Value for Money:

Proposed Measures to Improve Health Outcomes from Expenditure on Medicines and Health Technologies in Sudan

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NATIONAL MEDICAL SUPPLIES FUND

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Abstract

While advances in health technology over the last several decades have greatly improved life span and welfare in society, it is often perceived that the cost of these innovations has not been adequately offset by their benefit. Increased health care budgets in most countries have emphasized the need to demonstrate value for money from expenditure on health technologies. This paper aims to establish measures that secure the provision of safe and effective medicines to Sudanese patients at reasonable prices and that encourage the efficient and competitive supply of medicines.

As a 'desk-based' paper, the major source was published literature and the key strategies identified in the literature review (see list at the end of the document) have been modified to fit the Sudan context. The strategies that are advocated throughout the paper are based on the premise that the best value for money does not necessarily mean the lowest initial price option, but rather the best return on the money spent to meet the population's need for medicines and other medical technologies.

This paper identifies a number of strategies, which should be in place to ensure that expenditure on medicines provides value for money. These strategies include: use of therapeutically equivalent generic medicines; applying pharmacoeconomics; selection of medicines; control of medicine prices; rational use of medicines; improving adherence to treatment regimes; prohibiting unethical promotion by pharmaceutical companies; reducing medication errors and adverse drug reactions; promoting responsible self-medication; clinical pharmacy services; pooled procurement; safety, efficacy and quality of medicines; and management of medical devices.

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Acronyms

ADR	Adverse Drug Reactions
BE	Bioequivalence
CIF	Cost Insurance and Freight
CSP	Cost-Sharing Policy
FDA	Food and Drug Administration
FMOH	Federal Ministry of Health
GDOP	General Directorate of Pharmacy
HH	Household
HINARI	Health Internetwork Access to Research Initiative
HIV/AIDS	Human Immunodeficiency Virus/ Acquired Immune Deficiency Syndrome
MDGs	Millennium Development Goals
MHRA	Medicines Healthcare Products Regulatory Agency
MSH	Management Sciences for Health
NGOs	Non-Governmental Organizations
NHIF	National Health Insurance Fund
NMPB	National Medicines and Poisons Board
NMRAs	National Medicines Regulatory Authorities
NMSF	National Medical Supplies Fund
PHC	Primary Health Care
POM	Prescription Only Medicines
RUM	Rational Use of Medicines
SDG	Sudan Pound
SM	Self-Medication
SMC	Sudan Medical Council
SNMSB	Sudan National Medical Specialization Board
TRIPS	Trade Related Aspects of Intellectual Property Rights
USA	United States of America
WHO	World Health Organization

1. Introduction

Improving access to quality medicines improves health, reduces suffering and extends lives (Quick 2003). It is currently the most important strategy to reduce disability and death from disease. More generally, ensuring access to effective treatment is a high priority issue for international public health. With up to a third of the world's population having limited access to essential medicines, it is clear that by 2015 many countries will not be able to achieve their health related Millennium Development Goals (MDGs) (WHO 2011a). Four of the eight MDGs explicitly discuss the availability of medicines at the primary care or service delivery point levels (UN 2012). This is pertinent because without access to and appropriate use of quality medicines, health systems lose their ability to meet healthcare needs. Therefore lack of access to essential medicines in developing countries is one of the most pressing global health problems. World Health Organization (WHO) reported that people lack access to essential medicines where they cannot obtain the product they need to prevent or treat a medical condition (WHO 2004a). This could be due to many causes, such as the product needed is unavailable, not accessible or not affordable; but the most frequent reason is scarcity of financial resources, with the result that neither the poor nor their governments can afford to purchase essential medicines or ensure their appropriate use in well-run health systems (Wiedenmayer 2004a). Government expenditure on pharmaceuticals account for 10–20% of health expenditure in developed countries and 15-30% in transitional economies, whereas the figure is 25-66% in developing countries (WHO 2004a; World Bank, 1994). In Sudan, patients or their relatives may go into debt, or sell or mortgage some important and productive assets to meet the high cost of the tertiary care (Mohamed 2010). Others might be excluded from seeking care due to financial reasons. The borrowing of money and selling of valuable and productive assets to meet the costs of serious family illness, including medicines, are likely to have a significant negative impact on the already stretched household economy and contribute to increasing impoverishment (Kanji 1989; Russell 1996; Saurborn et al 1996; Pradhan and Prescott 2002; Wagstaff and van Doorslaer 2003; Xu et al 2003; WHO 2005a). For example, in the USA, 62% of US bankruptcies were triggered by medical bills (Himmelstein et al 2009). Even people with health insurance coverage are at risk, as insurers have shifted more financial responsibility for medical care to consumers in the form of high deductibles, copayments, and requirements that patients pay part of the costs for certain

procedures or appointments. Federal Ministry of Health (FMOH), National Health Insurance Fund (NHIF) and households (HH) are therefore continuously looking for ways to make savings on the budget.

The idea of paying for "value" in healthcare was boosted by Harvard business strategist Michael Porter, who argued that healthcare should focus on value outcomes for patients, defined as "health outcome per dollar of cost expended (Porter and Teisbert 2006). The concept of "value outcomes for patients" from money paid for health services is never considered or discussed in Sudan. The aim of this review is to present cost containment strategies that maximize the benefit to patients of money spent on health technologies in Sudan. Analysis by source of funding shows that the government in Sudan provides 21% of health expenditure and the balance (79%) is met by citizens themselves (Sabri 2003). This paper has identified a number of strategies which should be in place to ensure that expenditure on medicines provides value for money. These strategies include: use of therapeutically equivalent generic medicines; application of pharmacoeconomics; selection of medicines; control of medicines price; rational use of medicines; use of clinical pharmacy services; pooled procurement; emphasis of safety, efficacy and quality of medicines; and management of medical devices.

2. Sudan Health Care System

The government, through Federal and State Ministries of Health, is responsible for most health care services in Sudan, Primary Health Care (PHC) being the cornerstone of the government's strategy for achieving health for all. The government adopted a national health strategy as a part of a ten-year national comprehensive strategy (1992 to 2002). During this period, the government of Sudan passed several laws and decrees related to health sector reform. These regulations have led to substantial changes in the management and financing of health care services. These changes included the decentralisation of management and financing responsibilities of public health care facilities, the introduction of Cost-Sharing Policy (CSP) early in 1992, the launch of National Health Insurance Fund in 1996, the introduction of free emergency treatment at hospital outpatient departments. Subsequently a policy of free care for pregnant women and under-fives was launched in 2008. These will be discussed later in section 2.3 of this paper. The previous ten-year comprehensive strategic plan made some progress in the areas of health and development, however a lot remains to be done. Strategies to address health issues are reflected in the ambitious

comprehensive twenty-five year plan (2002 - 2027) for health development. The twenty-five year strategic plan recommends an increase in public spending on health services to reduce the burden of direct out-of-pocket payments for health services by users.

2.1 Organisation of the Health Sector

The Sudanese health care system is divided into primary, secondary and tertiary levels of care, which are under the three tiers of government, though with some overlapping of responsibilities. The lowest, the PHC level and service delivery, is delivered through PHC units, dressing stations, dispensaries, and health centres. These facilities are the responsibility of the locality. The health centre is the referral point for the lower-level facilities and, in principle, is staffed by a medical doctor, medical assistants, and nurses. In addition vertical programmes, in particular those for tuberculosis and the Expanded Programme on Immunisation, work through the primary level facilities but also sometimes establish independent posts in peripheral areas. The State governments provide the secondary and tertiary levels of health care and the service delivery is through general referral hospitals (which also provide some primary care). Finally, the Federal government is responsible for national specialised centres, for example, the renal transplantation centre and the national centre for radiotherapy and so on.

In addition to health services provision by Federal and State Ministries of Health, Ministry of Welfare and Social Security, Ministry of National Defence and Ministry of Interior, universities and the private sector (both for profit and not-for-profit) provide health services. As a result of the enhanced constructive efforts to achieve equitable access to public health facilities, some improvement in the health infrastructure was achieved in the past decade.

2.2 The Private Sector as a Health Care Provider

The economic liberalisation policy has led to a tremendous growth of private health care in the past decades. Under this policy, private health facilities may be established anywhere in the country. Public sector doctors are allowed to run their own private clinics outside office hours or to work in private hospitals, provided their public service obligation is not compromised. For example, the number of private hospitals; doctors' clinics; and pharmacies in Sudan increased from 5; 230; and 451 in 1992 to 170; 2,107; and 2,972 in 2012 respectively (GDOP 2012). Being profit driven, private facilities are concentrated in places where there is a demand, leading to an accumulation in urban and better-off

rural areas, particularly in Khartoum State and, to some extent, Gazera State. Private services are perceived to be of better quality than government services. The growth in private hospitals is driven mainly by the customers' need. It is not surprising that the focus of these hospitals is mainly on selective curative services and mainly accessed by the more affluent (Mustafa et al 2005). The bulk of the private health care facilities are single doctor clinics. An expansion of private sector secondary and tertiary care facilities is limited to a few states like Khartoum and Gezira States. Growth in the private sector should relieve some of the pressure of demand for public health services, allowing the government to concentrate more on the provision of services for the poor. However, growth in the private sector also requires government to fulfil a role in improving health care quality in Sudan and to take actions to reduce medical errors and enhance patient safety. This could be through development and evaluation of health technologies and practices of health professionals.

The private not-for-profit health care provision is operated by international and national Nongovernmental Organizations (NGOs). For example, in Khartoum State, such organisations operate up to 214 health facilities, mainly health centres (Mohamed 2010). A set of specialised health care systems also exist for specific subsets of the population. These systems include health care services operated by large firms for their employees and their relatives. Often such facilities are in urban areas. However, they also exist on large plantations in rural areas, for example, Khartoum Refinery Hospital in Al-Giely area.

2.3 Overview of Health Care Financing

During the past twenty five years, the government has introduced a number of initiatives to finance heath care, in general, and essential medicines in particular, as a part of the health system reform process. In this section, the adopted health financing mechanisms are presented.

