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Notional Ministry of Health
Directorate General of Pharmacy**



Assessment of the National Pharmaceutical Sector

Level II health facilities survey

North Sudan

2007



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List of Abbreviations:

ADR	Adverse Drug Reactions
AMR	Anti Microbial Resistance
Ar	Artesunate
CMS	Central Medical Supplies
DGoP	Directorate General of Pharmacy
DIC	Drug Information Center
DTC	Drugs Therapeutics Committee
EML	Essential Medicines List
FBPP	Federal Board of Pharmacy & Poisons
FMOH	Federal Ministry Of Health
GDP	Gross Domestic Product
HIV/AIDS	Human immunodeficiency virus/ acquired immunodeficiency syndrome
HAI	Health Action International
INN	International none-proprietary name
MRA	medicines regulatory authority
MDG	Millennium Development Goals
NDP	National Drug Policy
NGO	Non Governmental Organizations
ORS	Oral rehydration salt
PHC	Primary Health Care
RDF	Revolving Drug Fund
SDG	Sudanese Pound
SNF	Sudan national formulary
SOPs	Standard operating procedures
SP	Sulphadoxine and Pyrimethamin
STGs	Standard Treatment Guidelines
WHO	World Health Organization
WTO	The World Trade Organization

Executive Summary

The pharmaceutical sector has undergone many recent changes and a number of studies involving the assessment of national pharmaceutical supplies in Sudan were conducted in the past. Most of these studies used part of the core indications for assessment of pharmaceutical supplies but none have used the whole package of indicators. Therefore it was essential to assess the pharmaceutical sector in Sudan in accordance with the national drug policy.

The objectives of the study were to assess the country medicine sector and its ability to implement the national drug policies; identify the percentage of the public who are able to access essential medicines; and whether the medicines received are of accepted quality and rationally used. Fifteen key medicines that are the mostly commonly used in the northern states were selected as a basket of medicines for this study.

This study used the World Health Organizations package for pharmaceutical sector assessment, level II outcome indicators for health facilities survey.

The survey was conducted in six states that make up the geographical area of northern Sudan; namely Khartoum state, Nile River state, Red Sea state, North Kordofan state and Kassala state, in addition to Southern Darfur to represent the conflict area.

The health facilities chosen included both the public and private health sectors and medicine warehouses. Regarding patients included in the surveyed sample, they were selected using retrospective and prospective sampling.

The data analyzed to identify the gaps in the policies already in place and to identify any interventions needed to correct any deficits encountered.

The Southern states were excluded due to accessibility reasons and due to lack of any clear structural health system. Therefore, results of this study were not including the southern states.

▪ Findings

The main outcomes concluded were as follows:

1. Accessibility

- The percentage of the availability of key medicines taken into account was found to be higher in the private sector than in the public health facilities and warehouses. The availability of key medicines in the public health facilities was found to be 86.1% while in private pharmacies 95.1% and in warehouses 81.4%.
- The average number of days for out of stock was 21.4 days in the warehouses and 18.4 days in the public facilities.
- The average of record keeping was 28.5% in the public health facilities compared to 82.6% in warehouses.
- Based on facility prices in the public sector, 86% of the baskets of available essential medicines are affordable to most of the population. On the other hand, given the prices paid by patients, only 67 % are affordable.
- Based on both prices paid by health facility and prices paid by patients in the private sector, only 53% of the baskets of available essential medicines are affordable to the most of the population.
- The national median lowest price paid by patients for a basket of medicines was 2.02 times the international reference price in the public sector and 3.3 in the private sector. At the same time the national median lowest price paid by facilities for a basket of medicines was 1.6 times the international reference price in the public sector and 2.57 in the private sector.

In Darfur it was difficult to assess the contribution of non government organizations due to the variety of systems followed and the policies developed to govern and organize the work.

2. Quality of medicines

Regarding the quality of medicines the results have shown that 65% of store rooms and 55% of dispensing rooms in public sector have good storage conditions. However, 38% of store rooms and 20% of dispensing rooms scored less than 50% for conservation conditions. Adequacy of storage conditions and handling of medicines was found in 75% of warehouses.

Up to now, the country has not implemented a creative solution taking into account distance and country environment for the transportation of medicines to ensure maintaining the quality until reach the patients.

3. Rational use of medicines

- The median number of medicines per prescription was found to be 2.28.
- Median value of medicines adequately labeled was 61.9%.
- Percentage of patients who know how to use medicines in public health facilities Median value was 80%.
- The median value of patients receiving antibiotics was 63.3%.
- In 75% of public facilities 73.3% of prescribed medicines were antibiotics.
- The median value of the percentage of patients receiving injections out of the total prescriptions was 23.3%.
- Although the availability of the Essential Medicines List in public health facilities was 3.4%, the median percentage value of medicines prescribed according to the national EML was 83.6%.
- The median percentage value of medicines prescribed in generic names (INN) was 40.6%.

The Level 1 Questionnaire was used to compare the achievement and malfunctions of the pharmaceutical sectors between the years 2003 and 2007 to assess whether previous identified malfunctions were corrected at current time.

There was a tangible improvement in the adherence to the national drugs policy and the regulatory system guidelines. Regarding quality control there was an improvement in the sample collection, testing and governing.

The malfunctions noted were quite significant especially in the lack of support from the regulatory systems. It was also noted that the weakness in the medicines supply system with regards to regulations of the medicines prices and medicines donation.

The most significant malfunction noted was in the area of rational use of medicines where it lacked policies, commitments, promotional strategies, education and practices.

■ Conclusion

The survey and assessment of pharmaceutical sector both public and private, showed significant shortcomings regarding the expected services for the northern states of Sudan.

The strengths that have been shown in the assessment were included commitment of the government to the implementation of the National Medicine Policy, establishment of an independent drug regulatory authority and the significant growth in the number of importers, wholesalers and pharmaceutical outlets. As well establishing of the RDF project at all northern states resulted in a good availability of essential medicines in northern part of Sudan.

There was a considerable percent of the public who do not have to access essential medicines mainly due to affordability factors, in addition to availability factors in public health facilities in Darfur;

Essential Medicine needed by patients represent nearly 70% of the cost of the care compared to an excessive 90% in the Darfur state.

There is a need to establish a mechanism e.g. cost sharing mechanism, to improve accessibility to essential medicines.

The rational selection of medicines should be closely considered, since it influences the availability of medicines with the adequate distribution system and efficient prescribing and dispensing practices by health care providers.

■ Recommendations

The main recommendations were:

- The improvement of health outcome, access to health services, medicines supply , it's quality and rational use ; should not only be following the specific policies and guidelines but should be molded around the current structure of health care and the demand for the basket of essential medicines. It should also be considered how this will affect the dynamics of the pharmaceutical sector and both the public and private healthcare services.
- Developing and implementing a Committees' Program Scheme in the federal and state levels for both the public and private health care sectors in collaboration with Curative Medicines Directorate. This includes the development of guidelines and training manuals.
- Developing an action plan that covers the deficits identified by the indicators. This action plan should fit within the current pharmacy sector governmental strategic plan. Special consideration should be directed to implement a set of measures to improve the affordability situation in Sudan. In addition the services quality needs to be evaluated at different levels including a constant monitoring and evaluation system where results are reviewed and allied to the policies existent and any intervention planned.
- Establishing drug therapeutic committees to assist in improving health facilities medical supply system. Considering the decentralization of services, provision of supplies at the locality level, will be the most effective policy intervention that will ensure the most impact.
- Introducing educational campaigns to service users and service providers to ensure a more efficient outcome. This should include development of guidelines and training manuals about the good prescribing practice in collaboration with Curative Medicines Directorate.

Chapter (1)

Introduction

1.1. Background

Sudan, the largest country in Africa is located on the Eastern coast and it is bordered by nine countries. Its area is around one million square miles. The population of Sudan is estimated to be 35.4 million. According to the Comprehensive Peace Agreement, an intermediate level of government was introduced in southern Sudan known as the Government of South Sudan.

Sudan adopted the federal system (decentralization) in 1996 and this resulted in the division of 15 states in north and 10 in the south. Each state divides into localities giving a total of 199 localities in all states.

Sudan is detrimentally affected by conflicts. It has different political, socioeconomic and cultural factors that formulate a complicated health system structure, challenging expected achievements. Government resources are not sufficient to comply with the expanding demands and required services, including quality medicines with affordable prices to patients and communities. Details for the basic country indicators are shown in [Table \(1\)](#).

The current country's structure for health system includes three levels: federal, state, and localities. The federal level is concerned with policy making, planning, supervision, co-ordination, international relations and partnership. The state level is also responsible for planning, policy making and the implementation at its level, while the localities are mostly concerned with policy implementation and service delivery, including health, education, and development.

The Interim Constitution of the Republic of the Sudan states that the commitment of the Government should provide universal and free basic health services. In addition, Federal Ministry of Health (FMOH) policy indicates that the minimum package for Primary Health Care (PHC) services should include essential medicines. Nevertheless, only 22% of the existing primary health facilities are providing the minimum essential PHC package.

The epidemiological profile is marked by the heavy burden of endemic diseases, with a growing threat from HIV/AIDS and high risk of epidemics. Communicable diseases are a major concern. The main causes of morbidity and mortality are infectious and parasitic diseases: mainly tuberculosis, diarrhea, malaria, measles and acute respiratory infections. Southern Sudan hosts an estimated 80% of the total guinea-worm cases world wide. Sleeping sickness and Leishmaniasis are endemics in addition to many other epidemics: respiratory tract infections, diarrhea and Malaria with other diseases (2005& 2006).

“Out of pocket” is the principal system adopted for most of the health services in Sudan. The coverage of the national health insurance is still considerably low especially at state level; only about 23% of populations are covered. Medicines are covered in this scheme and the patients pay 25% of the prescription cost for their treatment.

Although there are some regulations in place for medicines prices, there is no well defined “national” pricing policy for medicines in Sudan. It depends on the individual organizations experience in the Directorate General of Pharmacy (DGoP), Central Medical Supplies Public Corporation (CMS), and Revolving Drug Fund project (RDF). In the private sector, 15% is the wholesalers margin, 20% is retailers margin and 35% as other additives.

The finance of the health services has changed from freely offered services to implementation of user fees in public health facilities. Yet emergency cases at hospitals are exempted from user fees as well as renal dialysis, immune suppressant medicines for renal implantation, chemotherapy, radiotherapy and treatment of hemophilia.

Table (1): Basic country indicators

Population Data			
	Figure	Year	Source
Total population	35.4 million	2004	WHO
% of population 0-14 years	43.2%	2004	WHO
% of population growth rate	2.5%	2004	WHO
Life expectancy at birth	55 years	2004	WHO
% of population are living in the urban areas	32%	2004	WB
Birth rate per 1000	37.8	2004	FMOH
Death rate per 1000	11.5	2004	FMOH
Basic Economic Indicators			
Indicator	Figure	Year	Source
GDP per capita	700	2006	FMOH
Total expenditure on health (per capita)	21	2003	WHO
Total governmental expenditure on health as % of total health expenditure	43.2	2003	WHO
Out-of-pocket expenditure as % of total health expenditure	54.6	2003	WHO
Per capita for total Medicines expenditure (all sectors)	US\$ 7	2005	FMOH
Per capita for public Medicines expenditure	US\$ 0.4	2005	FMOH
Key Health Indicators			
Indicator	Value	Year	Source
Pharmacists per 10000 population	0.20	2004	WHO
% of population with access to local health services	66%	2000	WHO

1.2. Pharmaceutical System in Sudan

Following the decentralization of the system, the pharmaceutical sector was reorganized to ensure the availability of essential medicines in sufficient quantity, good quality and at affordable prices. This situation analysis was supported by Level 1 Questionnaire and most of the results have been presented in this report as shown in [Annex \(2\)](#).

The Federal Board of Pharmacy and Poisons (FBPP) was created in 2001 to represent relevant parties in the governmental, private, and other sectors that deal with medicines. It has been considered as the national medicines regulatory authority in the country that is responsible for putting into effect the Pharmacy and Poisons Law, 2001. There is a directorate of pharmacy in each state that acts as a regulatory body i.e. implementing plans that are developed by the FBPP. The Pharmacy and Poisons law covers all regulatory related areas including marketing authorization of pharmaceuticals, good manufacturing practices, control on promotion and advertising of medicines, importation/exportation of medicines, licensing and inspection.

