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**Research Report: ZLC-2011-5**
**Optimizing Operations of a Pharmaceutical Regional Distribution Hub under Varying Regulatory Environments**
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# Optimizing Operations of a Pharmaceutical Regional Distribution Hub under Varying Regulatory Environments

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**Summary:** This thesis tackles the question of how to optimize operations of a pharmaceutical regional distribution hub in Africa. First, it analyzes the impact of the regulatory factors such as common label opportunities and import tariffs on supply chain performance. Secondly, it analyzes how innovative financing programs influence a pharmaceutical manufacturer´s supply chain.

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## KEY INSIGHTS

1. Common labeling can provide significant benefits in the form of pooling to a pharmaceutical regional distribution hub

2. When utilizing a regional distribution hub in the pharma industry, airfreight typically lowers total relevant supply chain cost

3. When utilizing innovative financing mechanisms pharma companies should incentivize distributors to increase product availability

## Introduction

Pharmaceutical companies have increased their focus on serving the African market for numerous reasons, such the presence of new innovative financing programs, corporate social responsibility and aid programs, or because of an increase in wealth that enables more individuals to afford pharmaceutical drugs (Foster, June 1990). In order to compete successfully in a market such as Africa, pharmaceutical companies need to focus on lowering the cost and increasing the availability of their products. Within the pharmaceutical market supply chain, operations are greatly influenced by regulatory constraints. By determining the optimal way to operate its supply chain under various regulatory environments, the manufacturer can make smart long-term investment decisions and maximize profit in emerging African markets. The consumer can also benefit from receiving drugs at a lower end cost.

## Methodology

The region of the East Africa Community (EAC) was chosen as the focus for the study due to the many potential future regulatory changes resulting from the formation of the EAC political, economic and customs union. The main regulatory cost drivers that were identified within EAC were:

1. Import Tariffs
2. Common Label Opportunities
3. Pharmaceutical Registration Harmonization

Import tariffs in the EAC have been eliminated for pharmaceutical products as of 2011, and pharmaceutical registration harmonization in the region is still quite uncertain and many years off. As a result, the analytical model developed focuses

primarily on opportunities related to utilizing common labeling. Common labeling can be used in regions such as EAC in order to reduce the number of SKU´s, where instead of one per country, one common labeled SKU is utilized for multiple countries within the region. Utilizing a common label allows the supply chain to obtain aggregation or pooling effects.

A likely trajectory of supply chain improvements was utilized in the model to show how a manufacturer could build upon different improvements to obtain the optimal operating environment. This trajectory is shown below.
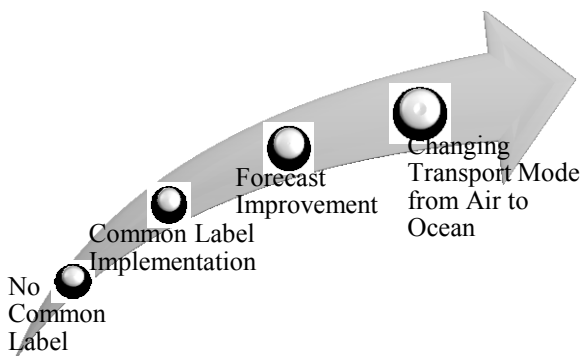


### Analytical Model

An interactive model was used where input variables can be tweaked by the user and the change in output can be seen graphically, with inputs and outputs seen in the table below:

| Inputs | Outputs |
|---|---|
| Demand data per country | Inventory<br><br>- Cycle<br>- Pipeline<br>- Safety<br>- Lost Sales |
| Shipping mode (Air, Ocean) | |
| The use of common Label (yes, no) | |
| % Improvement in forecast | Costs<br><br>- Holding<br>- Lost Profit<br>- Transportation |
| % Variability of mean demand | |
| Service level | |

The optimal setting depends on the product attributes and ultimate goals determined by the user.

Three graphic interactive models were presented. In the first model, all inputs can be changed including demand inputs per country in East Africa, with outputs changing accordingly.