2.3.1 Cost-Sharing Policy

Since independence in 1956 the Government of Sudan has provided health services to its citizens, including the free supply of medicines, funded by general resources (Mohamed 2000). As noted above the government has been constrained by an array of political and economic problems. In consequence, the proportion of GDP allocated for the health sector reduced from 1.5% between 1978 and 1982 (Wang'Ombe and Mwabu 1987) to 0.07% in 1990 (HDR 2003). As a result, the government of Salvation Revolution in 1989 faced the

question of how to meet the health needs of the population, especially the poor, with diminishing government resources. The Salvation Revolution wanted to maintain the provision of services of acceptable quality and at low cost, but this was possible only if more resources were brought into the system. Cost-Sharing Policy (CSP), as a component of an economic reform plan adopted in 1992 (known as the economic liberalisation policy), was introduced at the same time in all public health facilities throughout the country. It was seen as a solution to generate and free more resources for the health care system, in order to stop the deterioration of health services. The CSP planned to do so by alleviating frequent out-of-stock situations for medicines and other medical supplies, by covering non-salary recurrent costs and by encouraging doctors and other medical staff to work at health centres by giving incentives in a form of extra allowances. It also aimed to increase and maintain coverage, particularly for the poor who could not afford alternative private sources of medical care. In addition, the CSP aimed to strengthen community participation and to improve efficiency by reducing unnecessary utilization of public health facilities, following the principle that when a service costs money people will think twice about using it (Shaw and Griffin 1995). This is because the CSP introduced charges at the point of use. Finally, the CSP was intended to pave the way for other options of community participation in their health care cost, such as health insurance.

The CSP experienced a number of problems, due to insufficient training and preparation, non-phased implementation, and weak mechanisms to protect the poor (FMOH 2003). The fact is that revenues from CSP were not enough to bring the health services to a level that the population could clearly perceive as improvement. The resulting problems included reduction in access and utilization of health services, shortages of essential medicines and poor quality of services. As a consequence, the government launched Health Insurance Funds in different States (see below) as a radical solution to the problem of health care financing.

2.3.2 Health Insurance Scheme

As a part of Sudan government's commitment to meeting the health needs of the population, the government decreed compulsory social health insurance for all employees of public and private sectors in early 1996. It was introduced to overcome the drawbacks of payment at the point of service delivery (user charges), such as inability to pay and low revenue generation. NHIF aims to promote equitable access, improved quality of curative medical services and

increased revenues for the health sector in Sudan. According to the National Health Insurance Act (2001) all active individuals in both formal and informal sectors should be insured. The family of an insured person is included, and enjoys benefits from the insurance plan with the same premium. The family includes the wife, siblings (boys under 18 and girls until getting married), father and mother.

NHIF is funded through a variety of sources including 10% of the gross wage (4% from the employee and 6% from the employer). The government pays the premiums of retirees, poor people and full-time poor students from its various organisations, such as the Zakat chamber. Those who are not in the formal sector wishing to join the scheme pay a total of SDG480 annually (US$50 annually per family) in 12 equal instalments. Other sources of financing the Insurance Scheme comprise contributions from federal government, which has been increased from SDG75 million (US$29.4million) in 2011 to SDG446 million (US$79.6million) in 2014; revenues generated through investment of NHIF funds; charity donations and other forms of contributions that support the objectives of the insurance plan.

The benefit package includes all medical consultations, admissions, diagnostic procedures and therapeutics including surgical operations. Dental services are included with the exception of dentures and plastic surgery. The highest cost treatments for health problems including cardiac surgery, renal failure and cancers, are excluded. NHIF coverage also includes 75% of the cost of medicines on its approved list of essential medicines. The beneficiaries pay the remaining 25% of their prescription and pay the full cost of prescribed medicines not on the approved list. Each level of health professionals has a defined list of drugs that they allowed to prescribe (with different lists for medical doctor and specialists) and only generic medicines are allowed.

At the time of the celebration of its 20th anniversary in 2015, the NHIF provides limited insurance coverage for only 30% of the population (NHIF 2013). Most (25%) of the insured individuals are public sector employees, 18% are members of the informal sector, 44% are poor families, 7% are pensioners and 3% are students (NHIF 2013).

2.3.3 Free Medicines

To absorb the negative impact of user fees and to foster equity of access, the government policies on user charges defined entitlements to full or partial

exemption from payment for some types of preventive and curative care. Some medicines are provided free of charge through vertical programmes, funded by the government in collaboration with international donors to prevent the most prevalent infectious diseases, namely tuberculosis, leprosy, acute respiratory tract infections, Schistosomiasis and Leishmaniasis in endemic areas. Most PHC services are provided free of charge. These free services include: contraceptive pills for family planning; Ferrous Sulphate with Folic Acid tablets for pregnant women; immunisation programmes for six childhood diseases (measles, tetanus, poliomyelitis, whooping cough, diphtheria and tuberculosis); preventive doses of Vitamin A; condoms for the protection from sexually transmitted diseases, including HIV/AIDS; nutrition and growth monitoring of under-five children; anti-tetanus vaccination of pregnant women; and other preventive services for women of reproductive age. There are also exemptions for treatment of various categories of life-threatening diseases, including dialysis for renal failure, immunosuppressive medicines for renal transplant persons, radio-therapy and chemotherapy for cancer patients, haemophilia, blood transfusion and blood test for HIV/AIDS. The provision of the above mentioned services, free of charge, aims to ensure financial access, for the poor, to curative care of life-threatening diseases as well as for diseases which cause public health problems, such as tuberculosis. These arrangements also encourage the use of preventive services.

An additional measure to increase access and reduce hardship was the Presidential declaration in 1996 that emergency care would be provided free of charge, including any procedures and expenses incurred within the first 24 hours in hospital. In addition, the costs of many specialist care services, such as renal dialysis, cancer care, and cardiac treatment, are covered by the state. The decision to make care for under-fives and pregnant women free in 2013 was therefore the latest in a series of measures to shift the financing burden back from the population to the state. In 2015, the government expenditure on these diseases has been increased from SDG4.4million (US$2.7million) at the beginning of the free programmes in the late 1990s to SDG372 million (US$65.3million) in 2014 and shot up to SDG786million (US$134million).

2.4. Summary

The government health system is a three-tiered network. Strenthening Primary Health Care was adopted as a main strategy for health care provision in Sudan in 1976 and re-emphasised in the National Comprehensive Strategy for Health in 1992 and in the twenty-five years Strategic Health Plan 2002-2027. Health

services are provided through different public partners including, in addition to Federal and State Ministries of Health, the Ministries of National Defence, Interior, and Social Care. The public health care facilities provide a range of comprehensive subsidised health services including both preventive and curative services. However, these public partners are performing in isolation due to ill-defined managerial systems for co-ordination and guidance.

The private sector, encouraged by the government, witnessed a significant increase during the 1990s and the new millennium. Private health services are concentrated mainly in urban areas, are perceived to be of better quality than government services and are mainly accessed by the better-off. The private-for-profit sector provides mainly curative services at full cost plus profit. The private not-for-profit sector, mainly concentrated in displaced people's camps, provides both curative and preventive services at primary care levels either free (international NGOs) or on a Cost-Sharing basis (national NGOs).

During the past fifteen years, the government introduced a number of initiatives to finance heath care, in general, and essential medicines, in particular, as part of health reform. The lack of evidence-based policy-making system means that the government subjectively changes health care financing policies frequently. It is clear that the intent of the government has been to increase equity of access to health services of acceptable quality.

3. Methods

As a 'desk-based' proposal, the major source for mapping the proposal was the available literature. Descriptive and evaluation studies on value for money that has been spent on pharmaceuticals and other health technologies, the strategies and measures that determine or are intended to enhance the value that has been gained from expenditure on medicines, were reviewed. In this review, strategies and measures were defined as regulations, rules, policies, guidelines and financial and administrative orders made by governments, non-government organizations or private insurers. A broad range of sources was considered which included the peer-reviewed literature on medicine expenditure and purchasing policies as well as research studies and documents from influential international organizations, such as WHO. The scope of this proposal is intentionally wide to reflect the multi-dimensional nature of the pharmaceutical value for money strategies. This approach also provides a broad platform of ideas and research upon which appropriate policy recommendations can be formulated to improve

value for money spent by patients, health providers, health insurance and governments on pharmaceuticals and other health technologies in Sudan and in countries with similar economic and health systems. The following databases were initially searched for related studies limited to those written in English: MEDLINE, EMBASE, PubMed, International Network for Rational Use of Drugs (INRUD), WHO Medicines Documentation system, WHO library database, Pharmaceutical Pricing and Reimbursement Information , Health Action International, World Bank e-Library and World Bank Publications and Documents. Searches were undertaken in August 2014. The key words used in the literature search and the number of reviewed publications on each strategy is presented in appendix 1. To make sure the majority of publications on each strategy were captured, references that had been cited by authors of the published work on the strategies were checked. Most of the relevant journal articles have been downloaded from HINARI[1].

In this proposal, the key strategies identified in the literature review have been modified to fit the Sudan context. The strategies advocated by this paper build on the mix of strategies and measures described by authors of published research listed at the end of this document. The paper has summarized and interpreted their findings and recommendations to suit the context of Sudan. From reviews, document available and my personal knowledge (as a FMOH employee) in general, Sudanese health system has not been able to respond cost-effectively.

4. Achieving Value: Strategies to increase Benefits from Health Technologies

Management Sciences for Health (MSH 2012) notes that five of the 10 leading causes of waste in health systems relate directly to pharmaceuticals. WHO also estimates that, on average, African governments pay 34% to 44% more for medicines than is necessary. The distinction between cost and value is essential (Owens et al 2011). A high-cost intervention provides good value if its net benefit (the extent to which benefit outweighs harm) is large enough to justify the costs. Conversely, low-cost interventions may provide low value if they have little or no net benefit (Qaseem et al 2012). Because high-cost interventions may provide good value and low-cost interventions may not, efforts to control costs should focus on value rather than cost alone (Qaseem et al 2012). Therefore the government needs to introduce a set of strategies to control expenditure

1 HINARI is the programme set up by WHO together with major publishers, to enable low- and middle- income countries to gain access to one of the world's largest collections of biomedical and health literature.

on health technologies and to achieve more benefit and better value with its limited resources. This paper proposes a number of strategies and measures that will reduce cost of medicines and medical devices without causing an adverse impact on access to medicines. These strategies are discussed below.

4.1 Generic Medicines

Products having the same active ingredients are divided into two groups according to their origin: originator brands and generic versions. A generic medicine is a medicinal product with the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product "originator product", and whose bioequivalence (BE) with the reference medicinal product has been demonstrated by appropriate bioavailability studies (Directive 2004). The US Food and Drug Administration (FDA) approves a generic substitute (FDA 2012), if it has proven to be "identical, or bioequivalent, to a brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use".

