ADDIS ABABA UNIVERSITY

SCHOOL OF GRADUATE STUDIES

COST AS A ABRRIER TO ACCESS: AVAILABILTY, AFFORDABILITY AND IDENTIFYING COMPONENT COST OF ESSENTIAL MEDICINES

BY

MOHAMMEDSIED NURU (B.PHARM)

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List of abbreviations

ARVs	Antiretrovirals
ATP	Ability To Pay
CIF	Cost Insurance and Freight
CSA	Central Statistical Authority
DACA	Drug Administration and Control Authority
EDL	Essential Drugs List
EML	Essential Medicine List
ERCS	Ethiopian Red Cross Society
FMOH	Federal Ministry of Health
GDP	Gross Domestic Product
HAI	Health Action International
HH	Household
IB	Innovator Brand
IRP	International Reference Price
LPG	Lowest Price Generics
LIDE	List of Drugs for Ethiopia
MDGs	Millennium Development Goals
MOH	Ministry of Health
MPR	Median Price Ratio
MSH	Management Science for Health
MUP	Manufacturers Unit Price
NGO	Non Governmental Organization
OR	Odds Ratio
PFSA	Pharmaceuticals Fund and Supply Agency
SD	Standard Deviation
SPSS	Statistical Package for Social Science Research
SP	Special Pharmacy
USD	United States Dollar

WHO World Health Organization

Summary

Background: The World Health Organization (WHO) reported that one third of the world's population lacks reliable access to required medicines and the situation is even worse in developing countries and price is one of the factors that hinder access to essential medicines.

Objectives: To identify barriers in accessing, availability, affordability and component cost of essential medicines.

Methodology: The study was based on a cross-sectional study design. Quantitative methods were employed in the data collection. Price and availability data for 32 medicines was collected from each 10 public sector facilities, private sector retail pharmacies and other sector retail out lets. Exit interview were also done on 30 patients from each sector in a total of 150 patients from Addis Ababa and Benishangul Gumuz Regional state. Medicine prices were compared with international reference prices (IRPs) to obtain a median price ratio. The daily wage of the lowest paid unskilled government worker was used to gauge the affordability of medicines. Price component data were collected throughout the supply chain, and markups, taxes, and other distribution costs were identified.

Result: In private pharmacies, innovator brand (IB) prices were 27.47 times higher than the IRPs in Addis Ababa, while generics were 2.7 and 3.68 times higher in Addis Ababa and Benishangul Gumuz Regional State, respectively. In other sector retail out lets, the figures were 2.52 and 4.9 times higher for generics than the IRPs in Addis Ababa and Benishangul Gumuz respectively. Add-on costs had a substantial impact on medicine prices in all sectors. Retail pharmacy markups were 25 %–55 % and 25 %–247 % for IBs and generics, respectively. In the public sector, where medicines are free, availability was low even for medicines on the National Essential Drugs List. For a month's treatment for peptic ulcer disease and Arthritis people have to pay more than a month's wages when IB was used. In the study of exit interview around 61% of the respondents were able to pay for the prescribed medicines. The most important predictors of ability to pay (ATP) for the prescribed

medicine found in this study are, type of organization (whether governmental or private), educational status of the head of the household, amount of payment for the prescribed medicines and estimated average income of the household.

Conclusions: The availability of lowest price generics was low in the public sectors and prices of innovator brands were very high in the private sector of Addis Ababa. Markups for generic products are greater than for IBs. Reducing the base price without controlling markups may increase profits for retailers and wholesalers without reducing the price paid by end users. To increase access and affordability, promotion of generic medicines and improved availability of medicines in the public sector are required.

1. Introduction

International treaties and governments all over the world recognize health care as a fundamental human right. In order to improve health by tackling socioeconomic determinants of health, 189 heads of state endorsed the Millennium Development Goals (MDGs) in 2000: "To reduce poverty and hunger and to tackle ill health, gender inequality, lack of education, lack of access to clean water and environmental degradation" (WHO and MDG, 2000).

The MDGs were "Framed as a compact, which recognizes the contribution that developed countries can make through trade, development assistance, debt relief, access to essential medicines and technology transfer". Therefore, without access to essential medicines, this fundamental right as well as the United Nation's Millennium Development Goals Can not be realized (WHO and MDG, 2000).

One-third of the global population lacks reliable access to needed medicines (WHO, 2000). The situation is worse in the poorest countries of Africa and Asia where up to 50% of the population are unable to obtain necessary medicines (WHO/WTO, 2001). The price of medicine is considered one of the most important obstacles to access.

The purchase of medicines contributes significantly to the health care budget of developing countries, and drug expenditures may amount to 50%–90% of non personnel costs (Quick JD et al, 1997). In developing countries, studies and data on medicine prices are scanty. Measuring and understanding the reasons for the price of medicines is the first stage in developing medicine pricing policies that would ensure the affordability of medicine.

Up to 90% of the populations in developing countries have to buy medicines through out-of-pocket payments as opposed to around 20% in high income countries (WHO/WTO, 2001). Less than 10% of the population of Africa is protected by social insurance and publicly subsidized health services are both inadequate and located primarily in and around principal urban centers (WHO/WTO, 2001).

Duties, taxes, mark-ups, distribution costs and dispensing fees are often high, regularly constituting between 30% and 45% of retail prices, but occasionally up to 80% or more of the total (Bale, 2001). Prices are also influenced by whether the country observes patents, the level of domestic production of medicines, lack of competition between pharmaceutical manufacturers and weak or non-existent price controls (Quick JD et al, 1997).

In Ethiopia, import and wholesale are done by the public sector, private sector, NGO's and international organizations. The Pharmaceuticals Fund and Supply Agency (PFSA) is responsible for import and distribution to the public sector. PFSA has eight wholesale distribution branches (2 in Addis Ababa and 6 in different regions). The public procurement is done through international and local tenders as well as by direct purchasing or negotiation and it is also limited to the List of Drugs for Ethiopia (LIDE).

There are 11 manufacturers of pharmaceuticals out of this one is governmental. In the private sector, the total number of importers wholesalers has increased from only 11 in 1993 to 107 in 2007 (DACA, 2007). Procurement in the private sector is done by direct order to manufacturers abroad and it is also limited to the LIDE.

The drug retail activity is carried out by the public sector, private sector, city councils and the Ethiopian Red Cross Society (ERCS). In 2007, there were 320 pharmacies, 577 drug shops and 2121 rural drug vendors (FMOH, 2007). Moreover, each health care facility has its own medicine retail outlet.

In 2005/06, the total government drug budget was about 230 million birr, which was approximately 21% of the recurrent government health budget and represented a per capita drug budget of 3.2 birr. The total annual drug expenditure in the same year was estimated at 2.5 billion birr; out of which 1.1 billion birr was donation (WHO, 2007).

There are public health programs such as TB/Leprosy Control, Family Planning, Malaria Control, and HIV/AIDS Control, which are assisted by donors. Sources of drug financing

include government finance, private expenditure (i.e. user charges or out of pocket payments), external assistance, loan and private health insurance. The private expenditure on health for 2003 was 41.6% and (WHO, 2006) and the National Health Accounts for Ethiopia has estimated the private expenditure on drugs for 2004/05 is 76% of the total house holds health expenditure (WHO, 2007).

The goal of this study is to find out the price and availability of selected medicines as well as affordability of cost of treatment of common diseases to low - income people in Ethiopia.

2. Literature Review

"Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford." (WHO, 2002).

Essential medicines are central to a health system's success and the care it provides its clients. In developing countries, pharmaceutical costs are a health unit's largest expenditure after personnel costs (MSH, 1997), comprising 40-60% of total health costs (Perez-Casas et al, 2001).

This is true of both the public and the private sector: Kawasaki and Patten report that mission health facilities in eastern Africa regularly allocate 28% of their budget to medicines alone (Kawasaki & Patton 2002). Average per capita spending on pharmaceuticals in high-income countries is 100 times higher than in low-income countries (about US$ 400 compared with US$ 4).The World Health Organization (WHO) estimates that 15% of the world's population consumes over 90% of the global production of pharmaceuticals (by value) (WHO, 2004).

Furthermore, new pharmaceutical inventions, new diseases and a growing population put constant demands for additional pharmaceutical resources on the health sector. With fixed budgets and limited financial resources available, countries cannot simply increase their health budget in order to increase or maintain access to essential medicines.

In Member Countries of the Organization for Economic Co-operation and Development (OECD), many direct and indirect pharmaceutical price regulations remain in effect. However, in many low- and middle-income countries, national medicine pricing policies

have been shifting from price controls to deregulation under the influence of structural adjustment and reform programmers (Jacobzone, 2000).

National policies, medicine pricing and procurement strategies are required to ensure that medicines are affordable. While policies are also greatly needed to improve health infrastructure and financing as well as to ensure the rational use of medicines, high medicine prices are one of the biggest obstacles to access. Nevertheless, even in the face of a weak infrastructure and poverty, improvements in access can be achieved (Myhr, 2000).

Prices of the same medicines frequently vary between countries; some commonly used medicines have been found to be more expensive in developing countries than in industrialized ones and many studies have shown that affordability is unrelated to purchasing power (Bala &sogo, 2002).

The ex-manufacturer prices to countries – in particular for the private sector – are often confidential. Medicine price indicator guides provide the sales prices from large wholesalers of generically equivalent medicines to governments. However, they do not give the price patients must pay in either the public or private sectors and often do not include new, essential but patented medicines. A few countries have publicly available prices (Myhr, 2000).

2.1. Availability of medicines

In the public sector, the availability of generic medicines was very low, ranging from 9·7% in Yemen to 79·2% in Mongolia. Regional availability ranged from 29·4% in Africa to 54·4% in the Americas; mean availability in the public sector was lower than in the private sector in all regions (Cameron, 2008).

In the private sector, availability of generics was low, ranging from 50·1% in the western Pacific to 75·1% in Southeast Asia. High private sector availability of generics was recorded

in Syria (97·5%) and Chennai, India (91·8%), whereas low availability was seen In Chad (14·8%), Kuwait (36·3%), the Philippines (33·6%), and China (34·6% in Shandong and 38·3% in Shanghai). Similarly, private sector availability of generics in Africa ranged widely, from 14·8% in Chad to 79·1% in Ethiopia (WHO, 2006).

In many countries medicines are supplied free of charge to all or to specific categories of patients (Danzon, 2000). This is praiseworthy provided the medicines are available. Sadly for the sick and poor, this is rarely the case (Margaret & Dalia, 2007).

For example, asthma is a common chronic disease. As shown in Table 1, salbutamol inhaler was not found in any of the public sector facilities sampled in Uganda (where medicines in the public sector are free) or Mali, and in Indonesia only 13% of the facilities sampled stocked salbutamol inhalers (originator brand only). Therefore, asthmatic patients are forced to purchase an inhaler from the private sector where it is clearly unaffordable in all three countries (days worked to purchase 1 inhaler ranged from 2 to nearly 6 days) (Margaret & Dalia, 2007).

Table 1: Availability of salbutamol inhaler (public sector) and affordability (private sector)

	National Essential Medicines List	Availability Public sector facilities		Affordability Private Retail Pharmacies	
		Originator	Generic	Originator	Generic
Uganda	yes	0%	0%	5.6 days	2.0 days
Mali	yes	0%	0%	4.2 days	2.7 days
Indonesia	no	13%	0 %	4.1 days	

Source: (Margaret & Dalia, 2007)

2.2. Prices of medicines

High prices can limit access to basic medicines is an obvious statement. But it is worth stressing that high prices are an even bigger problem when consumers lack health insurance

and must meet all health care expenses out of their own pockets, as is the case for most citizens of the developing world. Furthermore, given the state of credit markets in most developing countries, external financing is also not a realistic option for the poor of the developing world (Saggi, 2007).

Some governments are purchasing expensive originator brand medicines that have been off patent for years (and hence cheaper generics exist). For example, in China/Shandong Province, Malaysia and Kuwait the survey data showed that no generics of carbamazepine were procured for the public sector. The originator brands purchased were high priced (MPRs 3.2 - 9). In Morocco and Kazakhstan both generics and the more expensive originator brand was procured by the government. Governments should not purchase expensive originator brands where quality-assured cheaper generics are available (Margaret & Dalia, 2007).

People are paying high prices for medicines; the price of originator brand atenolol 50mg tablets is over 40 times the international reference price in China/Shandong Province, Malaysia and Kuwait countries except India (where it is still high at 5 times the reference price). Even the lowest priced generic is very expensive in the above countries. The originator brand, Tenormin®, shows marked price variation (Margaret & Dalia, 2007).

Huge brand premiums e.g. in Uganda some originator brands are approximately 13 times the generic. High brand premiums are problematic if cheaper generics are not widely available, or the originator brand is sold to maximize pharmacy profits, or the medicine is patented and faces no competition, or doctors prescribe by originator brand name and in some cases generic substitution is not permitted (Myrh, 2000).

2.3 Affordability of treatment

2.3.1. Ability to pay

In many developing countries people are expected to contribute to the cost of health care from their own pockets. As a result, people's ability to pay (ATP) for health care, or the affordability of health care, has become a critical policy issue in developing countries, and a particularly urgent issue where households face combined user fee burdens from various essential service sectors such as health, education and water(Steven, 1996).

The interactions between households and the health system are important determinants of households' ability to cope with the costs of ill health. Health systems are frequently ineffective in reaching the poor, and often impose regressive cost burdens (Steven, 1996).

These problems are aggravated by the increasing burden of chronic illness in poorer countries. Poor households adapt their healthcare use to avoid costs they cannot meet, at the risk of deteriorating health. Financial strategies (e.g. borrowing, and reducing expenditure on other basic needs) used to finance healthcare may jeopardize household livelihoods, potentially leading to further impoverishment. Social resources and local infrastructure (such as transport, availability of healthcare) are important in enabling house holds to cope affordability of treatment (Jane Goudge et al, 2007).

2.3.2. Affordability to specific treatment

Affordable treatments are a vital prerequisite for ensuring access to essential medicines. The following acute and chronic conditions illustrate the dire situation for people in a number of countries when purchasing medicines from private retail pharmacies. A month's treatment with ranitidine tablets for a peptic ulcer, purchased by the lowest paid government worker, is unaffordable in all but West Bengal, India - for generics as well as the originator brand.

The affordability of fluoxetine treatment is startling. Armenians need to work over 50 days for a month's treatment – a totally unacceptable situation, when there are no public sector

facilities in Armenia. Treatment with fluoxetine purchased in the private sector is beyond the reach of people (Margaret & Dalia, 2007).

In private sector of Kenya the affordability of antimalarial treatment at the time of the survey (Sept 2004) (sulphadoxine-pyrimethamine was first line therapy) and needed less than 1 day's wage to purchase 3 tablets. ACT (artemether-lumafantrine) was clearly unaffordable in the private sector (and not available in the public sector). In December 2004 it was agreed that ACTs would be first line treatment except in pregnancy. It will be supplied free of charge. Availability will be crucial as the medicine is clearly not affordable in the private sector (HAI, 2007).

