CHAPTER I
INTRODUCTION

1.1. Overview

Medicines account for 20%–60% of health spending in low income and developing countries and up to 90% of populations in these countries purchase their medicines out of their pocket (Cameron, Ewen, Ross, Ball, & Laing, 2009). These facts reflect the importance of essential medicines as part of the whole health system in these country settings.

High medicines prices, low affordability and poor availability are key obstacle to access to treatment in many low and middle-income countries. Certainly, in those countries where the majority of the population still buys its medicines through out-of-pocket payments, the high cost of medicines (relative to the household budget) means that an illness in the family exposes that family to the risk of catastrophic expenditure. Too often the choice is made to go without.

Although the prices of medicines have an impact on the affordability of drugs and ultimately on access to essential medicines, little is known about the prices paid by consumers for medicines in low-and-middle income countries. In May 2003, WHO in collaboration with Health Action International (HAI) published a manual, "Medicines Prices a New Approach to Measurement". The manual describes a standardized methodology for collecting price data, availability, and affordability of selected medicines (brand and generics) from outlets in public, private and 'other' sector in a state or country. The methodology allows for determining medicine prices in comparison to an international reference price (IRP). The affordability is measured in terms of the daily wages of the lowest paid unskilled government worker. In addition, the manual also presents some automated analyses that can be interpreted easily. Thus, convenient comparisons between data obtained from various surveys are possible, since the indicators are defined consistently across all studies.

Access to essential medicines is a part of fulfillment of the right to the highest attainable standard of health (in short: the right to health), so why millions of patients go around the globe without treatments they need? The answer to this question is clear the reason is the price and availability of medicines to those who need them are

crucial factors, the price for the poor is simply too high and product are often not available, this may be not new to the sick and poor people but it has been news for those responsibility to ensure the health of citizen.

1.2. Significance of the problem

Medicines prices, availability and it is affordability now stand as one of the big issues and challenges facing healthcare finance, not only in Sudan but worldwide.

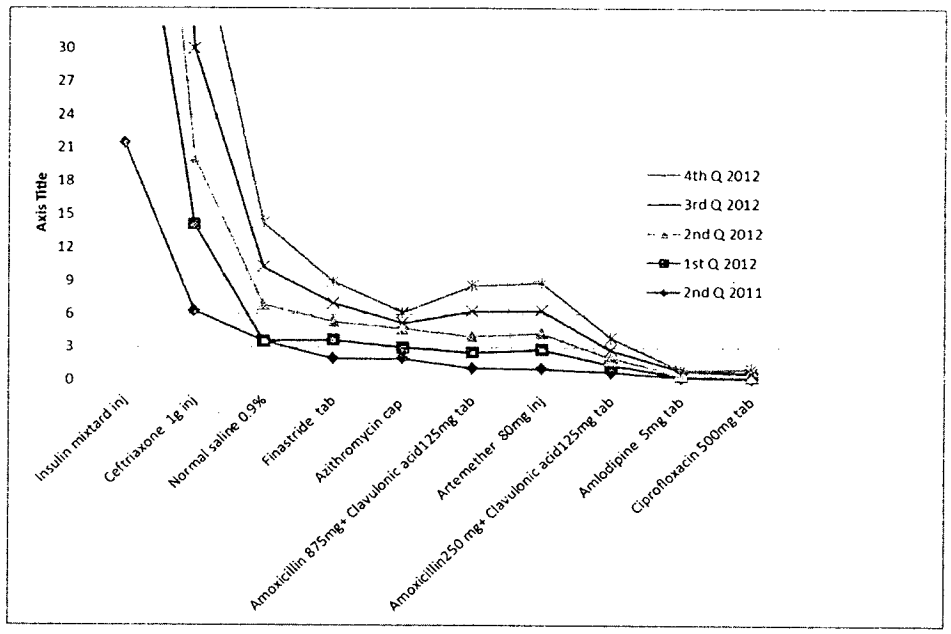
Medicines prices in Sudan kept increasing and pharmaceutical expenditure are escalating, Health insurance schemes, private and public are more vulnerable to such cost escalating when the premium remains constant.