The Federal General Directorate of pharmacy is responsible for developing pharmaceutical policies, essential lists of medicines and their rational use, hospital pharmacy and drug information systems.

The CMS is a semi autonomous public organization responsible for medical supplies in Sudan. The government delegates the CMS to provide medical supplies services to the entire population of Sudan, including the selection, procurement, storage and distribution of medicines. Within the CMS there is a major RDF project, which facilitates the process of supply and distribution of medical supplies through its states branches to different parts of Sudan, especially northern states.

The statistic report for the DGoP (2006) indicated that the Health Insurance covers only 12.3% of total population.

Private medicines distribution agencies work in the importation and distribution of medical supplies. The total number of agencies is about 283, 98% of which is based in Khartoum. About 12% of registered pharmacists work to this sector.

Although there is a number of pharmaceutical manufactures in Sudan, they are under developed and/or utilized in the production capacities.

Private retail medicine outlets combine both pharmacies and simple medicines stores. The distribution of these facilities in the past was not based on clear action plans.

Non governmental organizations (NGOs) are working in medicines supply in post conflict areas in Sudan.

The Pharmaceutical sector has several deficits regarding the number and capacity of the pharmacy workforce. Reports indicated that the average availability of pharmacists is 0.4 pharmacists per 10,000 population compared to the target which is 1 pharmacist per 10,000 population.

1.3. National Drug Policy (NDP)

Sudan is considered as one of the few countries in the region that started to put together the National Drug Policy. In 1981 Sudan introduced the first national pharmacy policy and this prompted WHO to extend its assistance to Sudan by implementing its NDP, especially for the physical rehabilitation of CMS buildings and facilities, capacity building of its human resources, and for the implementation of Sudan Essential Drugs Program. The NDP played an important role in promoting the concept of essential medicines, and in improving the national medicines supply system. It also promoted the rational prescribing, dispensing and use of medicines, improvement of education and training of health workers, strengthening medicines information, medicines research, and capacity building of human resources.

The last updated NDP was published in 2005. It was formulated according to the WHO guidelines on developing NDP with commitment to enforce the concept of essential medicines and its principles. The Federal Ministry of Health updated its National Health Policy in 2006, which included the NDP as part of Sudan's national health policy.

1.3.1. Objectives of the NDP

- To make available the needs of the population in terms of essential medicines of assured safety, efficacy and quality in adequate amounts at the least possible cost to the individual, the community and the state.
- To promote rational use of essential medicines.
- To provide up to date pharmaceutical services in accordance with the concept of pharmaceutical care, and to promote the role of the pharmacist in the maintenance and restoration of health and his contribution to the fight against diseases.

1.3.2. Components of NDP components

In addition to the NDP commitment to adopt the concept of essential medicines, there are nine major components as follows:

1. Pharmaceutical regulations and control that states the importance of establishing the Federal Board of Pharmacy and Poisons to act as the national medicines regulatory authority (MRA).
2. Quality assurance of medicines that states the responsibility of the MRA for the quality assurance of medicinal products throughout manufacture, importation, transportation, distribution and dispensing. Specifically, MRA is responsible for:
 - Standards, specifications and legal requirements.
 - Registration of medicinal products.
 - Laboratory quality control.
 - Licensing of pharmaceutical establishments.
 - Pharmaceutical inspection.
 - Pharmaceutical control in the states.
3. Supply of medicines, which states the aim of the NDP to ensure accessibility to safe, effective and quality medicines at affordable prices. Therefore the NDP states the role of both public and private sectors and their responsibilities to stick to the good procurement practices and good distribution practices.
4. Rational use of medicines, which targets the importance of developing strategies to improve the medicines implanting the concept of the national essential medicines list (EML), education, training and public education.
5. Pharmaceutical services in health institutions that is concerned with the responsibility of the government for provision of pharmacists at health facilities in the public sector. As well it is stated the necessity to improve the pharmaceutical services in hospitals, scientific researches, and pharmaceutical statistics and planning services.
6. Integration of medicinal plants in health systems for primary health care.

7. Technical and scientific cooperation with other countries in all themes related to medicines.
8. Monitoring and evaluation of the implementation of the NDP.
9. Adoption of the NDP by the government and developing a pharmaceutical master plan indicating the procedure of implementing all the components of the NDP.

1.4. Medicines Supply

Medicines supply in Sudan are obtained through public sector organizations; mainly CMS and through the private sector mainly the whole sellers and local manufacturers. The procurement of medicines in most cases is an open comparative tendering open for both local and international suppliers.

Chapter (2)

Methodology and Study Design

2.1. Justification of Study

1. During the last few years many changes took place in pharmaceutical sector but the impact of these changes has not been evaluated. Therefore investigating the national pharmaceutical sector in Sudan is one of the essential components in the NDP. However, due to various reasons including the political situation, this study was implemented in the northern states and the southern part of the country could not be included. In addition, the study included one of Darfur's states to represent a conflict area in Sudan, in order to give a more comprehensive picture about the situation..
2. In addition, the study will include one of Darfur's states to represent a conflict area in Sudan, which will be effective in the overall view and evaluation.
3. There is a need to check the effect of decentralization on the performance of the NDP with regard to the supply system for the public sector at state level.
4. The operational capacity of FBPP and DGoP will be the determining factors that need taken into considered.

2.2. Objectives of the study

The study aims to evaluate the situation of the country's pharmaceutical sector generally to:

- Assess a country's capacity to implement the various elements of the NDP;
- Monitor the processes by which the NDP is applied and the changes that occurred over a period of time;
- Measure the impact of implemented strategies;
- Collect baseline information on the pharmaceutical sector; and
- Identify priorities in the implementation of the revised NDP.

Specific objectives included:

- To identify the percentage of the public which have access to essential medicines;
- To recognize whether they are receiving medicines of good quality; and
- To know if the medicines are rationally used.

2.3. Scope and limitations of the data

The survey was conducted according to the WHO special package manual. The package contains two levels of core indicators, which were used in the survey:

Level I Structural and Process indicators: these were used to assess the existing structures and processes in the national pharmaceutical system. See [Annex \(2\)](#).

Level II Outcome indicators: these support Level I indicators by providing specific data about the important pharmaceutical outcomes.

The WHO methodology was adopted to match the inequitable geographical distribution of the population in Sudan and the capacities of health care services.

Data collection and analysis was adapted to produce results that can enable the identification of deficits in policies, plans and the interventions needed to fill these gaps, as well as enabling the comparison between Sudan and similar countries.

2.4. Indicators used for level II survey

2.4.1. Accessibility to Medicines

- Percentage of available key medicines in public health facilities, private pharmacies and warehouses supplying the public sector.
- Percentage of prescribed medicines actually dispensed or administered to patients in public health facilities.
- Average stock out duration (days) in public health facilities and warehouses supplying the public sector.
- Adequate record keeping at public health facilities and warehouses supplying the public sector.
- Affordability of treatment for adults and children under five years of age at public health facilities dispensaries and private drug outlets.
- Prices of key medicines in public health facilities in comparison to international reference prices.
- Prices of key medicines in private sector in comparison to international reference prices.

2.4.2. Quality

- Percentages of medicines expiring in public health facilities, private pharmacies and warehouses supplying the public sector.
- Percentages of adequacy of conservation conditions and handling of medicines in public health facilities and warehouses supplying the public sector.

2.4.3. Rational use of Medicines

- Average number of medicines per prescription in public health facilities.
- Percentages medicines adequately labeled in public health facilities.
- Percentage of patients in Public Health Facilities who know how to take medicines in public health facilities.

- Percentage of patients prescribed antibiotics in public health facilities.
- Percentage of patients prescribed injections in public health facilities.
- Percentage of prescribed medicines on the Essential Medicines List in public health facilities.
- Percentage of medicines prescribed by their generic name (INN) in public health facilities.
- Availability of Essential Medicines List in public health facilities.
- The availability of Standard Treatment Guidelines in public health facilities using certain tracer diseases.
- Prescriptions according to Standard Treatment Guidelines (STGs) using certain tracer diseases in public health facilities.

2.5. Sampling Procedure

2.5.1. Geographical areas included in study

In addition to the central level investigation using Level 1 Questionnaire, [Annex \(2\)](#), the survey has been conducted in six states that represent the different geographical areas in Sudan following the WHO selection criteria.

The southern Sudan states were excluded from the survey due to the following reasons:

1. Structure of health system: there is no clear structured health system that could be evaluated especially in the area of the pharmacy sector due to conflict during last years.
2. Geographical accessibility factors: it was difficult to access the south by roads.

The selected states for the survey were:

1. Khartoum state.
2. Nile River state.
3. Red Sea state
4. North Kordofan state
5. Kassala state.
6. Southern Darfur.

Southern Darfur was a part of the conflict area; therefore it was surveyed to measure a special situation in the Darfur states. Its data was not analyzed collectively with the other states data, but its results were used in comparison with the average data of the other states.

2.5.2. Sampling of health facilities

The total surveyed number was 37 public health facilities and 37 private pharmacies and 6 warehouses from central, regional and district areas. Within each region, the following facilities were selected:

- Six public health facilities were surveyed. The selection in the public sector included:
 - The biggest public hospital in the state,
 - One primary health center,
 - Four middle level public health facilities.
- One health facility from the federal hospitals.
- Six private outlets including the nearest private outlets to each public health facility selected in the survey.
- One warehouse, usually the biggest one.

2.5.3. Sampling of Patients

The survey included both retrospective and prospective sampling.

Retrospective (per health facility): Thirty patients' records were randomly taken from each health facility recorded not more than 6 months from the sampling dates. When a health facility had poor record systems, the data was collected prospectively instead of retrospectively.

Prospective (per health facility): Thirty patients were interviewed while they were leaving the dispensing area, the pharmacy or the health facility and after they have been medically checked and had received their medicines from the pharmacy.

A number of health facilities did not have adequate number of patients, so the targeted sample number could not be achieved.

2.5.4. Selection of Basket of Key Medicines

A list of 15 key medicines that were used to treat common health problems in the country were selected for the study regardless of the dosage form. The study measured the availability, presence of expired medicines, medicine price and stock out duration for this basket of medicines. These medicines are indicated in [Annex \(1\)](#).

Chapter (3)

Results

3.1. Presentation of the Results

The average of the results for all the states except southern Darfur was considered as national figures. South Darfur's results (referred as Darfur figures) were considered as special figures for conflict area and were used for comparison with the national figures.

Each indicator represents results from all surveyed sectors: public health facilities, private outlets, and warehouses.

In case of Southern Darfur state, as it has been chosen due to special considerations, its results was represented separately and then compared with the national average figure.

3.2. Facilities and Patients' Data

The total number of facilities surveyed in the study was 78 facilities, 31 of which were rural public health facilities. In addition 31 private pharmacies and 5 warehouses were also included in the sample [Table \(2\)](#).

Table (2): Number of Surveyed Health Facilities

Type of facility	National		Darfur	
	Number	% Rural	Number	% Rural
Public Health Facility	31	23%	6	16.7%
Private Pharmacies	31	6%	4	0%
Warehouses	5	0%	1	0%

The total number of patient interviewed was 2924 patients 55.1% of which was females [Table \(3\)](#).

Table (3): Percentage of females in the surveyed patients' data in public facilities

No of samples	Average		Median
	National	Darfur	
Total samples number	1703	231	
Total female number	875	115	
Percentage of female samples	50.4%	50.6%	55.1

3.3. Summary findings

The main results of the indicators used in the survey are shown in [Table \(4\)](#).