Generic versions of medicinal products are widely manufactured in the USA, European Union, China, South Asia, Eastern Europe, Africa and Latin America; regulatory requirements such as the need for BE (Cohen et al 2010) testing or product quality evaluation, including impurity and genotoxicity studies, are required at different degrees of stringency. However, in Sudan, National Medicines and Poisons Board (NMPB) does not require BE to prove the safety and efficacy of generic medicines. Although generic medicines may contain the same active ingredient, concentration, pharmaceutical form, and dosage as the originator drugs, they do not necessarily meet quality specifications of the innovators and this may potentially impact their effectiveness and safety profile. Therefore, a generic product may not be bioequivalent to the originator version, or of equal quality. As mentioned, the availability of quality medicines is essential for patients. Coreale and colleagues (2014) reported that although generic therapies can appear attractive owing to their low acquisition price, this may be offset by the potential risks, such as lack of treatment efficacy or unexpected safety issues from impurities or altered BE, arising from poor quality control in excipient selection, manufacturing processes, and packaging.

The affordability of prescription medications is one of the most pressing public health issues in Sudan (Mohamed 2010). Many patients take less than their prescribed doses to make medications last longer or do not obtain prescriptions at

all because of cost (Mohamed 2010). Similar situations exist even in developed world. Studies (Goldman et al 2004) showed that in the USA both patients without insurance coverage for drugs and those with such coverage underuse medications because of cost. This is why many have advocated shifting to lower-cost generic medications to improve affordability, reduce health care spending, and promote adherence to drug regimens (Kohl and Shrank 2007).

The economic aim of using generic medicines, with obvious repercussions in the area of public health, is only acceptable if it is subordinated to a primary aim, namely that of not harming the patient. This is why sensitive pharmaceutical products, such as medicines with narrow therapeutic margins[2], medicines used for the treatment of life threatening diseases, and biopharmaceuticals must be treated differently. For example, American society of transplantation recommended that generic immunosuppressive medicines should clearly labelled and distinguishable from innovator drugs and that patients should be educated to inform their physicians of any switch to or among generic alternative (Davit et al 2009).

In Sudan the Medicines and Poisons Act 2009 (the Act) stated that medicines must be prescribed generically in public health facilities to protect patients from the effect of promotional campaigns by drug companies. Prescribing brand-name medicines when therapeutically equivalent generic versions are available generates unnecessary medical expenditure, the costs of which are borne by the public in the form of higher out-of-pocket and copayments, increased health insurance costs, and higher free medicine projects' expenses. Presently, little is known about how frequently physicians comply with such article. To pursue this article of the Act, the NMPB must enforce regulations and strictly follow WHO guidelines for marketing authorization of multi-source (generic) medicines, such as BE. This is the crucial step to ensure safety, efficacy and quality of generic medicines. These stringent regulatory standards are needed in order to make sure that a generic product is therapeutically equivalent to its corresponding reference product. For example, the American FDA believes that therapeutically equivalent medicines can be substituted with the full expectation that both products will produce the same clinical response (Davit et al 2009).

Generic drugs are cheaper than innovative drugs because the costs of development (research and promotion) are lower, and this is reflected in the

2 These are medicines with small difference between therapeutic and toxic dose, including e.g. levothyroxine, warfarin, phenytoin, and digoxin.

final price (Guzmán 2011, Simoens and De Coster 2002). By using generic medicines, potential savings can be quite large. They may cost 30–90% less than equivalent innovative drugs (Guzmán 2011, Simoens and De Coster 2002, Greene et al 2011). For example, in 2008 generic medicines accounted for 83% of all prescriptions dispensed in primary care in England (DH 2010). Although generics make up the bulk of prescriptions, they cost much less when compared with the brand medicines, which comprise around 70% of National Health Services spending on drugs (Raftery 2013). Similarly, in 2012, generic medicines accounting for more than 75% of USA prescription (Kesselheim et al 2012) but less than 20% of the total costs of prescription medicine (Greene and Kesselheim 2011). Data from price surveys in 36 low and middle income countries show that in the private sector, prices of the lowest cost generic medicines were on average 2.6 times less expensive than the corresponding originator medicines (Cameron et al 2009). For example, in the private sector of 17 countries, the average savings for individual medicines would range from 9% to 89% if private sector purchasers switched from originator brands to the lowest-priced generic equivalents (Cameron and Laing 2010; Simoens and De Coster 2002). Savings would not, however, be confined to the private sector. For example, in public hospitals in China, over US$86 million could be saved from switching only 4 medicines from brand to generic product, saving patients an average of 65% (Cameron and Laing 2010).

Government needs to adopt a wide variety of policies to promote the use and to increase the volume of generic medicines. The key messages for generic medicines policies are: prices of generic medicines are lower compared to originator products if there is “enough” competition. Economic research has, generally, shown that most of the benefits of price competition are not obtained until four or five firms enter a market (Frank2007). Higher volume purchases through pooled procurement of medicines will reduce prices of generic medicines. However, as insurance coverage is still low in Sudan, it is important that FMOH and other agencies, such as NMPB, NMSF, NHIF, promote the use of generic medicines. The requesting by patients of non-prescription drugs by their brand name may reflect physicians’ insistence to prescribe brand names, and these are usually more expensive while offering no proven advantages over generic equivalents. The perception of some doctors in Sudan is that generic medicines are of inferior quality. They may be right in cases where generic medicines are approved without bioequivalence studies. So before opting

policies which promote generic medicines, FMOH and NHIF need to answer the question “are generics circulating in Sudanese market as safe and effective as the corresponding brand-name product ?”. The positive answer to this question assures that the population is being offered medicine of exactly the same quality, safety and efficacy as are found in the innovative drugs. Several prescribers stated that their concerns regarding the safety of generic products were about fillers and other inert ingredients. Reassurance of the safety and effectiveness of generic products is the first step to convincing doctors that there are uniform outcomes, independent of the source of the product. As a result, they will have no excuse not to write prescriptions using generic names of drugs. There is no doubt that, if FMOH, NMPB and NHIF start from the basis that a generic product is bioequivalent to an innovative one, and also results in a major saving for the health system, then the generic product should be the first choice. It is important for the FMOH and NHIF to gather evidence regarding the extent that generic medicines are therapeutically equivalence to their innovators. The public sector (and of course, ideally the private sector) should not promote the lowest price generic per se but rather lower-priced, quality assured generics (Kaplan et al 2012).

In summary, with the rising costs of healthcare and the uncertain global economic situation, governments and payers in many countries will require the increased usage of generic medicines. There is literature from high-income countries that suggests that insurance systems can successfully promote the use of generic medicines (Faden et al 2011). Chan (2011) in an opening remarks of a WHO meeting said that WHO not only supports generic products, it aggressively promote them whether through guidelines for conducting bioequivalence studies or through the prequalification programme. Generic products serve public health in multiple ways. In terms of improving access to medicines, price and quality must go hand in hand. An affordable price encourages good patient compliance, which improves treatment outcome and also protects against the emergence of drug resistance. NHIF could promote generic medicines by setting up incentives in the form of performance-based payments to reward doctors for compliance, improve health outcomes and lower overall medical spending. A comprehensive national generic medicine policy integrated within the broader framework of a national medicines policy, including strategies that align pro-generic medicine incentives with prescribers, dispensers and patients, would be the immediate option for developing countries (Nguyen et al 2015).

4.2 Pharmacoeconomics

Pharmacoeconomic (PE) analysis is the comparison of costs and consequences of using alternative medicines to maximize therapeutic outcomes of treatment and is especially useful when resources are limited. Demand side studies (Berndt et al1995; Ellison et al 1997; Kanavos et al 2007; Stern 1996; Jena et al 2009) suggest that patients only consider the price of therapeutic alternatives to a limited extent when making their consumption decision. Nevertheless, use of PE is important for priority-setting between treatments, since budgets are finite and there is great variance in value for money across products in the market. Some new products are costly but add little or no extra benefits when compared to existing cheaper medicines. In other situations new and more expensive drugs represent large potential health improvements. PE evidence can help decision-makers to judge whether the therapeutic benefits of using a new medicinal product are worth the extra cost (Drummond et al 2005). PE aims at optimal allocation of limited resources to maximize treatment outcomes from the use of medicines (Hughes 2010) and can therefore be used in the Sudan context to get the most health benefit possible from the budget allocated for FMOH and NHIF. In the UK, Britain's National Institute for Health and Clinical Excellence uses comparative effectiveness and cost-effectiveness analysis to advise the British National Health Service on what treatments should be provided through the service; medicines for which cost-effectiveness exceeds the threshold, conventionally set at £20,000 to £30,000 per quality-adjusted-life-year gained, are less likely to be approved for use by the National Health Services (Rawlins and Culyer 2004). Similarly, the American Recovery and Reinvestment Act of 2009 includes $1.1 billion for comparative effectiveness research (i.e. Research that compares medical treatments and procedures to determine which ones are most effective).

The consideration of value for money has not been stated in the regulations of medicines' registration. As a result, NMPB does not assess the value for money of the innovative or new products over the already registered ones. A marketing authorisation is therefore just a certification that a medicine is potentially effective for the treatment of a specific disease or medical condition. It does not imply that the medicine is more effective or safer than existing therapeutic alternatives nor the medicine cannot be priced higher than potential therapeutic alternatives. For medicines and devices, for example, importers and manufacturers focus on providing documents to meet the NMPB's regulations

and rather than providing answers to patients' and health professionals' questions about what works best and is safest, and for whom. No documents have been presented to compare different kinds of treatments, such as drug versus non-drug alternative treatments, and fewer still seek to distinguish patients who might have the greatest benefit and lowest risk of side effects from other patients who benefit less. The pharmaceutical industry can play an important role by producing clear cost-benefit and cost-effectiveness evidence for new products which are brought to the market. There is no institution that assesses whether the health benefits of a new pharmaceutical warrant its costs before market access is granted in Sudan. Also, there is no evidence that the entry of more generic medicinal products on the market lead to significant price reductions of therapeutic alternatives, or that therapeutic competition reduces pharmaceutical expenditures. In Sudan, the public sector relies on public tendering to control pharmaceutical expenditures. The private sector is regulated by prices that have been set by NMPB. NHIF has established a standing committee to update its list of medicines however the committee does not take into account evidence on cost-effectiveness of alternative treatment options. This is why the list of NHIF contains many alternatives from the same pharmacological group.