2.4 Component cost of medicines

The cost of getting an essential medicine to a patient includes the *base price* (*i.e.*, its price as sold from the manufacturer) as well as all costs for transportation, storage, import tariffs and taxes, wholesale and retail markups, staff salaries, stock losses and procurement practices. These latter costs – *hidden costs* – can more than double the manufacturer's price (Perez-Casas et al, 2001).

The base price of a medicine is not fixed. Different batches of the same product can be sold at different prices in different countries or even within one country. Prices paid to the manufacturer can vary enormously for many reasons, among them: access to market intelligence, size of market and level of competitiveness, economies of scale, procurement method used, the purchaser's financial history and whether the drug is still under patent (Bala & Sagoo, 2002).

"International price comparison in the field of pharmaceuticals is subject to many pitfalls, and retail prices, in particular, are often a distant relation to manufacturer's selling price. Import duties, taxes, wholesale markups, both formal and informal, can double the price of a drug between manufacturer and consumer." (WHO Secretariat, 2001)

This can be illustrated by taking the following table, which presents comparison examples of hidden costs, potentially under government control, from countries around the world. While each individual charge might seem inconsequential, their compounded effect results in hidden charges that consistently add more than 50% to the base price (Levison, 2003).

Table 2: Example of hidden costs on pharmaceutical purchases

	Sri Lanka	Kenya	Tanzania	S. Africa	Brazil	Armenia	Kosovo	Pune, India	Nepal	Mauritius
Import tariff	0%	0%	10%		11.7%	0%	1%	0%	4%	5%
Port charges	4%	8%	1%				4%	0%		
Clearance and freight		1%	2%						1.5%	5%
Pre-shipment inspect		2.75%	1.2%							
Pharmacy board fee			2%							
Importer's margins	25%						15%	25%	10%	
VAT				14%	18%	20%	0%			
Central govt. tax								4%		
Local town duty								1.5%		
Wholesaler	8.5%	15%	0%	21.2%	7%	25%	15%	10%	10%	14%
Retail	16.25%	20%	50%	50%	22%	25%	25%	15%	16%	27%
Total mark up	63.97%	54.22	74.3%	74.0%	82.3%	87.5%	73.6%	81.9%	48.8%	59.2%

Source :(Levison, 2003)

The prices of medicines are well above their production costs, and the profits of those in the distribution chain (pharmacists, dispensing doctors, wholesalers and even some governments) are frequently high, so there is an opportunity to bring prices down and so improve access to treatment (Bale, 2001).

2.5. Types of price regulation

Governments can regulate costs by instituting markup mechanisms (Table 3), applied to both wholesale and retail facilities. Implementing a price control mechanism, however, does not guarantee that it will be followed: governments must be able to monitor and enforce the mechanism. “In Costa Rica, the price control scheme has been in force for twenty years and its functioning has serious problems due to the difficulties which the authorities face in carrying out the required controls and monitoring of the retailer’s and pharmacist’s profit margins.” (WHO, 1995).

Table 3: Types of mark up mechanism

Price control mechanism	**Description**	**Comments**
Cost + fixed percentage	Wholesalers and retailers add a fixed percentage price.	May encourage stocking and sale of more expensive items.
Cost + declining percentage	The more costly the drug, the lower the percentage markup.	Provides incentives to sell less expensive items
Cost + fixed dispensing fee	A fixed fee is paid per prescription.	Reduces the incentive to prescribe or sell higher priced drugs.
Cost + differential pricing	Fee paid per prescription is higher for generic products.	Encourages generic prescribing.
Maximum allowable price	Involves price setting of producers’ price and fixed percentage markups for distribution.	Individual drug prices may be limited but incentives exist for retailers to sell more expensive drugs.

Source: (WHO, 1998).

The official markup rate can have little resemblance to the actual markup for two reasons: first, lack of enforcement allows markup rates to range much higher. In Nepal, the official markup is 16%; due to lack of surveillance and high demand, retailers receive as much as a

100% markup (Levison, 2003). Second, Vendors often offer discounts to preferred customers either for bulk purchases or for customer loyalty (Gray & Matsebula, 2000). In Sierra Leone, a previous employee of the private sector reported a 33% discount on a 50% wholesale markup for 'prime' customers. In Malawi, one private hospital adds a 70% markup and gives a 20% discount (Levison, 2003).

Instead of regulating by sector, governments have the option of regulating markups based on the number of "competitors" for a medicine. Unlike the method seen in Table 3, the reference pricing mechanisms described in Table 4 below focus governmental intervention on those product prices that the market system will not be able to influence.

Table 4: Types of mark up based on "competitors"

Drug: number of manufacturers	**Cost control mechanism**	**Comments**
Brand name drug (Single manufacturer)	Government price regulation.	Government can use Reference pricing.
Drug with therapeutic equivalent "Me-too" drugs (At least two manufacturers)	Leave to market forces.	There must be unimpeded access to information and competition.
Generic equivalents exist (Numerous manufacturers)	Government to remove barriers to competition (e.g. tariffs, taxes).	There must be price information and assured access.

Source :(Levison, 2003)

Government should set price controls for single manufacturer (brand name) drugs. As the evidence from Brazil showed, for drugs with therapeutic equivalents, market forces (competition) is sufficient to reduce cost, as long as the market is allowed to operate freely.

For drugs with generic equivalents, again the market will act to reduce cost, but the government can assist by guaranteeing that imported drugs are equal market participants by removing barriers to competition such as import duties (Levison, 2003).

This tri-partite mechanism is a large component of the system employed in Australia by their Pharmaceutical Benefits Scheme (PBS), which, despite constant expansion of the pharmaceutical sector, pays lower manufacturer prices than the US, UK, Canada or Sweden (Productivity Commission, 2001).

If needed, the government could strengthen these cost control mechanisms by setting a maximum price per month for a specific treatment. Public health workers can support these cost control mechanisms by surveying retail outlets and publishing prices (Levison, 2003).

2.6. The case of Ethiopia

In case of Ethiopia availability of the generic equivalents varied from sector to sector and from medicine –to medicine. For example, availability of lowest price generics was 76.5 %, 96 % and 78.6 % in the public health facilities, private pharmacies and SP/ERCS outlets, respectively. In contrast availability of most sold generics was 29.4 %, 68 % and 37.5 % in the public health facilities, private pharmacies and SP/ERCS outlets, respectively (FMOH&WHO ,2005).

Measured in terms of affordability, the cost of treating common diseases varied between innovator products and generic versions. For example, there was nearly 4-fold difference between the price of innovator brand of amoxicillin and its generic equivalent in the private pharmacies. Nearly 12-fold difference was also observed between the price of innovator brand glibenclamide and its generic equivalent in the private pharmacies (FMOH &WHO, 2005).

When a family with a combination of four disease conditions is considered, it was shown that the breadwinner, who is a lowest paid government employee, would need to work for nearly 3 days from public health facilities and 4.6 days for both SP/ERCS medicine out lets and private pharmacies to purchase the necessary lowest price generic version medicines (FMOH &WHO, 2005).

When the above situations are seen in the light of the income level of the Ethiopian people and the proportion of the total household income spent on medicines, it seems that costs of treatment of common diseases are unaffordable to the majority of the Ethiopian people (FMOH &WHO, 2005).

Regarding mark-ups on medicines prices, there is no ceiling set by law on the wholesale and retail mark-ups in all sectors. However, it was noted that wholesale mark-ups in general range from 20% - 40% of the landed costs of imported products and 5 % -10% of the ex-factory prices of locally manufactured products. Retail mark-ups range from 20 % - 30 %, depending on the type of the sector. But the rates in the private sector are unpredictable (FMOH & WHO, 2005).

3. Objectives of the study

3.1. General objective

To identify barriers in accessing (availability, affordability) and assess component cost of essential medicines.

3.2. Specific objectives

- To assess availability of essential medicines in different sectors;
- To determine how affordable are medicines for low income group of People
- To investigate the price component (taxes and duties levied on medicines and the levels of various mark-ups), which contribute to their retail prices.
- To compare the prices in different sectors within the country and with International Reference Prices.
- To compare the relative prices of innovator brand medicines and their generic equivalents.

4. Methodology

4.1. Study design

The study was based on a cross-sectional study design. Quantitative methods were employed in the data collection. The survey approach involved the use of check list, exit interview and structured questioner.

4.2. Source population

- The source population constituted all public health facilities, private and other drug outlets in Addis Ababa and Benishangul Gumuz Regional state.
- Pharmacists and other professionals (physicians, managers….) at PFSA, DACA, MOH, Customs Authority, Manufacturers of medicines, private importers and whole sellers.
- All clients at the public health facilities' pharmacy , private pharmacies and other drug outlets in Addis Ababa and Benishangul Gumuz Regional state.

4.3. Study population

- Public hospitals, health centers, private and other drug outlets selected based on the sampling procedure in Addis Ababa and Benishangul Gumuz.
- Clients (18 years and above) who purchased all the prescribed drugs.
- Key informants (Pharmacists and other professionals) at PFSA, DACA, MOH, Customs Authority, Manufacturers of medicines, private importers and whole sellers.

4.4. Description of study sites

Ethiopia is a large sized country, covering an area of 435,071 square miles (LCFRD, 2005). It is divided into nine administrative states that include: Oromia, southern Nations, Nationalities and people's Region(SNNPR), Amahara, Tigray, Afar, Benishangul Gumuz,

Gambella, Somalia and Harrai regional states and two chartered cites: Addis Ababa and Dire Dawa. The total population as of May 2007 was 73,845,035 with the 83.82 % of population living in rural areas (CSA, 2008).

Ethiopia is a low income country with a. about 23% of the population lives on less than US $1/day, and 77.8 % live on less than US $2/day (World Bank, 2005).The potential health service coverage including the private sector was 98.1% (FMOH, 2007). In 2003, the Ethiopian total expenditure on health was 5.9% of the Gross Domestic Product (GDP); out of this the private health expenditure was 41.6 % (World health report, 2005).

4.4.1. Addis Ababa

Addis Ababa with an estimated area of 530.14 square kilometers, based on figures from the Central Statistical Agency of Ethiopia (CSA) preliminary report in 2008 as of May 2007, it has an estimated total population of, 2,738,248 consisting of 1,304,518 men and 1,433,730 women (CSA ,2008).

The CSA estimated that presently there are no rural parts to the city, so 100% of the inhabitants are considered urban dwellers; Addis Ababa contains 24% of all urban dwellers in Ethiopia. This chartered city has an estimated density of 5,607.96 people per square kilometer and also houses 27 Hospitals, 29 Health Centers, 130 Health stations, 43 Health Posts 79 importers and whole sellers, 108 private pharmacies and 123 drug shops (FMOH, 2007).

4.4.2. Benishangul Gumuz

Benishangul Gumuz with an estimated area of 49,289.46 square kilometers has an estimated density of 12.68 people per square kilometer. According to 2008 CSA preliminary report as of May 2007, it had an estimated total population of, 670,847 consisting of 340,378 men and 330,469 women. Five hundred seventy two thousand eight hundred eighty two (85.4%) of the

population are estimated to be rural inhabitants, while 97,965 (14.6%) are urban (CSA, 2008).

The capital city for the Benishangul Gumuz Regional State is Assosa, which is 677 km from the capital city. During the time of study, Benishangul Gumuz had 2 Hospitals, 11 Health Centers, 56 Health stations, 65 Health Posts, 8 drug shops and 35 drug vendors (FMOH, 2007).

4.5. Sampling and sample size determination

The study adopted the WHO–Health Action International (HAI) methodology and was conducted in five public health facilities, five private pharmacies and five "other sector" pharmacies from both Addis Ababa and Benishangul Regional State (WHO & HAI, 2007).

The study areas purposively selected to be Addis Ababa and Benishangul Gumuz Regional State. Addis Ababa was selected because it is the capital city of Ethiopia and many importers including the governmental procurement agency (PFSA), whole sellers and retailers are concentrated. Benishangul Gumuz Regional State is one of the under developed regions of the country, which was not also included in the first similar study that was done by WHO and FMOH.

Selecting public sector facilities

For convenience, public health facilities were used to anchor the sample, with other types of medicine outlets chosen by their proximity to these facilities. In order the sample to be representative from the public sector facilities in Addis Ababa, two from the specialized hospitals and two randomly selected zonal hospitals and one randomly selected health center were sampled. From Benishangul Gumuz Assosa and Pawe Hospitals as well as three randomly selected health centers were used.

Selecting Importers, private and "other sector" pharmacies

From the importers and distributors side PFSA and others that import drugs within the list of selected medicines for this study were chosen. Ten pharmacies, five from each private and "other sector" pharmacies were selected based on their proximity to the public health facilities.

Selecting medicines

Among a total of 31 medicines included in the survey, 13 belong to the core list of medicines suggested by WHO–HAI for international comparison (WHO & HAI, 2007), and 18 were added as supplementary drugs. The core list medicines were selected on the basis of the global and sub Sahara African disease burden. The supplementary list was prepared on the basis of the local disease burden and all the medicines included in this study are included in the essential list of medicines for Ethiopia.

Selecting medicines for identifying component cost of medicines

In order to understand the pricing structure of the country four medicines Amoxicillin 500 mg capsule (generic), Mebendazol 100 mg tablet (IB), Cotrimoxazole pediatric suspension (generic) and Methyl dopa 250 mg tablet (generic) were chosen on the basis of their widespread use, availability and also considering medicines that are imported and locally produced.

Affordability

To assess affordability, ten common diseases from the acute and chronic conditions in Ethiopia were selected. The affordability was computed using the daily wage of the lowest-paid government worker, which has been assessed as 9.674 Birr daily.

Exit interview

To assess consumers' perception, exit interview were done on 30 patients from the public, private and other sector retail outlets of Addis Ababa and Benishangul Gumuz Regional State in a total of 150 patients. Prior to the actual study, a pilot study was conducted to test the accuracy and validity of the questionnaire at zewditu hospital.

4.6. Data collection and management

4.6.1. Data collectors

Six pharmacy students were selected for the data collection and exit interview from each study area. Prior to data collection, a one -day training was organized for the data collectors, which included an overview of the aim of the study and a detailed collective review of the research tools. This involved detailed presentation and discussion in English, followed by discussion of the translated (Amharic) version of the exit interview questioner (since the data collectors would be interviewing respondents in Amharic).

The training was followed by pre-testing of the tools at three facilities from each sector which were not included in the study. Both the data collectors and the investigator discussed lessons learnt from pre-testing to clarify some of the issues.

4.6.2. Data collection

Data collection took place between September and October 2008. Data collectors visited medicine outlets in pairs and collected information on medicine availability and price using a standard data collection form specific to the medicines being surveyed in Addis Ababa and Benishangul Gumuz. The Principal investigator checked all forms at the end of each day of data collection, and validated the data collection process by collecting data at 20% of the medicine outlets and comparing their results with those of the data collectors. Upon

completion of the survey the principal investigator conducted a quality control check of all data collection forms prior to data entry.

The principal investigator interviewed the key informants from different organization and in order to maintain consistency, the same procedures were followed for data collection in all study sites.