Table (4): Summary of findings

Indicator	Type of health facility	Average		Median
		National figure	Darfur figure	National figure
3.3.1. Accessibility to essential medicines				
3.3.1.1. Availability				
Availability of key medicines in public health facilities	Public health facilities	86.1%	61.7%	86.9%
	Private pharmacies	95.1%	90.0%	100%
	Warehouses	81.4%	73.3%	86.7%
% of prescribed medicines actually dispensed or administered to patients	Public health facilities	84.4%	68.9%	89.5%
Average stock out duration (Days)	Public health facilities	18.4	NA	0%
	Warehouses	21.4	21.3	9.5
Adequate record keeping	Public health facilities	28.5%	0%	0%
	Warehouses	82.6%	80%	100%
3.3.1.2. Affordability: calculations done based on the Lowest Daily Government Salary in Sudan which equals to 4.2 SDG = 2.1 US\$				
Affordability of treatment for adults Pneumonia (Days)	Public health facilities	1.3	2.9	3.6
	Private pharmacies	1.6	4.2	4.2
B-Affordability of treatment for children under 5 years -	Public health	0.59	0.4	0.6

Indicator	Type of health facility	Average		Median
Pneumonia (Days)	Private pharmacies	0.71	0.6	0.7
Affordability of treatment for adults – Malaria (Days)	Public health facilities	0.6	0.6	0%
	Private pharmacies	1.86	1.9	1.9
3.3.2. Quality				
% medicines expired ¹	Public health facilities,	0%	0%	0%
	Private pharmacies	0%	0%	0%
	Warehouses	0%	0%	0%
Adequacy of conservation conditions and handling of medicines	Public health facilities – Dispensing room	54.8%	66.7%	68.8%
	Public health facilities – Store room (if any)	64.6%	62.5%	50%
	Warehouses	75%	50%	75%
3.3.3. Rational use of Medicines				
% Medicines adequately labeled	Public health facilities.	55.5%	29.0%	61.9%
% Patients who know how to take medicines	Public health facilities	75.7%	80.2%	80%

¹ Expired medicines: The figure 0% is not a real statement as the practice differs in small outlets, especially in the rural areas in both the public and private sector, which are out of the scope of this study.

Indicator	Type of health facility	Average		Median
Number of medicines per Prescription	Public health Facilities	2.28	2.44	-
% Patients prescribed antibiotics	Public health facilities	65.0%	70.4%	63.3
% Patients prescribed injections	Public health facilities	28.6%	19.2%	23.3
% Prescribed medicines on the Essential Medicines List	Public health facilities	73.0%	65.2%	83.6
% Medicines prescribed by generic name (INN)	Public health facilities	43.5	50.1%	40.6
Availability of current Essential Medicines List	Public Health Facility	3.4%	-	0%

Availability of Standard Treatment Guidelines using certain tracer diseases

a-Availability of Standard Treatment Guidelines (Diarrhea + Malaria)	Public health facilities	0.1%	0%	0%
b-Availability of Standard Treatment Guidelines (Malaria Only)	Public Health Facility	54.8%	50%	

Prescribing according to STGs using certain tracer diseases

a- % Tracer cases treated according to recommended STG –

Diarrhea Under 5year age

Oral Rehydration Salt	Public health facilities	48.6%	30.6%	10%
Antibiotic	Public health facilities	58.8%	84.4%	60%
Antispasmodic and/or Anti diarrheal	Public health facilities	43.4	24.0%	30%

b- % of tracer cases treated according to recommended STG –

Indicator	Type of health facility	Average		Median
Malaria Adult				
Treatment of malaria with Artesunate + Sulphadoxine & Pyrimethamin	Public health facilities	64.1%	61.4%	70%
Other antibiotics	Public health facilities	40.8%	45.6%	40%
Other medicine(s)	Public health facilities	55.7%	77.2%	50%

As oral rehydration salt (ORS) and the combination of Artesunate + Sulphadoxine/Pyrimethamin (SP) availability are critical to public health, therefore their availability was separately calculated as shown in [Table \(5\)](#).

Table (5): Availability of ORS and Artesunate + SP in public health facilities

Medicine	National		Darfur	
	Public	Private	Public	Private
ORS	67.7%	83.9%	50%	83.3%
Artesunate + SP	100%	100%	100%	100%

3.3.1. Accessibility to essential medicines

3.3.1.1. Availability

3.3.1.1.1. Availability of key medicines in public health facilities and district warehouses

- The median availability of the basket of 15 key medicines in public health facilities and regional distribution points was found to be 86.85 %.
- The minimum availability was found to be 46.6% for the public facilities and the regional distribution points.
- 75% of facilities had all key medicines available.
- The average availability of key medicines in public health facilities was found to be 86.1%.

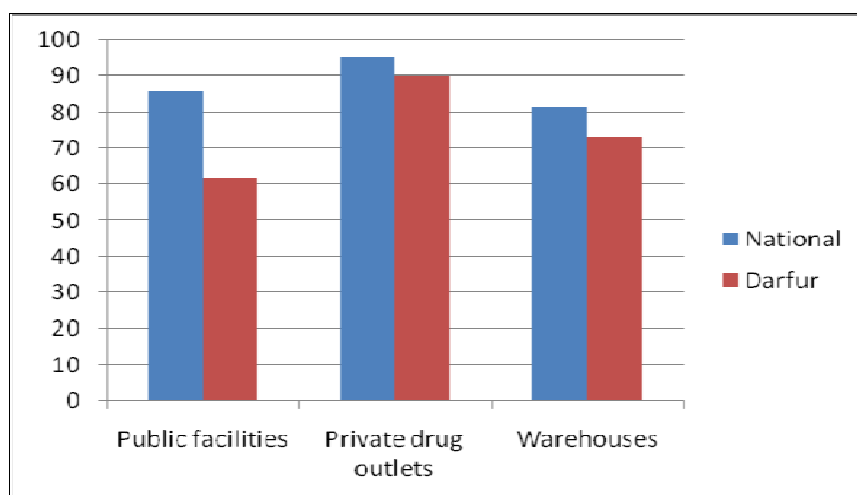
[Figure \(1\)](#) indicates the percentage of the availability of key medicines in public health facilities, private drug outlets and warehouses.

The availability of each of ORS and Artesunate + SP was measured separately due to their importance to health care in Sudan.

- In public health facilities the average availability of ORS was found to be 67% as national figure and 50% in Darfur;
- In private outlets availability was almost the same in Darfur and other surveyed states; 83.3% and 83.9% respectively.
- The availability of the combination of Artesunate + SP in public health facilities and private outlets was found to be 100%. In Darfur it was 100% in private health facilities, but less than 80% in public health facilities.

Figure (2) shows % of availability of ORS and Artesunate + SP tablets in public health facilities, private drug outlets and warehouses.

Figure (1): Percentage of availability of medicines in public health facilities, Private outlets and warehouses



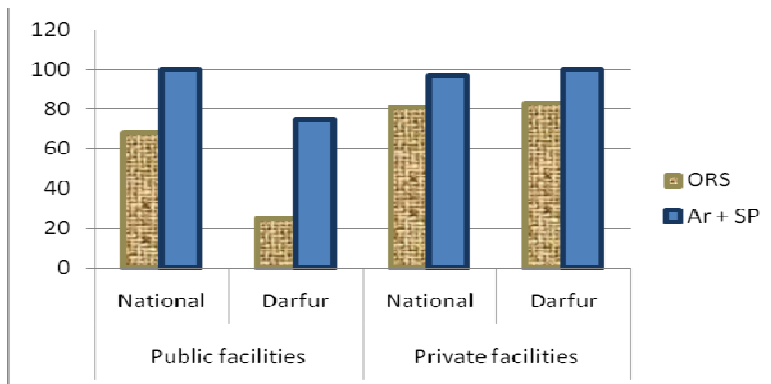
Recommendations

- Establishing units at state level to monitor the availability of medicines at lower level health facilities (public & private).
- A programme to build capacities in drug supply management at health facilities should be established and implemented.
- Norms, standards and guidelines should be widely available, adapted and their use should be enforced at all facilities.
- Developing of Drugs & Therapeutics committees Program scheme in the federal level and implement it at state level in collaboration with Curative Medicines Directorate/FMOH in order to manage medicines selection, procurement and rational use efficiently at health facilities.

3.3.1.1.2. Stock out

- Median stock out duration was 0% and the average stock-out duration was 18.3 days in public health facilities.
- 65.5% of the surveyed facilities did not experience stock out during the past 12 months.
- 13.8 % of the public health facilities experienced stock out for less than one month during the past 12 months.
- 20.7% of the public health facilities experienced stock out for more than one month. One facility had experienced 243 out of stock days.

Figure (2): Percentage of availability of ORS and Artesunate + SP



Recommendations

- Investigate why availability of ORS is low in public health facilities and develop intervention to increase the availability of all essential medicines.
- Investigate why some medicines are out of stock for a longer than one month period and develop ways to increase the availability of medicines in public health facilities and regional warehouses.
- Investigate why one region seems to have significant problems and had stock out for more than 6 months.
- Investigate and develop strategies for improving the quality of stock records in both the public health facilities and regional warehouses.

3.3.1.1.3. Percentage of prescribed medicines actually dispensed in health facilities

- The median percentage of medicines dispensed was found to be 89.45%.

- The value of the 75% percentile was 94.2 % of prescribed medicines.
- 25% of health facilities dispensed 75.2% or less of prescribed medicines.
- Minimum value of dispensed medicines was found to be 58% of prescribed medicines.
- 53.6% of health facilities dispensed 90% or less of the prescribed medicines.

Recommendations

- Investigate why not any facility dispensed 100% of the prescribed medicines.
- Investigate why more than 53% of facilities dispensed less than 100% of prescribed medicines.
- Investigate and develop interventions to ensure that all the prescribed medicines are dispensed to patients in public health facilities.

3.3.1.1.4. Adequate record keeping in health facilities

- The median percentage of adequately keeping records in health facilities was found to be 0%.
- The average percentage of adequately keeping records in health facilities was 28.5%.
- The average percentage of adequately keeping records adequately in Darfur was 0%.
- The median percentage of adequately keeping records in warehouse was 100%.
- The average percentage of adequately keeping records was found to be 82.6% in warehouses and 80% in Darfur.

Recommendations

- Develop, implement and monitor a set of national generic SOPs, Norms and Standards as part of the drug supply management.
- Dissemination of Norms and Standards to all levels of service, adapt and enforce them at all facilities.

3.3.1.2. Affordability

As the affordability is based on equity of medicines' prices, the following equation was used to know how much do the patients actually pay:

$$\frac{\text{Value of a basket of medicines in public/private sector}}{\text{Value of the same basket with the cheapest medicines in public/private sector}} \times 100$$

The average cost of medicines dispensed including the fees in public health facilities were calculated as are shown in Table (6), while Tables (7) and (8) show the details of the median lowest price of key medicines paid by health facility and by patient and the comparison of these prices to international reference prices in public and private sectors respectively.

Table (6): Average cost of medicines dispensed including fees in public health facilities

	National Figure	Darfur Figure
Average	9.8 SDG (4.9 US\$) equivalent to 67.6% of the total cost of treatment.	4.6 SP (2.3 US\$) equivalent to 94.6% of the total cost of treatment.
Median	7.85 SDG	

3.3.1.2.1. Price of key medicines at public sector

- Numbers are in SDG (1 SD = 0.5 US\$).
- The reference price (2007) doesn't include any additives as it is suppliers' prices and it was calculated for the same unit number.

Table (7): Prices of key medicines in public sector in comparison to international reference prices

Medicine	Number of Units	National Median Lowest price paid by		Reference Price
		Facility	Patient	
ORS powder/sachet	1 sachet	0.4	0.5	0.105324
Artesunate + SP Tablets (50mg+500mg+25mg)	9 Tablets	0	0	6.347178
Co-trimethoxazole Tablets (400 mg+ 80mg)	20 Tablets	1.25	2	0.73968
Amoxicillin 25 mg/ml suspension (100 ml)	I Bottle	2	2.45	1.206
Ferrous sulphate + Folic Acid Tablets (60 mg+ 0.4mg)	30 Capsules/Tablets	1.55	2.5	0.07839
Mebendazole Tablets 500 mg	1 Tab	1.45	1.5	0.30552
Tetracycline eye ointment 15 g ointment	I Tube	0.6	0.75	0.32562
Clotrimazole Ointment	I Tube	2.7	3.5	0.55476
Povidone Iodine Solution, 10%	I Bottle	2	2.5	0.9246
Diclofenac Tablets 25 mg	10 Tablets	0.8	1	0.10653
Metronidazole Tablets 500 mg	20 Tablets	0.8	1	0.61104
Antacid Tablets	10 Tablets	0.55	0.75	0.27939
Paracetamol 500 mg Tablets	10 Tablets	0.3	0.5	0.04824
Pyridoxine (Vitamin B6) Tablets 25 mg	10 Tablets	1.025	1.25	0.04221
Atenolol Tablets 50 mg	30 Tablets	3.6	4.5	0.52461
Total		19.025	24.7	12.19909

3.3.1.2.2. Price of key medicines at private sector

- Numbers are in SDG (1 SDG = 0.5 US\$).

The reference price doesn't include any additives as it is suppliers' prices and it was calculated for the same unit number.

