, in particular, high tariffs on imported goods may be beneficial to local pharmaceutical manufactures, as the cost of imported pharmaceuticals would be heightened. Such policies could essentially provide more incentives for buyers to purchase the locally produced products. However, these types of policies would go against neoliberalism in practice and would not likely be readily accepted by the WTO, reflecting the difficulties associated with the development of new infant industries in the Global South and the existing unfair trading practices benefiting the West.

Given the unique market structure for ARVs in Uganda, and the necessity that the number of patients already on ART not be reduced, import tariffs for ARVs could be detrimental to existing access to ARVs. It is evident that donor funding is not infinite, and that low cost generics have increased access substantially without significant funding escalations. Removing patients from their treatment programs, due to higher prices for imported ARVs would not only be counterproductive in terms of increasing access but

would be also be a step backward in the provision of ARVs for Ugandans. To account for this factor Sub-Saharan African countries implementing policies to protect local pharmaceutical industries, have excluded ARVs, antimalarials and tuberculosis medications from the list of imported products that would be subjected to import taxation, (MeTA, 2009). If QCIL were to carry out its plans to manufacture other drugs less tied to foreign aid, as described in chapter 6, the protectionist trading policies proposed by MeTA could benefit the company by reducing competition and increasing profit margins. Reducing the operational costs of the plant could translate into ARV cost reductions. Methods of lowering the prices of locally produced ARV medications would allow for QCIL to compete with imported generic versions without raising the prices of imported generics. However, if QCIL eventually produces the other non-essential medications, as planned, the company would stand to benefit from import tariffs, which could in turn help decrease operational costs and lower the prices of the ARVs produced.

One method used by India to support local pharmaceutical developments that may be beneficial in aiding QCIL to achieve a larger market share, is the use of subsidies for exported ARVs to other neighboring countries. These subsidies could provide incentives for East African countries to purchase the drugs produced at QCIL and increase the productive capacity of the factory. As in the case of the Indian ARVs, export subsidies exist to artificially lower prices, a factor which Baguma notes as a reason why QCIL has not been able to meet the same prices for its products as those imported from India (Personal Communication, January 27th, 2012).

Furthermore, Guimier, Lee, and Grupper (2004) suggest that subsidies to the costs of the APIs could be beneficial in reducing the prices of end products and increase the

factory's ability to reduce operational costs. This strategy could promote the purchase of the drugs from neighboring countries and ensure that NGOs will be able to procure ARVs from QCIL while continuing to maintain policies of providing treatment to the greatest number of patients.

Such subsidies typically are supported through government resources. However, in the case of Uganda, it is evident that government resources for ARVs remain extremely minimal and the price of subsidizing the drugs could limit the Ministry of Health's procurement capacity. Hence, two other options present themselves. First, foreign donors could instead implement subsidies, as currently notable organizations, including the World Bank, and the Gates Foundation contribute to subsidizing the cost of brand name medicine and vaccines, which are predominantly sold in select markets in the Global South (Sharife, 2011). The CHAI- UNITAID price reduction mechanism also offers similar subsidies for the price of brand name second line and pediatric ARVs, to provide incentives for the manufactures to continue to produce the medicine despite the low market value (UNITAID, 2012). If similar pools for subsidies were invented for domestically produced ARVs, both neighboring regions and NGOs could procure ARVs from QCIL. Costs could be lowered to below those of imported versions to increase procurement capabilities while benefiting the factory, and the Ugandan economy as well.

A second option could be for the Government of Uganda to arrange for the subsidies provided for exported Indian pharmaceuticals, to be applied to the drugs produced at QCIL. Given that Cipla has such huge stakes in the factory it stands to profit a great deal from increased production at QCIL. Since the South-South partnership continues to be a vital aspect of local production of ARVs in Uganda, it is fitting that such

cooperation could also include a form of financial assistance to help overcome some of the challenges associated with the growth of an infant industry. Moreover, the TRIPS Agreement and the TRIPS-plus trade regulations are increasingly limiting India's ability to produce generics. By further supporting trading partnerships, such as that of QCIL, it could help ensure the existence of profits from Indian pharmaceuticals companies. Given that Western companies are guilty of price distortions through their own use of subsidies, and tariffs (Pogge, 2008) price subsidies for the drugs produced at QCIL should not be overlooked as a strategy of cost reduction.

The second key issue in relation to the factory's ability to increase access to ARVs is that the major foreign funding sources must recognize the significance of purchasing the ARVs from QCIL. In the absence of their procurement of ARVs from QCIL, the company will continue to be constrained from the substantial majority of the market for ARVs in Uganda. If this remains the case, the drugs produced will not reach patients regardless of their costs. Quality assurance is a vital part of the distribution of all medications. However, large overarching funding agencies must acknowledge the ability for local manufactures to achieve these standards. While the Global Fund and MSF have the ability to procure from QCIL based on the WHO prequalification of the drugs, they must work towards carrying out potential plans to purchase the ARVs.

The policies currently in place prevent internationally accredited drugs from being procured by PEPFAR funded sources, which is significant, as the organization remains the largest supplier of ARVs in the country (Global Fund, 2007). In order for the organization to meet its proposed goals and objectives as outlined in the preceding chapter, it must actively work to help QCIL to receive US FDA approval for its products.

By restricting access to the market for PEPFAR funded ARVs, despite the fact that QCIL has demonstrated the quality assurance of the drugs produced at the plant, PEPFAR's procurement policies technically violate the WTO rules for free market competition. These policy barriers prevent quality drugs from being procured and impact the ability for local manufacturers to enter a significant portion of the market, reflecting the imposition of inequitable trade limitations.

PEPFAR's past unwillingness to accept WHO accredited generic ARVs produced by Indian companies restricted the entry of the drugs into the PEPFAR supported donor market for over two years, while big US pharmaceutical companies, the very ones who lobbied for the creation of PEPFAR, reaped the financial profits (Dietrich, 2007).

The issue of obtaining US FDA approval for generic drugs has surfaced again with the case of the local production of ARVs in Uganda. In an analysis of PEPFAR's operations, Dietrich (2007) explains the unique combination of factors, which led to the policy changes that facilitated the procurement of generic ARVs. He cites these factors as a strong group of key actors lobbying for the change in policy, foreign products matching those of the US, and a life or death situation for those requiring medications (2007). The situation described certainly mirrors that of QCIL. However, it is also reflective of the warning that despite the organization's past amendments "future humanitarian policies are more likely to resemble President Bush's original plan, which would have quietly pumped billions of dollars into US corporations" (2007, p.275). These imbalanced trade restrictions hinder the success of the industry.

An example of the role civil society can play in changing international policy can be seen in the case of South Africa. When South Africa amended its patent legislation to

begin to produce its own generic ARVs, the move was followed by a lawsuit from a coalition of American pharmaceutical companies with backing from the US Government, which sparked great protest by civil society groups across South Africa and by AIDS advocates worldwide (‘t Hoen, 2003). The US Government, under significant international pressure eventually withdrew their support from the lawsuit and in 2003 the amendments to the South African legislation were passed, allowing the country to begin manufacturing generic ARVs (2003). Political lobbying from civil society, has previously yielded attention to issues pertaining to the sale and procurement of generic products, and has benefited local manufactures of ARVs (Wilson, 2010). Similar activism from civil society in Uganda could also be beneficial for QCIL to achieve the ability to sell the drugs to the donor community. With a collective body of lobbyists for the local manufacturing of generic ARVs, PEPFAR and the US Government could be persuaded to change their existing policies. If this were to be the case, PEPFAR funded organizations in Uganda could gain the ability to procure from QCIL and the operation could substantially augment its ARV market share.