4.6.3. Data collection instruments

Medicine price data collection form

The six third year pharmacy students collected the data on the prices of medicines at their retail value and availability using a checklist from the selected facilities and procurement price was collected from PFSA by the principal investigator. The data collectors were also given a letter of endorsement that assured the anonymity of any information provided for the survey.

For each medicine, data were collected on the price and availability of innovator brand (IB) and lowest-price generic equivalent (LPG). The IB was determined nationally through preliminary surveys, while the LPG was determined at the facility level.

Price components data collection form

Medicine component costs were also recorded in the public, private and “other sector” retail pharmacy sectors in Addis Ababa and Benishangul Gumuz Regional State to assess pricing structure. For this, a separate form was developed and validated.

The WHO–HAI methodology was followed to collect data on the different stages in the distribution chain (WHO & HAI, 2007). Stage 0 of the component cost is manufacturer’s selling price (MSP). Stage 1 includes stage 0 and insurance and freight. Stage 2 includes customs charges, port charges, and quarantine charges after the arrival of medicines in the

country. It also includes finance, banking fees, and transport charges. Letter of credit charges are included in the finance and banking fees. Stage 3 includes distributors' and/or wholesalers' charges. Stage 4 is retailers' markups. Stage 5 is composed of the value added tax and goods and services tax.

Data collection started with the patient/retail price; all the fees collected and the costs were deducted until a cost approximating the MSP was arrived at. The patient/retail prices were collected in Addis Ababa and Benishangul Gumuz Regional State and the remaining fees were collected from Addis Ababa.

Exit interview

These involved the use of structured. Thirty clients from each of the three randomly selected facilities were interviewed in Addis Ababa and Benishangul Gumuz Regional State.

The interview focused on the clients' socio-demographic characteristics (age, sex, marital status, educational, employment status and occupation), and also in order to cross check their purchasing power, the interview included the household expenditure that is used as an indirect estimation of the household income. At the end of the interview the respondents were asked about the affordability of the prescribed drugs bought from the facility.

Key informants interview

The principal investigator did the key informants interview from Drug Administration and Control Authority(DACA), Federal Ministry of Health(FMOH), PFSA and Customs Authority in order to gather information on the national pharmaceutical sector, import tariffs on finished products, including exemptions for particular products financial charges incurred in importing pharmaceuticals, such as charges for letters of credit at the central bank or charges for foreign currency transactions; policies on taxes levied on medicines along the supply chain.

4.7. Study variables

Independent variables

Sex, age, level of education, marital status, employment, occupation, tax, import duties, whole sellers mark up, retailer mark up, percentage contribution of each add-on cost, procurement cost.

Dependent variables

- ✓ Medicine price at the retail value
- ✓ Availability of Essential medicines
- ✓ Affordability of essential medicines

4.8. Data entry, clean up and analysis

The data collected on the medicine price data collection form were entered by data entry clerk into the software International Medicines Price Workbook (v. 3.06). The prices were double entered to ensure accuracy. The Workbook's auto checker was also used to assist in the verification process.

The availability of individual medicines is calculated as the percentage (%) of medicine outlets where the medicine was found. Mean (average) availability is also reported for the overall 'basket' of medicines surveyed.

The Workbook software calculated the median price ratio (MPR) for each medicine type in each sector only if the medicine was available in at least four facilities. The MPR was the comparison of the local median unit price of the medicine with the median unit price in the Management Sciences for Health 2007 Price Indicator Guide (the IRP)(MSH, 2007).

Medicine Price Ratio (MPR) = $\frac{\textit{Median local unit price}}{\textit{International reference unit price}}$

The IRPs are the medians of recent procurement or tender prices offered by predominantly not-for-profit suppliers to developing countries for multi-source products (MSH, 2007). Normally, an MPR of 1 or less is taken as efficient procurement in the public sector (WHO & HAI, 2007).

To assess affordability data was collected on the prices of medicines and exit interview were employed. Ten common diseases from acute and chronic diseases in Ethiopia were selected and the affordability of treatment was computed using the daily wage of the lowest-paid government worker, which has been assessed as Birr 9.674 per day.

After data collection for the exit interview, each questionnaire was checked visually for completeness. The data were entered, cleaned using SPSS version 14.0 statistical software packages for analysis. Frequencies and measures of variation were used to describe the study population in relation to socio-demographic and other relevant variables. The strength of association and statistical significance between independent and dependent variables were assessed using crude odds ratio (with 95% confidence interval and P value). Multiple logistic regression analysis was performed using SPSS version 14.0 statistical software program to control the potential confounding variables.

4.9. Ethical consideration

Health research approval

Approval was obtained from the School of Pharmacy and Addis Ababa Health Research Ethics Review Committees.

Informed consent

The informed written and verbal consent process involved the data collector giving a verbal explanation to each potential participant on the nature of the study, its purpose, the procedures involved and the expected duration. Each potential participant was also informed that participation in the study was voluntary and that he/she could withdraw at any time, and that withdrawal of consent wouldn't affect his /her subsequent treatment or relationship with the facility staff or any other person.

The participants were assured that all information gathered would be treated as confidential and would be accessible only to the researchers, who would be responsible for its safe keeping. The confidentiality of both written and verbal responses was made known to the participants. The participants were also asked not to write their names and identification to assure anonymity.

5. Results

5.1. Availability of medicines on the day of data collection

5.1.1 Addis Ababa

In Addis Ababa, some of the public health facilities provide medicines for free patients only and the others give service both for free and self paid patients. Out of the five public facilities surveyed two facilities which were under the administration of Addis Ababa Health Bureau were giving services for free patients only.

Table 5: Mean availability of medicines on the day of data collection, public, other and private sector retail out lets in Addis Ababa, October 2008.

	Public sector (n = 5 outlets)		Other sector (n=5 outlets)		Private sector (n = 5 outlets)	
	All medicines (n = 27 medicines)		All medicines (n = 27 medicines)		All medicines (n = 27 medicines)	
	Originator brand	Lowest price generic	Originator brand	Lowest price generic	Originator brand	Lowest price generic
Mean availability (standard deviation)	0 % 0 %	71.9% (29.5 %)	14.8 % 19.9 %	76.9% (31.7%)	47.4 % (45.1 %)	85.2 % (26.9 %)

Table 5 shows the average availability of surveyed medicines of the three sectors in Addis Ababa. Generally availability of the lowest priced generics was higher in the private sector (85.2%) followed by the other and public sector with average availability of 76.9% and 71.9% respectively.

When analysis is limited to generic medicines listed on the National EML there were a slight increase for the three sectors studied, from 85.2% to 85.6%, 76.9% to 80% and from 71.9% to 75.2% for private, other and public sectors respectively (Fig 1).

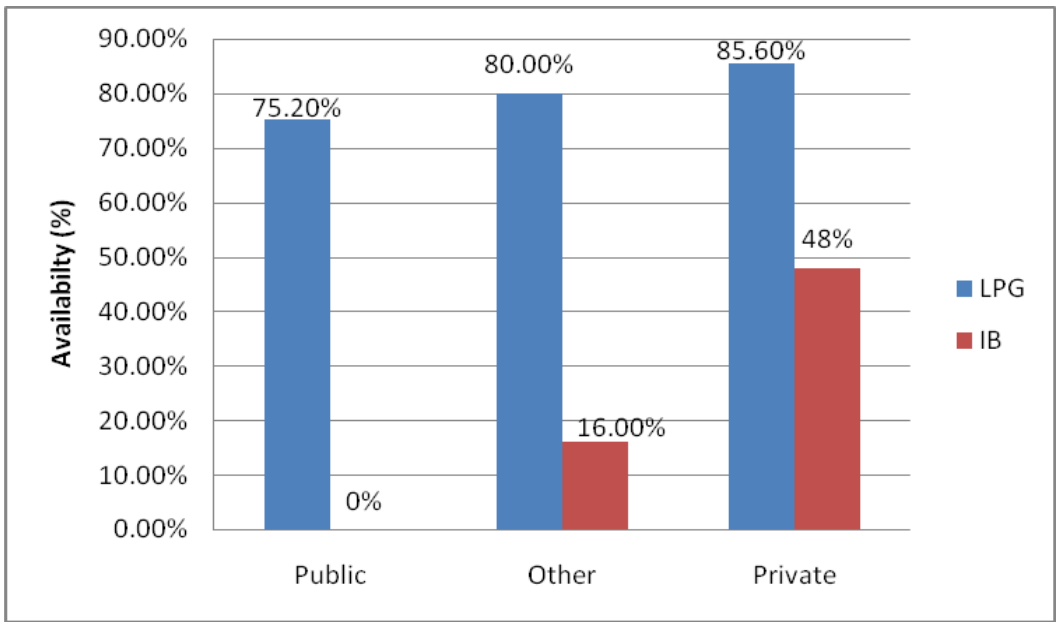

Fig 1: Availability of medicines with in Essential Medicine List in Addis Ababa, October 2008.

In the public sector generics were the only product type available; this is because the public procurement is restricted to generic medicines only. Whereas, in the other and private sector, the innovator brand was hardly available at 14.8% and 47.4% respectively.

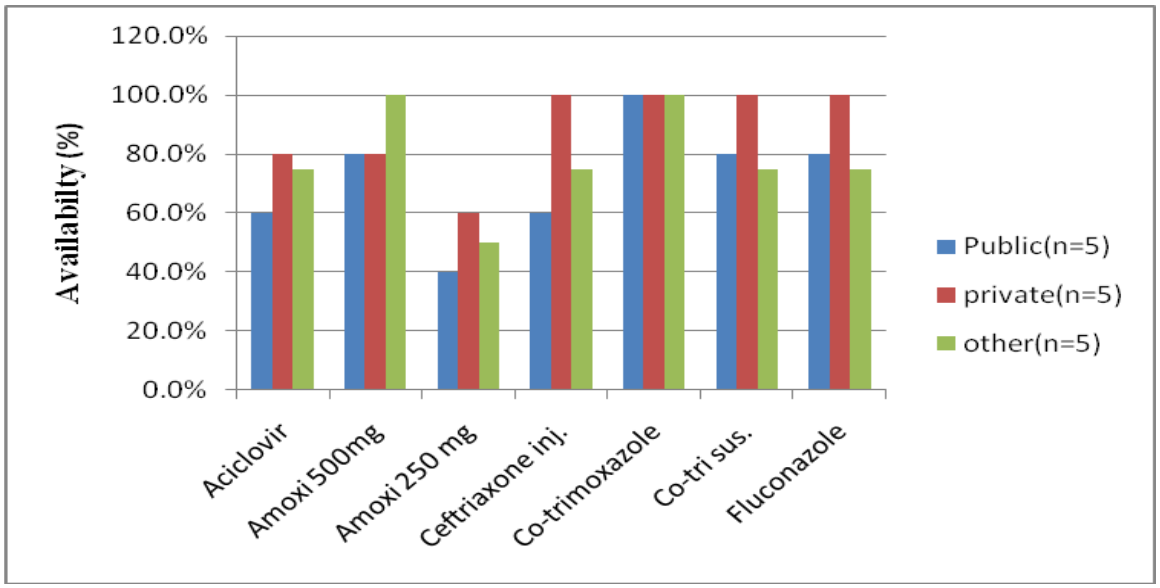

Fig.2: Availability of generic anti-infective drugs in Addis Ababa, October 2008.

When we see the average availability of generic antibiotics and antimicrobials are generally found in more than 60% of the three sectors studied except for Amoxicillin 250 mg (40%) in the public sector, 50% and 60% for other and private sectors respectively but Beclomethasone inhaler used for asthmatic patients was not found in any of the outlets of the public sector (Fig 2).

5.1.2. Benishangul Gumuz

The data for the public sector was collected from Assosa and Pawe hospitals as well as three randomly selected health centers. Five retail outlets from each private and other sector were selected based on their proximity to the public facilities. The public facilities serve both for free and self paying patients.

As shown in table 6; the public sector of Benishangul Gumuz, average availability was very low, and only 46.7% of the generic drugs were available. In the private pharmacies, the average availability of all surveyed medicines was 39.3% for generics and 0.7% for originator brands. In the other sector, only generics were found (43.2 %).

Table 6: Mean availability of medicines on the day of data collection, public, other and private sectors in Benishangul Gumuz, October 2008.

	Public sector (n = 5 outlets)		**Other sector (n=5 outlets)**		**Private sector (n = 5 outlets)**	
	All medicines (n = 27 medicines)		**All medicines (n = 27 medicines)**		**All medicines (n = 27 medicines)**	
	Innovator brand	**Lowest price generic**	**Innovator brand**	**Lowest price generic**	**Innovator brand**	**Lowest price generic**
Mean availability (standard deviation)	0.0% (0.0%)	46.7% (33.7%)	0.0% (0.0%)	43.2% (31.8%)	0.7% (3.8%)	39.3% (39.0%)
Mean availability (standard deviation)	0.0% (0.0%)	46.7% (33.7%)	0.0% (0.0%)	43.2% (31.8%)	0.7% (3.8%)	39.3% (39.0%)

The availability was also found low on the drugs, which are listed in the National EML. In the private sector, mean availability was 40.8% for generics and 0.8% for innovator brands. The average availability of generic medicines in the public and other sector retail outlets were 49.6% and 43.2% respectively (Fig 3).

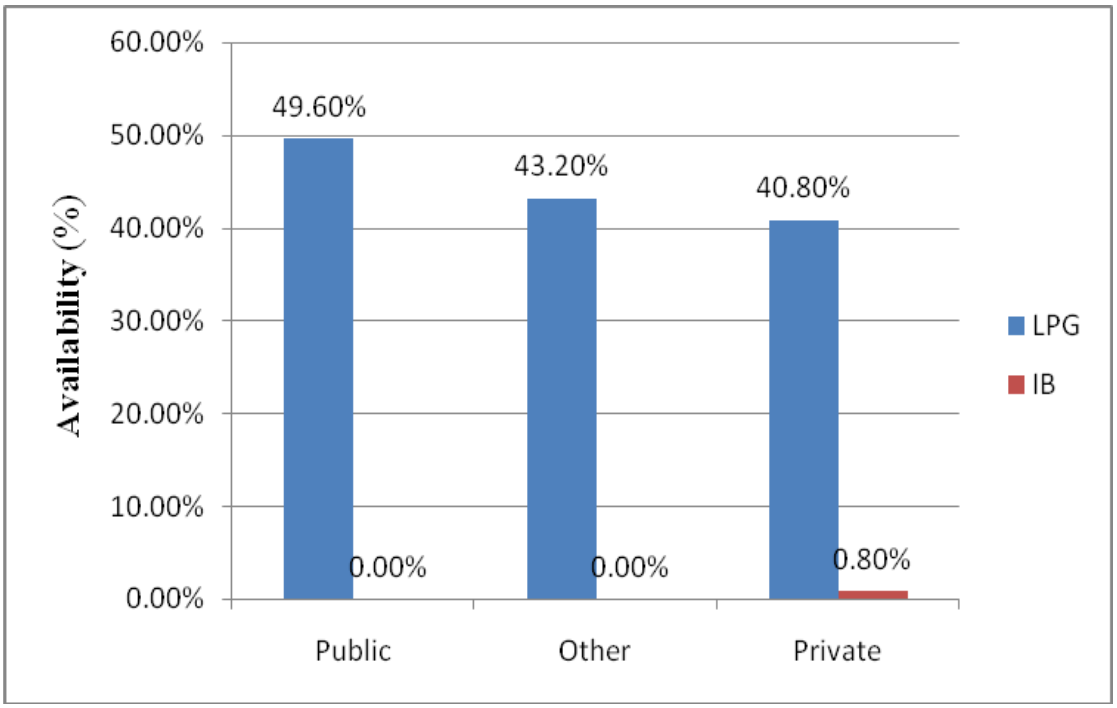

Fig 3: Availability of medicines with in EML of Benishangul Gumuz, October 2008.