Table (8): Prices of key medicines in private sector in comparison to the international reference prices

Medicine	Number of Units	National Median Lowest price paid by		Reference Price
		Facility	Patient	International
ORS powder/ sachets	1 sachet	0.55	0.75	0.105324
Artesunate + SP Tablets (50mg+500mg+25mg)	9 Tablets	6	7.5	6.347178
Cotrimoxazole Tablets (400 mg+ 80mg)	20 Tablets	1.4	2	0.73968
Amoxicillin 25 mg/ml suspension (100 ml)	1 Bottle	2.1	3	1.206
Ferrous sulphate + Folic Acid Tablets (60 mg+ 0.4mg)	30 Capsules/Tablets	4.2	5.1	0.07839
Mebendazole Tablets 500 mg	1 Tab	2.25	3	0.30552
Tetracycline eye ointment 15 g ointment	1 Tube	0.63	0.75	0.32562
Clotrimazole Ointment	1 Tube	2.8	3.5	0.55476
Povidone Iodine Solution, 10%	1 Bottle	3.2	4	0.9246
Diclofenac Tablets 25 mg	10 Tablets	0.7	1	0.10653
Metronidazole Tablets 500 mg	20 Tablets	1.4	2	0.61104
Antacid Tablets	10 Tablets	0.6	0.75	0.27939
Paracetamol 500 mg Tablets	10 Tablets	0.4	0.5	0.04824
Pyridoxine (Vitamin B6) Tablets 25 mg	10 Tablets	1.54	2	0.04221
Atenolol Tablets 50 mg	30 Tablets	3.6	4.5	0.52461
Total		31.37	40.35	12.19909

- The national median lowest price paid by patients for a basket of medicines was found to be 2.02 times the international reference price in the public sector and 3.3 in the private sector. At the same time the national median lowest price paid by facilities for a basket of medicines was found to be 1.6 times the international reference price in the public sector and 2.57 in the private sector.
- Public health facilities add an average of 31% as retail markup and the private facilities add an average of 25% on the wholesale prices.

- The prices for some medicines in both sectors were found to be high when compared to the international prices. These medicines were: Ferrous sulphate + Folic Acid (60 mg+ 0.4mg) tablets, Mebendazole 500 mg tablets, Clotrimazole ointment, Povidone Iodine solution 10%, Pyridoxine 25 mg tablets and Atenolol 50 mg tablets. For details see [Tables \(6\) and \(7\)](#).

The calculation based on the consideration of any treatment that costs more than income of one day as none affordable medicine. With regard to the lowest income, this is US\$ 2.00 per day:

- Based on facility prices of the public sector, 86% of the baskets of the available essential medicines are affordable to the most of the population. On the other hand, given the prices paid by patients, only 67 % are affordable.
- Based on both facility and patients' prices of the available essential medicines in the private sector, only 53% of the baskets of available essential medicines were affordable to the most of the population.

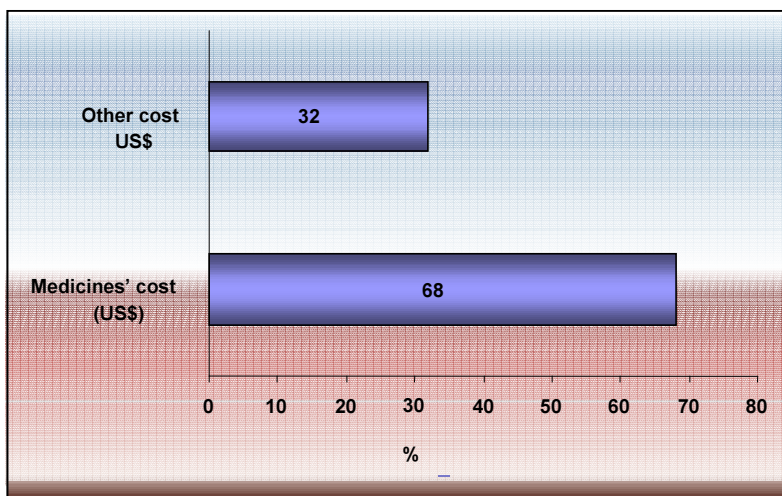
The results also showed, [Figure \(3\)](#) that medicines represent 68% of the total costs paid by patients in public health facilities in the surveyed states and 94% in Darfur.

Recommendations

- Design, establish and maintain a system for the monitoring and dissemination of the cost of essential drugs to both suppliers and consumers to ensure the availability of essential drugs to the consumers at the minimum possible prices.
- Periodical review of registered prices of medicines and use of international reference prices for comparison and ensuring suitability of the supply prices.
- Review of price components and reduce taxes on medicines.
- Regulatory authorities should have a mechanism to regularly check accurate pricing and to ensure the application of correct retail prices when outlets sell medicines to patients.
- Evaluate the impact of currently adopted cost-sharing scheme on the affordability to track the most effective ways that could reduce the burden on patients to pay for their treatment.
- Conduct in-depth assessment of affordability and its limiting factors among the community and develop interventions that reduce the problems.
- Enforcement of policies for prescribing in generic in public health sector.
- Implementing set of measures to improve the affordability in Sudan e.g. exempting the medicines and raw materials from all governmental fees, reviewing the pricing of essential medicines, implementing the generic policy in the public sector and make the information about prices public available.

- Develop a policy that brings the public medicines supply systems all together to improve the accessibility to essential medicines.

Figure (3): Percentage of medicines' cost from the total treatment cost



3.3.2. Quality

3.3.2.1. Adequacy of storage in public health facilities and regional distribution centers

Store and dispensing rooms

- 55% of store rooms and 65% of dispensing rooms have good storage conditions.
- 38% of store rooms and 20 % of dispensing rooms scored less than 50% for conservation conditions.

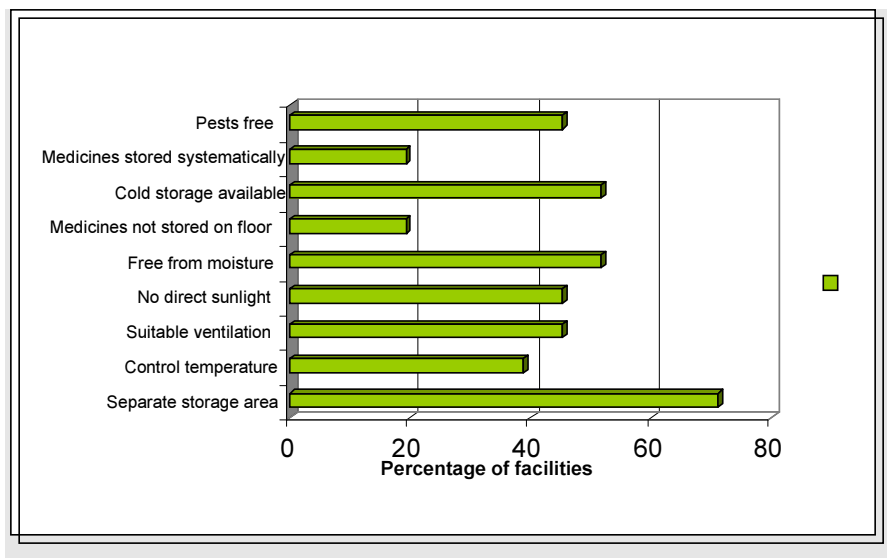
Figure (4) and (5) respectively show storage conditions found in store rooms and dispensing rooms in public health facilities.

Recommendations

- Identifying limitations in distribution and storage of pharmaceuticals at public health facilities at all state levels, and identify suitable interventions to improve the situation.
- Assess the stores infrastructure at different state levels and make the required rehabilitation.
- Develop and implement regular maintenance programs.
- Develop and implement regular training programs on monitoring storage conditions.

- Continuous supervisory visit to monitor the storage condition at all levels of states.
- Identifying limitations in distribution and storage of pharmaceuticals at public health facilities at all state levels, and identify suitable interventions to improve the situation.

Figure (4): Storage conditions at store rooms in public health facilities



3.3.3. Rational use of medicines

3.3.3.1 Number of medicines prescribed per patient in public health facilities

- The average number of medicines per prescription is 2.28.
- No facility was encountered an averaged more than three medicines per prescription.

Recommendations

- Plan interventions for prescribers to cope with unreasonable patient demands.
- Plan a public education campaign to reduce demands for unnecessary medicines.

3.3.3.2. Percentage of medicines adequately labeled in public health facilities²

- The median value of medicines adequately labeled was found to be 61.9%.
- 50 % of facilities had only 50% adequately labeled medicines.

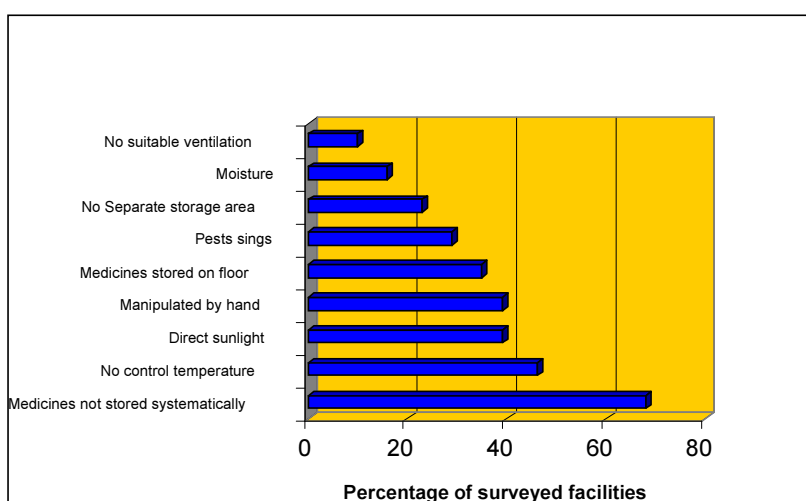
² The medicines should at least be labeled the name of the medicine, dosage and timing.

- Only one facility had 100% adequate labeling.
- In Darfur the median value was found to be only 10%.

Recommendations

- Develop guidelines and training could help to strengthen the significance of proper labeling.
- Continuous availability of equipment needed for proper labeling.
- Develop and implement managerial interventions to strengthen the significance of proper labeling.

Figure (5): Storage conditions in dispensing rooms in public health facilities



3.3.3.3. Percentage of patients in public health facilities who know how to take medicines³

- The Median value of patients who know how to take their prescribed medicines in public health facilities was 80%.
- In 67.9% of facilities more than 75% of patients had adequate knowledge.
- In 7% of facilities less than 50% patients had adequate knowledge about how to take their medicines.
- In one facility all patients did not have adequate knowledge.

³ The patient should know how to take all medicines dispensed by repeating what is on the label or written on the prescription.

- In Darfur the median value of patients who know how to take medicines was found to be 88.4%.

Recommendations

- Further investigation to identify the level of patients' knowledge about the use and storage of their medication.
- Establishing a public education programme to educate the publics about the use of medicines and to increase patient awareness.

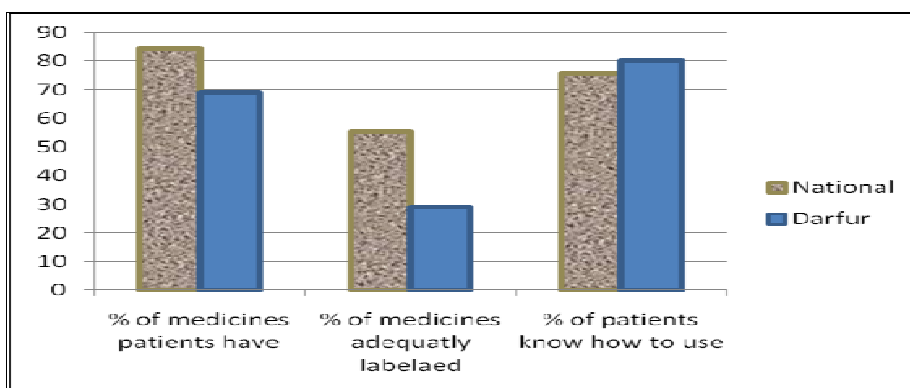
3.3.3.4. Percentage of patients receiving an antibiotic in public health facilities

According to all reviewed documents the antibiotic prescriptions on average should not exceed 30% of the total prescriptions.

- The median value of patients receiving antibiotics was found to be 63.3%.
- The average value of patients receiving antibiotics was found to be 65%.
- In 75% of public facilities 73.3% of prescribed medicines were antibiotics.
- In 10% of public facilities patients received only antibiotics.

Figure (6) shows the % of patients receiving antibiotics, % of medicines adequately labeled and the % of patients who know to use medicines correctly, while Figure (7) shows antibiotics prescribing behavior in public health facilities.