NGO collaborations with the Government

As the AIDS epidemic exploded in the 1990s, foreign organizations stepped in to put forth funding for AIDS rates reduction strategies and treatment plans for the provision of ARVs. While great strides were made in terms of heightening the number of patients being tested and receiving treatment, governments and their ministries of health continue to be severely burdened with the vast number of patients exhausting already minimal resources for health care. The response to the epidemic can no longer be treated as a

temporary emergency situation. It is evident that despite substantial foreign aid contributions since the early days of the epidemic infections will continue, as the number of new patients receiving treatment may not, due to dwindling resources. Thus foreign aid for the provision of treatment for HIV/AIDS patients must be treated as a method of enhancing the country's ability to provide ARVs to its population in need.

Currently the system of ARV provision in Uganda remains compartmentalized as individual organizations fund clinics and care centers through various funding sources. While select NGOs may partner with the Government, most clinics remain primarily independent from government services. In order for foreign aid to produce long-term results, organizations must work towards stronger collaborations with the national medical systems. An important aspect of increasing access to ARVs for those in the Global South, is to focus on not only the provision of affordable medications, but to ensure that fully functioning and adequate health systems are in place in order to distribute treatment and care at the national level. Clinics operating independently from national services inherently create a parallel system of care, as vast amounts of funding flow through private not-for profit clinics, while the government-run hospitals deteriorate. It is crucial for more NGOs to focus on improvements that directly benefit the public health care system, in order to concentrate on the long-term provision of treatment for HIV/AIDS patients and to reduce the Government's dependency on foreign aid.

Apart from pricing, the most critical factor in the success of locally produced ARVs in Uganda is the continued support of the Government, to purchase the drugs, combined with that of NGOs working in conjunction with bilateral and multilateral organizations. It is clear that without admittance to the market for ARVs procured with

foreign aid money developing drug industries, as in the case of QCIL, will not succeed in increasing access to patients in need. It is for this reason that organizations providing funding for the procurement of ARVs must work cohesively with local industries, and the Government, so that the production of ARVs locally can result in augmented access to essential medicines for HIV/AIDS patients. These organizations must strive to enhance the country's ability to develop a self-sustaining drug industry, for the prolonged existence of treatment program, instead of hindering it.

Long-term access to care

Providing a local source of ARVs enhances the country's self-sufficiency for the supply of essential medications. As well, the local production of ARVs has the ability to lower the prices of the drugs, and raise treatment numbers, as domestically producing medications can lead to significant reductions in import costs (Guimier, Lee, & Grupper, 2004). Additionally, the ever-fluctuating exchange rate of the Ugandan shilling provides incentive to purchase locally produced ARVs. By procuring from domestic sources the allocated government resources used to purchase the drugs will not be subjected to poor exchange rates, which could result in a lower amount of procured medications when purchased from abroad (2004).

For countries dealing with high prevalence rates of HIV/AIDS putting the largest number of patients on ARVs possible remains an important step in the treatment and the prevention process. Increasing the number of patients receiving treatment is now even more critical. If taken properly and regularly, ARV drugs are proven to prevent the spread of the disease in conjunction with improving the quality of life for patients. The scale up

of ARV treatment is undeniably important, but also as essential is the assurance of a long term supply of the medications to maintain the progress and past accomplishments in the fight against HIV/AIDS. By depending on external donations to fund national ARV programs, countries put the lives of millions at risk, if the main funding sources are cutback or retracted entirely. Uganda already experienced a withdrawal of funding in previous years and as of November 2011 it was denied an additional \$270 Million USD by the Global Fund due to the country's stance on the rights of homosexual minorities (Mugisa, 2011a). The grant was intended to put one hundred thousand patients on HIV treatment although the plan has since been suspended (2011). In the absence of a constant and sustainable supply of ARVs treatment centers will fail to be able to provide the drugs to patients, and many will be subjected to the development of drug resistances or untimely death.

Outlook on the future

In spite of the factors influencing the success of the FDI initiative for ARVs in Uganda, this research is hopeful that the country's generic pharmaceutical industry has the potential to achieve necessary price reductions. Given the company's cost reductions plans, as outlined in Chapter 6, and combined with the aforementioned proposed policy recommendations the industry could increase access to the medications while creating a self-sustaining industry for ARVs.

Access to ARVs is a multidimensional issue that must be looked at from several levels. In order for medications to reach the hands of patients, proper and adequate health care must be in place, where CD4 count testing can occur, and where trained medical

professionals can distribute the drugs to patients in the proper dosage. Supply chains must be fully functional, organized, and transparent to ensure the drugs arrive to a given site on time, in the correct amount, and for the accurate price. The NGO network in Uganda led to improvements in the availability of ARV drugs, since the onset of the epidemic and created care centers to treat patients. However, despite the billions of dollars that have been released, primarily to independent clinics, government services continue to be plagued with issues of overcrowding, under funding, and substantial difficulties with the distribution of ARV treatment. The gap in treatment only continues to grow wider. These factors notwithstanding, at the highest level the medications required for AIDS patients must first be readily affordable and accessible for the Government and international organizations to purchase.

The TRIPS Agreement significantly hinders the availability of these drugs, and makes it inherently difficult for countries to supply domestically produced essential medications to facilitate more locally economical prices. AIDS is an entirely treatable disease, with medication proven to drastically reduce transmission rates, yet it has affected millions where the medications remain unattainable, due their price. As Aginam (2010) states, “the disproportionate distribution of the mortality and morbidity burdens of AIDS between the poorer and industrialized regions of the world reinforces the “Life vs. Profit” debate” (p. 3). The human right to health is thus disregarded in place of Western pharmaceutical profits, and as a result of the neoliberal ideology behind the TRIPS Agreement.

Uganda, through its partnership with India, generated a bottom up solution to its HIV/AIDS problem, in an attempt to move away from its dependency on foreign aid for

the provision of ARVs. Through its assistance from Cipla, the joint venture enables Uganda as a LDC, to take advantage of the flexibilities in the TRIPS Agreement to manufacture ARV drugs, while benefiting from Cipla's pharmaceutical expertise. The arrangement also allows for Cipla to expand its industry, as it would otherwise be prevented from doing so. The initiative for increased drug access in Uganda is, unfortunately, hampered without support from the very institutions its AIDS program is reliant upon, to purchase the drugs produced at QCIL. Particularly, entry into the market for PEPFAR funded ARVs is crucial, as it remains the largest supplier of ARV drugs in the country. A challenge is presented, as the organization is known to have put the profits of its own country's pharmaceutical companies before the lives of those it seeks to save.

In today's global society, we must look towards development examples that seek to enhance human capabilities on a long term basis and ones that come from within the countries themselves. The commendable work that many organizations are doing to increase access to essential medications for HIV/AIDS patients, must not act as simply a momentary solution to a vast problem. These organizations must work more towards supporting the development efforts of a country, through promoting self-sustaining homegrown projects when given the chance to do so. Foreign aid will not last forever, nor was it ever intended to do so. There is an old Ugandan Proverb that states, "a full stomach does not last overnight", meaning that a single meal does not address the root of the hunger. This proverb can also be reflective of the issue of access to medication for AIDS patients, as temporary treatment plans do not help to resolve the underpinnings of the issue.