5.1.3. Availability of ARV drugs

The availability of ARV drugs in the public facilities of Addis Ababa and Benishangul Gumuz Regional State was 100% both for combination as well as single dose formulations. The ARV drugs provided under free donation schemes were therefore given to patients at no charge.

5.2. Public sector prices

Single order procurement prices were collected from PFSA and its median MPR was calculated. The procurement prices from PFSA were tender prices of 2007. Of the 27 medicines included in the survey, 22 generics were found in the public procurement sector; the public sector is procuring exclusively generic. Based on the median MPR, the public sector is procuring generics at 0.95 times their international reference prices (IRP) or 5% lower than the international price. Thus, the government procurement agency is purchasing efficiently. The inter quartile range shows little variation in median price ratios across individual medicines (0.64, 1.35).

In Addis Ababa out of the five public facilities four offered medicines for free, Therefore in these four facilities, only medicine availability data was collected. For the innovator brands, retail prices were not obtained in both study areas since the public facilities were required to buy from PFSA only. On the other hand, in Benishangul Gumuz regional state the median MPRs of seven lowest price generics were 2.66 with inter quartile range (1.91, 3.32).

6.2.1. Comparison of procurement and retail prices in the public sector of Benishangul Gumuz

In order to compare the procurement price with retail prices, only those medicines found in both public procurement and public sector medicine outlets were included in the analysis. Result shows that retail prices in the public sector are 90.4% higher than procurement prices for generic equivalents.

Out of the medicines found in both public procurement and retail outlets, the retail price is much higher for Mebendazol tablet and Tetracycline eye ointment which is 162% and 457% higher than their procurement price respectively (Fig 4).

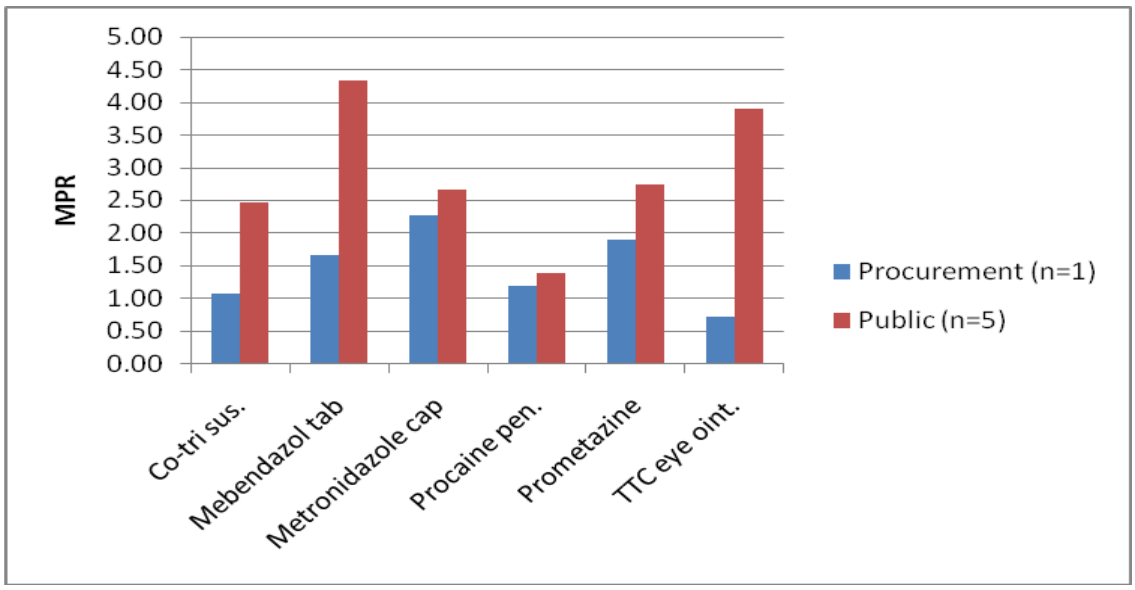

Fig. 4: Procurement and retail prices in the public sector: median price ratio for selected lowest priced generic medicines in Benishangul Gumuz, October 2008.

5.3. Private sector retail prices

As shown in table 7, in the private sector originator brand medicines are generally sold at 27.47 times their international reference price. Half of the originator brand medicines were priced at 16.37 (25th percentile) to 39.42 (75th percentile) times their international reference price in Addis Ababa. There is, therefore, higher variation in MPRs across individual originator brand medicines in the private sector of Addis Ababa and originator brand medicines were not found in Benishangul Gumuz Regional State.

The lowest price generic medicines are generally sold at 2.71 and 3.68 times their international reference price in Addis Ababa and Benishangul Gumuz respectively. Half of the lowest priced generic medicines were priced at 1.68 (25th percentile) to 4.25 (75th percentile) times their international reference price in Addis Ababa and 2.16 (25th percentile) to 6.64 (75th percentile) in Benishangul Gumuz.

Among the lowest price generic medicines; Clotrimazole topical cream (MPR = 29.89 and 23.85) and Tetracycline eye ointment (MPR = 8.86 and 7.09) were several times higher than their international reference prices in Benishangul Gumuz and Addis Ababa respectively.

Table 7: Ratio of median unit price to IRP in the private sector of Addis Ababa and Benishangul Gumuz, October 2008.

Region	Product type	Median MPR	25 % ile	75 % ile
Addis Ababa	Innovator brand (n = 11 medicines)	27.47	16.37	39.42
	Lowest price generic (n =22 medicines)	2.71	1.68	4.25
Benishangul Gumuz	Innovator brand (n = 0 medicines)	NF*	NF	NF
	Lowest price generic (n = 8 medicines)	3.68	2.16	6.64

*NF Data was not found

5.3.1. Brand premium among the private sector in Addis Ababa

As shown in table 8, only those medicines, for which both (n=9) the originator brand and a generically equivalent product were found, were included in the analysis to allow for the comparison of prices between the two product types. Results show that in the private sector, originator brands cost 15.2 times more, on average, than their generic equivalents. Thus, patients are paying substantially more to purchase originator brand medicines when lower-cost generics are available.

Table 8: Comparison of the prices of originator brands and generically equivalent products: in Addis Ababa, October 2008.

Type (n = 9 medicines)	Median MPR	25 %ile	75 %ile
Originator brand	29.35	23.93	40.5
Lowest price generic	1.92	1.42	3.38

5.4. Other sector retail prices

The results below in table 9 show that in the other sector innovator brand medicines were not found both in Addis Ababa and Benishangul Gumuz. The lowest price generic medicines are generally sold at 2.52 and 4.9 times their international reference price in Addis Ababa and Benishangul Gumuz respectively. Half of the lowest priced generic medicines were priced at 1.58 (25^{th} percentile) to 3.24 (75^{th} percentile) times their international reference price in Addis Ababa 3.10 (25^{th} percentile) to 10.85 (75^{th} percentile) in Benishangul Gumuz.

Table 9: Ratio of median unit price to IRP in the other sector of Addis Ababa and Benishangul Gumuz, October 2008.

Region	Product type	Median MPR	25 %ile	75 %ile
Addis Ababa	Innovator brand (n =0medicines)	NF*	NF	NF
	Lowest price generic (n = 13 medicines)	2.52	1.58	3.24
Benishangul Gumuz	Innovator brand (n = 0 medicines)	NF	NF	NF
	Lowest price generic (n = 4 medicines)	4.9	3.1	10.85

* NF Not found

5.5. Comparison of individual medicines prices

Table 10 and Fig. 5 illustrate that from the generic products, lowest price generic Omeprazole had the lowest median price ratio in all sectors (MPR= 0.70 in public health facilities, 0.72 in other sector outlets and 0.78 in the private pharmacies) while Clotrimazole topical cream had the highest median price (MPR=27.85) and (MPR=24.87) when sold in the private pharmacies and other sector respectively.

From among all the generic products sold in the public health facilities, metronidazole 250 mg capsule (which is a locally manufactured generic product) had a median price 4.83 times its international reference price.

Table 10: Median MPRs of some commonly used medicines in three sectors of Addis Ababa and Benishangul Gumuz ,October 2008.

Medicine name	**Innovator brand**	**Lowest priced generic**		
	Addis Ababa	**BG**	**Addis Ababa**	
	Private	Public	Other	Private
Clotrimazole topical cr.	170.97		24.87	27.85
Cotrimoxazole tab.	40.5	2.18	1.64	2.18
Diclofenac tab.	116.3	2.25	2.25	3.38
Methyldopa tab		1.08	1.7	1.61
Metronidazole cap		2.78	3.44	4.83
Omeprazole cap	38.34	0.70	0.72	0.78
Procaine penicillin inj.		1.27	1.28	2.11
Ranitidine tab	27.47		1.00	1.3
Salbutamol inhaler			0.70	1.04
TTC eye oint.		3.9	4.79	7.53

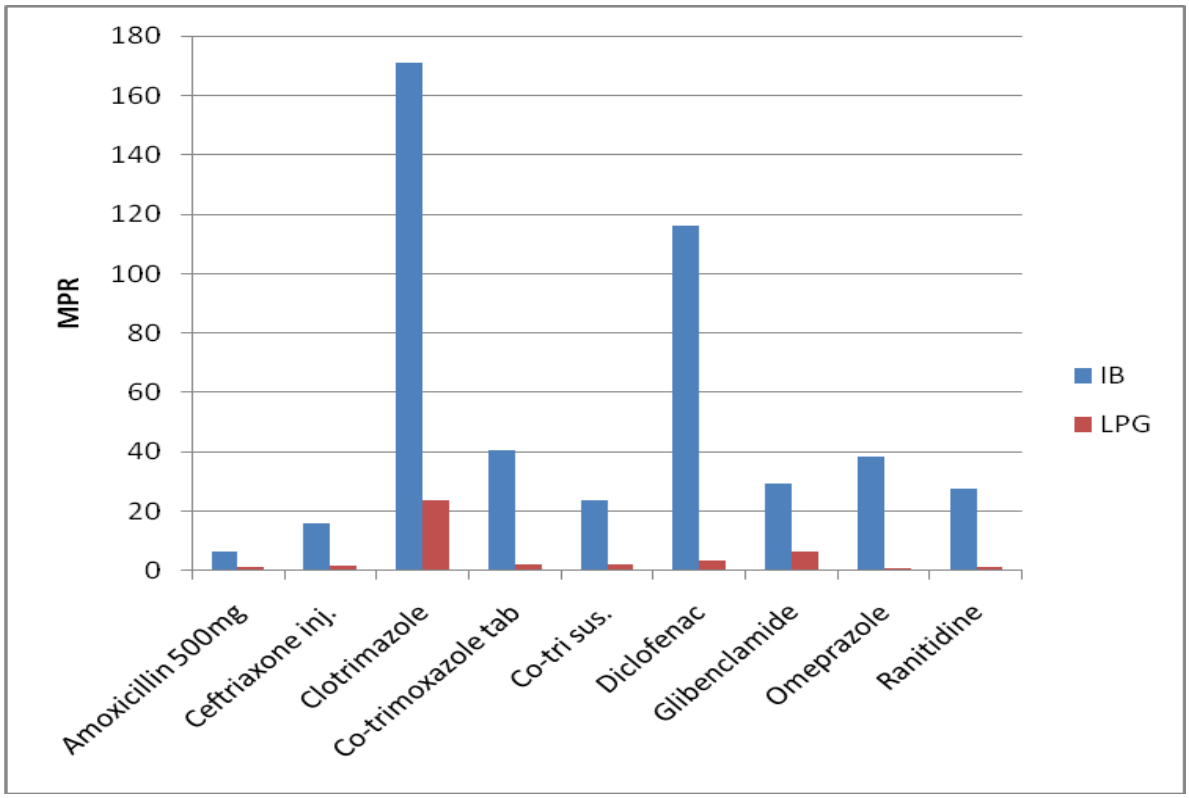

Fig. 5: Median price ratios for selected medicines, innovator brand and generic equivalents, private sector of Addis Ababa, October 2008.

Innovator brand products generally have high median price ratios. For example, Clotrimazole topical cream and Diclofenac 50 mg tablet in the private pharmacies had the highest median price ratio among the innovator brand products and their median price is nearly 170 and 116 times its international reference price (MPR=170.97 and MPR=116.3) respectively. Compared to the price of its generic equivalent in the private pharmacies, innovator brand Diclofenac 50 mg tablet was 103 times that of the lowest price generic equivalent (MPR =3.38).

5.6. Comparison of retail prices in the public, other and private sectors

As shown in table 11, only those medicines found in both sector medicine outlets were included in the analysis to allow for the comparison of prices between the two sectors. Since the public facilities in Addis Ababa provide medicines for free data were not found for the patient price. So the comparison in Addis Ababa is limited to the percentage difference between other and private sectors only.

Table 11: Retail prices of lowest generic medicines in the public, other and private sectors of Addis Ababa and Benishangul Gumuz, October 2008.

Region	Type of medicine	% difference Private To Public	% difference other to Public	% difference Other to Private
Addis Ababa	Lowest price generic	NF*	NF	-25.4% (n=13 medicines)
Benishangul Gumuz	Lowest price generic	81.8% (n=5 medicines)	91.7% (n=2 medicines)	39.7% (n=4 medicines)

*NF Data were not found

In the private pharmacies of Addis Ababa, retail prices were 25.4 % above retail prices in other sector outlets with respect to lowest price generics. In Benishangul Gumuz, the retail prices of the LPG in private pharmacies were 81.8% and 39.7% above the retail prices in public health facilities and other sectors respectively. In addition to that, retail prices in the other sector were 91.7% above to that of public health facilities (Table 11).

5.7. Affordability of treatment

5.7.1. Affordability to standard treatment regimens

The affordability of treatment for ten and five common conditions in Addis Ababa and Benishangul Gumuz respectively, was estimated as the number of days' wages of the lowest-paid unskilled government worker needed to purchase medicines prescribed in a standard dose. For acute conditions, treatment duration was defined as a full course of therapy, while for chronic diseases, the affordability of a 30-days' supply of medicines was determined. The daily wage of the lowest-paid unskilled government worker used in the analysis was 9.674 ETB.

As medicines are provided free in the public sector of Addis Ababa, affordability has been assessed for the private and other sector only. A one-month treatment of IB ranitidine (150 mg twice daily) for peptic ulcer required 39.3 days' wages, while its LPG cost 1.8 days' wages when purchased from private pharmacies of Addis Ababa. IB omeprazole (20 mg daily) cost 49.8 days' wages for a one-month treatment, while its generic cost about a day's salary.