Given the volatile exchange rate in Sudan people think that the prices of medicines keep up increasing and never come back again. Pushing scarce resources available for pharmaceuticals to be not enough to supply the essential medicines for possible target of populations in the public sector, even the private sector including agencies importing medicines fail to supply the needed pharmaceuticals and the volume of imported medicines gone down from € 285 million in 2010 to €119 million in 2011 and drop dramatically to €54 million till September 2012[i], this fact shows significant problem in the supply side of the medicines in the whole country, that failure in the supply side is sharply reflected in the demand side, e.g. some public hospitals announces acute shortage in medicines supply e.g. The Atomic Hospital and National, while National Health Insurance Fund (NHIF) report on December 2012 shows acute shortage in medicines, about 194 items out of 537 were not found in the local pharmaceutical market (NHIF, 2012). Despite that shortage NHIF mentioned in report the cost of the medicines is escalating dramatically, it increased by 18% from the 2011 to the first half 2012, the same increment was noticed from the 1st half 2012 to the 3rd quarter 2012, while it increased by 36% from the 3rd to the 4th quarter 2012[1]. The figure below shows the medicines prices trend purchased by NHIF during 2nd quarter 2011 and 1st, 2nd,3rd and 4th quarter 2012, explain clearly how the medicine prices purchased by NHIF through competitive bidding tender was increasing dramatically e.g. the price of Insulin Mixtard increases by 40%, Ceftriaxone 1g injection by 90%, Normal Saline 0.9% by 12.7%, Amoxicillin 875mg+ Clavulonic

[1] National Health Insurance Fund (2nd half 2012 tender report October 2012)

acid125mg tab by 108% and Artemether 80 mg/ml injection increases by 132% since 2011 to 4th quarter 2012.

Figure 1. 1 Prices trend of 10 high cost medicines in NHIF, Sudan



Source: NHIF tender reports 2011-2012

The high price of medicines is major concern for policy maker, insurance companies, public insurance, FMOH, SMOHs and patients as well, because high price can affect medicines affordability (ability of patient to buy their essential desired medicines) and availability, because scarce resources make insufficient quantities of essential medicines available which can be more less and less when it's prices increase. As equal access to medicines should be one of the health system objectives, really for that reason access to essential medicines is one of the MDGs should be achieved. Increasing medicines prices can affect the financing sustainability of healthcare system as whole. While low priced medicines which patients can afford can help improve population's health.

There are a great agree that competition are not usually present in pharmaceutical market at least to insure competitive efficient prices, hence there are consensus agreement that interventions either to promote competition or to regulate prices[2]. To give clue result to find optimum price regulation system is highly demanded now in Sudan.

[2] HAI, External Reference Pricing, 2011

If the outcomes of the regulation are difficult to predict, suppliers are forced to take decision with high uncertainly, like in Sudan when the government policies on exchange rate is not clear, many pharmaceutical companies keeps their medicines and ban distributing medicines, the result was increasing medicines prices and reduce medicines availability.

The major implications of increasing medicines price in Sudan are:

1. National Health Insurance Fund (NHIF) mentioned in a conference joint all ministers of states social affairs, ZAKAT state trustees in August 2012 that the Medicines costs increased to more than (18%-50%) with less than one year (during the 4th quarter 2011 and the 3rd quarter 2012).looking fo answers and communicate the magnitude of the problem among stakeholders. The question that t is it that reasonable? Is that incremental costs are due to fluctuating and volatile exchange rate? Or some pharmaceutical companies just keep increasing the price?
2. In December and during country budgeting process NHIF call for support from national government and ask for increasing premium especially for poor families who are their premiums paid by Federal Ministry of Finance (tax-based) or by ZAKAT chamber (Muslims Contributions).because pharmaceutical cost is escalating (see table 1-1 below)

Table 1. 1 Medicines cost in relation to total expenditure in NHIF

Period	Pharmaceutical cost/month	%Ph. cost from the total Expenditure
2011	7 Millions SDG	29%
1st&2nd quarter	13 Millions SDG	43%
3rd quarter 2012	18 Millions SDG	60%

Source: NHIF tender reports, 2011/2012

3. In August 2012 Central Medical Supplies (CMS) mentioned that 42 items of emergency medicines were out of their stock.

Paper published by WHO Controlling medicine prices in Sudan: the challenge of the recently established Medicines Regulatory Authority conclude that The current pricing system, in both public and private sectors, is of limited benefit in controlling escalating medicine prices in Sudan. There is gab to be address.