Bibliography:

- Abbott, F. (2002). The TRIPS Agreement, Access to Medicines, and the WTO Doha Ministerial Conference. *Journal of World Intellectual Property*, 5.
- Agbonifo, P. (1983). The State of Health as a Reflection of the Level of Development of a Nation, *Social Science and Medicine*, 17(4), 2003-2006.
- African Union (2007). *Pharmaceutical Manufacturing Plan for Africa*. Third Session of the African Union Conference of Ministers of Health. Johannesburg; 9-13 April, 2007. Retrieved March 24, 2012 from http://www.africa-union.org/root/UA/Conferences/2007/avril/SA/9-13%20avr/doc/en/PHARMACEUTICAL_MIN_DRAFT.pdf
- (2008). Progress Report on the Pharmaceutical Manufacturing Plan for Africa. *Special Session of the African Union Conference of Ministers of Health*. Geneva: African Union
- Aginam, O. (2010). Global Health Governance, Intellectual Property and Access to Essential Medicines: Opportunities and Impediments for South-South Cooperation. *Global Health Governance*, 4(11).
- Agrawal, P. & Saibaba, P. (2001). TRIPS and India's Pharmaceutical Industry, *Economic and Political Weekly*, 36(39), 3787-3790.
- AIDS Span (2011). Global Fund Issues Call for Applications Under the Transitional Funding Mechanism, *AIDS Span News*. Retrieved December 12, 2011, from <http://www.aidspace.org/index.php?issue=171&article=1>
- Allen, T. & Heald, S. (2004). HIV/AIDS Policy in Africa: What Has Worked in Uganda and What has Failed in Botswana? *Journal of International Development*, 16(8), 1141-1154.
- Ananthakrishnan, G. (2012, March 14). A Historic Move to Make Drugs Affordable. *The Hindu*. Retrieved on March 17, 2012 from <http://www.thehindu.com/todays-paper/tp-opinion/article2992620.ece>
- Anderson, J. (1989). Uganda's Pioneering Support Organization. *AIDS Watch*, 6(8).
- Anderson, T. (2010, May). Tide Turns for Drug Manufacturing in Africa. *The Lancet*, 375(8), 1597-1598.
- Angell, M. (2004). Excess in the Pharmaceutical Industry. *Canadian Medical Association Journal*, 171(12), 1451-1453.

- AVERT (2012a). *History of HIV/AIDS in Africa*. Retrieved February 12, 2012, from <http://www.avert.org/history-aids-africa.htm>
- (2012b). *HIV/AIDS in Uganda*. Retrieved January 10, 2012, from <http://www.avert.org/aids-uganda.htm>
- Bassudde, E. (2010, December 2). Where Have all the ARVs Gone? World AIDS Day Supplement. *New Vision*. Retrieved December 16, 2011, from <http://www.newvision.co.ug/news/149256-where-have-all-the-arvs-gone-world-aids-day-supplement.html>
- Bajaj, V. & Pollock, A. (2012, March 6). India's Supreme Court to Hear Dispute on Patents. *The New York Times*. Retrieved on March 6, 2012, from <http://www.nytimes.com/2012/03/07/business/global/indias-supreme-court-to-hear-long-simmering-dispute-on-drug-patents.html?ref=asia>
- Berg, A. (1973). *The Nutrition Factor*. Brookings Institute: Washington, DC.
- Berg, B. (2009). *Qualitative Research Methods for the Social Sciences* (7th ed.). Toronto: Allyn & Bacon.
- Bhagwati, J. & Desai, P. (1970). *India: Planning and Industrialization*. New York: Oxford University Press.
- Biernacki, P. & Waldorf, D. (1981). Snowball Sampling: Problems and Techniques of Chain Referral Sampling. *Sociological Methods and Research*, 10(2), 141-163.
- Boseley, S. (2010, March 12). Protect the Drug Giants' Patents and Harm the Health of the Poor? *The Guardian*. Retrieved on December 14, 2011, from <http://www.guardian.co.uk/society/sarah-boseley-global-health/2010/mar/12/hiv-infection-pharmaceuticals-industry?INTCMP=SRCH>
- Bruton, H. (1989). Import Substitution. In H. Chenery & T. Srinivasan (Eds.). *Handbook of Development Economics* (pp. 1601-1644). (2nd ed.). Oxford: Elsevier Science Publishers.
- Bugembe, A. (2009, January 10). Ministry of Health Stocks Enough AIDS Drugs. *Saturday Vision*. Retrieved July 24, 2011, from <http://www.newvision.co.ug/D/8/220/667553>
- Businge, C. (2012, January 27). Rwanda to Buy Uganda's Drugs. *New Vision*. Retrieved January 27, 2012, from <http://www.newvision.co.ug/news/628633-rwanda-to-buy-uganda-s-drugs.html>
- Catholic Bishops of Uganda (1989). *The AIDS epidemic –Message of the Catholic*

Bishops of Uganda. Kampala: Marianum Press.

CapitalWorks (2011). *Alternative Assets and Investments*. Retrieved November 25, 2011, from http://www.capitalworksip.com/index_web.html

Challu, P. (1991). The Consequences of Pharmaceutical Product Patenting, *World Competition*, 15, 65-126.

Cipla (2011). *Cipla Corporate Profile*. Retrieved November 25, 2011, from <http://www.cipla.com/corporateprofile/history.htm>

Central Intelligence Agency (2012). *The World Fact Book: Uganda*. Retrieved on March 28, 2011, from <https://www.cia.gov/library/publications/the-world-factbook/geos/ug.html>

Cohen, G. (2004). *Technology Transfer: Strategic Management in Developing Countries*. London: Sage.

Cohen, J. (2011). Breakthrough of the Year: HIV Treatment as Prevention. *Science*. 334(6063), 1628.

Cohen, J., Gyansa-Lutterodt, M., Tropey, K., Esmail, L., and Kurokawa, G. (2005). TRIPS, The Doha Declaration and Increasing Access to Medicines: Policy Options for Ghana. *Globalization and Health*, 1(17), 1-10.

Cohen, J. & Lybecker, K. (2005). AIDS Policy and Pharmaceutical Patents: Brazil's Strategy to Safeguard Public Health. *The World Economy*, 28(20), 211- 230.

Cohen-Kohler, J., Forman, L., & Lipkus, N. (2008). Addressing Legal and Political Barriers to Global Pharmaceutical Access: Options for Remediating the Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the Imposition of TRIPS-plus Standards. *Health Economics Policy and Law*, 3, 229-256.

Commission on Human Rights (2003). *Commission on Human Rights Resolution 2003/29, Access to Medications in the Context of Pandemics Such as HIV/AIDS, Tuberculosis, and Malaria*. Geneva: Office of the United Nations High Commissioner for Human Rights.

Commission on Intellectual Property Rights (2002). *CIPR Final Report: Integrating Intellectual Property Rights and Development Policy*. London: CIPR. Retrieved March 24, 2012, from http://www.iprcommission.org/graphic/documents/final_report.htm

Committee on Economic, Social, and Cultural Rights (2000). *The Right to the Highest*

Attainable Standard of Health. General Comment 14. (Cat, E/C.12/200/4). Geneva: United Nations.

Condoms Not Answer, Says African (1987, July 21). *Sidney Morning Herald*.

Corbin, J. & Strauss, A. (2008). *Basics of Qualitative Research* (3rd ed.). Thousand Oaks: Sage Publications Inc.