To buy Amoxicillin 500mg (21 capsules), the patient had to pay 1.4 and 1.5 days' wages in private pharmacies, while 1.1 and 1.2 days' in other sector of Addis Ababa and Benishangul Gumuz respectively. In addition to that purchasing brand Amoxicillin cost about 6.3 days' wages in the private sector of Addis Ababa.

The one month treatment at Addis Ababa for IB Diclofenac (50 mg twice daily) cost about 32 days' wages at private, while the LPG cost 1.2 days' wages in the other sector. In the private pharmacies of Addis Ababa Patients had to pay 6.8 days' salary to buy the IB glibenclamide, while for generic products they had to spend 1.6 days' salary. On the other hand, the patient at Benishangul Gumuz had to pay about 2 day's salary at the private sector.

Table 12: Number of days' wages of the lowest paid government worker needed to purchase standard treatments in Addis Ababa, October 2008.

Disease condition and 'standard' treatment			Day's wages to pay for treatment		
Condition	Drug name, strength, dosage form	Treatment schedule	Lowest price generic		Innovator brand
			Other sector	private sector	private sector
Asthma	Salbutamol 100 mcg/dose inhaler	1 inhaler of 200 doses	NF	2	NF
Diabetes	Glibenclamide 5 mg cap/tab	1 tab x 2 x 30 days = 60	0.7	1.6	6.8
Hypertension	Methyldopa 250 mg cap/tab	1 tab x 30 days = 30	1.4	1.3	NF
	Hydrochlothiazide 25 mg cap/tab	1 tab x 2 x 30 days = 60	1.6	1.9	NF
Depression	Amitriptyline 25 mg cap/tab	1 tab x 3 for 30 days = 90	2	3.5	NF
Pediatric respiratory infection	Co-trimoxazole 8+40 mg/ml suspension	5ml twice a day for 7 days = 70 ml	0.5	0.6	6.8
Adult respiratory infection	Amoxicillin 500mg cap/tab	1 cap x 3 for 7 days = 21	1.1	1.4	6.3
	Ceftriaxone 1 g/vial injection	1 vial	NF	1.5	14.7
Arthritis	Diclofenac 50mg cap/tab	1 tab x 2 x 30 days = 60	1.2	0.9	32
Ulcer	Ranitidine 150 mg Cap/tab	1 tab x 2 x 30 days = 60	1.8	1.8	39.3
	Omeprazole 20mg cap/tab	1 cap x 30 days = 30	1.2	0.9	49.8

While treatment of pediatric respiratory infection was the most affordable in all the sectors of Addis Ababa and Benishangul Gumuz as it takes less than a day's wage to treat (Table 12 and 13), the treatment of Depression with Amitriptyline was the least affordable requiring 3.5 days' wages for the full course of treatment (one month) when purchased from the private pharmacy of Addis Ababa.

Table 13: Number of days' wages of the lowest paid government worker needed to purchase standard treatments in Benishangul Gumuz, October 2008.

Disease condition and 'standard' treatment			Day's wages to pay for treatment		
Condition	Drug name, strength, dosage form	Treatment schedule	Lowest price generic		
			Other	private	public
Diabetes	Glibenclamide 5 mg cap/tab	1 tab x 2 x 30 days = 60	1.6	1.9	1.0
Hypertension	Methyldopa 250 mg cap/tab	1 tab x 30 days = 30	1.2	1.4	0.9
Pediatric respiratory infection	Co-trimoxazole 8+40 mg/ml suspension	5ml twice a day for 7 days = 70 ml	NF	0.6	0.5
Adult respiratory infection	Amoxicillin 500mg cap/tab	1 cap x 3 for 7 days = 21	1.2	1.5	1.1
Ulcer	Omeprazole 20mg cap/tab	1 cap x 30 days = 30	0.6	1.9	0.9

Generic Omeprazole is 3.3 times more affordable in other sector than private pharmacies in Benishangul Gumuz. Treatment with generic Omeprazole is about 2700% less expensive than the innovator brand of the same product for a month's course of therapy in Addis Ababa. This means that a worker would need to work additional 48 days to be able to afford the innovator brand of the same medicine.

As shown in fig 6, if we assume a family where the father has diabetes, the mother has ulcer and the child has respiratory tract infection. The lowest-paid government worker had to pay a total treatment cost of 2.4 and 4.4 days' wages in the public and private sector of Benishangul Gumuz respectively, while the total treatment cost 3.1 days' salary in the private sector of Addis Ababa. If innovator brands are purchased, treatment costs would raise to 63.6 days' salary.

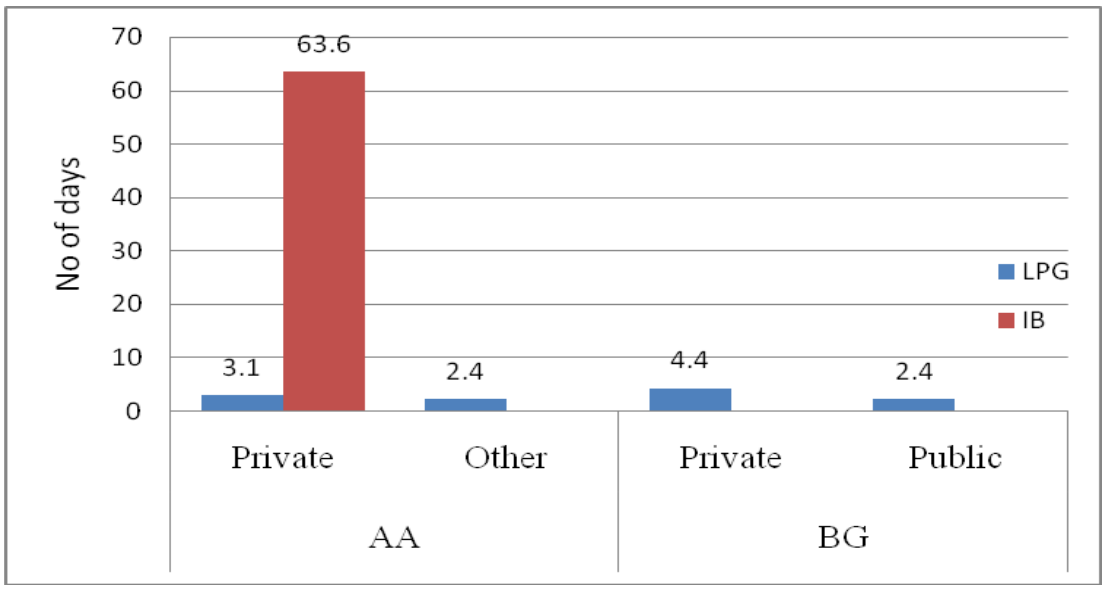

Fig 6: Treatment cost of a combination of ARI, ulcer, and diabetes mellitus in a family using LPG and IB, October 2008.

5.7.2. Reported socio-demographic characteristics of exit interview respondents

The total sample size taken from the five facilities in Addis Ababa and Benishangul Gumuz was 150. Out of these, 140(93.3%) household heads and 10(6.7%) adult household members responded for the questionnaire. Around 97 (64.7%) were males and 53 (35.3%) of them were females. As shown in table 14, the mean age of the respondents was 37.2 years (SD of 11.8 and Range of 20 – 72 years). The majority of the respondents were married and 53.3% of them were self employed. More than 85% of the study population can at least read and write. The average family size per household was 4.8 (SD of 2.6, Range of 1-18).

The average estimated monthly income of the 143 respondents, who were willing to report their income(n=143), was 828.53 ETB and the median was 721 ETB. Twenty five percent of the respondents had income less than 500 ETB and 75% earn less than 1108 ETB. The average total household expenditure was 902.2 ETB and the first quartile lies at 556.9 ETB and the third quartile at 1113 ETB.

Table 14: Socio-demographic characteristics of exit interview participants, Addis Ababa and Benishangul Gumuz, October 2008.

Socio-Demographic characteristics	Frequency	%
Age group (n=150)		
<25	14	9.3
25-40	77	51.3
>40	59	39.3
Residence (n=150)		
Urban	99	66
Rural	51	34
Educational status (n=150)		
Illiterate	20	11.3
Can read and write	13	8.7
1-6	20	11.3
7-12	65	41.3
College and above	32	21.3
Occupation (n=150)		
Government employee	37	24.7
Private organization employee	22	14.7
Self employed	83	55.3
Unemployed	2	1.3
Others*	6	4
Marital status(n=150)		
Single	46	30.7
Married	102	68
Divorced	1	0.7
Widowed	1	0.7
Family size (n=150)		
<3	79	52.7
3-6	43	28.7
>6	28	18.7
Households own (n=150*)*		
Radio	133	88.7
Electricity	100	66.7
Tap water	88	58.7
Television	79	52.7
Monthly Income(n=143)		
<500	31	20.7
500-1000	67	44.7
>1000	45	30
Affordability of treatment (n=150)		
Yes	91	60.7
No	59	39.3

Regarding possession of the households, the majority of the Respondents (60.9%) live in their own home, 133 (88.7%), 88 (58.7%), 100 (66.7%) and 79 (52.7%) of the households posses radio, tap water, electricity and television, respectively.

In Benishangul Gumuz, the commonest agricultural products on the area are maize (70.7%), Sorghum (52.6%) and Nug (46.3%). The mean amount of Maize and Sorghum produced per household was 4.3 and 5.5 Quintal respectively. On average, the households own 3.2, 2.9, 4.4 and 6.0 cattle, sheep, goat and hen respectively.

5.7.3. Factors affecting ability to pay for treatment

Exit interview was done on average monthly income, out of pocket expenditure and different socio-demographic characteristics. Therefore, it was tried to asses which factors are influencing individual's ability to pay for the prescribed medicines. Different socio demographic and economic related variables were entered in stepwise regression. As can be seen in Table 15, type of the facility was found as an explanatory variable for client's ability to pay. Respondents from Benishangul governmental hospital were 6.2 times more likely able to pay and also other sectors of Benishangul and Addis Ababa were 3.8 and 6.5 times more likely able to pay for the prescribed medicines as compared to the private sector of Addis Ababa respectively (P- values of 0.002, 0.015 & 0.001 respectively).

Residence was also identified as a factor that has an effect on ability to pay for the prescribed medicines. Respondents who reside in rural area was 0.425 times less likely able to pay for the prescribed as compared to urban dwellers (p- value=0.015).

Educational status of the head of the household was also found to be associated with their ability to pay. People who are 1-6 grades were 3.5 times and those who finished high school were 16.3 times more likely able to pay than illiterate once. This was statistically significant at p value of 0.000 and 0.014 respectively ($p<0.01$).

Table 15: The ability to pay characteristics of exit interview participants, Addis Ababa and Benishangul Gumuz, October 2008.

Variables	Frequency	P-value	Crude OR (95% CI)	Adjusted OR (95% CI)
Type of organization				
♦ Private Addis	29	.002	1.00	
♦ Private BG	30	.342	1.663 (.582-4.747)	
♦ Other Addis	31	.001	6.514 (2.087-20.329)	**
♦ Other BG	30	.015	3.800 (1.293-11.70)	
♦ Governmental BG	30	.002	6.243(1.994-19.542)	
Residence				
♦ Urban	99		1.00	**
♦ Rural	51	.015	.425 (.292-.849)	
HH has Electricity				
♦ Yes	100	.026	2.199 (1.099-4.402)	**
♦ No	50		1.00	
Education				
♦ Illiterate	20	.005	1.00	
♦ Informal education	13	.176	2.722 (.638-11.61)	
♦ 1-6	20	.061	3.500(.945-12.966)	**
♦ 7-12	65	.030	3.284(1.120-9.633)	
♦ >12	32	.000	16.333(3.954-67.473)	
Average HH Income				
♦ <500	31	.000	1.00	
♦ 500-1000	67	.000	29.659(6.481-135.732)	42.729(3.263,559.587) .004*
♦ >1000	45	.000	67.062(13.219-340.21)	41.646(2.095,827.873) .014*
Average HH Expenditure				
♦ <500	32	.000	1.00	
♦ 500-1000	69	.000	13.125(4.119-41.821)	**
♦ >1000	49	.000	42.000(11.239-156.95)	
Amount of payment				
♦ <10	36		1.00	
♦ >10	114	.000	0.094(.027-.325)	0.028(0.002, 0.358) .006*

*P value

** This was not significant after controlling confounding factors

The monthly income of the respondents was also associated with their ability to pay. As compared to those respondents with income <500 Birr, those with income 500-1000 were almost 29 times and those with income >1000 were 67 times more likely able to pay for the prescribed medicines at P values of 0.000. This factor was even found to be significant after controlling for potential confounders like educational status of the head of the house hold, amount of payment for the prescribed medicines and type of facility (adjusted OR=42.72 and 41.646, p-values=0.004 and 0.014 respectively).The amount of payment for the prescribed medicines had also shown an impact on the affordability.

Average household monthly expenditure was found as a predictor for client's ability to pay for the prescribed medicines. Respondents with average monthly expenditure of more than 1000 ETB were 42 times and those with average monthly expenditure 500-1000 were 13 times more likely able to afford as compared to those whose monthly expenditure less than 500 ETB ($p < 0.01$) (Table 15).

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5.8. Component cost of medicines

The final price paid for a medicine whether by the government or a patient reflects the manufacturers selling price plus all the intervening price additions. These additions include the cost of importing, distributing and dispensing the medicine. The results from key informant interview show that there is no ceiling set by law on the wholesale and retail mark-ups in the country. However, generally PFSA charges 20-40% wholesale mark-up on imported medicines and 5-10% on locally manufactured products.

As shown in fig 7, the private sector of Addis Ababa, for a locally produced product, the manufacturer's selling price represents around 72% of the final patient price. The wholesaler and retailer mark-ups on the average account for 11% and 17% of the patient price respectively. Whereas, in Benishangul Gumuz for the same locally produced product; the manufacturer's selling price represents around 63% of the final patient price. Similarly the wholesaler and retailer mark-ups account for 16% and 21 % of the patient price respectively.

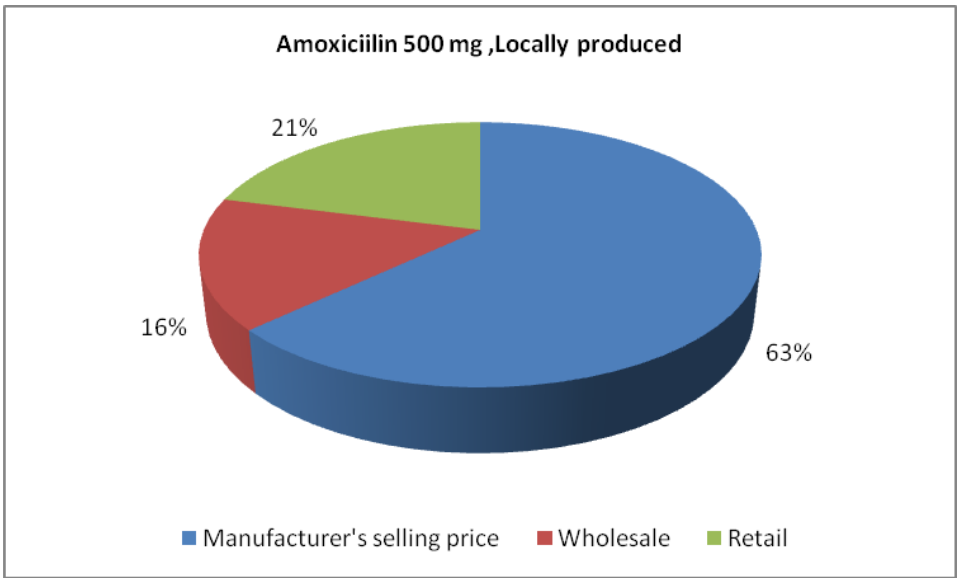

Fig 7: Percentage contribution of price components to final price in the private sector of Addis Ababa, October 2008.