In conclusion, the need to maximize the benefits from allocated budgets for FMOH and NHIF during the current difficult economic situation places an ever greater responsibility on policy-makers, prescribers and dispensers to be conscious of costs. The policy-makers at FMOH and NHIF need to apply the principles and methods of PE evaluation. Moreover, medicine price regulations, which clearly state value-based pricing, need to be enforced to help patients who obtain their prescription medicines in the private pharmacies. PE studies help in ensuring that the money available to the patients, FMOH and NHIF is spent effectively and fairly. Because its budget is so limited, the FMOH and NHIF must recognize the fact that they cannot do everything for everybody. Publicly funded PE studies (i.e. comparative effectiveness research) could improve health care in Sudan by producing and publicizing independent, comprehensive research about what works best for patients. Pharmacists, with their unique knowledge of medicines, are crucial in using PE analysis to influence expenditure and distribution of resources on medicines (Purkiss 2006).

4.3 Selection of Medicines

Essential medicines are those, which address priority healthcare needs of the population. Since its inception, the concept of essential medicines aims to

increase availability and accessibility of medicines in low-income countries (WHO 2000a). Increased access to high quality essential medicines is today viewed as the most important global strategy to reduce the burden of diseases (Wiedenmayer 2004b). WHO proposes the use of an evidence-based approach in the selection of essential medicines, with cost-effectiveness comparisons being one of the key criteria (WHO 2003a).

4.3.1 Advantage of Short List

The medicine list is a fundamental exercise to public supply organizations that use a cost-recovery mechanism that uses a fixed medicine fund (one time capital investment) and is not a profit-making project. It is necessary for these organizations, such as NHIF and free medicine projects (i.e. publicly financed medicines), to procure and distribute only those medicines that are most needed and cost-effective. The selection of medicines for the national list of essential medicines must focus on these high priority medicines. From an economic perspective, it is good to keep the number of medicines to be procured, distributed, and reimbursed as small as possible. This reduces certain costs, increases access and facilitates appropriate use of medicines. Having a limited fund, the selection of a short list of medicines increases coverage by increasing purchased quantities of each item, and leads to maximum use of the small budget available. The FMOH, NHIF and other public organizations, in their medicine selection have to balance cost factors with those of efficacy, safety, ease of administration, and other considerations. The supply of high-cost, low volume medicines should be left to the private sector, since such medicines can tie up working capital and result in losses due to low usage and expired items. Generally, the advantages of having a short list of medicines include:

a. reduced procurement costs: when fewer medicines are selected, larger quantities of each medicine can be purchased which should reduce the cost per item;
b. efficient stock-keeping: a small number of medicines eases stock management because there is less movement in and out and fewer registers and document to be kept;
c. improved access to medicines: selection of fewer essential medicines increases access to the most essential medicines by permitting the purchase of increased quantities of each item;

d. effective quantification: quantification of the limited number of medicines is easier and more accurate;
e. cost effective use of funds: having limited funds, the selection of fewer medicines increases the coverage and leads to maximum use of the small budget available;
f. appropriate prescribing of medicines: reducing the variety of available medicines can improve treatment decisions because the training of prescribers is facilitated, side effects are easier to memorise and, above all, opportunities for irrational treatment can be reduced.

4.3.2 Medicine Formulary and Treatment Guidelines

Regardless of who is going to pay their costs, medicines should only be prescribed when they are necessary. And in all cases the benefits of administering the medicine should be considered in relation to the risks involved (WHO 2008). Bad prescribing habits lead to ineffective and unsafe treatment, exacerbation or prolongation of illness, distress and harm to the patient, and higher cost.

Treatment and prescribing practices in different public health facilities in Sudan are not always in compliance with national and international standards (Witter et al 2010). This is a critical issue. Free medicines will exacerbate the situation. If the government is funding free care, then the free care should be appropriate and cost-effective. This implies that a considerable effort is required to develop simple protocols for treatment of common diseases where these do not yet exist, and to educate staff in their use. Generally, formularies have been developed in response to specific forces which have affected pharmaceutical utilization and costs (Giaquinta 1994). Specifically, formularies are in response to an increased awareness and access to health services requiring more medicines, inflation in the acquisition cost of pharmaceuticals, increasing utilization, and the introduction of new technology. To be effective in controlling the cost of medicines while providing quality care, the development of formularies and standard treatment guidelines must be evidence-based and requires the co-operation of all stakeholders, including FMOH, NHIF, pharmacists, physicians, the pharmaceutical industry, and patients. Finally, payments to facilities and incentive payments to staff should be linked with monitoring compliance with these standards. In addition, basic norms for equipping facilities should be enforced (Witter et al 2010).

4.3.3 Summary

The efficient provision of cost-effective medicines will increase access to treatment at public health facilities. The improvement in access to essential medicines depends on the regular availability of essential quality medicines at affordable prices near to where people live, particularly in rural areas. One of the core pillars to hit this target is the exercise of medicine selection. The selection of medicines must focus on high priority medicines. The national list of essential medicines should include products that can be used to treat common health problems in Sudan. Economically, it is good for the government to keep the number of medicines as small as possible, as the short list reduces the wastage of limited resources. In addition, using a small number of medicines eases stock management and reduces losses and this is significant because the potential risk of losses, expiry of stocks, and damage of medicines and so on in public health facilities is borne by the public organizations, such as NHIF. Finally, a carefully selected medicine list ensures stable medicine financing and enables the FMOH to focus efforts on making selected medicines regularly available in widely spread public health facilities. As a result, the overall costs of buying medicines at private pharmacies and travel expenses incurred by users will be reduced. An introduction of evidence-based drug formularies in Sudanese hospitals and clinics, coupled with a requirement to provide cost-effectiveness evidence when new therapeutic alternatives are introduced into the market, may help to contain pharmaceutical expenditure growth in the future.

4.4 Pricing of Medicines

Final consumer prices are generally made up of a combination of the unit price charged by the manufacturer, port charges, insurance, freight and clearance costs, pre-shipment inspection fees, a pharmacy board fee, importer's margins, central government taxes, state government taxes, local duty, and wholesalers' and retailers' mark-up. Typically the largest mark-ups are the importers', wholesalers' and retailers' margins, which can add 50% to 80% to the ex-factory price. For individuals in developing countries, the price of essential medicines may be burdensome; these costs are usually borne by families (WHO 2004a). Various strategies adopted by governments to reduce the burden of medicine costs include: promotion of competition among quality generic medicines, negotiation of prices and therapeutic competition for patent drugs, use of the provisions mentioned under the agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) to increase affordability of medicines still

under patent, reduction of duties and taxes, and reduction of wholesale and retail margins.

The reason for price controls is a failure of market discipline to operate in medicines markets. For Sudan, where medicine expenditures are mainly out-of-pocket, price controls set at whole and retail levels appear to be the best approach. In Sudan, the current unlawful practice of putting fixed mark-ups (i.e. 15% and 20%) encourages both wholesalers and retailers to promote the sale of products with high CIF prices. The regulations of pharmaceutical pricing 2010, legally obliges the importers to fix sliding mark-ups for whole and retail prices ranging from 15%, 17.5% to 20% and 20%, 22.5% to 25% respectively, depending on the total cost to their warehouses in Khartoum. The sliding scale of putting highest mark-up on lowest CIF prices will encourage wholesalers sell and retailers to dispense low price, assured-quality medicines rather than the more expensive products. It was made in order to maximise the savings to patients, FMOH and NHIF and to release more resources for improved patient care.

It is well documented that drug prices create ''affordability'' barriers to healthcare payers and, as such, government and non-governmental agencies in Sudan must enforce the price regulations to avoid stretching what are already inadequate medicine budgets. The enforcement of this regulation could be done through the publication of the medicine retail price on the outer package. However, aggressive application of price controls, especially where prices are fixed at very low levels, may incite producers and suppliers to restrict supplies and encourage emergence of black markets and hinder growth of generic markets (Grace 2003). One way out of these negative responses is to structure transparent, evidence-based price control and to negotiate the price of medicines with the manufacturers and importers at the time of product registration and before market entry. This must be carefully done, as price negotiations by NMPB before or at medicine registration may delay diffusion of new drugs (above that associated with regulation of safety, efficacy and quality) and diminish pharmaceutical benefits for consumers. The NMPB must ban the recently emerging practice of 'commercial' NGOs (as middlemen) who buy medicines from importers (i.e. wholesalers) and sell to retailers. Although the practice is legal, a medicine can pass through a number of middlemen in the supply chain which compounds the selling price to patients.

In conclusion, control of medicine prices is not enough, by itself, to contain expenditure on medicines (Lambrelli and O'Donnell 2011).The cost of drugs

is covered by patients (68%), health insurance (32%) and FMOH, so the rate of increase in expenditure places an additional burden on an already severely strained social insurance fund, FMOH and patients (46% of Sudan population are below poverty line).There are no clear policy efforts to contain healthcare expenditure in Sudan. However, the FMOH through its medicine regulatory agency, has recently responded to increasing pharmaceutical expenditures by seeking to control the prices of pharmaceuticals. In Sudan, access to social health insurance is compulsory for the formal sector. NHIF's reimbursement system provides little incentives for physicians and patients to be price conscious in their prescription and consumption of medicines.

4.5 Rational Use of Medicines

The rational use of medicines (RUM) includes defining which medicines are most needed, identifying the most cost-effective treatment for particular conditions while taking full account of quality and safety as well, and then ensuring that medicines are used effectively (Dukes et al 2003). Access to medicines is made worse by irrational use of medicines, which is a major problem worldwide. It is estimated that half of all medicines are inappropriately prescribed, dispensed or sold, and that half of all patients fail to take their medicine properly (WHO 2004a). This section presents the strategies that will promote the rational use of medicines.

4.5.1 Cost-Conscious Prescribing Behaviour

Doctors often have no idea about the true cost of treatments; raising their awareness about treatment costs is an important strategy because the medical costs themselves can affect patients' health. Recent studies (Himmelstein et al 2009) documented other ways in which medical costs affect patients; those struggling with high medical debt have been found to skip important treatments and stop taking prescribed medications. New research (Gower 2014) also shows that medical debt can lead to a diminished quality of life and high levels of psychological stress for both patients and their families.