1.3. Research Questions

1. What is the status of availability of selected essential medicines in the public, private and RDF sector in Sudan?
2. Is medicine prices in Sudan vary among states, sectors and from other countries?
3. How affordable are medicines for treating common conditions for people on a low income?
4. What are the factors that affect patient's medicine price?

1.4. Research Objectives

1.4.1. General objectives

To analyze the prices, availability and affordability of selected essential medicines in Sudan

1.4.2. The Specific objectives are: to

1. Identify the status of availability of selected essential medicines in Sudan cross public, private and RDF sectors and to compare them.
2. Compare the prices of the selected essential medicines with the international reference price and cross Sudan states, private, public and RDF sectors.
3. Analyze affordability of selected standard treatment for common disease.
4. Analyze factors that affect patient's medicine price.

1.5. Scope of the Study

Study 50 selected essential medicines in private, public and Revolving Drug Fund (RDF) in six states in Sudan (Khartoum, Gazeera, River Nile, West Darfur, Sinnar and Red Sea) in February to March, 2013.

1.5.1. Rationale of the scope

***The* 6 states**: were selected in such way that it can represent the whole country of Sudan, while the 50 essential items were selected according to the following criteria:

The fifty items:

- *Inclusion Criteria*: 14 items are from the global core items recommended by WHO for international comparison, 16 items are from the WHO/EMRO core list for comparison (Sudan in WHO /EMRO region) to facilitate country comparisons within the region and 20 items are selected to represent country health priorities. All selected Medicines are in the EML of Sudan in most important chronic and non-chronic disease.
- *Exclusion Criteria*: items that have no reference price in MSH 2011

1.6. Hypothesis

1. There is no difference in medicine prices among states.

   H_0: $\mu_1 = \mu_2 = \mu_3 = \mu_4 = \mu_5 = \mu_6$; if the prices are the same in all states

   H_A: $\mu_1 \neq \mu_2 \neq \mu_3 \neq \mu_4 \neq \mu_5 \neq \mu_6$; if the prices are different in different states

1.7. Background

1.7.1. Demographic and socio economic indices

Sudan is one of the largest African countries with population of 30,804 $\times 10^3$, the average house hold size is 5.7 and about 33.2% considered as urban, the dependency ratio is 84%. The economic activity rate is 37.4. However the unemployment rate for age greater than 10 and less than 25 is 40%, while proportion of elementary occupation is 30.5% and the proportions of employers is only 6.8%.(NSB, 2011).

The incidence of poverty in Sudan is 46.5, while severity of poverty is 7.8 and the average house hold consumption per person per month is 148 SDG, only 4% of population have saving or current accounts (FMoF, 2009)

1.7.2. Health indices

The life expectancy at birth was 59.8 year (2011) for both male and female. The infant mortality rate is 79/1,000, while children under five year age mortality rate was 111/1,000, the maternal mortality rate is 417(NSB, 2011). The leading causes of death are Malaria, pneumonia, Septicemia, Other Heart Diseases The 10 leading causes of mortality in hospitals in Sudan are: Malaria, pneumonia, Septicemia, Other

Heart Diseases, malignant neoplasm, disorders of the circulatory system, heart failure, acute renal failure, diabetes mellitus and malnutrition while the leading cause of admission are malaria, child birth, pneumonia, caesarean, obstetrics & gynecology, diarrhea & enteric gastritis, asthma, coetaneous abscess, diabetes and apportion.(FMoH, 2010).