Correa, C. (2002). Public Health and Intellectual Property Rights. *Global Social Policy*. 2(3), 261-278.

Cullet, P. (2003). Patents and Medicines: The Relationship Between TRIPS and the Human Right to Health, *International Affairs*, 79(1), 139-160.

Danzon, P. (1997). *Pharmaceutical Price Regulation: National Policies Versus Global Interests*. Washington, DC: American Enterprise Institute Press.

David, P. (1992). *Knowledge, Property, and the System Dynamics of Technological Change*. Paper presented to World Bank Annual Conference on Development Economics, Washington DC, 30 April -1 May.

Dietrich, J. (2007) The Politics of PEPFAR: The President's Emergency Plan for AIDS Relief. *Ethics and International Affairs*, 21(3), 277-292.

Dionisio, D., Fabbri, C., & Messeri, D. (2008). HIV Drug Policies and South Markets: Settling Controversy. *Therapy*. 5(5), 707-717.

Easterly, W. (2006). *The White Man's Burden*. New York: The Penguin Press.

Economist, The (1997, August 16). *India and Pakistan at 50: Happy Anniversary?* Retrieved November 15, 2011, from <http://www.economist.com/node/153844>

(1999, September 23). *White Man's Shame*. Retrieved April 19, 2012, from <http://www.economist.com/node/325062>

(2011, October 22). *Adventures in Capitalism*. Retrieved December 12, 2011, from <http://www.economist.com/node/21532448>

Escobar-Andrae, B. (2011). North-South Agreements on Trade and Intellectual Property beyond TRIPS: An Analysis of US Bilateral Trade Agreements in Comparative Perspective. *Journal of Intellectual Property Rights*. 16, 477-499.

Farmer, P. (2005). *Pathologies of Power: Health, Human Rights, and the War on the Poor*. Berkley: University of California Press.

Fink, C. (2000). Policy Research Working Paper No. 2352. How Stronger Patent

Protection in India Might Affect the Behavior of Transactional Pharmaceutical Industries, *The World Bank Development Research Group*.

Fisher, M. (2005). Global AIDS Treatment Drive Takes Off. *Africa Renewal*, 19(1).

Floyd, K., Gilks, C. (1998). Costing and Financing Aspects of Providing Antiretroviral Therapy. In E Van Praag, S. Fernyak, & A. Kat (Eds.), *The Implications of Antiretroviral Treatments* (pp. 63-78). Geneva: World Health Organization.

Freidman, M. (1962). *Capitalism and Freedom*. Chicago: The University of Chicago Press.

Gilson, L. & Raphaely, N. (2008). The Terrain of Health Policy Analysis in Low and Middle Income Countries: A Review of Published Literature 1994–2007. *Health Policy and Planning*, 23(5), 294-307.

Global Fund (2007). *Uganda GFATM Round 7 Country Proposal*. Geneva: Global Fund.

(2007, July). *Uganda Proposal Forms Round 7*. Geneva: Global Fund

Government of Brazil (1996). *Brazilian Patent Law Industrial Property Law*, 9(27).

Government of Uganda (2010) *UNGAS Country Progress Report Uganda 2008-2009*. Geneva: UNAIDS.

Govindaraj, R., Reich, M., & Cohen, J. (2000). World Bank Pharmaceuticals Discussion Paper. *Human Development Network*. Washington, DC: World Bank. Retrieved January 13, 2012, from <http://siteresources.worldbank.org/HEALTHNUTRITIONANDPOPULATION/Resources/281627-1095698140167/Govindaraj-WBPharmaceutical-whole.pdf>

Guimier, J., Lee, E., & Grupper, M. (2004). *Processes and Issues for Improving Access to Medicines: The Evidence Base for Domestic Production and Greater Access to Medicines*. Department for International Development's (DFID) Health Systems Resource Centre (HSRC). London: HSRC.

Haakonsson, S. & Richey, L. (2007). TRIPS and Public Health: The Doha Declaration and Africa. *Development Policy Review*, 25(1), 71-90.

Harvey, D. (2005). *A Brief History of Neoliberalism*. Oxford: Oxford University Press.

Heavner, J. (2011, May). Supply Chain Heroes. *USAID Frontlines*. Retrieved January 17, 2011, from http://www.usaid.gov/press/frontlines/fl_apr11/FL_apr11_GLOBAL.html

- Hellerstein, R. (2004). Do Pharmaceutical Firms Price Discriminate Across Rich and Poor Countries? Evidence From Antiretroviral Drug Prices. *Economist International Research Federal Reserve Bank of New York*. Retrieved September 12, 2011, from <http://www.ny.frb.org/research/economists/hellerstein/JDE2.pdf>
- Heywood, M. (2002). Drug Access, Patents and Global Health: “Chaffed and Waxed Sufficient”, *Third World Quarterly*, 23(2), 217-231.
- Heilprin, J. (2011, November, 24). Global Fund Halts New Programs. *Associated Press*, Retrieved December 13, 2011, from <http://www.google.com/hostednews/ap/article/ALeqM5hNuUYuJ7l5mBDaBt6ZPQAUIK8G7g?docId=407ec30744cf47319a81c36572d72ce6>
- Hunter, S. (2003). *Black Death: AIDS in Africa*. New York: Palgrave MacMillan.
- Hyman, J. (2005, January 1). Cipla’s Yusuf Hamied Speaks Out. *AIDS Link*. Global Health Council Publications. Retrieved November 27, 2011, from <http://www.globalhealth.org/publications/article.php3?id=1259>
- International Labour Organization (2000, June 8). *AIDS a Major Threat to the World of Work*. ILO Retrieved November 25, 2011, from <http://www.ilo.org/public/english/protetion/trav/aids/index.htm>
- James, J. (2004, December 31). Indian Changes Patent law to Meet WTO Treaty, Making New Medicines Less Available to Most Citizens, Other Countries. *AIDS Treatment News*, Retrieved November 20, 2011, from <http://www.aidsnews.org/2004/12/india-patent.html>
- Joseph, S. (2003). Pharmaceutical Corporations and Access to Drugs: The “Fourth Wave” of Corporate Human Rights Scrutiny. *Human Rights Quarterly*, 25(2), 425-452.
- Kagolo, F. (2011, May 7). Uganda: Museveni Warns Health Officials on ARVs. *New Vision*. Retrieved January 20, 2012, from <http://allafrica.com/stories/201105090070.html>
- Kapczynski, A. (2009). Harmonization and Its Discontents: A Case Study of the TRIPS Implementation in India’s Pharmaceutical Sector, *California Law Review*, 97(1571), 1-66.
- Kaplan, W. & Laing, R. (2005). *Local Production of Pharmaceuticals: Industrial Policy and Access to Medicines. An Overview of Key Concepts, Issues and Opportunities for Future Research* (HNP Discussion Papers). Washington DC: World Bank.