"Financial toxicity," is the new term for the myriad negative effects that high medical costs can have on patients' well-being. However, there are reasons beyond profiteering and fear of litigation that lead to wasteful medicine and needless costs to patients. Some doctors argue that their ethical responsibilities oblige them to prescribe the "best possible treatment" regardless of cost; others may be used to thinking that patients' insurance covers most costs; other doctors

may order unnecessary tests out of habit, or simply to satisfy patient expectations. This could explain why, for example, the cost of a prescription of the health insurance (i.e. SDG 39) in Khartoum state is more than 2 times the cost of a prescription in the user-fee system (i.e. SDG 19). Finally, with malpractice suits being an ever-present threat in the USA, doctors may also practice "defensive medicine" by ordering every possible test out of fear that they could be sued for missing an important clue to disease (Gower 2014).

To control rising pharmaceutical expenditures, many countries have implemented regulatory measures that target physicians' prescribing behaviour and promote generic prescribing. These measures include: the prescription of medicines using only the generic name (International Non-proprietary Name); incentive payments for doctors in health facilities linked to prescribing; dissemination of information to promote the use of generics; the use of prescribing guidelines or protocols; monitoring of prescribing behaviour; and the introduction of rewards (such as pay-for performance, training, opportunities for sponsored postgraduate studies for medical doctors or sub-specialties for specialists) and disciplinary systems. International experience (Ghislandi et al 2005; Paris 2005; van de Wolf1 et al 2005; Mossialos and Srivastava 2008; Barros et al 2007) suggests that such measures can reduce the prescription of medicines with ambiguous effectiveness, promote the prescription of generic drugs and reduce overall pharmaceutical expenditures. For example, in England, financial rewards for meeting targets have had the desired effect and evidence from three Western European countries suggests that prescribing incentives schemes can control drug costs and promote good prescribing practice (Sturm et al 2007). Financial incentives directed at pharmacists, such as the use of preferential margins on generic products or fixed dispensing budgets could also being used (Lambrellia and O'Donnell 2011). In Sudan, generic substitution is allowed. However, it is halted by the fact that pharmacies' profits are directly linked to the price of the product dispensed, providing a disincentive to dispense cheaper medicines.

In summary, currently in Sudan, neither cost containment nor efficiency is actively pursued through incentives provided to doctors to prescribe rationally. The escalation of pharmaceutical expenditures in Sudan can be more broadly attributed to the lack of incentives for cost-conscious behaviour throughout the health sector including the health insurance funds, hospitals, doctors, pharmacists and patients.

4.5.2 Multiple Medications

Taking multiple medications is an important risk indicator for individuals, due to the increased risk of drug interactions, adverse drug reactions (ADR), and diminishing adherence to drug therapy (Gorard 2006; Bjerrum et al 1997; Colley and Lucas 1993; Salazar et al 2007). Moreover, excessive use of medicines is recognized as a common problem in health care (Gorard 2006; Colley and Lucas 1993; Bushardt and Jones 2005). Multiple medication may cause avoidable health expenditure, both directly due to redundant drug sales and also indirectly due to the increased risk of hospitalization caused by drug-related problems (Bjerrum et al 1997; Cahir et al 2010) as a result of the risk for drug-interactions and ADR increasing exponentially with the number of drugs consumed (Cadieux 1989). For example, in the UK the cost of drug-related problems is reported to cause approximately 6% of all admissions to hospitals and 11% of all admissions amongst elderly patients (Krahenbuhl-Melcher et al 2007; Kongkaew et al 2008). A critical measure in Sudan to reduce multiple medication problems would be the development of new approaches to strengthen rational medicine prescribing patterns. These could be in the form of continuing in-service medical education programs linked to new or revised evidence-based clinical guidelines to treat common diseases and the issue of therapeutic pocket guides that offer a quick guide to doctors on how to treat the most common health problems.

4.6 Improving Medication Adherence

WHO referred to non-adherence as "a worldwide problem of striking magnitude" and improving adherence to medication has become a priority for health care policy makers (WHO 2003b). Medical non-compliance has been identified as a major public health problem that imposes a considerable financial burden upon modern health care systems (Horne 1997; Morris and Schulz 1992; Donovan and Blake 1992; Donovan 1995). It has been estimated that the cost of treating health problems resulting from the adverse effects or the inappropriate use of medicines is equal to or greater than the cost of the medicines themselves (WHO 2011b).With increasing numbers of medications shown to do more harm than good when taken differently from what has been prescribed, low adherence is a growing concern, because it is seriously undermining the benefits of health care (Horne 1997; Haynes et al 1997; Melnikow and Kiefe 1994). Researchers (see, for example, Haynes et al 2008; Horne et al 2006) suggest that 30% to 50% of patients do not take their medication for chronic conditions

as prescribed. Estimates indicate that 28% of new prescriptions are unfilled (Fischer et al 2010) and among patients who do obtain medications, adherence rates are often less than 50% (Haynes 2002). Non-adherence to medicines is a major health care cost and quality problem, with numerous studies (Morris and Schulz 1992; Donovan 1995) showing high rates of non-adherence directly related to poor clinical outcomes, high health care costs, and lost productivity. The cost to patients of non-adherence is a missed opportunity for treatment gain and, if their condition worsens, a possible decline in their quality of life. Costs also arise from the perspective of the health care system; the cost of unused or unwanted medications exceeds, for example, £100 million annually in the UK (Department of Health 2008). In the USA, the cost of non-adherence has been estimated at $100 billion to $300 billion annually, including costs from avoidable hospitalization, nursing home admissions, and premature deaths (Osterberg and Blaschke 2005). Non-adherence also leads to thousands of serious adverse events or deaths each month (Editorial 2006). Other research (Sokol et al 2005) indicates that 33% to 69% of medicine-related hospital admissions are caused by poor adherence, with a resulting estimated cost as high as $100 billion a year in the USA. Additionally, lack of compliance to medical advice interferes with therapeutic benefits of medications and can lead to additional diagnostic and treatment procedures, resulting in further health care costs (NCPIE 2007). Furthermore, poor adherence to antimicrobials can increase disease spread and lead to the development of drug-resistant strains amongst the population. Finally, patients who do not adhere to prescribed instructions have poor treatment outcomes (Dunbar-Jacob and Mortimer-Stephens 2001; Ghali -et al 1988; Vinson et al 1990). This is considered as a source of ongoing frustration to doctors (Melnikow and Kiefe 1994).

Reasons for non-adherence are varied and complex, though researchers (Osterberg and Blaschke 2005) have identified some common predictors of poor adherence. While the most common reason for non-adherence is simply forgetting to take a prescribed medicine (AHA 2009), other reasons included lack of patient knowledge, skills, support to appropriately self-manage complicated medication regimens (Murray et al 1986; Hope et al 2004), nuisance, potential side effects, not wanting to consume anything “unnatural”, and lack of perceived benefit. Patient characteristics that may lead to poor adherence include advanced age, cognitive impairment, depression, attitudes and beliefs about the importance of the medication and the disease being treated (i.e. patient

lacks insight into the illness). A substantial portion of medication non-adherence is driven by out-of-pocket costs (i.e. competing demands for resources at the household level) of multiple medications (Soumerai et al 2006; Hsu et al 2006; Thorpe 2006). Unfortunately, those with multiple chronic conditions (and presumably using more medications) are most susceptible to cost-related non-adherence (Soumerai et al 2006). Health care systems and clinician barriers include insufficient access to physicians, lack of trust between clinician and patient, physicians' negative attitudes (Tarn et al 2006), inadequate knowledge about the disease (Petrilla et al 2005; Osterberg and Blaschke 2005), inadequate follow-up or discharge planning, missed appointments, polypharmacy, frequent (more than once daily) dosing, and complexity of treatment. Studies (Tarn et al 2006) showed that deficits in the information and education that physicians provide to patients when starting treatments with new medications contribute to noncompliance with the treatment. Physicians frequently omitted critical information, such as the name of the medication, purpose of the medication, duration of treatment, dosing schedule, and expected adverse effects of new medications (Editorial 2006). Physician failure to provide adequate information at the time of prescribing invites non-adherence even from the most fastidious and motivated patients. Compliance with treatment is a key link between process and outcome in medical care (Urquhart 1996).

The solution to the problem of non-adherence lies in efforts to stimulate better prescribing of, and adherence to, essential medications that will increase value by improving population health, avert costly emergency department visits and hospitalizations, and improve quality of life and productivity (Shrank et al 2009). Physicians may increase medication adherence and promote patient safety by minimizing the number of drugs and the number of daily drug doses. In patients with multiple chronic diseases, keeping the drug list as short as possible is especially important. Some commonly prescribed medications have few benefits relative to the risks they confer and should rarely be used. Reduced out-of-pocket costs may encourage many patients to continue using those medications with the greatest benefit (Fendrick and Chernew 2006). Formularies that limit the choice of medications may reduce risks to patients while encouraging limited use of drugs that have few benefits relative to risks. Formularies may also have the beneficial effect of delaying widespread use of new drugs that add little value beyond what is already available and have uncertain safety profiles.

Literature (Roumie et al 2006; Haynes et al 2002; Petrilla et al 2005) shows that interventions which successfully improve adherence generally involve patient education and structural support (such as patient reminders), more frequent clinic visits, simplifying the patient's drug regimen by reducing the daily number of tablets or capsules consumed and reducing medication costs. Published works (Ali et al 2003; Tsuyuki et al 2002; Tsuyuki et al 2004; Lee et al 2004) also proved that the involvement of pharmacists in assessing adherence and offering advice to physicians about simplifying and improving drug regimens enhances patients' compliance. Direct counseling of patients by pharmacists may be particularly promising because of their specialized training and knowledge of medications and their availability to patients. Policymakers at FMOH and NHIF need to consider emphasizing the importance of pharmacists in promoting medication adherence in order to reduce health care use and associated costs of chronic diseases, such as heart failure. Community pharmacies could improve their services, such as promoting medication review and adherence. Such services must be supported by the health policies of FMOH and NHIF. Educating pharmacists about new services, such as medication review and adherence is crucial to the success of the health policies and plans. This education programme will enable pharmacists to feel competent and skilled in delivering the new services. Pharmacy education needs to provide pharmacists with an understanding of the often complex issues underlying patients' reasons for non-adherence (Horne et al 2006). Improved collaborative relationships between doctors and pharmacists who work in the same area will increase the likelihood of delivering effective services to support patients with their medication adherence, for instance, better communication and consistency of information and advice about prescribed medicines. A study of Murray and colleagues (2007) proved that the pharmacist intervention improved adherence with cardiovascular medications, including the proportion of medications taken, the reliability of scheduling these medications, and the amounts of medications refilled. They showed that the return on investment is $14 for every dollar spent on the intervention.