The health infrastructure in Sudan is considered with very big gap that can affect access to health care table (1-2) shows the number of people per facility

Table 1. 2 The health facilities statistics in Sudan 2010

Facilities	**Pop/facility**
Hospitals	1.0/100,000
Hospital beds	74/100,000
Primary Health care Unit and centers	15/100,000
Licensed pharmacies	5.9/100,000

Source: FMoH, 2011

1.7.3. Pharmaceutical policy and regulation

In Sudan a National Health Policy (NHP) exists from which the National Medicine Policy (NMP) documented. The NMP cover 10 basic issues concerning medicine policies, these includes Selection of essential medicines, Medicines pricing , Procurement, Distribution and regulation, Pharmacovigilance, Rational use of medicines, Human resource development, Research, Monitoring and evaluation and Traditional medicine (FMoH, 2010)

The pharmaceutical regulatory authority is semi-autonomous agency known as the National Medicines and Poisons Board (NMPB) that established in 2006. There also a legal provision for inspections of pharmaceutical companies and pharmacies, the NMPB has its own inspectors at the capital of Sudan and it depends on the pharmaceutical administration at the region level (FMoH, 2010)

To import medicine to Sudan the MDR ask for sample of the product for testing according to the legal provisions available. Also the legal provision restrict local manufacturer to be licensed and comply with Good Manufacture Practice (GMP) although GMP is not widely known and DRA not enforcing this issue as well

as the National Good Pharmacy Practice Guidelines which was published by the Medical Council but not enforces.

There is National Laboratory for testing the quality of medicines, the sample either collected by the DRA or those from the samples before entry at the port, in 2010 7536 samples were taken from the market and tested for their quality 816 items (10.8%) fail to meet the quality standard, the result of that test was not published to the public, instead the DRA ask to recall the items which fail to pass the quality test.

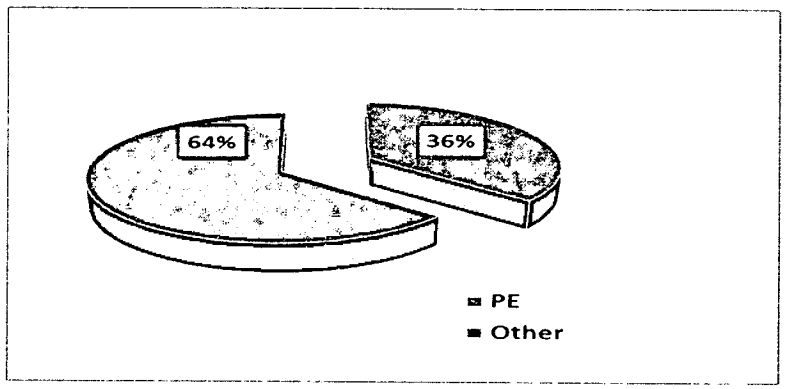
Free advertising of medicines is not allowed as stated in the legal provisions and the direct advertising of pharmaceuticals is abandoned, permission is needed from the NMPB before advertising[3]

1.7.4. Medicines finance and supply

The main sources of financing pharmaceuticals in Sudan are the health insurance (public, private and military), government tax-based subsidies like 1st 24hours emergency treatment, children under five and vaccination, other sources of finance like donors (malaria treatment) and charity organizations. However out of pocket represent more than 60% of pharmaceutical expending (PE) in Sudan. Pharmaceutical expenditure in Sudan represents 36% of total health expenditure (THE) (see figure 1-2 below)

[3] Sudan Pharmaceutical Profile, FMoH, 2010

Figure 1. 2 Pharmaceutical Expenditure, Sudan 2010



Source: Sudan Pharmaceutical profile, 2010

1.7.5. Patient's fees and co-payments

At the point of healthcare delivery there fees patients has to pay especially when they ask for services not supported by the already known programs, same thing for medicine outlet. But for NHIF subscriber have to pay 25% of the whole prescription cost, while in private health insurance this copayment vary with in the benefit package from 0% to 25%, it reach to zero in military services. Also the rate of reimbursement varies in the different categories mentioned before.(FMoH, 2010)