Figure (6): Percentage of patients receiving an antibiotic in public health facilities



Recommendations

Investigate why prescribing of antibiotics was high and accordingly develop interventions.

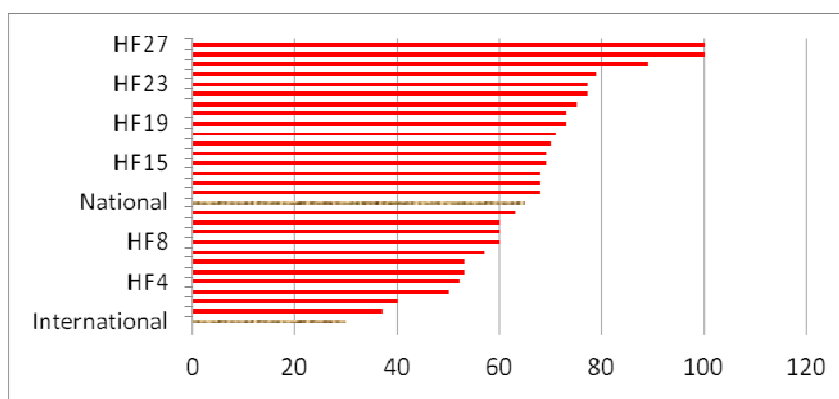
3.3.3.5. Percentage of patients prescribed injections in public health facilities

- The median value of the percentage of patients receiving injections out of the total prescriptions was found to be 23.3%.
- In 44.8% of the surveyed facilities, 30% of patients or more received injections.
- The median value in Darfur was found to be 15%.

Recommendations

- Follow-up assessment of injection records in various facilities.
- Design educational interventions for health workers on viable prescription guidelines.

Figure (7): Antibiotics prescription behavior in public health facilities



3.3.3.6. Percentage of prescribed medicines on the Essential Medicines List in public health facilities

- The median percentage value of medicines prescribed according to the national EML was found to be 83.6%.
- The percentage of medicines prescribed according to the national EML was 75% or more in 65.5 % of surveyed facilities.

Recommendations

- Investigate why medicines are prescribed off national list.
- Review the essential medicines list and update it.

3.3.3.7. Percentage of medicines prescribed by generic name (INN) in public health facilities

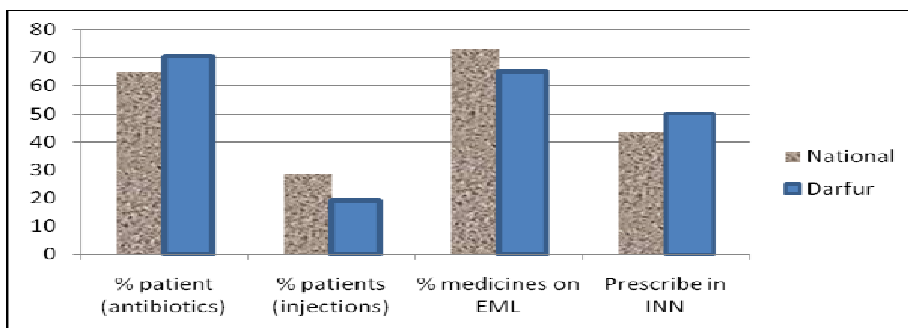
- The median percentage value of medicines prescribed in generic names (INN) was found to be 40.6%.
- The use of generic names in prescriptions (INN) was found to be less than 50% in 75.8% of the surveyed public facilities.

Recommendations

- Investigate why medicines not prescribed in generic names and develop interventions to increase generic naming.

Figure (8) shows the compliance to the prescribing package (patients receiving antibiotics, percentage of patients receiving injections, percentage of prescribed medicines on essential medicine list and percentage of medicines prescribed in INN) in public health facilities.

Figure (8): Prescribing indicators package



3.3.3.8. Percentage of availability of Essential Medicines List in public health facilities

- Only one public health facility was found having Essential Medicines List. This was representing 3.4% of the surveyed facilities.

Recommendations

- Investigate and accordingly develop interventions to identify reasons for the lack of the Essential Medicines List in more than 93% of public health facilities.

3.3.3.9. Percentage of availability of standard treatment guidelines in public health facilities using certain tracer diseases

- 93.1% of the facilities did not have standard treatment guidelines in public health facilities.
- Only two public health facilities had the standard treatment guidelines.

3.3.3.10. Prescribing according to STGs using certain tracer diseases in public health facilities

Diarrhea

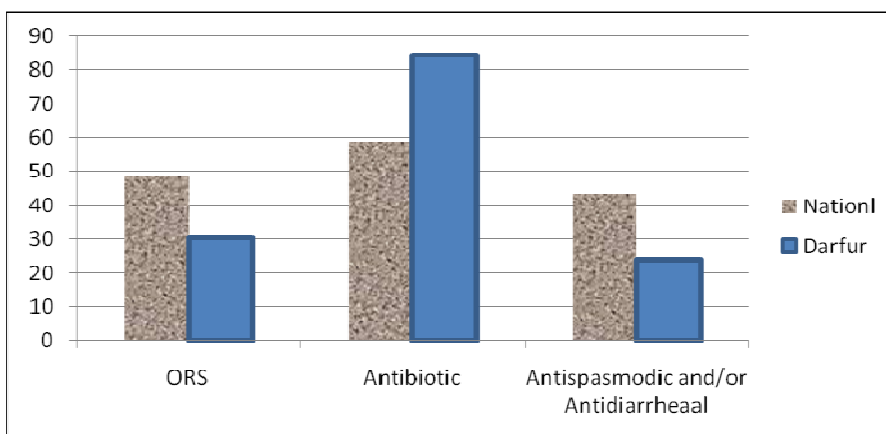
- Only 49% of children (those under 5 years of age) received ORS (31% in Darfur).
- The median value for antibiotics prescribed in public health facilities as part of children medicines to treat diarrhea was found to be 60%.
- 51.6 % of the public health facilities prescribed antibiotics to more than 50% of children as part of their medicines to treat diarrhea.
- The median value for antispasmodic prescribed in public health facilities as part of children medicines to treat diarrhea was 30%.

Figure (9) shows the percentage of patients under 5-years diagnosed with diarrhea and received antibiotics, antispasmodic and ORS treatments.

Recommendations

- Develop educational interventions to reduce the high percentage of prescribing of antibiotics in diarrhea.
- Develop educational interventions to eliminate the use of antispasmodics.
- Develop educational interventions to achieve 100% ORS.

Figure (9): Percentage of patients (under 5 years) with Diarrhea and received antibiotics, antispasmodic and ORS treatments



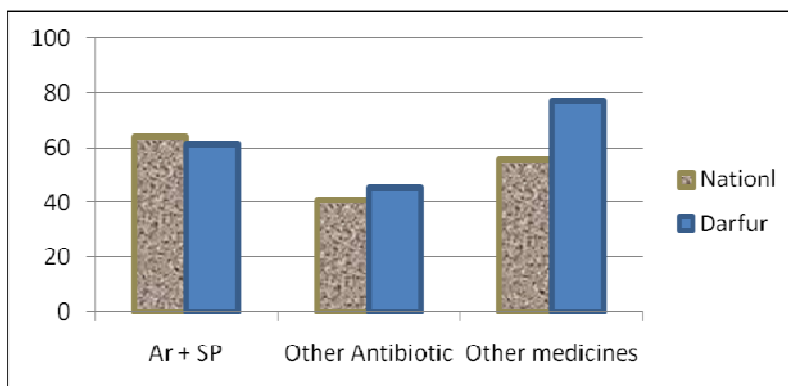
Malaria

Percentage of cases diagnosed with malaria and received the first line medicine (Artesunate + SP).

- The median value of patients treated with the first line medication and according to recommended standard treatment guidelines was found to be 70% of the cases.
- The average value was only 64.1% of cases.
- The median value for antibiotics prescribed in public health facilities for patients with malaria was found to be 40%.

Figure (10) shows the percentage of patients diagnosed with malaria and received Artesunate + SP, antibiotics, or other treatments.

Figure (10): Dispensing indicators package



Additional Recommendations

- Conducting further in-depth study on areas where shortcomings were noted to identify the underlying causes and developing suitable interventions.
- Developing and implement NDP master plan that sets responsibilities and budget line.
- Establishing of national standing committee that responsible for the developing and disseminating the national EML, STGs, Sudan National Formulary and other strategic documents.
- Developing and implementing guidelines and training manuals on the good prescribing.
- Conducting training to improve the dispensing practices.

- Introducing review and feedback systems on the practice of prescribers and the dispensers.
- Developing and implementing programmes to build capacities of the pharmacy assistants as they are as the main providers in the health facilities.
- Services quality in the area of drug supply and other pharmaceutical services need to be evaluated at different levels of the system. Regular monitoring system should be especially developed for this purpose at the national level, and the results should be linked to the planning process.

The study focused on the services provided by the public sector rather than the private sector, as the public sector is the main partner in health services provision to the public in terms of coverage and affordability.

Chapter (4)

Interpretation and Discussion of Results

4.1. Interpretation of results on main objectives of NDP

4.1.1. Accessibility to essential medicines

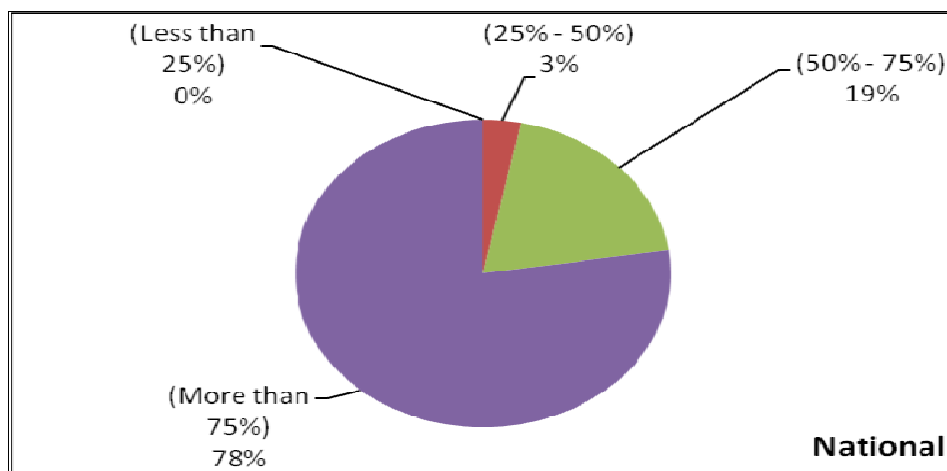
4.1.1.1. Availability

The results indicate that the availability of key medicines in the private sector is higher than in the public sector, and in the public sector it is even higher than in warehouses. However, patients found 86.1% of their needs in public health facilities comparing to 95.1% availability in private pharmacies. In Darfur, the availability is slightly less than that of the national level.

The National Essential Medicines defines the medicines that should be used at each level including those for primary health care facilities; therefore the availability of medicines at public health facilities depends on the level and type of service provided by the facility.

The availability of key medicines in 78% of the health facilities, at the national level, was found to be more than 75% of the basket of the selected medicines; while in Darfur most of health facilities had an availability level range from 50% to 75%. No facility had an availability of less than 25% of key medicines. However, 3% had availability ranges from 25% to 50%. Details for the percentage of availability in public health facilities are shown in figure (11) and (12).

Figure (11): Availability of essential medicines pattern (%) in public health facilities⁴



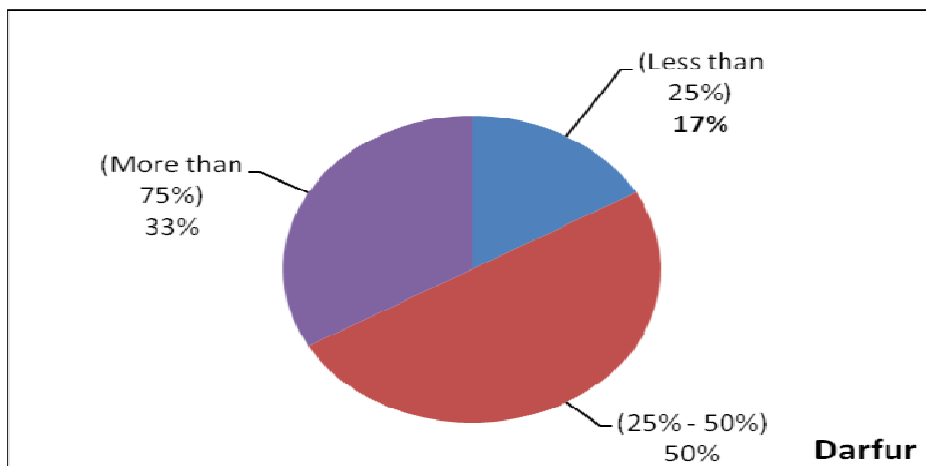
Availability of information on medicines is an essential part of the medicine itself. This information is usually available through medicine leaflets, drug information centers (DIC), public education, controlled promotion, etc. The study did not measure this parameter about information for medicines.