- Kinsman, J. (2010). *AIDS Policy in Uganda: Evidence, Ideology and the Making of an African Success Story*. New York: Palgrave Macmillan.
- Kerouedan, D. (1997). Access to Antiviral Therapies in African Countries. *The Lancet*, 349, 1704.
- Kohli, A. (2007). *State and Redistributive Development in India*. Geneva: United Nations Research Institute for Social Development.
- Konopnicki, D. & Clumeck, N. (2004). A Perspective of the History of HAART. In E. De Clercq & A. Vandamme (Eds.), *Combination Therapy of AIDS*. (pp.25-40). Geneva: Birkinhauser Verlag.
- Koshy, S. (1995). The Effect of TRIPS on Indian Patent Law: A Pharmaceutical Industry Perspective. *Boston University Journal of Science and Technology Law*, 1(123).
- Lewis, S. (2006). *Race Against Time*. Toronto: House of Anansi Press.
- Love, J. & Hubbard, T. (2004). Make Drugs Affordable: Replace TRIPS-Plus by R&D-Plus. *Bridges*, 6, 3-4.
- Mafabi, N. (2011, July, 8). Opposition Responds to Museveni's State of the Nation Address. *The Daily Monitor*. Retrieved on July 8, 2011 from <http://mobile.monitor.co.ug/News/-/691252/1195204/-/format/xhtml/-/65se29z/-/index.html>
- Maseruka, J. (2009, January, 30). Medical Stories Get Strict on Drugs. *The New Vision*, Retrieved on January 6, 2012, from <http://www.newvision.co.ug/PA/8/13/669723>
- Maseruka, J. & Asimwe, B. (2011, November 4). Rising Number of New HIV Cases Worries Experts. *New Vision*, Retrieved December 12, 2011, from <http://www.newvision.co.ug/news/18896-rising-numbers-of-new-hiv-cases-worry-experts.html>
- Maxwell, J. (2005). *Qualitative Research Design: An Interactive Approach*. Thousand Oaks: Sage Publications Limited.
- McCabe, A. (2007). Rhetorics of Power and Development: Intellectual Property Rights and the Pharmaceutical Industry in Brazil. *Prospectives on Global Development and Technology*, 6(4), 585-610.
- McNeil, D. (2000, December 1). Selling Cheap 'Generic' Drugs, India's Copycats Irk Industry. *The New York Times*. Retrieved November 25, 2011, from <http://www.nytimes.com/2000/12/01/world/selling-cheap-generic-drugs-india-s-copycats-irk-industry.html?pagewanted=all&src=pm>

Médecins Sans Frontières (MSF). (2007). Indian Court Rulings in Novartis Case Protects India as the “Pharmacy of the Developing World.” *MSF Press Release*.

Retrieved November 16, from

<http://www.msfaccess.org/about-us/media-room/press-releases/indian-court-ruling-novartis-case-protects-india-pharmacy>

(2010a, March, 27). HIV/AIDS Treatment Gap Widens in Africa. *MSF News Bulletin*. Retrieved December 14, 2011, from http://www.msf.org.uk/donor_retreat_20100525.news

(2010b, May). *No Time to Quit: HIV/AIDS Treatment Gap Widening in Africa*. HIV Report. Brussels: Médecins Sans Frontières.

(2010c, July). *Untangling the Web of Antiretroviral Price Reductions*. (11th ed.). Campaign for Access to Essential Medicines. Geneva: Médecins Sans Frontières.

(2011, July). *Untangling the Web of Antiretroviral Price Reductions*. (14th ed.). Campaign for Access to Essential Medicines. Geneva: Médecins Sans Frontières.

Medicines Transparency Alliance (MeTA) (2009, November). The Role of Local Manufacturers in Improving Access to Essential Medicines. *Africa Health, November 2009*, (40-42). Retrieved July 16, 2011, from http://www.medicinestransparency.org/fileadmin/uploads/Documents/MeTA-Uganda_AfricaHealth.pdf

Mercer, C. (2006). Working with Partners: NGOs and CBOs. In V. Desai & R. Potter (Eds.), *Doing Development Research*. (pp. 94-104). Thousand Oaks: Sage Publications.

Mikkelsen, B. (2005). *Methods for Development Work and Research: A New Guide for Practitioners* (2nd ed.). Thousand Oaks: Sage Publications.

Ministry of Health (MoH) (2003a, May). *Logistics and Procurement Decisions and Issues for Consideration for Initiating and Expanding Access to ARV Drugs*. Retrieved December 15, 2011, from http://www.who.int/hiv/amds/countries/uga_LogisticsProcurementDecisions.pdf

(2003b, June). *Antiretroviral Treatment Policy for Uganda*. Kampala: Government of Uganda.

(2009). *National Antiretroviral Treatment Guidelines for Adults, Adolescents, and Children*. E.T. Katabira, M.R. Kamya, I. Kalyesubula, A. Namale (eds.) 3rd ed. June, 2009. Government of Uganda.

- (2010). *Status of Antiretroviral Therapy Service Delivery in Uganda*, Quarterly Report April –June 2010. Kampala: Government of Uganda.
- (2011a, June). *Health Sector HIV/AIDS Strategic Plan 2010/11-2014/15*. Retrieved December 2, 2011, from http://www.health.go.ug/docs/HSSP_III_2010.pdf
- (2011b). *Annual Health Sector Performance Report, Financial Year 2009/2010*. Kampala: Government of Uganda.
- Monk, H. (2011) *Human Development and Economic Activity: Government Expenditure and Health in Cuba and Kerala*. Lambert Academic Publishing.
- Mooney, P. (1996). The Parts of Life: Agricultural Biodiversity, Indigenous Knowledge, and the Role of the Thirds System. *Development Dialogue*.
- Morel, C. *et al.* (2005). Health Innovations in Developing Countries to Address Diseases of the Poor. *Innovation Strategy of Today*, 1(1), 1-15.
- Moyo, D. (2009) *Dead Aid: Why Aid Is Not Working and How There is Another Way for Africa*. New York: Farrar, Straus, and Giroux.
- Mugisa, A. (2011a, November 15). Global Fund Withholds Shs 700b for ARV Treatment Over Gay Rights. *New Vision*. Retrieved January 29, 2012, from <http://www.newvision.co.ug/news/30010-Global-Fund-withholds-shs700b-for-ARV-treatment-over-gay-rig---.html>
- (2011b, August 18) Eritrea to Buy ARVs from Uganda. *New Vision*. Retrieved January 29, 2012 from <http://www.newvision.co.ug/PA/8/13/762990>
- Myers, S. B. (2008). A Healthy Solution for Patents: How India's Legal Victory Against a Pharmaceutical Giant Reconciles Human Rights with Intellectual Property Rights. *Vanderbilt Journal of Entertainment and Technology Law*, 10(763), 1-27.
- Myrdal, G. (1968). *Asian Drama: An Inquiry into the Poverty of Nations*. New York: Pantheon.
- National Academy of Sciences (2007). *PEPFAR Implementation: Progress and Promise*. Washington: National Academies Press.
- National Institutes of Health (2011, 12 May). *Treating HIV-Infected People with*

Antiretrovirals Significantly Reduces Transmission to Partners. [Press Release]. US Department of Health and Human Services. Retrieved December 14, 2011, from <http://www.nih.gov/news/health/may2011/niid-12.htm>

Nelson, R.; Shultz, T.; & Slighton, R. (1971). *Structural Change in a Developing Economy*. Princeton: Princeton University Press.

Nozick, R. (1974). *Anarchy, State, and Utopia*. New York: Basic Books.

Nussbaum, M. (1997). Capabilities and Human Rights. *Fordham Law Review*. 66(2), 273-300.

Okeru, A., Serutoke, J., Madraa, E. & Namagala, E. (2003, May). *Scaling Up Antiretroviral Therapy: Ugandan Experience Case Study*. WHO Perspectives and Practice in Antiretroviral Treatment. Geneva: World Health Organization.