In the second and third models, a similar setting as in the first model was used without the ability to change demand inputs, but a comparison with respect to the base scenario (No common label & air transport) is provided as inputs change. With the comparison to the base model, users will immediately know if they are better or worse off as the change presented is a percentage change from the base model.

### Results & Conclusions

As there are numerous scenarios that can be examined by users, a few select scenarios were chosen to show the effect on main supply chain metrics
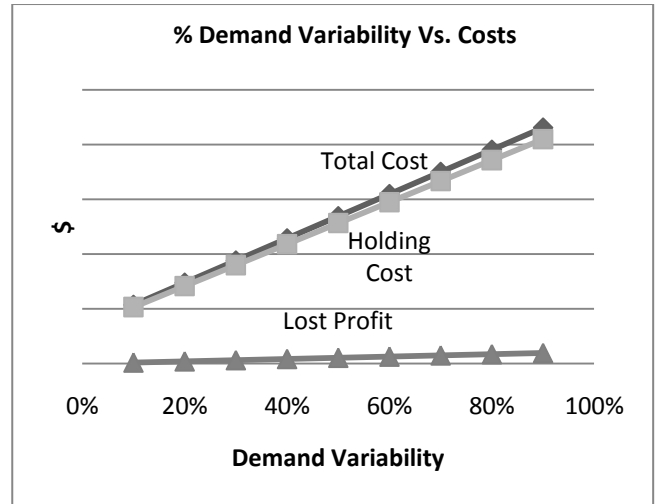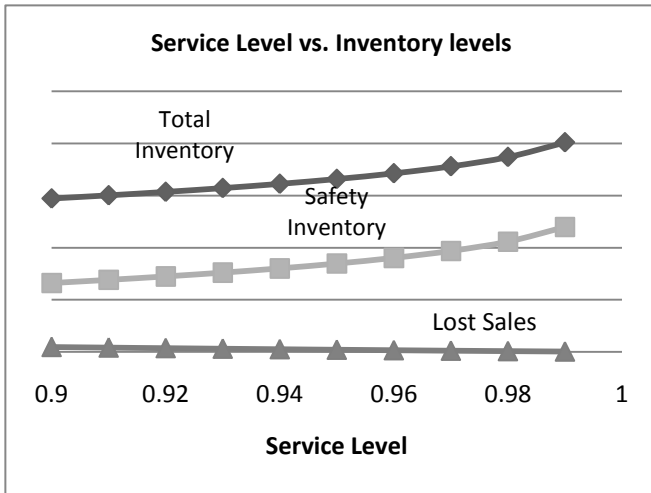
In the first scenario (Shipping Mode), it was apparent that the benefit from shipping by air outweighs the benefit from shipping by sea as more safety stock and holding cost will be incurred due the long lead-time involved.

In the second scenario (The Use of Common Label), it was apparent how common label creates savings due to the advantage of the pooling and aggregation effect where uncertainties are reduced.

In the third scenario (Product Life Cycle), it was shown that the overall supply chain costs and inventory levels will increase for new products as there are more uncertainties in demand. However, it was advised that some qualitative measures need to be taken in consideration when launching new products.

In the fourth and fifth scenarios (Service Level & Demand Variability), it was shown that the total supply chain cost increases as demand variability increases, as more uncertainties are created in the system. In regards to service level, as it increases, more costs will be incurred for holding more inventory. However, at one point it can be offset by reducing lost sales as profit increases, and it is easy to determine this point while performing sensitivity analyses while changing the inputs.

The graphs below illustrate the tradeoffs as service level and demand variability is changed.