⁴ Darfur is not included in data for this figure.

It is also important to consider Drug Therapeutic Committees (DTCs) as a policy in the near future as a strategic option that assures the availability of most cost effective medicines at health facilities.

The partnership between the public and private sector is vital for the system in countries like Sudan. The findings indicated that there is major contribution from the private sector, and many items in RDF stores and public health facilities are supplied through the private companies. This indicates integration of both sectors as well as the flexibility of the RDF system to provide items that are not supplied by CMS directly from the private sector.

Figure (12): Availability of essential medicines pattern (%) in public health facilities in Darfur



4.1.1.2. Affordability

In 2006 a medicines' price survey was conducted in Sudan in five northern states by the ministry of health in collaboration with WHO and HAI. According to the results of this study, 44% of the surveyed medicines (total 42) were not affordable, using the lowest daily wage for governmental employee. Accordingly the government should develop, implement and monitor policies to improve this. In addition, a discussion was raised on what should be entailed in affordability calculations. Should it only include the cost of treatment or should it also include other expenses like fees, transportation, etc.

Previous studies indicated that patients may save up to 49% of the cost of medicines if they buy the lowest generic available in outlets, rather than buying brand products. This variation in medicine prices is more observed in private health facilities due to existence of private multi-suppliers. Nevertheless, when essential medicines were not prescribed in generic names, prescriptions could be expensive and often contained many products.

The study observed that anti-malarial in 38% public health facilities were not free although they are supposed to be freely supplied through global fund programs.

There is also a need to conduct household surveys to identify factors affecting accessibility to essential medicines, including patients' perception on availability, affordability, and the quality of services, as well as the ability and willingness to pay. In Darfur, post conflicts area, NGOs sector were not incorporated to work through one system which made it difficult to measure their contribution in improving the health system.

4.1.2. Quality

A proper transportation system is important to prevent the negative impact of climatic conditions on the quality of medicines, especially in a large and hot country like Sudan. However, Sudan is not considering controlling measures needed to transport medical supplies around the country. The main modes of transport used by major public suppliers are cargo trucks from Khartoum to the different states. At state level, 25% of hospitals and 35% of health centers were dependent on the rented trucks to transport their orders from RDF to the health facility.

4.1.3. Rational use

- The results indicate that the average knowledge of the patients is considerably higher compared to expectations. The treatments prescribed are not in accordance with the standard treatment guidelines.
- Promotion plans for the rational use of medicines should be created to re-introduce the Essential Medicines List into the practice of pharmacies and other health practitioners. This should focus on the concept of essential medicines and the way it will help patients to get only their needed medicines in good quality and affordable prices.
- As training is one of the important tools to reduce the problem of the irrational use of medicines, but the impact of the training sessions that have been conducted up to now was not evaluated before.

4.2. Main achievements and Malfunctions in Pharmaceutical Sector

During the last years there has been a shift in priorities, plans and policies; these changes were responsible for the transformation of the Pharmaceutical Sector system's structure.

Details of achievements and malfunctions during last decade are shown in [Tables \(9\)](#) and [\(10\)](#).

Table (9): Achievements in pharmaceutical sector during last 5 years

Area	Achievements up to 2007
NDP	- Updated official document with implementation plan
Regulatory system	- Update the pharmacy law to establish an autonomous MRA - Increase number of sample collected and tested in post marketing surveillance
Medicines supply system	- Establishing of the RDF project in 18 states

Area	Achievements up to 2007
	- Increasing of budget used in pharmaceutical supplies - Introducing of free medicines system for some diseases
Rational medicines use	- Establishing unit for rational use of medicines in FMOH

Table (10): Malfunctions in Pharmaceutical Sector

Area	What was not achieved
Regulatory system	- Capacity of the inspection system still needs technical and logistical support. - Limited capacity of the quality control laboratory. - No harmonization established with other countries. - No Adverse Drug Reaction monitoring and reporting system. - No legislations to control the drug promotion and regulations does not include civil societies
Medicines supply system	- No medicines prices monitoring system in different sectors. - No regulations mandate the publicity of retail prices. - No guidelines to control donation.
Production & trade	- Limited list of generic products are formulated in the country. - Limited capacity for Research and Development (R&D) in local manufacturers. - Preparations for WTO jointing are not collaborated and clear.
Rational medicines use	- No standing committee responsible for the update of EML, STG, NF and other documents. - No Sudanese National Formulary (SNF) document available at all levels. - No incentives set to promote supply, prescribing and dispensing of generic medicines. - No Continuous Professional Development (CPD) center for pharmacy assistants has been established. - No national medicines & poisons information center. - No public education programmes on rational use of medicines (especially antibiotics & injections). - No national body for monitoring and promoting the rational use of medicines (consensus body). - Establishment of DTC in hospitals was very weak. - No fund allocated to the Anti-Microbial Resistance (AMR) containment program implementation.

4.3. Comparison of results between Sudan and similar countries

Results obtained from the Sudan 2007 report were compared with data obtained from other reports from similar low income countries as shown in [Tables \(11\)](#) and [\(12\)](#).

1 = Data from *World Medicines Situation 2004*.

2 = Data from *Using indicators to measure country pharmaceutical situations 2006*.

Table (11): Comparison of country structure indicators and low income countries

Indicator		North Sudan 2007	Low Income Countries
Population with access to essential medicines		NA	60% (1)
Per capita from total Medicines expenditure		US\$ 7	US\$ 10.7 (1)
Per capita from public medicines expenditure		US\$ 0.4 2005	US\$ 1.1 2000 (2)
NDP implementation plan in place		Yes	64% (2)
Number of medicines in the EML		565	286 (2)
Sudan medicines formulary		No	66% (Yes) (2)
Percentage of procurement done by international competitive tender		89%	91% (1)
Adverse Drug Reaction (ADR) monitored		No	32% (2)
Legislation on generic medicines in public sectors	Prescribing	No	59% (Yes) (2)
	Substitution	No	80% (Yes) (2)
Law of pharmaceutical promotion and advertising		No	55.6% (1)
Regulation of pharmaceutical promotion and advertising		No	88.7%
Establishment of DTCs	Referral hospitals	1%	52.1% (2)
	General hospitals	NA	38.8% (2)
	Provincial hospitals	NA	36.2% (2)
Regional efforts in harmonization of medicines regulation		No	Initiatives (1)
Intellectual Property Rights for pharmaceuticals		NA	-

Table (12): Comparison of country survey results and similar countries

Indicator		Sudan	Low Income Countries
Availability of key medicines in public sector		86.1%	66.5% (1)
% of prescribed medicines dispensed or administered to patients at public health facilities		84.4%	89%(2)
Affordability of treatment for Pneumonia, adults	Public health facilities	1.3	0.8(2)
	Private outlets	1.6	1.7(2)
Affordability of treatment for Pneumonia, children	Public health facilities	0.6	1.4(2)
	Private outlets	0.7	1.9(2)
Affordability of treatment for malaria, adults	Public health facilities	0.6	NA
	Private outlets	1.9	
% of medicines expired in public health facility dispensaries, private medicines outlets and warehouses supplying the public sector		0%	0%(2)
Adequacy of conservation conditions	Public health facilities	64.6%	75%(2)
	Warehouses	75%	86.4%(2)
% of medicines adequately labelled at public health facility dispensaries		55.5%	74.6%(2)
% of patients know how to take medicines at public health facility dispensaries		75.7%	88.0%(2)
Average number of medicines per prescription		2.3	2.4 (1)
% patients prescribed antibiotics in public health facilities		65.0%	51.7%(2)
% patients prescribed injections in public health facilities		28.6%	23.1%(2)
% prescribed medicines on the essential medicines list at public health facilities		73.0%	71.7% (1)
% medicines prescribed by generic name (INN) at public health facilities		43.5%	60.3% (1)
Availability of essential medicines list at public health facilities		1%	54.4%(2)
Availability of standard treatment guidelines at public health facilities		54.8%	Na
% of Patients receiving 1 st line medicines in	Diarrhea/ORS (under 5 Years)	48.6%	80.0%(2)
	Malaria /Artesunate + SP (Adult)	64.1%	NA (2)

Chapter (5)

Conclusion

5.1. Conclusion

The assessment of the pharmaceutical sector using level I and Level II core indicators included public and private pharmaceutical sectors. The assessment has shown a number of strengths in the implementation of the NDP. As well, the assessment has shown a significant shortcoming in the expected outcomes from implementation of the NDP in the northern states of Sudan. The NDP targets accessibility of all population to quality and rational used medicines.

The strengths include:

- Commitment of the government to the implementation of the NDP;
- Establishment of an independent drug regulatory authority; and
- Growth in the number of pharmaceutical outlets especially through RDF project at all northern states as well as an increase in the number of importers and wholesalers.

On the other hand, among the shortcomings that have been shown in the assessment were the following:

- There was a considerable percent of the public who do not have to access essential medicines mainly due to affordability factors, in addition to availability factors in public health facilities in Darfur;
- Essential medicines that are needed by patients represented about 70% of the cost of the healthcare compared to an excessive 90% in the Darfur state;
- There was a long stock-out period of essential drugs in specially public health care facilities (18.4 days);
- NDP wide variation in storage conditions of public health care facilities; many of them falling below acceptable level of storage conditions and handling of medicines;
- NDP insufficient record keeping in public health facilities.
- Standard treatment guidelines and national list of essential medicine were not available at health facilities; and
- Poor dispensing and prescribing practices was observed.

There is a need to establish a mechanism e.g. cost sharing mechanism, to improve accessibility to essential medicines. Moreover, poor people should have a special mechanism to obtain their needs from essential medicines.

The selection of essential medicines procedure should be reviewed to help in influencing the availability of these medicines. As well adequate supply and distribution system is needed. The prescribing pattern and dispensing by healthcare providers should be improved.

5.2. Proposed Action Plan

An action plan that considers most of the priority areas identified according to the obtained results is proposed. It is based on the most relevant policy options that could lead to the anticipated improvement. Details of the proposal are shown in [Table \(13\)](#).

Table (13): Proposed action plan to improve pharmaceutical sector

Action		By Whom
Pharmacy management and control system		
Expected Outcome	Strong pharmacy governing bodies in the public sector	-
Activity	Support the establishment of Federal Board of Pharmacy and Poisoning technically and financially	Ministry of Finance
Activity	Development and implementation of Drugs & Therapeutics committees Programm scheme in selected states.	DGoP + State Ministry of Health + WHO
Availability and Supply of Essential Medicines		
Expected Outcome	Increase the availability of medicines from 85% to 90% at public health facilities by the end of 2009	-
Activity	Increase the contribution of the local production in the public supply procurement.	CMS
Activity	Establishment of monitoring and surveillance units at states level in selected states.	DGoP + WHO
Activity	Improve the quality of services at health facilities through reports from monitoring and surveillance units	States – DGoP
Quality of Medicines		
Expected Outcome	Ensure quality of medicines circulated in the country.	-

Activity	Establishing harmonization network with countries in the areas of medicines regulation (Egypt, China, Gulf union)	Federal DGoP
Activity	Include of public health facilities in the current inspection system plans at states level.	DGoP (federal/states)
Activity	Improve the storage practice in public health facilities from 65% to 85%.	DGoP (federal/states) + RDF
Activity	Establishing ADR monitoring and reporting system.	Federal DGoP + WHO
Affordability of Essential Medicines		
Expected Outcome	Decrease in the price of basket essential medicines	-
Activity	Exempting the medicines and raw materials from all governmental fees	Ministry of Finance
Activity	Revising the pricing of EM with incentives to decrease the prices	Federal DGoP + CMS
Activity	Establishing medicines price monitoring system in selected states.	Federal DGoP
Activity	Increase the information sharing process about medicines price (publishing +pre-printed price)	Federal DGoP
Activity	Development and enforcement of legislation to implement the generic policy (prescribing and substitution) in the public sector	FBPP
Activity	Development of specific measures that consider the groups at risk (Extremes of age + Disasters)	Federal DGoP
Rational use of medicines		
Expected Outcome	Improved achieved in the use of medicines at different levels	-
Activity	Establishment of national standing committee that responsible for the development of national EML, STGs, SNF and other strategic documents.	FBPP
Activity	Organizing nation wide educational campaign and declare specific day in the year for this purpose	Federal DGoP + WHO

Activity	Development of guidelines and training manuals about the good prescribing practice.	Federal DGoP + WHO
Activity	Increase the capacities of the pharmacy assistants (technicians) working in the public sector.	Federal DGoP + WHO
Activity	Development of drug promotion and monitoring system at the federal level and inclusion of civil societies in such system.	FBPP
Activity	Distribute and disseminate the national EML at states level.	DGoP (federal/states)
Activity	Increase the awareness of the prescribers about the STG and its importance.	DGoP (federal/states)

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Annex (1): Basket of Key Medicines

A list of 15 key medicines used to treat common health problems must be selected to measure availability, presence of expired medicines, medicine price and stock out duration.