O'Manique, C. (2004). *Neoliberalism and AIDS Crisis in Sub-Saharan Africa*. New York: Palgrave Macmillan.

Oxfam (2002). *Access to Antiretroviral Therapy in Uganda*. Kampala: Oxfam June 2002.

Patton, M. (2002). *Qualitative Research and Evaluation Methods*. (3rd ed.). Thousand Oaks: Sage Publications.

Pécoul, B. (2004). New Drugs for Neglected Diseases: From Pipeline to Patients. *PLoS Medicine*, 1, e6.

President's Emergency Plan for AIDS Relief (PEPFAR) (2005). *Implementing the ABC Approach*. Retrieved March 12, 2010 from <http://www.pepfar.gov/guidance/75852.htm>.

(2012). The US President's Emergency Plan for AIDS Relief: Five-Year Strategy. PEPFAR. Retrieved January 16, 2012, from <http://www.pepfar.gov/strategy/document/133251.htm>

Pharmaceutical Technology (2011). *Quality Chemical Industries Uganda*. Retrieved November 25, 2011 from <http://www.pharmaceutical-technology.com/projects/qualitychem/>

Pinheiro, E., Antunes, C., & Fortunak, J. (2008). A Survey of the Syntheses of Active Pharmaceutical Ingredients for Antiretroviral Drug Combinations Critical to Access in Emerging Nations. *Antiviral Research*, 79(3), 143–165.

Private Equity Africa (PEA) (2011, July 3). *TLG Completes New QCIL Funding Round*. Retrieved November 25, 2011 from <http://www.privateequityafrica.com/deals/tlg-completes-new-qcil-funding-round/>

- Pogge, T. (2008). *World Poverty and Human Rights*. Cambridge: Polity Press.
- Poku, N. (2005). *How the Poor are Dying*. Cambridge: Polity Press.
- Putzel, J. (2004). The Politics of Action on AIDS: A Case Study of Uganda. *Public Administration and Development*, 24(1), 19-30.
- Republic of Uganda (RoU) (2000). *The National Strategic Framework for HIV/AIDS Activities in Uganda: 2000/1-2005/6*. Kampala: Government of Uganda.
- (2011). *Annual Health Sector performance Report, Financial Year 2009/2010*. Kampala: Government of Uganda.
- Rodrik, D. & Subramanian, A., (2004). From 'Hindu Growth' to Productivity Surge: The Mystery of the Indian Growth Transition. *International Monetary Fund Working Paper*. Retrieved October 27, 2011 from <http://www.imf.org/external/pubs/ft/wp/2004/wp0477.pdf>
- Rubin, J. & Rubin, S. (1997). *Qualitative Interviewing: The Art of Hearing Data* (2nd ed.). Thousand Oaks: Sage.
- Sharife, K. (2011, June 29). The Great Billion Dollar Drug Scam. *Aljazeera*. Retrieved on March 5, 2011 from <http://www.aljazeera.com/indepth/opinion/2011/06/20116297573191484.html>
- Sachs, J. (2001). *Microeconomics and Health: Investing in Health for Economic Development*. Report of the Commission on Macroeconomics and Health. Geneva: WHO.
- Sachs, J. (2005). *The End of Poverty*. London: Allen Lane.
- (2011, November 25). Washington Leaves Millions to Die. *The Huffington Post*. Retrieved November 25, 2011 from http://www.huffingtonpost.com/jeffrey-sachs/washington-leaves-million_b_1112746.html?ref=fb&src=sp&comm_ref=false
- Sen, A. (1999). *Development As Freedom*. New York: Anchor Books.
- Seeratan, N. (2001). The Negative Impact of Intellectual Property Patent Rights on Developing Countries: An Examination of the Indian Pharmaceutical Industry. *St Mary's Law Review on Minority Issues*, 3(339), 1-60.
- Ssenkibirwa, A. (2011, December 2). Donor Funding Cuts to Affect 300,000 on ARVs,

Government Says. *The Daily Monitor*. Retrieved December 14, 2011, from <http://www.monitor.co.ug/News/National/-/688334/1282818/-/bg8khyz/-/index.html>

Sserwanga, M. (2008, May, 18). Widening Access to HIV/AIDS Drugs in Uganda. *DFID Newsroom*. Retrieved July 12, 2011 from <http://webarchive.nationalarchives.gov.uk/+http://www.dfid.gov.uk/news/files/meta-uganda.asp>

Stewart, F. (1987). Money and South-South Cooperation. *Third World Quarterly*, 9,(4), 1184-1205.

Stiglitz, J. (2006). Scrooge and Intellectual Property Rights. *British Medical Journal*. 333 (23-30 December 2006), 1279,1280.

't Hoen, E. (2002). TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond. *Chicago Journal of International Law*. 3(1), 27-46.

(2006). Report on the Commission on Intellectual Property Rights, Innovation and Public Health: A Call to Governments. *Bulletin of the World Health Organization*, 84(5), 421-423.

Thomas, C. (2002). Trade Policy and the Politics of Access to Drugs. *Third World Quarterly*, 23(2), 251-264.

TLG Capital (2011). *Homepage*. Retrieved November 25, 2011 <http://www.tlgcapital.com/home/>

Tomar, D. (1999). A Look into the WTO Pharmaceutical Patent Dispute Between the United States and India. *Wisconsin International Law Journal*, 17(579), 1-23.

Trouiller, P., Oliaro, P., Torreele, E., Orbinski, J., Laing, R., & Ford, N. (2002). Drug Development for Neglected Diseases: A Deficient Market and a Public Health Policy Failure. *Lancet*, 359, 2188-2194.

Uganda AIDS Commission (UAC) (1992). *Ugandan AIDS Commission Statute*. Kampala: Uganda AIDS Commission.

Uganda Law Reform Commission (2004). *A Study Report on Industrial Property Law*. Law Com. Pub. (12) of 2004. Kampala: Ugandan Law Reform Commission.

UNITAID (2012). *Market Approaches*. Retrieved January 20, 2012 from: <http://www.unitaid.eu/>

- United Nations (2012). *United Nations Universal Declaration of Human Rights*. UN. Retrieved January 20, 2012, from <http://www.un.org/en/documents/udhr/index.shtml>
- (2002). *Abuja Declaration on HIV/AIDS, Tuberculosis, and Other Related Infectious Diseases*. Abuja: United Nations.
- United Nations Programme on HIV/AIDS (UNAIDS) (2002, July 12). *Africa Faces Dual Tragedy as Famine and AIDS Strike in Tandem*. News Dispatch. Rome: UNAIDS.
- (2010) Sub-Saharan Africa Factsheet. *UNAIDS Global Report*. Retrieved on March 30, 2012 from http://www.unaids.org/documents/20101123_FS_SSA_em_en.pdf
- (2012a). *Uganda Country Profile: Treatment and Care*. Retrieved on March 1, 2012 from <http://www.unaids.org/en/regionscountries/countries/uganda/>
- (2012b). AIDS Dependency Crisis: Sourcing African Solutions. *UNAIDS Issues Brief*. Geneva: UNAIDS.
- (2012c). New Initiative Launched to Deliver Better, Cheaper Medicines to Africa. *UNAIDS Featured Stories 2012 April 2, 2012*. Retrieved on April 2, 2012 from <http://www.unaids.org/en/resources/presscentre/featurestories/2012/april/20120402eacregulatorymedicines/>
- United Nations Development Program (UNDP) (1999). *Human Development Report*. New York: Oxford University Press.
- United Nations Industrial Development Organization (UNIDO) (2010). *Pharmaceutical Sector Profile: Uganda*. Vienna: United Nations Industrial Development Organization.
- Uvin, P. (2004). *Human Rights and Development*. Bloomfield: Kumarian Press.
- Van Dyck, P. (2007). Importing Western Style, Exporting Tragedy: Changes in Indian Patent Law and Their Impact on AIDS Treatment in Africa. *Northwestern Journal of Technology and International Property*, 6(138), 1-15.
- Vargas, J.; Fears, D. (2009, March 15). At Least 3% of D.C. Residents Have HIV or AIDS, City Study Finds; Rate Up 22% from 2006. *The Washington Post*. Retrieved April 16, 2012, from <http://www.washingtonpost.com/wp-dyn/content/article/2009/03/14/AR2009031402176.html?sid=ST2009031402211>
- Vermeulen, N. (2010, May 14). Uganda's Luzira Drug Factory: Quality Generic ARVS

Versus Patents and Their Promoters. *Consultancy Africa Intelligence*.