Increasing compliance to prescribed treatment is an important strategy that improves population health at the lowest possible cost. NHIF's physicians could be held accountable not only for their own adherence to guideline-driven medical care but for their patients' adherence as well. With their salaries indirectly tied to patients' behavior, physicians who have signed contracts or their employers with NHIF will theoretically be more motivated to educate patients about medication therapy and to address barriers to its use.

Prescribing of medicines that lower the number of tablets per day needed to achieve the desired therapeutic effect, combining individual medicines into a single tablet, or reducing side effects all help to eliminate several of the known barriers to adherence. Health professionals should gain insight into the best ways to provide counseling to patients, target messaging, use patients' social networks to promote healthier behavior, and deploy health information technology to promote appropriate medication use. Finally, the doctor-patient relationship, communication and shared decision-making are important factors affecting compliance.

In summary, medication non-adherence is very expensive for the health system and is not just a patient problem. Improving adherence holds great potential to contribute to better health outcomes and more effective chronic care management. Recognition of the value of improving patient adherence by FMOH and NHIF will help in implementing policies and plans that encourage patients to use their medicines as directed. Efforts to improve adherence represent win-win solutions in which patients, employers, insurers and the public all benefit. This is because failure to take medicines as prescribed increases health care costs and exacts a significant human toll. FMOH and NHIF may invest in studying lower-cost ways to help patients be healthier.

4.7 Prohibiting Unethical Medicine Promotion

The role of the pharmaceutical industry in the escalation of costs cannot be neglected. In Sudan, current legislation does not regulate the magnitude of pharmaceutical companies' budgets devoted to promotional activities. The actual content of these activities remains beyond control. It is common to find pharmaceutical industry representatives in doctors' clinics updating them on new treatments and relevant pharmaceutical research. Given the lack of control on cost-effective prescribing, it is possible, although as yet unconfirmed in Sudan setting, that this industry promotion encourages the prescription of medicines which only have modest therapeutic gain over alternatives. This section, presents the important of pharmaceutical industry promotion on both prescribers and dispensers.

4.7.1 Doctors and pharmaceutical industry relationships

Published research (see, for example, Lambrellia and O'Donnell 2011) suggests that prescribing patterns of doctors, primarily the increasing tendency to prescribe expensive labeled products rather than generic substitutes, are

significant cost drivers. To contain pharmaceutical expenditures and improve their cost-effectiveness in Sudan, as elsewhere, there is a desperate need for an integrated information system that will provide data necessary for the systematic monitoring of prescribing patterns.

Doctors who received industry-provided flight tickets and accommodation to participate in conferences, free samples, and those who meet with industry representatives are more likely to prescribe their sponsors' drugs. These factors work together to increase the likelihood that physicians will prescribe their sponsors' drugs, and clearly serve a marketing function. Potential interventions that could dramatically reduce this practice include enforcement of the Medicines and Poisons Act and strengthen the current generic substitution of interchangeable products by pharmacists, with exception of certain items, such as narrow therapeutic index medicines. In addition, hospitals and health systems could consider policies that prevent individual physicians from receiving samples and instead require samples be given to hospital's pharmacy. The differences in prices of the same drugs and the promotional campaigns by medical representatives of pharmaceutical companies have given rise to perceptions about the quality of specific brands.

One of the major drivers might be the unhealthy and unethical relations between many doctors and some drug companies (Editorial 2013). There are allegations that staff of drug companies improperly use cash and other incentives to encourage the prescription of their pharmaceutical products (Editorial 2013, Gulland 2014). For example, a recent report has found that nearly all of the 20 largest global drug companies have been involved in unethical practices, such as bribery or corruption in the past two years (Gulland 2014). Given the ever growing number of medicines, if physicians do not have access to scientific information and do not have enough technical knowledge to make a critical appraisal of new medicines, the prescription process will be vulnerable to marketing techniques by the pharmaceutical industry, and decisions will not be taken in terms of the best option for the patient and the health system as a whole. As a result, patients may not have access to the right drugs and may pay for medicines that do not work.

This paper has no evidence to suggest that these allegations against drug companies are true in Sudan. However, some observers, for example, the secretary general of consumer protection society, claim that bribing doctors to boost drug prescriptions by some drug companies is an open secret and that this alleged

practice will compromise the public's trust in doctors. The varieties of unethical relationships that are alleged to exist between some doctors and some of the drug companies in Sudan are said to range from cash kickbacks, lavish gifts or entertainment, and all-expenses-paid trips. In a meeting of NMPB in 2009, the former president of Sudanese doctors union clearly stated that he encourages all doctors in Sudan to participate in conferences and meetings sponsored by drug companies. He added that he sees no problem if a doctor's cost of travelling and accommodation paid for by a drug company. Such practice has been banned in many countries including, for example, USA and India (Epstein 2012; Mudur 2010).There is real concern that doctors' prescriptions are therefore not based solely on patient need and clinical evidence, but may be biased by commercial interests.

The perceived unethical association between physicians and industry in Sudan is worrying, because it inevitably harms patients as well as doctors. It damages the doctor–patient relationship and, ultimately, Sudan's whole health system. The allegations about drug companies, although unproven, have clearly rung an alarm bell for Sudan's regulatory authorities (NMPB, Sudan Medical Council, FMOH) to ensure the drug industry promotes products in a responsible, ethical, and professional way. Limits must be placed by Sudanese authorities (e.g. NMPB and Sudan Medical Council) on what can be said and done by drug company sales representatives. This means doctors in Sudan will receive more balanced information. Currently, sales representatives are not regulated in Sudan. The NMPB needs to approve regulations to govern the practice of sales representatives. The chambers of medicines manufacturers and importers need to develop a code of practice to control the behavior of medical representatives.

4.7.2 Bonus (free goods) to Retail Pharmacies

"Bonusing" refers to the practice of giving free stock or reduced prices linked to the volume of purchases. A typical example would be a "buy 10 and get 2free" offer. Studies (Gray 2009) showed that excessive promotion of medicines contributes to high expenditure on pharmaceuticals. Legislation must be in place to prohibit the practice of free gifts and "bonusing" to doctors and pharmacies respectively. In Yemen, the bonus prohibition has reduced price of certain medicines by more than 30% (HAI 2009). The value of free medicines imported to Sudan during the first 6 months of 2010 was US$ 17.6 million, which is equivalent to 30% of the value of medicines imported by the private sector (Mohamed and Yahya 2012). The origins of these medicines were mainly

Jordan, India and Pakistan. Some importers gave from 50% to100% free medicines per invoice. Opponents of free goods policy argued that this practice has weakened the control of medicine prices in Sudan. According to them, it is difficult for inspectors to trace the free medicines because it is left up to the pharmacies either to reduce their prices by spreading the cost of goods over all invoiced items or to sell the free goods as if they had paid for them. The opponents of "bonusing" thought that the bonus also distorts medicine prices and unnecessarily escalates their cost. Retail pharmacies tend to sell medicines of companies that offer free goods in preference to those who do not. Certain importers do not give free goods and rely mainly on promotion done by their medical representatives. Promotion is a very effective tool and doctors prescribe the promoted products, but at the dispensing level, pharmacy staff substitute the prescribed products with those from pharmaceutical companies that give free goods. This practice hits hard on patients who do not know the price of alternative medicines, which in most cases is cheaper. It is clear that the CIF prices of these medicines have been inflated by the importers and their principal manufacturers. This was confirmed by pharmacists working in medicine importing companies who explained that the cost of free goods is already added to the CIF prices (Mohamed and Yahya 2012).

4.8 Reducing Medication Errors and Adverse Drug Reactions

A medication error may be defined as any preventable event that may cause or lead to inappropriate medication use or patient harm, while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems including prescribing, order communication, product labeling, packaging and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use (Dean et al 2002; Hoxsie et al 2006). In the UK, medication issues contribute to between 5 and 20% of hospital admissions and re-admissions (Barnett et al 2011). Almost half are preventable.

Before a medicine is granted a licence so that it can be made available on the market, it must pass strict tests and checks to ensure that it is acceptably safe and effective. All effective medicines, however, can cause side effects (also known as adverse drug reactions), which can range from minor to very serious. For a medicine to be granted a licence, the expected benefits of the medicine must outweigh the possible risks of the medicine causing adverse effects in patients. Sometimes, it is difficult to tell whether a possible side effect is due to

a medicine or something else. Medicines and Healthcare products Regulatory Agency (MHRA) of the UK defines an adverse drug reaction (ADR) as a response to a medicinal product which is noxious and unintended. Response in this context means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility. The reaction may be a known side effect of the drug or it may be new and previously unrecognised (MHRA 2014). Generally, all medicines can cause side effects. Some may not yet be known and others appear after taking a medicine for a long time or even after stopping a medicine. Many side effects are mild, but some can be serious and even life-threatening. In the UK, an ADR reporting scheme has been running for over 40 years. This scheme receives reports of suspected ADRs or side effects from healthcare professionals and patients for medicines and vaccines. In the USA, the number of deaths because of medication errors and the adverse effects of medicines used in hospitals increased from 2,876 in1983 to 7,391 in 1993 (Lesar et al 1990), whereas in the UK admissions related to ADRs cost the National Health Services up to £466 million annually (Barnett et al 2011).

ADRs have been regarded as a major public health problem since they represent a sizable percentage of admission causes and an economic burden (Camargo et al 2006 and Patel et al 2007). However, at least 80% admissions due to ADRs are supposed to be potentially avoidable because they are dose related reactions, and thus predictable from the known pharmacology of the drug. They could be avoided by closer patient clinical and laboratory monitoring, applying protective measures, selecting other drugs and patient education (Camargo et al 2006; Hooft et al 2006; Lazarou et al 1998; Routledge et al 2004; Rivkin 2007). Pharmacovigilance includes the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems, especially long-term and short-term side effects of medicines (Salmeroń-Garcıá et al 2010). FMOH, through NMPB, needs to develop and implement a drug surveillance system to address medicine safety concerns in Sudan. However, this project requires radical reform in the health system including, for example, a register for patients and a limited number of medicines of the same molecule and dosage form. Other interventions include medicines reconciliation, patient counseling, and improved discharge communications (Audit Commission 2001).