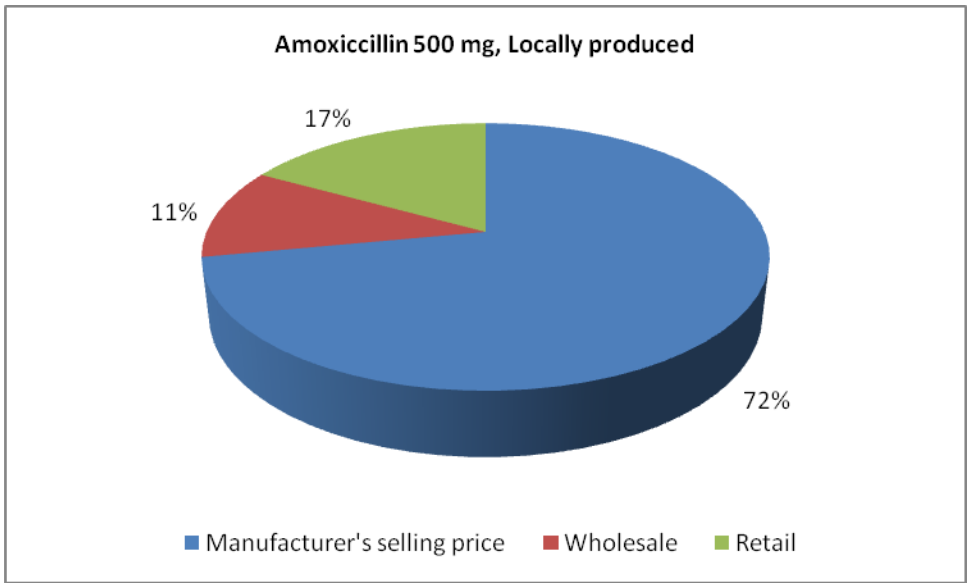

Fig 8: Percentage contribution of price components to final price in the private sector of Benishangul Gumuz, October 2008.

For an imported generic medicine, the cost price in the public sector of Benishangul Gumuz represents 20% of the final price with wholesale and retail mark-ups accounting for 7% and

71% respectively. Handling cost and import tariff represent each1% of the final price charged to patients (Fig 10). But this is not the case when we see the proportions of the cumulative mark up of the CIF; the import tariff represents 5% of the CIF with retail mark- up accounting 247.5 % of the whole seller price (Fig 9).

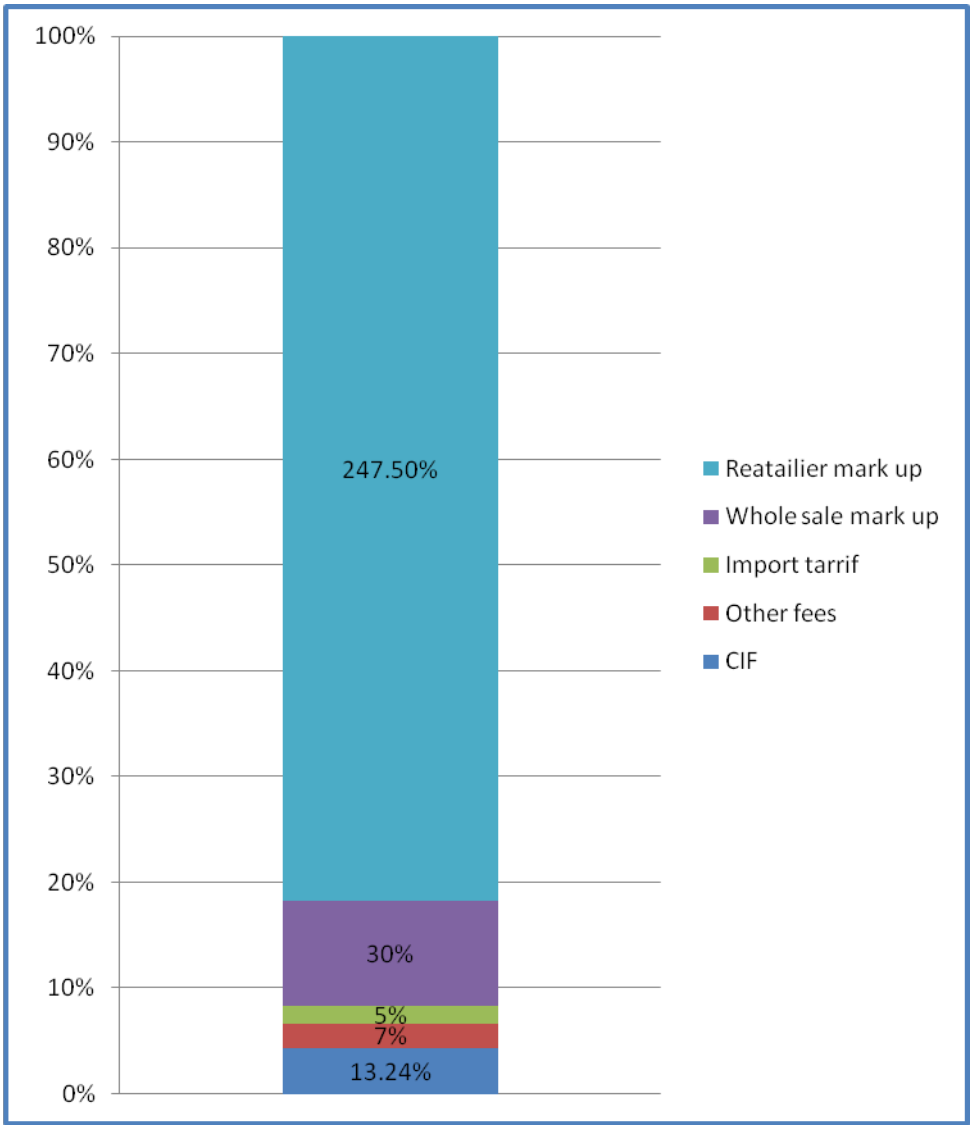

Fig 9: Proportions of cumulative mark up on the CIF price of imported generic medicine of public sector in Benishangul Gumuz, October 2008.

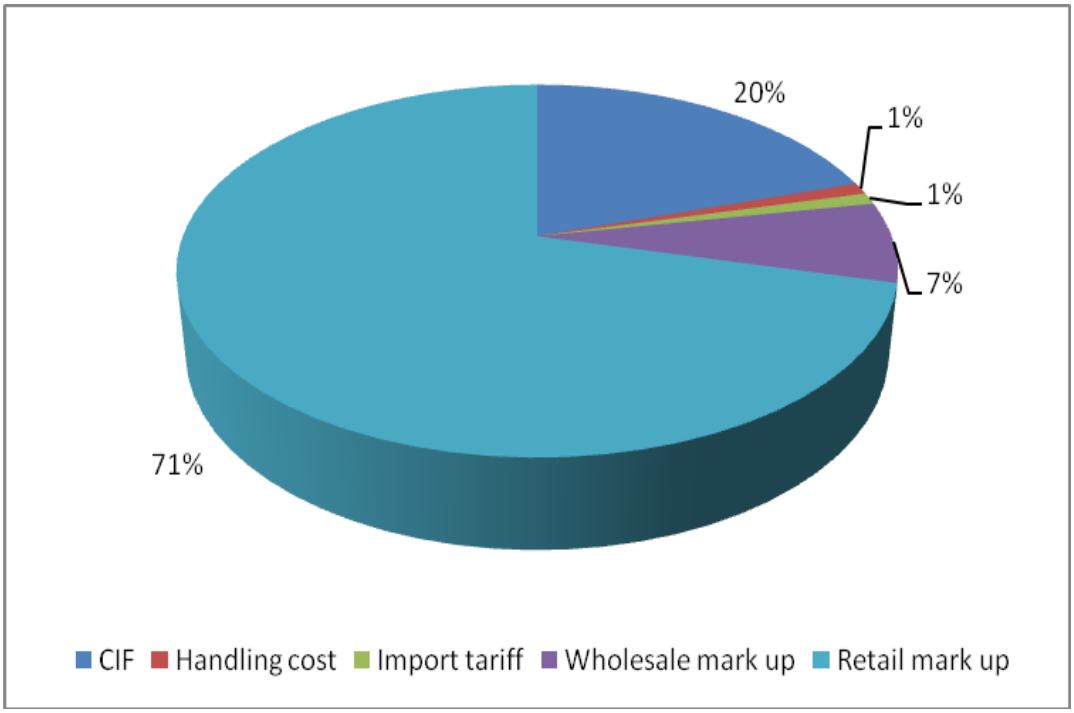

Fig 10: Percentage contribution of price components of imported generic medicine to final Price in Benishangul Gumuz, October 2008.

6. Discussion

In Ethiopia, public procurement prices are relatively efficient, as shown by purchase prices with MPR of 0.95, that is 5% lower than the international reference prices. Although the majority of medicines procured fell below the International Reference Prices, the fact that some items were much higher than the IRP indicated some inconsistencies in the procurement process. For example the procurement prices for clotrimazole topical cream and metronidazole capsule were 6.6 and 2.3 times higher than the international market respectively.

Even though Ethiopia is purchasing below the international price but a little bit higher when compared to other East African countries with MPR (of) 0.55 and 0.67 for Kenya and Tanzania respectively (WHO, 2006).The price of most locally produced products were higher than the IRP; this is because the public procurement agency (PFSA) gives an incentive of 10-15% trade off to local manufacturers.

The innovator products were not found in public procurement sector. The non-availability of this brand of innovator brand products in the public procurement sector is due to the fact that the procurement of medicines is governed by the National Essential Medicine list and standard treatment guidelines where only generic medicines are encouraged.

The finding of the present study found very large differences in the prices of the same generic product between the three sectors surveyed and also between the innovator brand and their generic equivalents.

There were also significant inter-regional differences within the private sector for the same medicine, with prices in Benishangul Gumuz being often most expensive, the median of median prices of lowest price generic products were almost three times and four times in Addis Ababa and Benishangul Gumuz respectively; above the international reference prices

which is a little above the WHO/HAI recommendation that is two times above the international price (WHO & HAI, 2007).

Measured in comparison with international reference prices, private retail prices of Addis Ababa for the innovator brands were a median of 27.47 times the international reference prices, which is higher when compared with the previous study of Ethiopia and Kenya with MPR of 13.51 and 17.75 respectively(FMOH, 2005; HAI , 2007).

The present study also revealed that innovator brands were on average 15.2 times more expensive than their generic equivalents. The result is much higher when compared with that of Kenya (4.9 times) and Ghana (3.74 times) (HAI, 2007; HAI 2006).

Retail prices for lowest price generic medicines in the public sector of Benishangul Gumuz were very high in terms of international pricing(MPR=2.66). This result was also compared with Tanzania and Kenya as these countries have shown efficient procurement and pricing. In the public sector of Tanzania, a median MPR 1.1 has been observed (HAI, 2007). A similar situation was found in Kenya, where a median MPR of 1.65 was noted for lowest price generics (HAI, 2007).

In the public sector of Benishangul Gumuz, retail prices were 81.8% and 91.72% lower than retail prices in the private and other sector outlets with respect to lowest price generics respectively. These results show that patients are paying significantly more for medicines in the private sector than in the public sector. Given the low availability in the public sector, this is a cause for concern.

Generally, the availability of medicines in the public sector was very low with the average availability of 46.7% and 71.9% in Benishangul Gumuz and Addis Ababa respectively. The result of Kenya (65%), Tanzania (47%) and Uganda (55%) shows a similar out put as compared to the present study (HAI, 2007).

The low availability of medicines at public sector could have direct implications on access, as patients are then forced to buy these medicines from private pharmacies or other sector. Due to non availability of many drugs, many patients now dig deep into their pockets to pay for medicines (Zulkefli, 2006) .Better availability in the public sector would put pressure on private sector to lower generic prices.

Measured in terms of affordability, the daily wage of the lowest-paid government worker is used to estimate treatment affordability. At the time of the survey, the lowest paid unskilled government worker earned 9.674 ETB (US$ 0.98) per day. According to the World Development Report 2005, 77.8% of the population of Ethiopia lives on less than US$ 2 per day and 23% on less than US$ 1 per day (World Bank, 2006).

A substantial proportion of the population earns less than the salary of the lowest paid government worker and hence the affordability for many Ethiopians will be lower than what is presented for this worker Further, the cost to the patient varied considerably depending on whether the patient sought treatment in the public, other or private sector; and whether the patient was prescribed the innovator brand or the generic equivalent.

Overall, medicines were found to be unaffordable to a large proportion of the population; purchasing treatments for chronic conditions was found to require many more days' work than purchasing treatments for acute conditions. In the private sector of Addis Ababa, the majority of treatments cost more than the daily wage of the lowest paid government worker when lowest price generics are used. The treatment of peptic ulcer using ranitidine for a month would need to spend 1.8 days when generics are used. If originator brand omeprazole is prescribed and dispensed, the lowest paid government worker would need to spend 49.8 days' wages to purchase medicines from the private sector.

The burden is especially great for a family needing treatment for several conditions at the same time, e.g. using the lowest priced generic medicines, it would take at least 3.1 days' wages for the lowest paid unskilled government worker to purchase a medicines for a child

with acute respiratory infection, an adult with diabetes and an adult with a peptic ulcer; treatment with innovator brand medicines would require 63.6 days' salary for a months treatment – clearly unaffordable in both cases.

In this study of the exit interview, the average estimated monthly household income was birr 828.5 with standard deviation of 542.57.This average household income was higher when comparing with other studies done in Arbaminch was 132 birr (Frehywot, 2006) and that of North Gonder was birr 398(Habtamu, 2007).

The study revealed that around 61% of the respondents were able to buy for the prescribed medicines. This finding is higher than the study done in Malaysia, where 51% of the respondents were able to pay for the necessary medicines (Zaheer and Izham, 2003). This was explained by the reason that since health improvement measures tend to be relatively more beneficial to low-income groups, poor people tend to spend as equal amount as those with better economic status to improve their health status(Stina and Tore, 2001).