Retrieved January 29, 2012, from

http://www.consultancyafrica.com/index.php?option=com_content&view=article&id=405:ugandas-luziria-drug-factory-quality-generic-arvs-versus-patents-and-their-promoters&catid=61:hiv-aids-discussion-papers&Itemid=268

Vernan, J. (2004). Examining the Link Between Price Regulation, Reimportation, and Pharmaceutical R&D Investment. *Health Economics*, 14(1), 1-16.

Whyte, S. Whyte, A. Meinert, L., & Kyaddondo, B. (2004). Treating AIDS: Dilemmas of unequal access in Uganda. *Journal of Social Aspects of HIV/AIDS Research Alliance*, 1(1), 14-26.

Willis, K. (2005). *Theories and Practices of Development*. London: Routledge.

(2006). Interviewing. In V. Desai & R. Potter (Eds.), *Doing Development Research*. Thousand Oaks: Sage Publications.

Wilson, K. (2009). *A Manufactured Solution? The Transfer of Technology to Developing Countries for the Local Production of Affordable Antiretrovirals: Case Studies From Tanzania and South Africa*. Doctoral dissertation, University of Toronto.

Wilson, K., Whiteside, A., Cohen-Kohler, J.C. (2008). The 'Price is Right'? Promoting Local Production for ARVs in Sub-Saharan Africa. *Eurohealth*, 14(2), 29-32.

Wolf, M. (2005). *Why Globalization Works*. New Haven: Yale University Press.

World Health Organization (WHO) (1977). Smallpox Surveillance. *Weekly Epidemiological Record*, 52(49), 398-391.

(1999). *Operational Principles for Good Pharmaceutical Procurement. Essential Drugs and Medicines Policy*. Geneva: WHO, Interagency Pharmaceutical Coordination Group.

(2001). Globalization, TRIPS and Access to Pharmaceuticals. *WHO Policy Perspectives on Medicine*, Retrieved on January 19, 2012 from <http://apps.who.int/medicinedocs/pdf/s2240e/s2240e.pdf>

(2008). Uganda Edges Closer to AIDS Treatment for All. *Bulletin of the World Health Organization*, 86(6), 417- 496. Retrieved on December 6, 2011, from <http://www.who.int/bulletin/volumes/86/6/08-020608/en/index.html>

(2008, June). Uganda Edges Closer to AIDS Treatment for All. *Bulletin of the World Health Organization*, 86(6), 432-435.

(2010a). *Essential Medicines*. World Health Organization. Retrieved November 12, 2011 from http://www.who.int/medicines/services/essmedicines_def/en/index.html

(2010, July). *New Progress and Guidance on HIV Treatment*. World Health Organization. Retrieved December 13, 2011, from <http://www.who.int/hiv/pub/arv/ARTfactsheet/en/index.html>

(2010b). *Transaction Prices for Antiretroviral Medicines and HIV Diagnostics From 2008 to March 2010*. World Health Organization. Retrieved October 25, 2011 from http://www.who.int/hiv/pub/amds/gprm_report_may10/en/index.html

(2011). Uganda Reverses the Tied of HIV/AIDS. *Health A Key to Prosperity*. Retrieved November 12, 2011, from <http://www.who.int/inf-new/aids2.htm>

World Health Organization/ United Nations Programme of HIV/AIDS (WHO/UNAIDS) (2011). Groundbreaking Trial Results Confirm HIV Treatment Prevents Transmission of HIV. *WHO UNAIDS Joint Press Release*. Retrieved November 4, 2011, from http://www.who.int/hiv/mediacentre/trial_results/en/index.html

World Trade Organization (WTO) (2011a). *Intellectual Property: Protection and Enforcement*. Retrieved November 27, 2011, from http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm

(2011b). *What are "Intellectual Property Rights"? Frequently Asked Questions About TRIPS*. Retrieved December 16, 2011, from http://www.wto.org/english/tratop_e/trips_e/tripfq_e.htm#WhatAre.

(2012). *About the WTO- A Statement by the Director-General*. Retrieved February 12, 2012 from http://www.wto.org/english/thewto_

York, G. (2011, December 9). HIV on the Rise Again. *The Globe and Mail*. Retrieved December 12, 2011, from <http://www.theglobeandmail.com/news/world/africa-journal/hiv-on-the-rise-again-in-uganda/article2266267/>

Appendix 1: Interview Guide

NGO Questions:

Background Information:

1. How long have you worked for the NGO?
2. How long has this NGO been operating in Kampala?
3. What are the main goals and objectives of this NGO?
4. How does your organization attempt to meet these goals and objectives?

Access to Antiretroviral Medication Information:

1. Approximately how many people is your organization providing antiretroviral (ARV) drugs to?
2. Which drugs does your organization supply in the ARV regimes it provides?
3. From what source(s) does your organization receive the ARV treatment drugs?
4. Which country (countries) of origin does the drugs your organization currently provides come from?
5. Approximately what percentage of the drugs you provide is produced in North America or Europe?
6. Approximately what percentage of the drugs you provide is produced in Brazil or India?
7. Approximately what percentage of the drugs you provide is produced in Uganda?
8. Has the source of any of the drugs used in the ARV regimes you provide changed from in the past?
9. If so, what was/were the prior supplier(s)?
10. If so, what was the cause of the change in suppliers?
11. How has the amount of drugs your organization provides changed since it first began to distribute the medication?
12. Do all of the patients you provide ARVs to receive the same brands and combinations of medications?
13. If not what is/are the reason(s) for this?
14. What patented brands of medicine within the ARV treatment regime does your organization distribute?
15. Are the drugs donated to your organization? (If 'No' skip to question 11)
16. If so, who donates them?
17. Does your organization purchase the drugs?
18. If so from where?
19. Does your organization donate or sell the drugs to the patients?
20. If the answer was 'Sell', at what cost are the drugs sold at?
21. How often does your organization receive shipments of ARVs?
22. Has your organization ever run out of ARVs?
23. If so, what was/were the reasons?

24. If so, how long did the shortage last for?
25. How are the drugs distributed?
26. Has the construction of the QCIL drug manufacturing plant affected the amount of ARVS your organization is able to supply?
27. If 'Yes', in what way?
28. If 'No', why not?
29. What measures does your organization take to account for quality control of the drugs you distribute?
30. Has your organization ever experienced issues with receiving expired drugs?
31. If 'Yes', where did the drugs come from?
32. What factors affect where the drugs are received from?