**Service Level vs. Inventory levels**

Total Inventory

Safety Inventory

Lost Sales

0.9  0.92  0.94  0.96  0.98  1

**Service Level**

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**Service Level Trade offs**

Holding Cost & Lost Profit

Holding Cost

$$

Lost Profit

90%  92%  94%  96%  98%  100%

**Service Level**

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**% Demand Variability vs. Inventory Levels**

Total Inventory

Safety Inventory

Lost Sales

$

0%  20%  40%  60%  80%  100%

**Demand Variability**

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**% Demand Variability Vs. Costs**

Total Cost

Holding Cost

Lost Profit

$

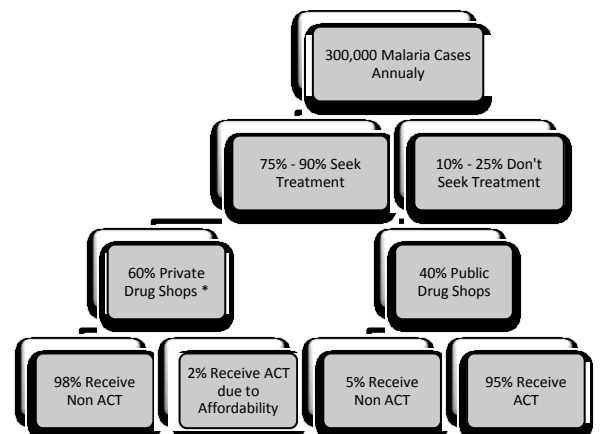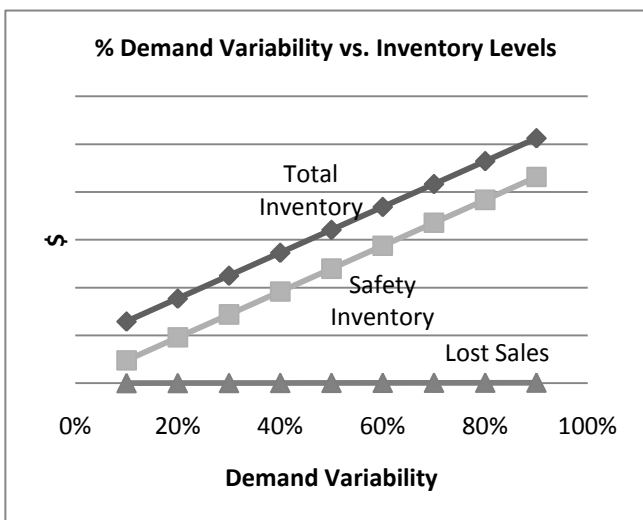0%  20%  40%  60%  80%  100%

**Demand Variability**

## Innovative Financing Program Introduction

There are many innovative financing opportunities available to pharmaceutical manufacturers in order to increase the reach of pharmaceutical products and reduce the cost to end consumers. As these programs such as Affordable Medicine Facilities-malaria (AMFm) or GAVI for vaccines become more prominent, pharmaceutical companies will need to understand how these programs impact their supply chain. Gaining a better understanding of these impacts will allow a pharmaceutical company to better take advantage of the financing programs.
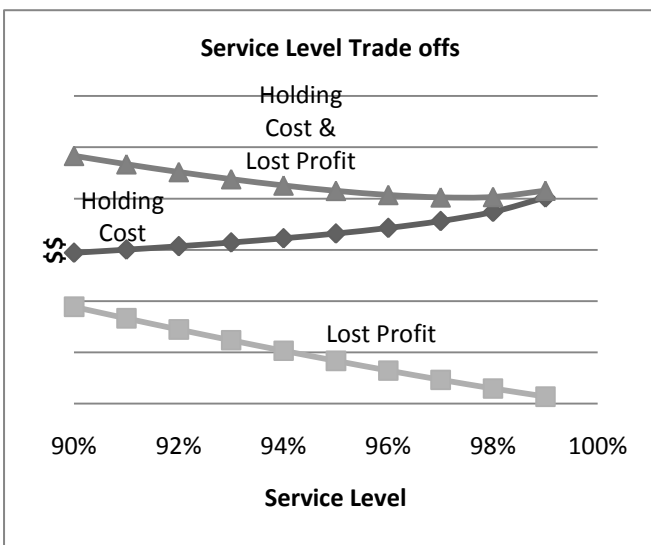
## AMFm Background

The table below shows on average how the 300,000 annual cases of malaria in Africa are treated, where the patient receives treatment, and what type of medicine is received (Yadav, 2010; *The Economist*, 2007). The goal of the AMFm program is to increase the availability of Artemisinan Combined Therapy (ACT) drugs. ACT's have proven to be the most effective drug against malaria; also, in the long term, use of ACT's will help prevent the development of resistance by the malaria carriers (The Global Fund).