Several important factors seem to explain the affordability of respondents for the prescribed medicines during the crude analysis. However, some of the variables turned to have no association during the multivariate analysis. Most important predictors found in this particular study to have significant association with ability to pay for the prescribed medicines during the adjusted analysis were, type of facility(whether governmental or private), educational status of the head of the household, amount of payment for the prescribed medicines and estimated average income of the household. Being average household income >500 ETB and educational status >12 were more likely able to pay for the treatment.

The household income, consumption and expenditure survey conducted in 2004/05 by the Central Statistical Authority of Ethiopia (CSA, 2007) indicates that only 0.73 % of the total household income is spent on health and medical treatment. This is lower than half of the one day's wage of a lowest paid government employee. But, it is important to note that this one

day's wage is not meant to cover the cost of medicines only. In other words, the portion of monthly income of the lowest paid government employee that can be spent on medicines alone is much less than his/her one day's wage. When above parameters considered together show that cost of treatment for common diseases seem to be unaffordable to the majority of the population in Ethiopia.

Prices of medicines are determined by a combination of variables, including government policy, degree of competition in the public and private markets, health system capacity, intellectual property protection, non-tariff barriers and import tariffs. Also, the cost of medicines incorporates several added costs prior to reaching patients and includes the base prices (i.e. its price as sold from the manufacturer) as well as all costs for transportation, storage, import tariffs and taxes, wholesale and retail mark-ups, staff salaries, stock losses and procurement practices. These hidden costs can be often more than double the manufacturer's price (Perez-Casas et al., 2001). In order to reduce costs, stakeholders in the health sector need to understand what the hidden cost components are and how they affect the total cost.

The present study demonstrated add-on costs had a substantial impact on medicine prices in all sectors in Ethiopia. In retail pharmacies, actual markups of 25%–247% were found for generics, and 25%–55% for innovators. In Kenya, the private retail sector (for imported medicine) had a wholesale markup of 15%–30% and a maximum retailer markup of 20%–33%.While the retailer's markup is 15%–25% (HAI, 2007). In Brazil, the private retailer's markup was around 27% (HAI, 2006). In Nigeria a retailer margin of 30% was found for generic cotrimoxazole suspension (HAI, 2006) much lower than the present study of Benishangul Gumuz (247.5%).

Generally, high markups along the supply chain drive up prices and make medicines less affordable; therefore prices of medicines can be lowered substantially by reducing the markups. Components analysis indicated high MPRs on the costliest IBs, principally reflecting high manufacturers' prices.

The IB prices remain unaffected even in the presence of generic competition because they are being sold with progressive profits to the manufacturers, distributors, and retailers. Generics are more affordable than IBs, and they could be even more so if markups were restricted and there were incentives to encourage increased use of generics.

Medicine price determination is a complex process, and most national markets are highly segmented with different procedures applying in different sectors and to different medicines. ‘‘Free markets’’ do not apply with medicines under patent, as these by definition confer a degree of market exclusivity to the manufacturer. Manufacturers frequently set different prices in different markets even within the same country (Babar et al., 2007).

In Ethiopia, for IB medicines, generally the conditions for a properly functioning market are not met, as there is a supplier monopoly for these particular medicines. The actual situation in Ethiopia differs from sector to sector as well as by type of medicine. Branded generics, the most numerous generics, are more akin to other branded commodities, in that they compete with each other and are therefore subject to normal supply and demand pressures in determining their prices.

The higher markups on generics observed in the components analysis suggest that the prices of innovator drugs are used as a limit to generic pricing. In such a situation, price controlled generics may be a sensible way out of the problem. Nevertheless, printed maximum retail prices on packs of selected generic medicines as in India, could be used as a mechanism to ensure that retail prices do not diverge excessively from IRPs. In the process, this would put downward pressure on other generic prices and on the prices of IBs (by raising the price differential or ‘‘brand premium’’) (Kotawani, 2007).

Overall high prices in Ethiopia, compared to the reference prices, might be exemplified when retail generics from private sector cost six to eight times’ international bulk purchase prices. Therefore, government involvement in pharmaceutical pricing practices is necessary because leaving the financing and supply of drugs entirely to the market economy may also fail to

achieve public health objectives. Pricing regulations can be found in most of the European and Middle Eastern countries, Australia, New Zealand, the Far East, and Canada (Taylor, 2008).

However, Ethiopia, a low-income developing country, so far practices none of the pricing methods mentioned above. Price controls can also be implemented in a variety of ways, some of which cause less distortion in the medicines market than others. Perhaps the most efficient and effective is to use, in purchasing, price benchmarks in countries at comparable economic levels, to ensure that a country is not becoming a ‘‘high price island’’ .Reference pricing sets or limits the price of an individual drug by comparison with the price of other drugs in other countries.

Access to affordable and lower priced medicines are the aims of National Drug Policy of Ethiopia (ENDP, 1993), but according to this study’s findings, these aims are not being achieved. A medicine pricing policy and a price monitoring system is required in Ethiopia. Prices may also be controlled by fixing margins of retailers and wholesalers, and enforced by marking maximum prices on packs.

7. Limitation of the study

Study results may be limited by the fact that data are inherently subject to outside influences such as market fluctuations and delivery schedules. In addition, the reliability of median price ratios is dependant on the number of supplier prices used to determine the median MSH international reference price of each medicine. In cases where very few supplier prices are available, or where there is no supplier price and the buyer price is used as a proxy, MPR results can be skewed by a particularly high/low international reference price.

A further limitation is that availability is determined for the list of survey medicines, and therefore does not account for the availability of alternate strengths or dosage forms, or of therapeutic alternatives. Finally, the methodology does not include informal sectors, such as markets and general stores, as the quality of the medicines found in such sectors cannot be assured.

8. CONCLUSION

The principal conclusions of the study are as follows:

- The over all availability of medicines in the public health facilities and other sector retail outlets especially in Benishangul Gumuz was very low. Consequently, patients are forced to purchase drugs at higher prices in private pharmacies or go to informal sector or forgo treatment.

- Innovator brand products were not available in public health facilities and were hardly available in other sector medicine outlets. They were not available in the government procurement agencies either.

- The public procurement sector in Ethiopia procures relatively low as compared with International Reference Prices.

- In general, prices of medicines were lowest in public health facilities and highest in private pharmacies. Prices in other retail outlets were in between that of the two sectors.

- When compared with International Reference Prices, the prices of generic products in public health facilities and other sector medicine outlets were relatively higher. But their prices in the private pharmacies were very high.

- The prices of innovator brands were significantly higher than prices of their generic equivalents.

- Costs of treatment of common diseases were lowest in public health facilities followed by other sector retail outlets and private pharmacies..

- The community's ability to pay was influenced by socio-economic factors, price of the prescribed medicines and belief about health.

- There is no control on prices of medicines in Ethiopia. Consequently, wholesale and retail mark ups vary from sector to sector and from medicine-to-medicine depending on the market situation.

- The major contributors to the total cost of medicines to patients were retail mark-ups followed by wholesale mark-ups.

9. Recommendations

Based on the above findings, the following recommendations are made:

- Investigate the cause of low availability of medicines in the public health facilities and other sector medicine retail outlets.

- Development of a pricing policy which could contain aspects of price control, and incentives to reduce prices.

- Implementing different financing options such as community revolving drug schemes and health insurance schemes.

- Introduction /revision of exemptions or differential fee system to ensure access by the poorest.

- The generic policy implementation should be strengthened by emphasizing campaigns to promote generics, increase consumer awareness, and introduce incentives for pharmacists and doctors to prescribe and dispense generics.

- Undertaking in-depth study on the existing pharmaceutical marketing system in order to establish effective price monitoring system.

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Annex 1

Operational definitions

***Affordability*:** The cost of treatment in relation to peoples' income. In this survey, the daily wage of the lowest paid unskilled national government worker is used for comparison with the cost of a defined course of treatment for a specific condition.

Brand name: The product that was first authorized world wide for marketing (normally as a patented product) on the basis of the documentation of its efficacy, safety and quality, according to requirements at the time of authorization: e.g. Valium.

Cost, insurance, freight (CIF): Shipping term meaning the seller must pay the costs, insurance and freight charges necessary to bring the goods to the port of destination.

Cumulative per cent mark-up: is a measure of how much higher a certain price is above the MSP price. For example, if the MSP price is 100 and the price at the end of Stage 2 is 118, the cumulative % mark-up is 18%.

***Lowest price generic medicine*:** A generic medicine which has the lowest price among the generic medicine available**.**

Mark-up: A certain percentage added to a purchasing price to cover the cost and profit of the wholesaler or retailer.

Other sector: A retailer other than private and public retail out lets. Eg Special pharmacies and ERCS pharmacies.

Per cent contribution to the final price is a measure of a certain price as a percentage of the final medicine price. For example, if the total Stage 2 costs are 23.00 and the final medicine price is 46.00, the per cent contribution of Stage 2 to the final price is 50%.

Procurement price: The price paid by the government, wholesalers and other purchasers to procure medicines.

Retailer: A company that sells goods to consumers. In the pharmaceutical sector, the retailer is the pharmacy or any other medicine outlet.

Wholesaler: A company that buys goods from a manufacturer or importer and sells it to retailers.

Annex 3

Price components data collection form

Name of data collector:	Mohammedsied Nuru
Region:	A.A/Benishangl gumuz
Sector:	Purblic/Private/Other sector
Name/code of dispensing outlet:	
Product name, dosage, strength:	Amoxicillin Cap. 500 mg
Manufacturer:	GSK and AnF
Pack size:	
Product type:	❑**Innovator brand** ❑ generic
Production:	❑ imported ❑ locally produced

Any additional information about target medicine:

Stage 1	Type of charge	Charge basis	Price to which charge is applied	Amount of charge	Comments
	Manufacturers selling price	price			
	Insurance and freight				
	CIF				

	Type of charge	Charge status	Charge basis	Price to which charge is applied	Amount of charge	Comments
Stage 2: Landed price						

Source:

	Type of charge	Charge status	Charge basis	Price to which charge is applied	Amount of charge	Comments
Stage 3: Wholesaler or medical store	Procure price	value				

Source:

	Type of charge	Charge status	Charge basis	Price to which charge is applied	Amount of charge	Comments
Stage 4: Retailer or dispensary	Procure price	value				

	Type of charge	Charge status	Charge basis	Price to which charge is applied	Amount of charge	Comments
Stage 5: Dispensed price	Selling price	value				

Addis Ababa University
School of pharmacy
Department of Pharmaceutics

Annex 4. Individual Consent form for exit interview questionnaire

Cost as a barrier to access; Availability, affordability and component cost of essential medicines in Addis Ababa and Benishangul Gumuz Regional state

- Date of interview _____ Interviewer identification _____
- Time to complete interview: start time _____

  Finish time _____

  Total (minutes) _____

Instruction to the interviewer: it is critical that you read this greeting to the client, and continue only if she/he gives her/his consent. For each item in the rest of the interview circle the response(s) or describe as appropriate.

Good morning /after noon. My name is _____ and I am here today on behalf of the research team of Addis Ababa University to collect information on the availability and price of medicines. The Regional Health and administrative bodies have approved this research. We would like to ask you some questions about your personal and household characteristics such as income, education, household member, and your view about affordability of medicines.

If you agree to participate, it will take about 30 minutes for us to complete this interview. I will not write down your name and every thing you tell me will be kept confidential. If you choose not to participate, it will not affect services you receive in this facility. However, we would be very happy if you participated. May we continue?

Indicate that the client consented: (circle as appropriate) yes__ No__

(If No, thank the client for her/his time and go to the next interview.)

To be completed by the interviewer

I certify that I have read the above statement to the interviewee and the client has consented.

Name/Sign._____

Supervisor's name: _____ Signature: _____

Checked on: ____ (day)/_____ (month) 2001 E.C.

Annex 5

Exit Interview

1. General Information

Date of the interview_____

Name of organization_____

Residence_____

2. Age of the respondent_____

3. Sex ☐ Male ☐ Female

4. Marital status. A. Single

B. Married

C. Divorced

D. Widowed

5. Educational status of the head of household

A. Illiterate

B. Can read and write

C. 1-6

D. 7-12

E. College and above

6. Are you head of the household? ☐ Yes ☐ No

7. How many people reside in the household? _____

8. What is the Occupation of the head of the household?

A. Government employee

B. Private organization employee

C. Self employed

D. Unemployed

E. Other

9. Average monthly income from this work _____

10. If the respondent is a farmer

A. Type of production? _____

B. How much (yearly)? _____

11. Do you have any other source of income? If yes how much? _____

12. Does your household have? If yes mark “X”

A. Tap water ☐ E. Car ☐

B. Electricity ☐ F. Home ☐

C. Radio ☐ G. Land ☐

D. Television ☐ H Domestic Animals ☐ How many? _____

13. What is the average household expenditure per month for each of the following?

A.Fooditems_____ F. Transport_____ K. Edir+ Ekub _____

B. Electricity _____ G. Telephone ____ L. Health _____

C. Water _____ H. House rent ____ M. Tax _____

D. Clothing_____ I. Fuel _____ N. Others_____

E. Education _____ J. Saving_____

14. What was your problem? _____

15. Can you show me what is prescribed for your disease? _____

16. How much did you pay for the prescribed medicine? _____

17. Is the treatment affordable for you?

☐ Yes ☐ No

Annex 6: Structured questionnaire

Questions	Responses	Explanations
1. NATIONAL MEDICINES (DRUGS) POLICY (NMP)		
1.1 Is there a National Medicines Policy (NMP) document? *If no, skip to 2.*	☐**Yes** ☐**No** ☐**Don't Know**	A national medicines (drug) policy document is a written expression of the government's medium to long term goals and priorities for the pharmaceutical sector and the main strategies for attaining them.
a) If yes, is it an official or draft document?	☐**Official** ☐**Draft** ☐**Don't Know**	Mark "official" if the NMP document has been endorsed or officially adopted by the government otherwise mark "draft".
b) What year was it last updated?	**Year** _____	Indicate the year of last update whether the document is still in draft form or has been officially adopted.
1.2 Is there an NMP implementation plan that sets activities, responsibilities, budget and timeline?	☐**Yes** ☐**No** ☐**Don't Know**	
a) If yes, when was it last updated?	**Year** _____	
2. REGULATORY SYSTEM		
Regulatory authority		
2.2 Is there an existing formal medicines regulatory authority?	☐**Yes** ☐**No** ☐**Don't Know**	
2.3 What are the sources of funding for the medicines regulatory authority: Regular budget from the government:	☐**Yes** ☐**No** ☐**Don't Know**	
Fees from registration of medicines:	☐**Yes** ☐**No** ☐**Don't Know**	
Other:	☐**Yes** ☐**No** ☐**Don't Know**	
2.4 Is there medicines regulatory authority website providing publicly accessible information on any of the following: legislation, regulatory procedures, prescribing information (such as indications, CI's, side effects, etc.), authorised companies, and/or approved medicines?	☐**Yes** ☐**No** ☐**Don't Know**	