Private Drug Procurement Agencies

Background Information:

1. How long have you worked for the company?
2. How long has this company been operating in Kampala?
3. What are the main goals and objectives of this company?
4. How does your company attempt to meet these goals and objectives?

Access to Antiretroviral Medication Information:

1. Which drugs does your company supply in the ARV regimes it procures?
2. From what source(s) does your company receive the ARV treatment drugs from?
3. From which country (countries) of origin do the drugs your company currently procures come from?
4. Approximately what percentage of the drugs you procure is produced in North America or Europe?
5. Approximately what percentage of the drugs you provide is produced in Brazil or India?
6. Approximately what percentage of the drugs you provide is produced in Uganda?
7. Has the source of any of the drugs used in the ARV regimes you procure changed from in the past?
8. If so, what was/were the prior supplier(s)?
9. If so, what was the cause of the change in suppliers?
10. What patented brands of medicine within the ARV treatment regime does your company procure?
11. Does your company donate or sell the drugs to the patients?
12. If the answer was 'Sell', at what cost are the drugs sold at?
13. How often does your company receive shipments of ARVs?
14. Has your company ever run out of ARVs?
15. If so, what was/were the reasons?
16. If so, how long did the shortage last for?
17. How are the drugs distributed?

18. Has the construction of the QCIL drug manufacturing plant affected the amount of ARVs your company is able to supply?
19. If 'Yes', in what way?
20. If 'No', why not?
21. What measures does your company take to account for quality control of the drugs you distribute?
22. Has your company ever experienced issues with receiving expired drugs?
23. If 'Yes', where did the drugs come from?
24. What factors affect where the drugs are received from?

Government Personal (Health Sector) Survey Questions:

Background Information:

1. What is your position within the Government of Uganda?
2. How long have you served in the Government of Uganda?

Access to Antiretroviral Medication Information:

1. How does the current government policy facilitate ARV drug procurement?
2. How has the policy focus changed from the past?
3. What caused the changes?
4. Does the Government provide free ARVs to patients in hospitals, clinics ect.?
5. If 'No' how much do the ARVs cost, per person per year in a government hospital or clinic?
6. Does the Government rely on other outside sources to provide ARVs to Ugandans, such as funding from foreign governments or NGOs?
7. If 'Yes' who are the major financial donors?
8. If 'Yes' does the Government control where the drugs are purchased from?
9. Are drugs ever directly donated to the Government to distribute in hospitals and clinics?
10. If 'Yes' what organization (s) have donated the drugs?
11. If 'Yes' what brand of drugs have been donated?
12. What measures do government health services take to ensure quality control of the drugs?
13. Approximately what percentage of AIDS patients in Uganda use government services to obtain ARV drugs?
14. What role did the Government of Uganda play in facilitating the development of the Cipla drug manufacturing plant?
15. Has the construction of the Cipla drug manufacturing plant affected the amount of ARVs the Government has been able to supply, in state-run clinics, hospitals ect.?
16. If 'Yes', in what way?

Government Personal (Foreign Trade Sector) Survey Questions:

Background Information:

1. What is your position within the Government of Uganda?
2. How long have you served in the Government of Uganda?

Questions regarding the partnership between Cipla and the Government of Uganda

1. What role did the Government of Uganda play in facilitating the development of the Cipla drug manufacturing plant?
2. Was the partnership initiated by the Government of Uganda or by Cipla?
3. What were the goals and objectives behind the partnership between the
4. Government of Uganda and Cipla?
5. In the absence of the support from Cipla, would the Government of Uganda have pursued the domestic production of ARVs?
6. If 'Yes', through what means?
7. If 'No', what factors would have prevented the Government from pursuing the domestic production of ARVs?

Cipla Executive Survey Questions:

Background Information:

1. How long have you worked for this company?
2. What is your role within the company?

Access to Antiretroviral Medication Information:

1. Can you explain the nature of the partnership between Cipla and the Government of Uganda?
2. Who are the main financial beneficiaries of the partnership?
3. Who are the primary and secondary buyers of the drugs?
4. How are the drugs distributed to the buyers?
5. What types of drugs are being produced at the plant?
6. What measures does the plant take to ensure quality control of the drugs?
7. What is the quantity of drugs being produced annually at the plant?
8. What is the price of ARV drug therapy per person per year, when the drugs are manufactured at the Cipla plant?
9. Has the plant ever experienced a shortage of buyers?
10. If so, what was the cause?

This research specifically aims to determine if the domestic production of antiretroviral drugs can be a successful and viable option to increase access to ARVs, by using the case study of Uganda. The research is intended to explore a potentially economical way to provide ARVs to populations with HIV/AIDS in order to move away from a dependence on foreign aid, which does not guarantee continued long term access to the medications. Since ARVs do not cure the infection and must be taken daily for the duration of the patient's life, it is important to develop ways to increase access to the medications in a manner that facilitates the long term drug procurement.

This research will specifically focus on analyzing Uganda's ability to increase affordable access to antiretroviral drugs through the construction of the Quality Chemicals drug factory in Kampala and the influence that NGOs have had on the success of the endeavor. The results of this research will help to determine if the operation has been successful in increasing access to ARVs for Ugandans and discuss whether the project will be sustainable for the future. The research will also investigate the issues the operation may face in regards to achieving its goals and objectives.

This study will advance our knowledge of the effects and impacts that the domestic production of ARVs has on marginalized HIV positive populations in addition to the impact that the presence of foreign donors may have on a country's ability to successfully develop a pharmaceutical sector.

As well, the research will aid in investigating the potential for the same method of accumulating ARV drugs, as in the Ugandan case study, to be transferred to other African states. The research is intended to explore the potential for heightening health equity, for HIV/AIDS patients in the developing world.

WHAT WILL I HAVE TO DO?

Participants are expected to either answer a series of questions via email or over the phone. The interviews may take any time between 10 and 30 minutes to complete depending on the information that participants will be providing.

WHAT ARE THE POTENTIAL RISKS FOR PARTICIPANTS?

The nature and type of the interviews are not expected to cause any physical harm to participants. Participation in this study is completely optional and voluntary, and there are no anticipated risks that taking part in this study will be detrimental to the interviewees. The information provided will be completely confidential and if desired your identity can be completely anonymous. You should only answer questions that you feel comfortable answering.

HOW CAN I WITHDRAW FROM THIS STUDY?

At any time throughout the duration of the interview, you may withdraw from this study without penalty by simply expressing in words that you no longer wish to finish the interview. In order to withdraw at a later date, you can do so by contacting the principal researcher, up until January 31st, 2012. In the case of withdrawal, all data collected from the interview will be omitted from the final report.

WHAT WILL BE DONE WITH MY INFORMATION? WHO WILL HAVE ACCESS TO IT?



SAINT MARY'S
UNIVERSITY SINCE 1802

One University. One World. Yours.

PATRICK POWER
LIBRARY

Department Office

T 902.420.5534

F 902.420.5561

Research Ethics Board Certificate Notice

The Saint Mary's University Research Ethics Board has issued an REB certificate related to this thesis. The certificate number is: 12-063 .

A copy of the certificate is on file at:

Saint Mary's University, Archives
Patrick Power Library
Halifax, NS
B3H 3C3

Email: archives@smu.ca
Phone: 902-420-5508
Fax: 902-420-5561

For more information on the issuing of REB certificates, you can contact the Research Ethics Board at 902-420-5728/ ethics@smu.ca .