300,000 Malaria Cases Annualy

75% - 90% Seek Treatment

10% - 25% Don't Seek Treatment

60% Private Drug Shops *

40% Public Drug Shops

98% Receive Non ACT

2% Receive ACT due to Affordability

5% Receive Non ACT

95% Receive ACT

When utilizing the innovative AMFm financing program, the program host (currently The Global Fund) provides payment directly to the manufacturer for approximately 95% of the PO value and the first-line buyer or distributor pays the remaining 5%.

The charts below illustrate the difference in price at each stage of the supply chain for malaria medication. As can be seen, on average the price is significantly reduced.

## ACT distribution without AMFm
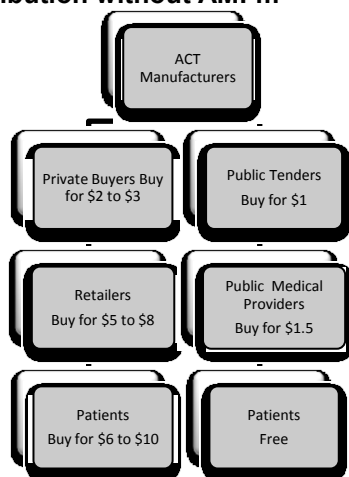


## ACT Distribution Utilizing AMFm Program
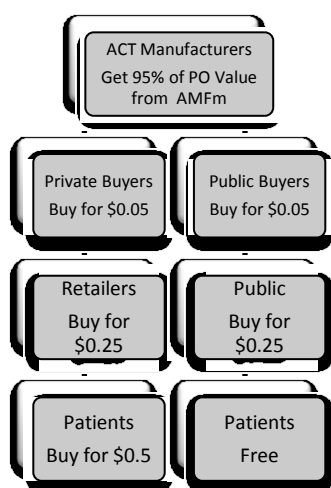


The significant difference in price between ACT's utilizing AMFm and those not utilizing the program will lead to a competitive situation in which it will be extremely difficult to compete in an AMFm country without utilizing the program. The current market share held by manufacturers who are members of the program is shown below. Overall, generic drug manufacturers have been more successful utilizing the program to date than originators.



Manufacturers' Market Share
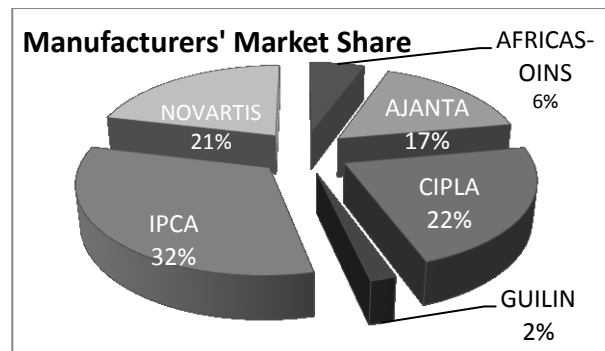
## AMFm Recommendations

In general, utilizing a program such as AMFm will impact a manufacturer´s supply chain. There will be restrictions on utilizing only approved first-line buyers as well as receiving payment on the same purchase order from two different sources, amongst other impacts.

Based upon these supply chain impacts, our study has identified several key recommendations for a company utilizing the AMFm program.

1) Prepare for operational changes, mainly receiving payment from two different sources
2) Analyze opportunities for collaboration by changing standard supplier terms from letter of credit to open account
3) Understand the impact of public information and visibility causes on interactions with distributors and agents - all AMFm information is public
4) Work with wholesalers/ distributors who can ensure greater market penetration of ACTs to remote and rural areas
5) Ensure that ACTs are present in the appropriate retail outlets and that the proper set of wholesalers/distributors is being used to reach necessary retail outlets.
6) When marketing manufacturer-specific ACT medications in-country focus on product attributes as differentiators due to common AMFm logo marketing campaigns.

## Works Cited

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