1.7.6. Medicines distribution channel in Sudan

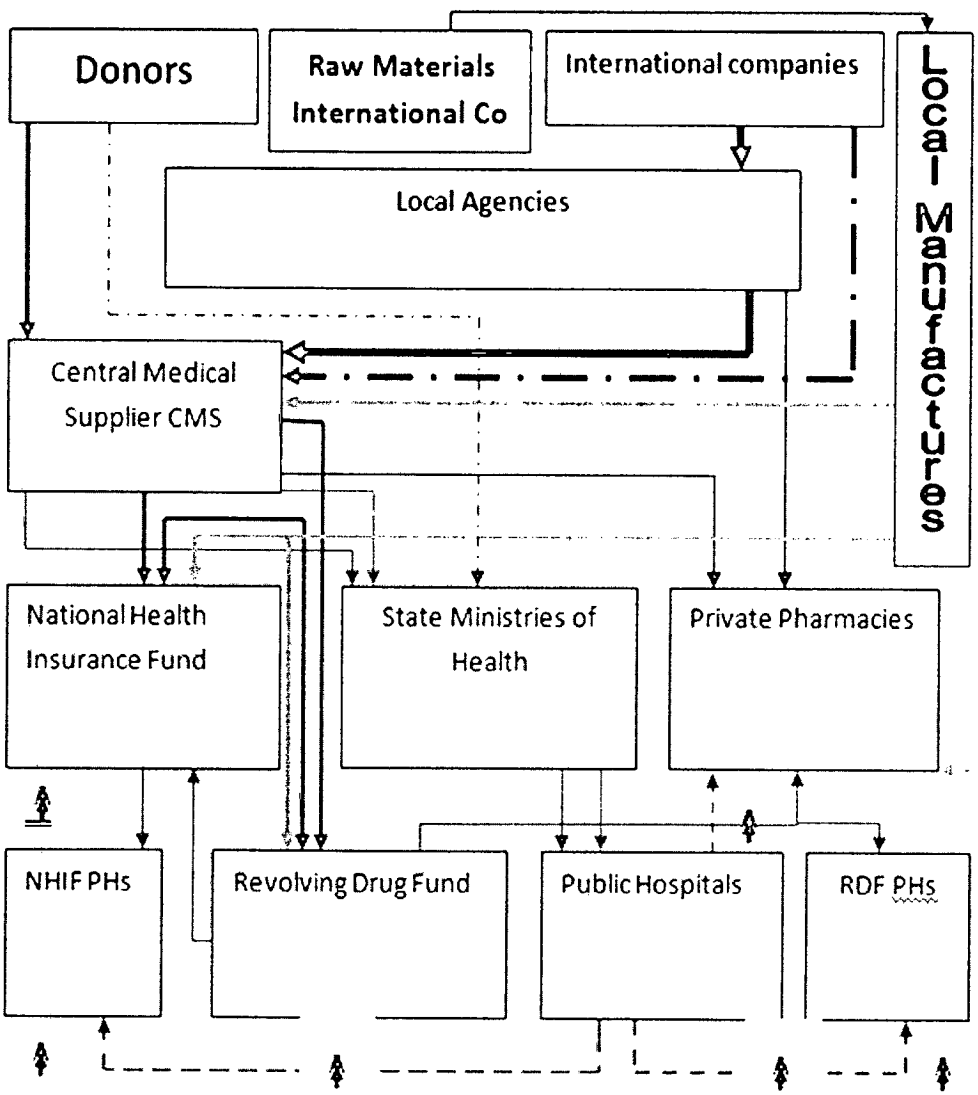
Medicines supply and distribution channels in Sudan is not so far integrated, especially in the public sector where the main procurement agents form the local markets are, NHIF, the Military Medical Services (MMS), Police Medical Services, Revolving Drug Fund and HI corporation Khartoum state. But CMS the main supplier for the public hospitals perform local and international tender biding to supply medicines.

Despite the big size of the public sector there still no unique supply. However the MMS and NHIF are the only public sectors that perform tender biding to supply their branches.in different states of the country. However the CMS is government main supplier that import from outside country it change it is objectives in 1990s and become one of the main competitor to the private sector and it expand their activities in all states by establishing RDF which contributes to sustain the medicines supply in remote areas (Mahgoub, 2009). Any regional RDF has it is own supply system and

medicines outlets where they provide retail services although they supply part of their medicines from CMS and local manufacturer and other local agencies.