The prescriber has to be knowledgeable enough to choose an effective treatment that is suitable for the individual patient, taking into account age, infirmity, and possible interactions with other medicines. Having selected the right medicine

and the correct dose, the prescriber has to transmit the message to the dispenser. The dispenser then has to hand the medicine to the patient, or to a carer or nurse, who has to see that the medicine is given in the correct way and at the specified times. Medication errors occur because of the complexity of this process, but there are several ways in which risk can be minimized: changing the risk management culture; induction and training; redesigning processes to reduce errors; and developing clinical pharmacy services. Clinical pharmacy applies pharmaceutical expertise to help to maximize medicine efficacy and health outcomes and minimize medicines toxicity in individual patients. It allows pharmacists to become part of the clinical team and to anticipate medication errors. Medication review on admission by a pharmacist can also identify if an admission is due to prescribing errors or to adverse reactions to medicines in the community. Medication review on admission can help to identify such problems and report them back to doctors.

4.9 Promoting Responsible Self-Medication: the Challenge of Health System

Self-medication (SM) has become quite common in developed (Blenkinsopp and Bradley 1996, Branstad 1994) as well as developing countries (Kamat and Nichter 1998, Shankar et al 2002) possibly masking serious medical conditions (Blenkinsopp and Bradley 1996).This has resulted in the misuse of over-the-counter products through overuse, using several medicines concurrently, or using home remedies to treat potentially serious diseases (Editorial 2000). SM can be defined as the use of drugs to treat self-diagnosed disorders or symptoms, or the intermittent or continued use of a prescribed drug for chronic or recurrent disease or symptoms (WHO 2000b).

SM is potentially associated with many problems including drug-induced disease; waste of scarce resources (WHO 2002); incorrect self-diagnosis (Bradley and Bond 1995; Kennedy 1996); the emergence and spread of antimicrobial resistance (WHO 2001); inadequate treatment of a disease that can result in disease progression and its complications. Inappropriate dosing may result in serious morbidity and even mortality, poor patient outcomes, adverse drug reactions and eroded patient confidence in health system.

Patient choice of non-prescription medication was found to be based on advice received from pharmacy staff, informal advice from health professionals, friends and relatives, or selected products based on their previous experiences with similar symptoms or similar diseases. Another source of risky SM is the

acquisition of POM drugs from pharmacies without a prescription. In 2009, the NMPB published a classification for medicines circulating in the Sudan market. This publication has classified medicines to controlled medicines, prescription only medicines (POM), pharmacy medicines and over-the-counter medicines. The publication restricts retail pharmacies from selling medicines without a prescription, including antibiotics. The classification book has not been disseminated. Because of the absence of clear medicine classification at pharmacies, weak enforcement of regulations, the shortage of pharmacists who own their own pharmacies, the profit driven behaviour of some retailers, and the illegal sale of POM (including antibiotics) remain common problems in Sudan.

Several studies (for example, Figueiras et al 2000) reveal the presence of different factors that influence SM. These factors include patient satisfaction with the healthcare provider, the delay and the time costs entailed in a doctor's appointment, cost of medicines, avoiding the cost of doctors' visits, the ailments being considered too minor to see a doctor; educational level, socio-economic factors, income level, age and gender. The malpractice of prescribing medicines despite the absence of clear indications, and the issuing of prescriptions before the diagnosis has been verified, indirectly encourage people to go directly to a pharmacy and buy their medications.

SM might be a consequence of poor implementation of and control over the laws and regulations influencing prescribing and, even more, influencing distribution of community pharmacy services. In Sudan, because of ignorance of the regulation requiring at least 100 meters distance between pharmacies and the fact that the majority of pharmacies are owned by non-pharmacists, pharmacies have become more and more business orientated. Fierce competition and unprofessional ownership of pharmacies has made selling medicines the focal point of the business at the expense of the evidence-based practice. As a result, the ethics that govern the practice of the pharmacy profession in Sudan are gradually fading.

Measures to tighten control and monitoring of non-prescription use of medicines in communities nationwide are urgently needed. These strategies may include employing more pharmacists by enforcing the regulations, which clearly state that private pharmacies must be owned by pharmacists. This will ensure legal dispensing and rational use of medicines. FMOH needs to develop a plan that specifies that by 2020 all retail and pharmacies of public health facilities must have licensed pharmacists present to oversee the quality use of medicines.

Moreover, and critically, the government should deepen public hospitals reform and remove medicine mark-ups. The income of health facilities and prescribers' incentives (in both public and private health sectors) should not be linked to medicine sales. This change would reduce non-prescribed use of medicines in communities (Fang 2014).

Additionally, government funding for public and professional education on the appropriate use of medicines is also needed. In the long term, national surveillance of non-prescription use of medicines and antibiotic resistant bacteria in communities would help estimate the prevalence of self-medication and the development of resistance to antibiotics and guide future public policy. A training programme for doctors and other prescribers can reduce inappropriate use of medicines. To achieve a significant decrease in SM, FMOH also needs to design programmes for lay people. The programmes should be carefully designed, understandable and they should make public aware of the negative effects of SM. Such programmes will encourage patients to see prescribers, instead of dropping into a pharmacy to buy medicines. Starting mandatory continuous education programs that target pharmacists and their assistants is recommended so that pharmacy staff can play a more active role in helping people reaching appropriate decisions related to their health. Considering the breadth of medicine available without a prescription and the problems that can arise with medication use, community pharmacies in Sudan have the potential to make a huge impact by ensuring medicines are used appropriately. Finally, proper and adequate training of pharmacy staff to diagnose and treat, and to know when to refer patients, would be crucial. Pharmacists in Sudan have to play a key role in protecting and improving public health and providing appropriate advice to consumers on the safe use of drugs intended for SM.

The main duties of pharmacists in community pharmacies involve dispensing of medicines with very comprehensive pharmacist-patient interaction. In Sudan, community pharmacies do not maintain patient medication records and seldom use technology for patient care. Although the regulations pertaining to drug dispensing are in existence, these regulations are not strictly enforced in community pharmacies. Patients visit a community pharmacy to purchase a product much like they would at a supermarket. In Sudan, like most other developing countries (Krishnaswamy and Raghuram 1983; Hardon 1987; Haak 1988; Price 1989; Bi et al 2000; Shankar et al 2002), having a valid prescription is not enforced for receiving POM. With the exception of narcotics and major

tranquilizers, patients can buy any medication without a prescription. The health authorities have to enforce the regulations to prohibit the selling of POM without prescription. The NMPB must urgently update and disseminate the classification of registered medicines according to their safety and level of use to all pharmacies in Sudan. For example, in Europe, where the market is well-regulated, SM is controlled by dispensing only safe medicines that have been already classified as non-prescription medicines (de Melo et al 2006). Replication of the European experience in regulating SM practice will contribute to reducing the burden on physicians and the health system.

To conclude, a major drawback of self-treatment is the lack of clinical evaluation of patients, which could result in misdiagnosis and delays in appropriate treatment (Hamel et al 2001). Therefore, it is highly recommendable to invest in an expansive medicine education programme directed towards the lay people about the possible risks of an inappropriate use of medicine. Educating health care professionals is not enough while patients still have the possibility of making their own decisions as to whether to self-medicate themselves or not. It is important that FMOH take its responsibility in regulating SM. In fact responsible SM is a good practice, which can reduce public expenditure and improve health care.

4.10 Clinical Pharmacy Services

There is increasing recognition that providing consumers with medicines alone is not sufficient to achieve the treatment goals (WHO 2011b). The WHO (2011b) also reported that pharmacists, as health-care professionals, should be part of any comprehensive health system and play an important role in improving access to health care and in closing the gap between the potential benefit of medicines and the actual value realized. The pharmacists' role also includes promotion and support of the safe, effective and rational use of medicines among the population that they serve. The pharmacist's involvement in therapeutics extends from the initial development of new chemical entities and their formulation into medicinal products, through their testing, marketing and distribution and to their supply to patients and ultimately to the monitoring of patients taking them. However, this role takes different forms in different parts of the world. In recent years, the orientation of the pharmacist in many countries has shifted from the product to the patient. The focus of attention is now firmly on the pharmaceutical needs of the patient rather than the preparation of an elegant product (now performed by industry). These patient-focused activities have evolved into the concept of

'pharmaceutical care', which has been defined as 'the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life' (Hepler and Strand 1990). Pharmacy, no less than medicine or nursing, is a profession in which lack of care can result in patient harm or death. This may result, for example, through failure to spot a dosage error, or through the supply of the wrong drug (Barber et al 1994). Effective use of professional expertise and health resources should eliminate inefficiency and duplication of effort (Crown 1999; Galt 1995; Stoate 2001) in health care delivery. Most medication-related interventions by pharmacists occur retrospectively; their early involvement in the prescribing process may help to optimise the use of medicines (Davies et al 1994; Hindmarsh 2001; Carmichael and Cichowlas 2002). Pharmacist interventions in medication management, including monitoring of therapy, are accepted in the hospital setting (Galindo et al 2003). The pharmacists see their clinical role fulfilled and their professional status enhanced, as it promotes greater involvement with patients and increases therapeutic options (de Melo et al 2006). Provision of clinical pharmacy services is the future direction of hospital pharmacy practice, as stated by the International Pharmaceutical Federation (2009).

Clinical pharmacy services have positive clinical, human and economic impacts. The studies (Schumock et al 1996, 2003; Bond et al 2000, 2002; Bond and Raehl 2004; Kaboli et al 2006; Pickard and Hung 2006; Bond and Raehl 2007; De Rijdt et al 2008; MacLaren et al 2008; Perez et al 2008; Anderson and Schumock 2009) have shown that the clinical pharmacy services facilitate appropriate prescribing; prevent adverse drug events; reduce medication errors; reduce patient length of hospital stay; lower mortality; improve patient knowledge, adherence and quality of life; and reduce costs. Pharmacists are valuable members of the health care team and among the most accessible health care providers. Pharmacists have roles in health promotion, disease management, and medication review, with in-depth training in pharmacology, clinical therapeutics, and patient care, skills that are at present significantly underused. It is increasingly clear that medicines should be provided to consumers by making the best use of professional expertise and scarce health resources (Nissen 2011).

A persistent failure to make full use of the knowledge and skills of pharmacists has long been one of the profession's recurrent preoccupations. FMOH must recognize that the use of the pharmacist's clinical skills and expertise are an integral part of delivering better services to patients. FMOH needs to move

toward greater involvement of pharmacists in medication therapy management. Increasingly, these services are seen as valuable in improving quality and lowering costs. Patients critically need the services of pharmacists. Currently patients are receiving medications without knowing how to take or use the medication appropriately or receiving the coaching from pharmacists who can have a great impact on therapy outcomes. Previous literature reviews have highlighted that implementing clinical pharmacy services does not always require additional funds but can occur by the reallocation of existing resources (Kaboli et al 2006).