Questions	Responses	Explanations
Marketing authorization		
2.7 Are there legal provisions for marketing authorization?	☐ **Yes** ☐ **No** ☐ **Don't Know**	Marketing authorization is an official document issued by the medicines regulatory authority for the purpose of marketing or free distribution of a product after evaluation for safety, efficacy and quality and/or after registration of a product for marketing.
2.8 How many medicinal products have been approved to be marketed? *(count total number of unique dosage forms and strengths)*	**Number** ____	Tablets, capsules, injections, elixirs and suppositories should be counted in different strengths.
2.9 Is a list of all registered products publicly accessible?	☐ **Yes** ☐ **No** ☐ **Don't Know**	
Licensing		
2.14 Are there legal provisions for licensing of the following:		
Manufacturers:	☐ **Yes** ☐ **No** ☐ **Don't Know**	
Wholesalers or distributors:	☐ **Yes** ☐ **No** ☐ **Don't Know**	
Importers or exporters of medicines:	☐ **Yes** ☐ **No** ☐ **Don't Know**	
Quality control		
2.19 Is there a quality management system in place?	☐ **Yes** ☐ **No** ☐ **Don't Know**	This question is asking if there is an officially defined protocol for ensuring the quality of medicines, including testing of medicines to be registered, collection and testing of samples, reporting results, corrective actions to be taken when poor results are found and preventative measures to be taken to reduce future incidence of poor results.
2.20 Are medicine samples tested for the following regulatory purposes: Medicines registration:	☐ **Yes** ☐ **No** ☐ **Don't Know**	
Post-marketing surveillance:	☐ **Yes** ☐ **No** ☐ **Don't Know**	
2.23 What is the total number of samples tested in the last calendar year that failed to meet quality standards?	**Number** ____	
2.24 Are there regulatory procedures to ensure quality control of donated medicines?	☐ **Yes** ☐ **No** ☐ **Don't Know**	
2.24 Are there regulatory procedures to ensure quality control of imported medicines?	☐ **Yes** ☐ **No** ☐ **Don't Know**	

Questions	Responses		Explanations
Dispensing and prescribing			
2.30 Are there legal provisions for the following:			
Licensing and practice of prescribers:	☐**Yes** ☐**No** ☐**Don't Know**		
Licensing and practice of pharmacy:	☐**Yes** ☐**No** ☐**Don't Know**		
2.31 Is prescribing by generic name obligatory in the:			.
Public sector:	☐**Yes** ☐**No** ☐**Don't Know**		
Private sector:	☐**Yes** ☐**No** ☐**Don't Know**		
2.32 Is generic substitution permitted at:			
Public pharmacies:	☐**Yes** ☐**No** ☐**Don't Know**		
Private pharmacies:	☐**Yes** ☐**No** ☐**Don't Know**		
2.33 Are there incentives to dispense generic medicines at:			Incentives may include dispensing fees or mark-ups which provide financial incentive for dispensers to dispense lower-priced generic medicines.
Public pharmacies:	☐**Yes** ☐**No** ☐**Don't Know**		
Private pharmacies:	☐**Yes** ☐**No** ☐**Don't Know**		
Promotion and advertising			
2.34 Are there provisions in the medicines legislation/regulations covering promotion and/or advertising of medicines?	☐**Yes** ☐**No** ☐**Don't Know**		
3. MEDICINES SUPPLY SYSTEM			
3.1 Is public sector procurement pooled at the national level (i.e. there is centralised procurement for the regions/provinces)?	☐**Yes** ☐**No** ☐**Don't Know**		Mark "yes" if public sector procurement is centralised and medicines are procured for the entire public sector by a national procurement body even if in some instances, such as cases of stock outages, public sector facilities procure medicines through other means.
3.2 Who is responsible for public sector medicines procurement and distribution:	***Procurement***	***Distribution***	
Ministry of Health:	☐**Yes** ☐**No** ☐**DK**	☐**Yes** ☐**No** ☐**DK**	
Non-governmental organization (NGO):	☐**Yes** ☐**No** ☐**DK**	☐**Yes** ☐**No** ☐**DK**	

Questions	Responses		Explanations
Private institution contracted by the government:	☐**Yes** ☐**No** ☐ **DK**	☐**Yes** ☐**No** ☐ **DK**	Mark "yes" for private institution contracted by the government if the government contracts or makes an agreement with a private entity to procure or distribute medicines for the public sector, e.g. if an agreement is made with a private company to distribute medical items and supplies to public sector district warehouses and health facilities.
Individual health institutions:	☐**Yes** ☐**No** ☐ **DK**	☐**Yes** ☐**No** ☐ **DK**	
3.3 What type of tender process is used for public sector procurement and what is the percentage of the total cost for each:		***Percentage of total cost***	Competitive tender is a procedure for procuring medicines which puts a number of suppliers into competition. Purchasing is done on the basis
National competitive tender:	☐**Yes** ☐**No** ☐ **DK**	____**%**	National competitive tender is open to all or a limited number of local suppliers only.
International competitive tender:	☐**Yes** ☐**No** ☐ **DK**	____**%**	International competitive tender is open to all or a limited number of local and international suppliers though sometimes conditions give preference to either local or international suppliers.
Negotiation/direct purchasing:	☐**Yes** ☐**No** ☐ **DK**	____**%**	In negotiation/direct purchasing the buyer approaches one or a small number of suppliers and either buys at the quoted prices or bargains for a specific service arrangement.
3.6 Is public sector procurement limited to medicines on the Essential Medicines List (EML)?	☐**Yes** ☐**No** ☐**Don't Know**		
4. MEDICINES FINANCING			
4.1 What is the total public or government expenditure for medicines in Birr (US$) for the most recent year for which data are available?	**US$** ____ **Year** ____		This question is asking for the total amount the government has spent on medicines, including government allotment, health ministry expenditure, donor contributions channelled through the government, etc.

Questions	Responses	Explanations
4.2 Is there a national policy to provide at least some medicines free of charge (i.e. patients do not pay out-of-pocket for medicines) at public primary care facilities?	☐ **Yes** ☐ **No** ☐ **Don't Know**	If medicines are provided for free but patients must pay service fees, mark "yes" here. If some facilities provide medicines for free but there is not a consistent national policy that applies to all primary public health facilities, mark "no" here. If there is a national policy to provide medicines for free at primary public health facilities, but facilities are not required to abide by the policy and not all facilities provide medicines for free, mark "no" here.
b) Which of the following types of patients receive medicines for free: Patients who cannot afford them:	☐ **Yes** ☐ **No** ☐ **Don't Know**	
Children under 5 years of age:	☐ **Yes** ☐ **No** ☐ **Don't Know**	
Older children:	☐ **Yes** ☐ **No** ☐ **Don't Know**	Mark "yes" for "older children" if children over 5 years of age receive medicines for free, regardless of the age limit, for example mark "yes" if children under 12 receive medicines for free.
Pregnant women:	☐ **Yes** ☐ **No** ☐ **Don't Know**	
Elderly persons:	☐ **Yes** ☐ **No** ☐ **Don't Know**	
4.3 Which fees are commonly charged in public primary care facilities: Registration/consultation fees:	☐ **Yes** ☐ **No** ☐ **Don't Know**	
Dispensing fees:	☐ **Yes** ☐ **No** ☐ **Don't Know**	
Flat fees for medicines:	☐ **Yes** ☐ **No** ☐ **Don't Know**	- A flat fee for medicines is a fee which remains the same irrespective of the number of medicines or the quantity of each medicine dispensed.
Flat rate co-payments for medicines:	☐ **Yes** ☐ **No** ☐ **Don't Know**	A flat rate co-payment is a fixed amount that a patient must pay either per medicine or per prescription to cover part of the cost of medicines, the other part being paid by an insurer or government.

Questions	Responses			Explanations
Percentage co-payments for medicines:	☐**Yes** ☐**No** ☐**Don't Know**			A percentage co-payment is a fixed percentage of the cost of prescribed medicines that a patient must pay to cover part of the cost of medicines, the other part being paid by an insurer or government. The amount a patient pays will depend on the medicine and the number of units of that medicine prescribed.
4.4 Is revenue from fees or the sale of medicines used to pay the salaries or supplement the income of public health personnel in the same facility?	☐**Always** ☐**Frequently** ☐**Occasionally** ☐**Never** ☐**DK**			Mark "yes" if any percentage of collected fees or medicines sales is used to pay salaries, expenses and/or in any way supplement the income of public health personnel in the same facility.
4.5 Do prescribers dispense medicines?	***Public sector*** ☐**Always** ☐**Frequently** ☐**Occasionally** ☐**Never** ☐**DK**	***Private sector*** ☐**Always** ☐**Frequently** ☐**Occasionally** ☐**Never** ☐**DK**		
4.6 What proportion of the population has health insurance?	☐**All** ☐**Some** ☐**None** ☐**DK**	☐**All** ☐**Some** ☐**None** ☐**DK**		
4.7 Are medicines covered by health insurance?	☐**All** ☐**Some** ☐**None** ☐**DK**	☐**All** ☐**Some** ☐**None** ☐**DK**		
4.9 Is a national medicine prices monitoring system for retail/patient prices in place?	☐**Yes** ☐**No** ☐**DK**	☐**Yes** ☐**No** ☐**DK**	☐**Yes** ☐**No** ☐**DK**	A national medicine prices monitoring system for retail/patient prices is any means of regularly tracking and comparing over time retail/patient medicine prices in the public, private and/or NGO sectors.
4.10 Are there regulations mandating retail/patient medicine price information to be made publicly accessible?	☐**Yes** ☐**No** ☐**DK**	☐**Yes** ☐**No** ☐**DK**	☐**Yes** ☐**No** ☐**DK**	In order for retail/patient medicine price information to be considered publicly accessible, one or more of the following or similar measures should be taken: prices should be available on the web or to anyone contacting the responsible authority, prices should be periodically published in national newspapers or official publications, prices should be posted in health facilities/pharmacies, etc.

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Questions	Responses			Explanations
4.11 Are there official written guidelines on medicine donations that provide rules and regulations for donors and provide guidance to the public, private and/or NGO sectors on accepting and handling donated medicines?	☐ **Yes** ☐ **No** ☐ **DK**	☐ **Yes** ☐ **No** ☐ **DK**	☐ **Yes** ☐ **No** ☐ **DK**	Countries may have differing definitions for medicine donations which may include not only products but also monetary gifts earmarked for a particular product from a named source (e.g. manufacturer, organization or other country).
6. RATIONAL USE OF MEDICINES				
6.1 Is there a national Essential Medicines List (EML)?	☐ **Yes** ☐ **No** ☐ **Don't Know**			Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to disease prevalence, evidence on efficacy and safety, and comparative cost-effectiveness.
a) If yes, how many unique medicine formulations does the national EML contain?	**Number:** ____			.
c) When was the national EML last updated?	**Year:** ____			
d) Is the national EML being used in the following:				Mark "yes" if the EML is currently being used.
Public sector procurement:	☐ **Yes** ☐ **No** ☐ **Don't Know**			
Public insurance reimbursement:	☐ **Yes** ☐ **No** ☐ **Don't Know**			
Private insurance reimbursement:	☐ **Yes** ☐ **No** ☐ **Don't Know**			
e) Is there a committee responsible for the selection of products on the national EML?	☐ **Yes** ☐ **No** ☐ **Don't Know**			This refers to a formally recognised committee with members of different expertise and from different agencies/organizations.
6.2 Are the following types of standard treatment guidelines (STG) produced by the health ministry for major conditions?	***National STG*** ☐ **Yes** ☐ **No** ☐ **DK**	***Hospital level STG*** ☐ **Yes** ☐ **No** ☐ **DK**	***Primary care STG*** ☐ **Yes** ☐ **No** ☐ **DK**	
a) If yes, when were the STGs last updated?	**Year** ____	**Year** ____	**Year** ____	
6.16 How frequently are the following types of medicines sold over the counter without any prescription:				This question is asking how often antibiotics and injections which require a prescription to be dispensed are sold without a prescription, regardless of laws prohibiting such practice.
Antibiotics:	☐ **Always**	☐ **Frequently** ☐ **Occasionally**		
Injections:	☐ **Always**	☐ **Frequently** ☐ **Occasionally**		

Questions	Responses	Explanations
1. Retail		
S1.1 How many licensed private retail medicine outlets are there in the country?☐	**Number** _____	"Licensed" refers to medicine outlets that are subjected to evaluation against a set of requirements and issued a permit to operate (license).
S1.2 What proportion of patients access medicines through: a) public/government sector b) formal private sector c) Other: specify: d) Other: specify:	 **a)** _____% **b)** _____% **c)** _____% **d)** _____%	The formal private sector refers to licensed medicine retail outlets and licensed retail drug stores. Common other sectors include non-government organizations, mission health facilities, or dispensing doctors.
S1.3 Are there public medicine outlets which sell medicines in public health facilities?	☐**Yes** ☐**No** ☐**Don't Know**	
S1.4 Are there private pharmacies which sell medicines in public health facilities?	☐**Yes** ☐**No** ☐**Don't Know**	
2. Medicines financing		
S2.1 What proportion of medicines by *volume* are imported?	_____% **Year** _____	
S2.2 What proportion of medicines by *value* are imported?	_____% **Year** _____	
3. Medicines supply system		
S3.1 Are there regulations for local preference in public procurement?	☐**Yes** ☐**No** ☐**Don't Know**	Local preference purchasing means that domestic companies will be preferred even if their prices are not the lowest.
4. Regulatory authority		
S4.1 Do the fees charged for the registration of medicines differ between:		
a) Originator brands and generic equivalents	☐**Yes** ☐**No** ☐**Don't Know**	
b) Imported and locally produced medicines	☐**Yes** ☐**No** ☐**Don't Know**	
5. Medicine pricing policies		
S5.1 Does the government set the price of some/all originator brand products?	☐**Yes** ☐**No** ☐**Don't Know**	
a) If yes, please describe how this is done (e.g. direct price controls, international reference pricing):		Direct price controls refers to price-setting using a pricing formula, e.g. production costs + a % margin. International reference pricing refers to comparing prices to those in other countries.

S5.2 Does the government set the price of some/all generic products?	☐**Yes** ☐**No** ☐**Don't Know**	
a) If yes, please describe how this is done (e.g. direct price controls, national reference pricing):		National reference pricing refers to setting prices by comparing the prices of similar medicines (by molecule or therapeutic class; originator brand or generics) on the national market.
S5.3 Are prices set in the private sector for medicines on the national Essential Medicines List?	☐**Yes** ☐**No** ☐ **No national EML**	This question is asking whether price-setting is limited to medicines on the national EML.
S5.4 Are prices of medicines set as part of market authorization?	☐**Yes** ☐**No** ☐**Don't Know**	Marketing authorization is an official document issued by the medicines regulatory authority for the purpose of marketing or free distribution of a product after evaluation for safety, efficacy and quality and/or after registration of a product for marketing.

Annex 9

Declaration

I the undersigned, declare that this is my original work, has never been presented in this or any other university and that all the source materials used for the thesis have been duly acknowledged.

Name Mohammedsied Nuru Mohammednur_

Signature _____

Place _____

Date of submission _____

This thesis has been submitted for examination with my approval as a university advisor.

Name Dr. Teferi Gedif

Signature _____

Date _____

Name Dr. Damen Hailemariam

Signature _____

Date _____