NHIF has it is own drug supply system and it is own medicines outlets as well as MMS, figure (I-3) shows medicines distribution channels in Sudan, where there are scattered purchasing especially in the public sector

Figure 1. 3 Medicines Distribution Channel in Sudan

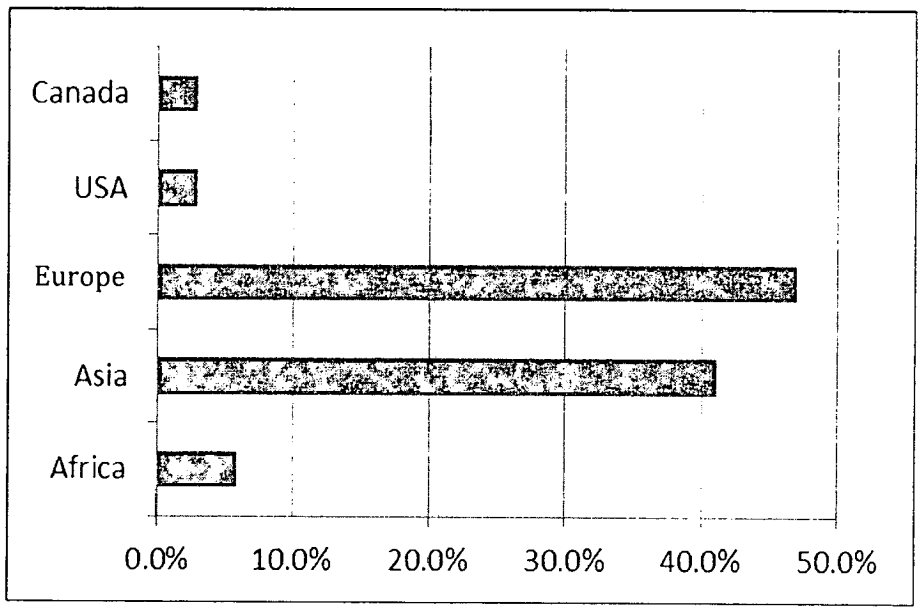


1.7.7. Sudan pharmaceutical industry

Sudan has 36 local pharmaceutical factories no one of them categorized as R & D factory, three of these factories are public, while the number of pharmaceutical agents are 112 agency, they import medicines from 36 different worldwide countries,

the diagram below in figure (I-4) represent the continental share for exporting medicines to Sudan, just in term of number of countries

Figure 1. 4 Per cent of countries in each Region, 2012

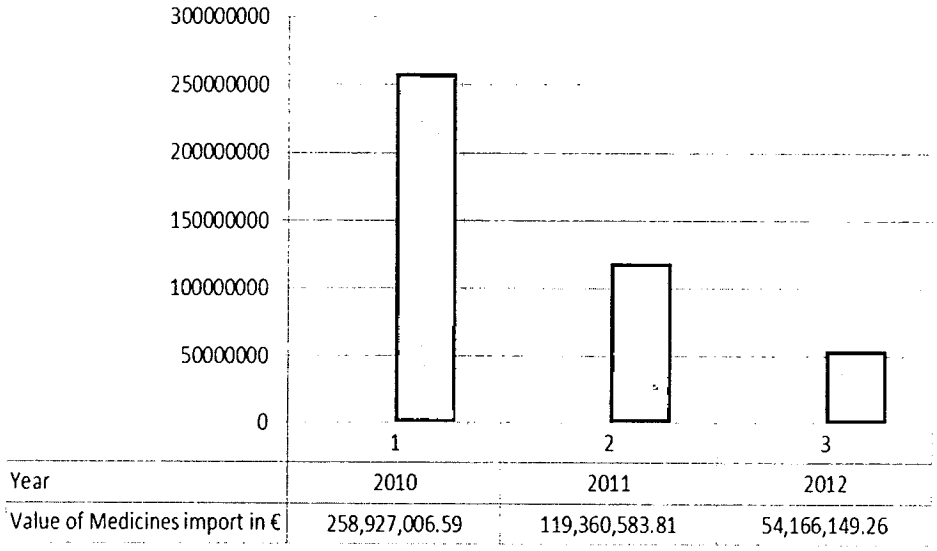


[Source: NMPB, Sudan, 2012]