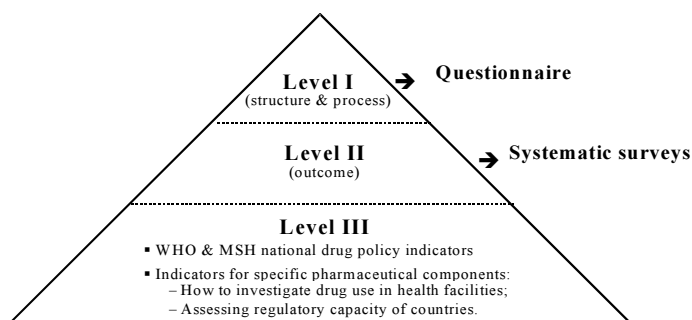
1. ORS
2. Artesunate + Sulphadoxine +Pyrimethamin
3. Cotrimethoxazole
4. Amoxicillin
5. Ferrous sulphate + Folic Acid
6. Mebendazole
7. Tetracycline eye ointment
8. Clotrimazole
9. Povidone Iodine
10. Diclofenac
11. Metronidazole
12. Antacid
13. Paracetamol
14. Pyridoxine (Vit. B6)
15. Atenolol

Annex (2): Sudan National Pharmaceutical Sector Assessment Level 1

The political situation in Sudan directly affects the formulation of this assessment design, especially in the sampling process, which will be detailed below. Therefore the plan developed for this assessment has considered the conflicts and post conflicts effects on the health system structure and processes.

The study adopted the same design as that proposed in the manual *Core Indicators on Country Pharmaceutical Situations* by using Level 1 Questionnaire and Level 2 Survey data collection forms as shown in figure (13).

Figure (13): Pharmaceutical sector assessment structure



Study Purpose and Indicators

For the purpose of urgency these results will be used in the planning process for the next period, Level 3 will be applied later on as there is possibility to carry it out efficiently whenever the resources are available.

Indicators Used

The indicators used in this assessment are same as that proposed in the *manual for Core Indicators on Country Pharmaceutical Situations*.

Questionnaire on structures and processes of country pharmaceutical situation

Country	Sudan	Date (dd/mm/yyyy)	
Name of respondent(s)	Dr Abdolhamid	Position(s)	Consultant, Pharmaceutical Directorate
1. NATIONAL MEDICINES (DRUG) POLICY (NMP)			
1.1 Is there a National Medicines Policy (NMP) document? (See glossary for a definition of NMP.) If no, skip to 1.4.	Yes		
Is it an official or draft document?	Yes		
What year was it last updated?	Year 2005		
1.2 Is there an NMP implementation plan that sets activities, responsibilities, budgets, and timeline?	Yes		
If yes, when was it last updated?	Year		
1.3 Is the NMP integrated into a published/official national health policy/plan? If yes, when was it last updated?	Yes	Year 2007	
1.4 Is there a national policy on traditional and complementary/ alternative medicine (TM/CAM) either as part of the medicines policy or health policy or as a separate document? (TM/CAM is defined in the glossary.)	Yes		
If yes, when was it last updated?	Year 1998		
1.5 Has a national assessment/indicator study been conducted? If yes, what areas have been studied and when was the most recent study covering each area conducted?	No		
Overall pharmaceutical situation:	No	Year	
Rational use/prescription audit:	Yes	Year 2004	
Access:	Yes	Year 2006	
2. LEGISLATION/REGULATION			
2.1 Is there a medicines law? If yes, when was it last updated?	Yes	Year 2001	
Which of the following areas are covered by medicines legislation and when was each last updated?			
Establishment of regulatory authority:	Yes	Year 2001	
Marketing authorisation of pharmaceuticals:	Yes	Year 2001/1974	
Manufacturing of medicines:	Yes	Year 2001/2003	
Distribution of medicines:	Yes	Year 2001/2003	
Promotion & advertising of medicines:	Yes	Year 2001/2003/1978	
Importation of medicines:	Yes	Year 2001/2003	
Exportation of medicines:	No		
Licensing & practice of prescribers:	Yes	Year 2006	
Licensing & practice of pharmacy:	Yes	Year 2006	
Herbal medicines (See glossary for definition):	Don't Know	Year	
Empowers inspectors to enter premises and collect samples and documentation:	Yes	Year 2001	
Requires transparency, accountability and code of conduct in regulatory work:	No		
2.2 System and operation of medicines registration:			
a) Is marketing authorisation required for medicines to be sold? If yes, how many medicinal products have been approved to be marketed? (express as number of dosage forms & strengths)	Yes	Total 5250	
Is marketing authorisation required for herbal medicines to be sold? If yes, how many herbal medicinal products have been approved to be marketed? (express as number of dosage forms & strengths) (See glossary for a definition of herbal medicines)	Yes	Total 50	
b) Are there detailed written guidelines, including reference guidelines and criteria, for submitting applications for the registration of medicinal products? Are there guidelines covering the registration of herbal medicines?	Yes	Yes	
c) Is the WHO Certification Scheme certificate required as part of the marketing authorisation process?	Yes		
d) Is INN used in the registration of medicines?	Yes		

e) Is a list of all registered products publicly accessible? (<i>Registered product is defined in the glossary.</i>)	Yes	
2.3 Is there a computerised registration system that facilitates retrieval of information on registered products? (<i>Registration system is defined in the glossary.</i>)	Yes	
Is there a medicines regulatory authority website providing publicly accessible information on any of the following: legislation, regulatory procedures, prescribing information (such as indications, counterindications, side effects, etc.), authorised companies, and/or approved medicines?	No	
2.4 Is licensing a requirement? (<i>Licensing is defined in the glossary.</i>) If yes, is it based on site inspection of: Manufacturers: Importers/wholesalers: Retail distributors/pharmacies:	Yes Yes Yes	
2.5 Are there written national guidelines/codes/checklists for the inspection of: Manufacturers: Importers/wholesalers: Retail distributors/pharmacies:	Yes Yes Yes	
2.6 Is prescribing by generic name obligatory in the: Public sector: Private sector:	Yes No	
Is generic substitution permitted at: (<i>Generic substitution is defined in the glossary.</i>) Public pharmacies: Private pharmacies:	Yes Yes	
2.7 Is promotion/advertisement of medicines regulated by: Company self-regulation: Government agency or medicines regulatory authority:	No Yes	
Are civil society/non-governmental organisations involved in review, assessment, or surveillance of promotion/advertisement of medicines?	No	
Do regulations on promotion/advertisement of medicines include: (<i>See glossary for the distinction between promotion and advertisement.</i>) Published ethical criteria for medicines promotion: Pre-approval for promotional materials: Pre-approval for advertisement materials: Explicit prohibition on advertising prescription medicines: Detailed restrictions on advertising non-prescription medicines:	Yes No Yes Yes No	
2.8 Are adverse drug reactions (ADR) monitored? If yes, what is the total number of each of the following for the most recent year for which data is available? Total number of validated ADR reports received: Total number of reporting physicians: Total number of physicians in country: Are ADR of herbal medicines monitored?	Don't Know ____ (Year ____) DK ☒ ____ (Year ____) DK ☒ ____ (Year ____) DK ☒ Don't Know	
3. QUALITY CONTROL OF PHARMACEUTICALS		
3.1 Testing of medicines samples collected last year for regulatory purposes (i.e. including drug registration and post-marketing surveillance, but excluding testing done in conjunction with procurement activities): Total number of samples collected: Total number of samples tested: Total number of samples that failed identity or assay:	<i>Total number of samples</i> 2728 2231 296	Don't Know ☐ Don't Know ☐ Don't Know ☐
3.2 Where have the above samples (<i>see 3.1</i>) been tested: Government quality control laboratory: Local academic institutions: Quality control laboratory in another country: Private quality control laboratory:	<i>Percentage of total samples tested</i> 100% ____% ____% ____%	Don't Know ☐ Don't Know ☐ Don't Know ☐ Don't Know ☐

4. ESSENTIAL MEDICINES LIST (EML)						
4.1 Are there Essential Medicines Lists (EML)? (<i>An Essential Medicines List is a government-approved selective list of medicines or national reimbursement list</i>)		Total number of medicines	Year of last update			
National EML:	Yes	841	2007			
State or provincial list:	No					
List for primary health care:	Yes		2007			
4.2 Are EMLs being used in: Public sector procurement:	Yes					
Public insurance reimbursement:	Yes					
Private insurance reimbursement:	No					
4.3 Are local herbal medicines included on the national EML?	No					
5. MEDICINES SUPPLY SYSTEM						
5.1 Who is responsible for public sector drug procurement and distribution? What percentage of the total cost is each responsible for?		Procurement	Distribution			
Ministry/Department of Health:	Yes	___%	Yes	___%		
Non-governmental organisation (NGO):	No	___%	No	___%		
Private institution contracted by the government:	No	___%	No	___%		
Individual health institutions:	No	___%	No	___%		
5.2 Is government procurement limited to medicines on the EML?	No					
If no, is a percentage of the budget set aside for non-EML items?	Yes					
What is the percentage?	15%					
5.3 Type of tender and percentage of the total cost for each: (<i>Tender is the process by which competing bids are entered for a particular contract.</i>)			Percentage of total cost			
National competitive tender:	Yes		22%			
International competitive tender:	Yes		68%			
Negotiation/direct purchasing:	Yes		10%			
5.4 Is drug registration a prerequisite for government purchases?	Yes					
6. MEDICINES FINANCING						
6.1 What is the total public or government budget for medicines in US\$ for the most recent year for which data is available?	\$ 49 million, Year 2006					Procurement Value
6.2 Are there guidelines on medicines donations that cover the public sector, the private sector, or non-governmental organisations (NGO)?	Public Sector	Private Sector	NGO			
	No	DK	Yes			
6.3 Which medicines are free at primary public health facilities:						
All medicines are free of charge:	No					Global Fund
Malaria medicines are free:	Yes					Fund
Tuberculosis medicines are free:	Yes					Fund
Sexually transmitted diseases medicines are free:	Yes					Fund
HIV/AIDS-related medicines are free:	Yes					Fund
Medicines are free to those who cannot afford them:	No					Global Fund
Medicines are free for children under 5 years of age:	Yes					Global Fund
Medicines are free for pregnant women:	No					Global Fund
Medicines are free for elderly persons:	No					Global Fund
No medicines are free of charge:	☐ (Don't Know ☐)					Global Fund
6.4 Which fees are charged in public health facilities:						
Registration/Consultation fees:	Yes					
Dispensing fees:	No					
Flat fees for medicines:	Yes					
Flat rate copayments:	No					
Percentage copayments:	Yes					
(<i>Co-payments cover part of the cost of medicines, the other part being paid by an insurer or government.</i>)						
6.5 Is revenue from fees or drug sales used to pay the salaries of public health personnel in the same facility?	Never					
6.6 Health insurance: (<i>Health insurance is any prepayment scheme for health care costs additional to but excluding</i>	Public	Private				