Sudan national essential medicines list contain 542 and the registered medicines are 7,401 items as trade names not generics, from which is only 103 represent 21% as registration frequencies, the top registered item as frequencies were Metformin tablet and Multivitamins each registered 29 times.

The annual value of medicines import on the last 3 years shown in the figure below (I-4) can reflect how is the medicines market in Sudan suffer much to import medicines, as local agencies and pharmaceutical companies complain that there is hard currency shortage and the gap is very clear when compare the value of medicines imports in 2010, 2011 and 2012, may be the effect of inflation (see figure I-5) the trend of the consumer price index in Sudan tells the pressure on the local currency due to inflation. The steady increasing in the CPI which medicines contribute to was reflected on medicines prices.

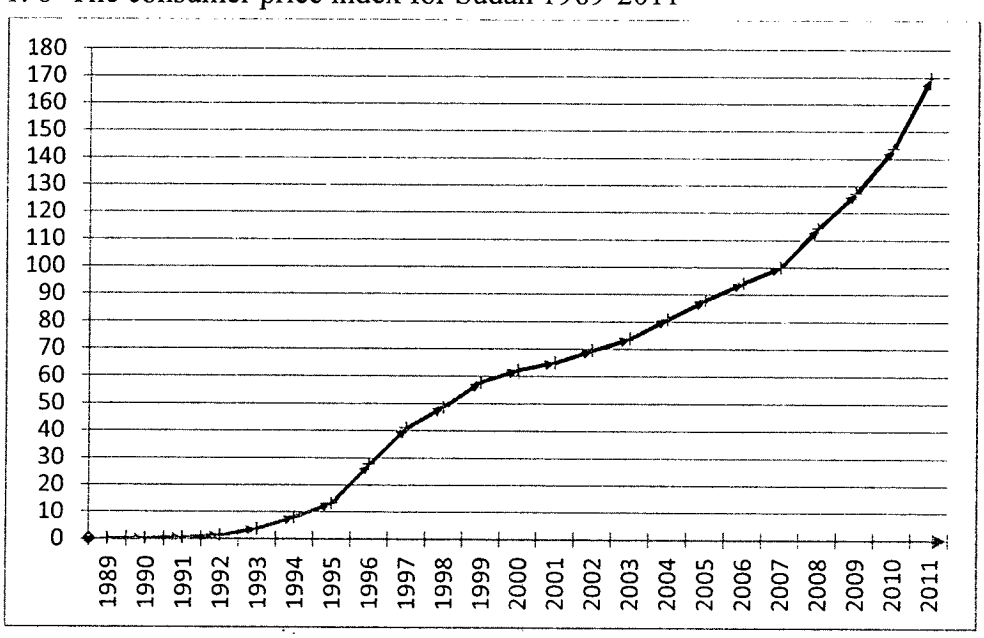
Figure 1. 5 The value of medicines imports 2010, 2011, 2012



Year	2010	2011	2012
Value of Medicines import in €	258,927,006.59	119,360,583.81	54,166,149.26

Source: National Medicines and Poisons Board, Sudan, 2012

Figure 1. 6 The consumer price index for Sudan 1989-2011



Source:(NSB, 2012)

1.7.8. The price components of medicine in Sudan

In the public sector where exclusively represented by CMS, the C&F is determined by the tender committee where the NMPB has no regulation on that, although they are represented in that committee as committee member, the price

components mentioned in the table (I-4) below, shows the government fees and other expenses charged to medicines before it reach warehouse. In addition in figure I- 6 where the CMS mark-up in Sudan 20% for private and public facilities and 12% for the RDFs

Table 1. 3 The price components by CMS till 2012, Sudan

Price component	C & F	
	% (By air)	% (By sea)
Fees (taxes)		
• Customs tax	10.0	10.0
• Wound tax	1.0	1.0
• Port fees	1.2	2.5
• Total	12.2	13.5
Other expenses		
• Clearance expenses	7.0	7.0
• Insurance	2.0	2.0
• Others	1.0	1.0
• Bank charge	2.0	2.0
• Transportation	-	35
• Total	12.0	15.5

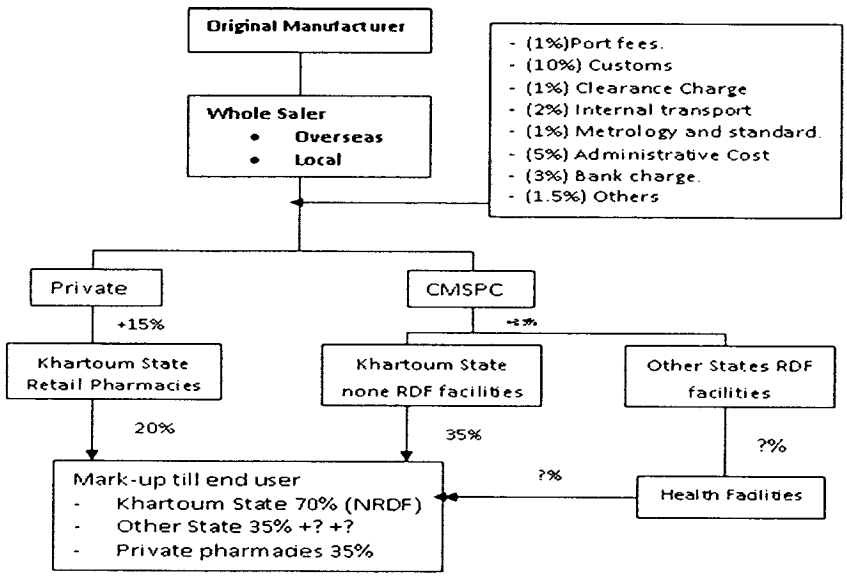
C&F = cost and freight.

Wound tax: tax source to support military

Source: G.K.M. Ali 1 and A.Y. Yahia 2, WHO

While in the private this can be vary and in different region there is different markup in the private and public sectors (see figure I-5)

Figure 1. 7 Medicines Price Mark-up in Sudan



?% Mark-up varies by state and its health facilities
CMSPC = Central Medical Supplies Public Corporation; RDFs = revolving drug funds

Source: Eastern Mediterranean Health Journal, Vol. 18 No. 8 • 2012

The pricing system in the public sector based on a medicine's total C&F (i.e. wholesalers add a fixed percentage to the price they pay for the manufacturers from abroad), NMPB fixes maximum percentage mark-ups for all medicines for 2 stages of the distribution. Wholesaler's profit is 15% of the total costs to their central warehouses in Khartoum, and retailer's profit is 20% of the wholesaler's price, such system gives incentives to the whole seller and retailer to buy and sell high margin medicines for maximum profit that can affect medicines affordability and accessibility as well, this can give partial clue to the report mentioned that less than 50% of Sudanese has access to essential medicines. The government tax 1.5% to the retailer and 15% for profit. The C&F prices determined in NMPB where there is committee to evaluate and discuss with the importer the suggested prices and finally agreed before that the committee look to the brand price of the innovator for the same medicine.

1.7.9. The price mark-up in pharmaceutical

It is clear as shown in the figure (I-6) above the final price almost double or more than purchaser price. The government fees charged to the medicines is about

24.5% when it reaches to the port (port fee 1%, customs 10%, clearance charge 1%, internal transport 2%, metrology and standard 1%, administrative cost 5%, bank charge 3%, others 1.5%). While the mark-up charged by CMS to the retailer pharmacies is 35%, but only 15% is private companies charge as mark-up to the private and public retailer pharmacies. Khartoum state RDF charge 35% mark-up to the medicines that from CMS while 20% to medicines from the private companies, but other states RDF and private pharmacies charge higher mark-up, and that mark-up vary between the different states.