<i>subsidies funded through the Ministry of Health budget.)</i> What percentage of the population has health insurance? Are medicines covered by health insurance? Of the covered medicines, what percentage of the cost is covered:		Some Some 75%		Some Some 75%			
6.7 Is there a pricing policy on medicines that covers the public sector, the private sector, or non-governmental organisations? If yes, does it apply to:		Public sector Yes Some Yes 15% Yes 20% Yes Yes	Private sector Yes Yes 15 % Yes % Yes Yes	NGO No Yes 15% No % DK DK			
7. ACCESS TO ESSENTIAL MEDICINES							
7.1 In your opinion, what percentage of the population has regular access to essential medicines (i.e. minimum of 20 most essential medicines available and affordable at public and private facilities within a one-hour walking distance)?		40%				20%	
7.2 What percentage of:		Public health facility The population is within one-hour walking distance to: 50% Facilities have essential medicines available: 70% The population can afford essential medicines at: 40%	Private health facility 35% 85% 15%	Public or private retail drug outlet 10% 95% 15%			
8. PRODUCTION							
8.1 What is the medicines production capability in the country? Research and development of new active substances: Production of pharmaceutical active starting materials: Formulation from pharmaceutical starting materials: Repackaging of finished dosage forms:		No No Yes Yes					
8.2 For each of the following types of local production, indicate number of factories and total annual sales in US\$ for the most recent year for which data is available: Starting materials: Finished products: Products containing active substances developed/marketed for the first time during the last 5 years:		Number of factories 22 5	Sales in US\$ \$61,000,000 \$722,000	Year 2006 2006	Don't know DK ☒ DK ☐ DK ☐		
8.3 What is the total volume and US\$ value of the medicines market? Generic medicines compose what percentage of market volume and value?		Volume _____, Value \$270,000,000 Volume 90%, Value 50%					
9. RATIONAL USE OF MEDICINES							
9.1 Are there standard treatment guidelines (STGs) produced by the health ministry/department for major conditions? (STGs are recommendations about how to treat a clinical condition.) National STG: STG for hospital level: STG for primary health care level:		Yes Yes Yes	Number of conditions/diseases 9	Year of publication or review _____ _____ _____			
9.2 Is there a National Medicines Formulary manual? (A formulary manual contains summary drug information.) If yes, does it cover only medicines on the Essential Medicines List? What year was it last published/reviewed:		No Yes/No/Don't Know Year _____					
9.3 Are any of the following aspects of the essential medicines concept generally part of the basic curricula in most health training institutions/universities for: (Essential medicines are those that satisfy the priority health care needs of the population. See glossary for a definition of problem-based pharmacotherapy.) Doctors: Nurses: Pharmacists: Pharmacy assistants: Paramedical staff:		Essential Medicines List Yes Yes Yes Yes DK	Standard Treatment Guidelines Yes Yes Yes No DK	Problem-based pharmacotherapy No No No No No	Rational prescribing No No No No No		

9.4 Are there independent publicly or non-commercially funded obligatory continuing education programs which include use of medicines for: Doctors: Nurses/midwives/paramedical staff: Pharmacists: Pharmacy aides/assistants:	Don't Know Don't Know Yes No	
9.5 Is there a public or independently funded nationally accessible (e.g. by phone) medicines information centre or service co-ordinated by the Ministry of Health, academia, and/or a non-commercial non-governmental organisation that provides information on demand to: Prescribers: Dispensers: Consumers:	Yes Yes Yes	<u>Not</u> <u>National</u> <u>Khartoum</u> <u>State</u> <u>±</u> <u>5 Other</u> <u>States</u>
9.6 Has there been any public education campaign concerning rational medicines use in the previous two years conducted by Ministry of Health/non-governmental organisation/academia on the following topics: Use of antibiotics: Use of injections: Other topics/issues:	Yes No Yes	
9.7 How often do the following personnel prescribe at the primary health care level in the public sector? Doctors: Nurses/midwives/paramedical staff: Pharmacists: Pharmacy aides/assistants: Personnel with less than one month formal health training:	Frequently Frequently Frequently Frequently Frequently	
9.8 Is there a government department with a specific mandate to promote the rational use of medicines and co-ordinate medicines use policies?	Yes	
9.9 What proportion of facilities have a drugs and therapeutics committee? (A drugs and therapeutics committee promotes the safe and effective use of medicines in the facility or area under its jurisdiction) Referral hospitals: General hospitals: Regions/provinces:	None Few Few	
Is there a mandate for drugs and therapeutics committees in the national medicines policy?	Yes	
9.10 Is there a national strategy to contain antimicrobial resistance?	No	
Is there a national reference laboratory to coordinate epidemiological surveillance of antimicrobial resistance?	Yes	
Is there a funded national intersectoral task force to coordinate the implementation of interventions to promote appropriate use of antimicrobials and prevent the spread of infection?	Yes	
9.11 Are the following medicines sold over the counter without any prescription? Antibiotics: Injections:	Frequently Frequently	
10. INTELLECTUAL PROPERTY RIGHTS PROTECTION AND MARKETING AUTHORIZATION (See glossary for definitions of terms used in this section.)		
10.1 Is patent protection legally provided for pharmaceutical products? If yes, indicate: Year introduced: Type: Duration of patent validity:	Yes Don't Know _____	

10.2 Which intellectual property right protection regime/activities are provided for traditional medical knowledge?	TRIPS: DK Sui generis regimes: DK Digital library: DK National inventory of medicinal plants: DK Others: DK None: ☐ (DK ☐)	Year introduced ____ ____ ____ ____ ____	Duration of data protection ____ ____ ____ ____ ____	
10.3 TRIPS Agreement (Agreement on Trade Related Aspects of Intellectual Property Rights):				
a) Is your country a World Trade Organization Member? <i>If no, skip to 10.4</i>	No			
b) Has national legislation been modified to implement the TRIPS Agreement? If yes, what year did it go into effect?	Don't Know Year ____			
c) Is your country availing itself of the transitional period provided by Article 65 of the TRIPS Agreement?	Don't Know			
d) If your country is a least-developing country (LDC), has it availed itself of the transitional period accorded to LDCs in Article 66 of the TRIPS Agreement?	Yes			
10.4 Have parallel importing provisions on pharmaceuticals been incorporated into national legislation? If yes, have these provisions been applied?	DK DK			
10.5 Have compulsory licensing provisions for pharmaceuticals been incorporated into national legislation? If yes, under what conditions?	DK National emergency: Don't Know Public non-commercial use: Don't Know Remedying anti-competitive practices: Don't Know Other: Don't Know			
10.6 Are generic pharmaceutical manufacturers allowed to use patented inventions for the purpose of obtaining marketing approval prior to patent expiration?	DK			

COMMENTS ABOUT INDICATORS AND VALUES

Item Number	Comment

Questionnaire on structures and processes of country pharmaceutical situation

Glossary of Terms:

Advertisement: A set of activities undertaken to advertise medicines. It is usually targeted to the general public and it is usually limited to over-the-counter medicines.

Compulsory licensing: This term is used when the judicial or administrative authority is allowed by law to grant a license, without permission from the holder, on various grounds of general interest (absence of working, public health, economic development, and national defence). “Working” of a patent is the execution of the invention in the country of registration.

Co-payments: Co-payments cover part of the cost of medicines, the other part being paid by an insurer or government.

Drugs and therapeutics committee: A drugs and therapeutics committee promotes the safe and effective use of medicines in the facility or area under its jurisdiction.

Essential Medicines List: An Essential Medicines List is a government-approved selective list of medicines or national reimbursement list.

Essential medicines: Essential medicines are those that satisfy the priority health care needs of the population.

Generic substitution: The practice of substituting a product, whether marketed under a trade name or generic name, by an equivalent product, usually a cheaper one, containing the same active ingredient(s).

Health insurance: Health insurance is any prepayment scheme for health care costs additional to but excluding subsidies funded through the Ministry of Health budget. The purpose of question 6.6 is to identify how much protection the population has against exposure to the cost of medicines at the time people are sick. Prepaid financing is the usual method for providing such protection. Public funding through the (prepaid) Ministry of Health budget is the most widespread form of prepayment. Question 6.5 attempts to identify additional prepayment protection (percentage of the population covered and degree of protection against medicine costs) such as private or employer-based health insurance, community prepayments schemes, social health insurance (health care funded through social security systems), etc.

Herbal Medicines: Herbal medicines are plant-derived material or preparations with therapeutic or other human health benefits, which contain either raw or processed ingredients from one or more plants. Herbal medicines include herbs, herbal materials, herbal preparations and finished herbal products, which are classified in the medicines category according to a national regulatory framework. Finished herbal products and mixture herbal products may contain excipients in addition to the active ingredients, however, finished products or mixture products to which chemically defined active substances have been added, including synthetic compounds and/or isolated constituents from herbal materials, are not considered to be herbal. In some countries, herbal medicines may also contain, by tradition, natural organic or inorganic active ingredients which are not of plant origin.

Licensing: Licensing is a system that subjects all premises to evaluation against a set of requirements before a specific activity (e.g. manufacturing, storage etc.) is authorised to take place.

Medicines formulary manual: A formulary manual contains summary drug information.

National medicines (drug) policy (NMP): A national medicines policies is an expression of the government’s goals and priorities for the medium to long term for the pharmaceutical sector. It also identifies the main strategies for attaining them. It provides a framework within which the activities of the pharmaceutical sector can be coordinated. It covers both the public and private sectors, and involves all the main actors in the pharmaceutical field.

Parallel importing: Parallel importation is importation, without the consent of the patent-holder, of a patented product marketed in another country either by the patent-holder or with the patent-holder’s consent. Parallel importation enables promotion of competition for the patented product by allowing importation of equivalent patented products marketed at lower prices in other countries.

Problem-based pharmacotherapy: Problem-based pharmacotherapy is a problem-based practical approach to teaching prescribing.

Promotion: A set of activities undertaken to promote prescription of prescription-only medicines. It is usually targeted to health providers only and it is usually forbidden to target the general public.

Registered products: Products that have been evaluated for quality, safety and efficacy and thence authorised for marketing.

Registration system: A system that subjects all products to evaluation of quality, safety and efficacy before they are authorised for marketing.

Standard Treatment Guidelines (STG): STGs are recommendations about how to treat a clinical condition.

Tender: Tender is the process by which competing bids are entered for a particular contract.

Traditional medical knowledge: Knowledge related to traditional medicine (see definition of *Traditional medicine and complementary/alternative medicine*).

Traditional medicine and complementary/alternative medicine (TM/CAM): Traditional medicine is the sum total of the knowledge, skills, and practices based on theories, beliefs and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in prevention, diagnosis, improvement or treatment of physical and mental illnesses. The terms “complementary medicine” and “alternative medicine” can be used interchangeably with “traditional medicine” in some countries. The term “complementary and alternative medicine” can also be used to refer to a broad set of health care practices that are not part of the country’s own tradition and are not integrated into the dominant health care system.

Transitional period: TRIPS provides transitional periods during which countries are required to bring their national legislation and practices into conformity with its provisions. The latest dates for WTO Members were/are: 1996 for developed countries; 2000 for developing countries (as a general rule); 2005 for developing countries who had not introduced patents before joining the WTO; and 2006 for least-developed countries (extended to 2016 by the Doha Declaration). The TRIPS Agreement specifically recognizes the economic, financial, administrative and technological constraints of the least-developed countries. It therefore provides the possibility for further extension of the transitional period.

TRIPS Agreement (Agreement on Trade Related Aspects of Intellectual Property Rights)

Article 65: Transitional Arrangements

1. Subject to the provisions of paragraphs 2, 3 and 4, no Member shall be obliged to apply the provisions of this Agreement before the expiry of a general period of one year following the date* of entry into force of the WTO Agreement.
2. A developing country Member is entitled to delay for a further period of four years the date of application, as defined in paragraph 1, of the provisions of this Agreement other than Articles 3, 4 and 5.
3. Any other Member which is in the process of transformation from a centrally-planned into a market, free-enterprise economy and which is undertaking structural reform of its intellectual property system and facing special problems in the preparation and implementation of intellectual property laws and regulations, may also benefit from a period of delay as foreseen in paragraph 2.
4. To the extent that a developing country Member is obliged by this Agreement to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of this Agreement for that Member, as defined in paragraph 2, it may delay the application of the provisions on product patents of Section 5 of Part II to such areas of technology for an additional period of five years.
5. A Member availing itself of a transitional period under paragraphs 1, 2, 3 or 4 shall ensure that any changes in its laws, regulations and practice made during that period do not result in a lesser degree of consistency with the provisions of this Agreement.

Article 66: Least-Developed Country Members

1. In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of 10 years from the date of application as defined under paragraph 1 of Article 65. The Council for TRIPS shall, upon duly motivated request by a least-developed country Member, accord extensions of this period.
2. Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base.

* [WIPO note] January 1, 1995