Over the past two decades, pharmacists around the world have been authorised to prescribe an increasing range of medications following clear protocols. In a number of countries, including the United Kingdom, the United States, Canada, and New Zealand, pharmacists already can legally prescribe a range of medicines previously prescribed only by medical practitioners, with one of the most progressive and highly publicized examples being the expansion of prescribing rights to UK pharmacists and other health care practitioners (Crown 1999). In Sudan, pharmacists are being produced from universities in record numbers (1,000 graduates annually in recent years) and with a greater skill base than ever before. It would be a travesty to fail to provide career opportunities to allow interested graduates to use their skills to full advantage. It seems the climate is right for pharmacists to move forward and expand their professional roles by embracing a future that includes prescribing. There must be new roles for them, including some in primary health care working side by side with doctors. Others will do more and different things in hospital and community pharmacies. Key areas where the role of pharmacists could be expanded are the management of prescribed medicines; management of treatment for long-term conditions and common ailments; promotion and support of healthy lifestyles; and advice and support for other health professionals (RPSGB 1997).

The developing clinical role of the pharmacist has been one of the most exciting and encouraging developments in recent years (Anderson 2002). The pharmacists' role has shifted from a focus on the preparation and supply of medicines to a focus on the sharing of pharmaceutical expertise and knowledge with doctors, nurses and patients. Developments in pharmaceutical care are occurring in both the hospital and in community settings.

Evidence also supports that provision of cognitive services by community pharmacists improves patient health outcomes and reduces health care costs

(Farris 2002). Studies (Crown 1999; Galt 995; Stoate 2001; Shaw 2004; Alliance NHS 2004; Hall 2004) proved that clinical role of pharmacists is expected to demonstrate multiple benefits for health care delivery and organization, patient convenience, access, patient safety, concordance with clinical management plans, efficiency in general practice and hospitals, waste reduction, reduction of doctors' workload and professional satisfaction for pharmacists. For widespread acceptance, services provided by pharmacists must be promoted to the public, health care system administrators and government (Anonymous 2000). This because clinical pharmacists will help prescribers and patients make informed decisions about medicines (Gilbert 2015)

4.11 Pooled Procurement

Bulk purchasing arrangements in which there is drug suppliers' competition for consolidated market demand strengthens bargaining leverage of purchasers; regardless of whether multi-source products or monopoly supplied drug products are being procured. Simple bulk volume purchasing of drugs (with no attempts to create suppliers competition for consolidated market demand) is akin to discounting based on absolute volumes.

Bargaining leverage of procurement agencies can be increased through consolidated market demand. The strategy relies on effective demand quantification (using consumption or morbidity based methods) and timely inventory management and less costly inventory holding, resulting in reduced frequency of purchasing low-cost drugs and panic buying. Failure to quantify demand not only undermines negotiating leverage but, on average, results in losses of $13 for every $100 spent on drugs (World Bank 1994). Having properly estimated demand, consolidating drug purchases is the next key step to reaping the benefits of market-share discounts, which conflicts with decentralization policy that offers autonomy in purchasing to health facilities. However, consolidated purchasing does not lead to the complete erosion of decentralization policy. Huff-Rousselle and Burnett (1996) evaluations of a group-purchasing organization, the Eastern Caribbean Drug Service, showed consolidated purchasing reduces unit costs by over 50% in its first procurement cycle. Since NMSF has infrastructure, the next challenge is to build capacities and expand functions of procurement units to operate as price-sensitive purchasers. The NMSF has the benefit of protecting ''up front'' prices, free of private distributors' markups.

Economic theory and empirical evidence provides enough reason to suggest pro-competitive countervailing buyer power is a viable solution for affordability in Sudan. The public sector medical supply organizations will be of great value considering pricing in the private sector tends to move in tandem with the public sector. For instance, a study by Maiga, and others (2003) in Mali, showed the interdependence between public and private sectors such that lower public prices led to lower private prices. The efficiency and financial viability of the NMSF is most sensitive to administrative failures, especially medicine delivery times and demand quantification. Therefore, supply chain optimization will be critical to the effectiveness and efficiency of NMSF. The NMSF should be supported by investments in physical human resources. The NMSF employees must have advanced experience in logistics, inventory management, quantification and forecasting, integrated information systems, training in mastering negotiation and legal skills for writing up valid, sustainable purchasing contracts, and so on). They should have leadership and institutional commitment to aggressively secure affordable prices for Sudan households.

As a result of resource wastage, more is spent on medicines than is necessary. This does not mean there is no need for extra funding to enhance medicine accessibility in Sudan (there is) but it makes little sense to keep pouring money into wasteful channels. The efficient resource allocation and purchasing by the FMOH and NMSF respectively are critical to derive the most out of scarce resources.The international community and development partners will have to provide financial and nonfinancial assistance for investments in capacity and institution building and supply chain optimization.

In many developing countries, pharmacists play a crucial role in the procurement of pharmaceuticals. The importance of appropriate procurement practices has been emphasized by WHO's Essential Drugs and Medicines Policy Department, which has shown that some developing countries routinely pay 150–250% of world market prices for essential drugs (WHO 2000c). With their specialist knowledge, pharmacists are in an excellent position to ensure that the most cost-effective medicines are bought in the most appropriate quantities from reputable suppliers and that they are delivered where and when they are required.

The tendering process should promote the procurement of low price but quality products (Kaplan et al 2012). Velasquez and colleagues (2003) define a three-pronged strategy as the basis of cost-containing procurement. The strategy comprises national and international competitive bidding, price discounting, and

bulk purchasing. The objectives for implementing tendering programs are the same in all countries, that is, achieving cost savings on the pharmaceutical budget by lowering prices of pharmaceuticals. In the short term, significant savings can be achieved but the results on long term are still unclear (Price Waterhouse Coopers 2009). For example, a study which investigated the pharmaceutical policy in the Netherlands found that the introduction of tendering caused a decrease of medicine prices by 76–93% (Dylst 2011).

Patient compliance could become a problem, especially for patients with chronic illness, if they have to switch their pharmaceutical every time the contract is granted (Maarse 2009). This negative implication of tendering could be mitigated by long-term contracts. A solid legal framework has been present for long-term contract, as pharmaceutical suppliers may challenge the procedure. A long term contract (i.e. 5-yearsupply contract) will, in reality, be renegotiated annual contracts over a 5-year period with contract extensions offered as long as preferred suppliers maintain their ''best-discounted price status''.

Criteria to grant the tender have to be strict and transparent for all participants. The quality, the lowest price and the guarantee of sufficient quantity have to be amongst these criteria. Recognizing that the winners have to be rewarded sufficiently, as there are otherwise no incentives to participate in the program, it is the NMSF's policy to award only one winner. However, in certain sensitive items, such as intravenous fluids, the quantities are divided between the first two winners. 80% for the first winner and the remaining 20% went to the second winner, provided that the second winner meets the first winner price and other facilities, if any. Shortages of medicines could endanger the safety of the populations' health and this has to be prevented at all time. In the rest of its items and where it is more likely that shortages would occur because of only one winner, and to avoid such shortage, NMSF nominates the second lowest bid as a backup. When the preferential supplier cannot deliver the sufficient pharmaceuticals, the backup supplier will provide those pharmaceuticals. NMSF must state in the contract that the winning supplier who failed to supply its awarded items has to bear the extra costs.

In summary, arranging purchases at the lowest possible total cost, making use of generic rather than branded products where appropriate, can help to ensure that as many people as possible benefit from the limited resources available for the acquisition of medicines (Anderson 2002). NMSF must make efforts to increase its knowledge of domestic and global pharmaceutical markets to

reduce price information asymmetries and ignorance. In order to ensure effective implementation of its activities and to address the needs of the corporation and customers, NMSF also must carefully determine evaluation criteria to consider quality, costs and risk factors to get best value for money. NMSF purchases medical supplies and services that are required to achieve NMSF's mandate. NMSF needs to work closely with stakeholders to procure quality assured medicines and other medical supplies at the best value for money. The quality standards of pharmaceuticals must be harmonized through the pooled procurement programme for all governmental organizations. The NMSF must take the lead and ensure safety and efficacy of medicinal products throughout their stated shelf-life.

4.12 Safety, Efficacy and Quality of Medicines

WHO (2004a, p.93) reported that 'the quality of medicines varies greatly, particularly in low-income countries, both in manufacturing and in the distribution system'. In many of these countries, 20% to 30% of samples collected from markets fail quality tests (WHO 2004b). For example, the percentage of drugs that failed quality control testing was found to be 92% in the private sector of Chad (WHO 1996). It has been estimated that up to 15% of all medicines sold across the world are fake (Cockburn, et al 2005). About 70% of counterfeit[3] medicines were reported by developing countries mainly in Africa and Asia (Helling-Borda 1995; WHO 1998; Newton et al 2001, 2002). Reports from Asia, Africa, and South America indicate that 10% to 50% of prescription medicines in certain countries may be counterfeit (Rudolf and Bernstein, 2004). For instance, in Nigeria where fake medicines may be more prevalent in circulation (60% -70%) than genuine medicines (Osibo 1998), 109 children died in 1990, after being administered fake Paracetamol (Alubo 1994). Other cases were reported in Haiti in 1995 and in India in 1998, where the consumption of counterfeit Paracetamol cough syrup led to eighty-nine deaths and thirty infants deaths respectively (WHO 2006a). Even in developed countries with well-controlled drug distribution systems, counterfeit medicines are believed to be in existence. For example, in the USA the proportion of drugs that are counterfeit is thought to be less than 1% (Rudolf and Bernstein 2004). Within the UK, Andalo (2004) reported that two counterfeit medicines found their way into the legitimate medicine supply chain for the UK during 2004.

3 Products that are deliberately and fraudulently mislabelled with respect to identity and/or source (WHO 2003a)

Poor quality or counterfeit medicines may lead to low efficacy, adverse clinical results, treatment failure or death and to public health problems by encouraging drug resistance. In the long term, they may result in the waste of limited resources (WHO 2006a). Regulation and secure supply of essential medicines are the basic devices employed by most governments to protect the public health against the production, import and distribution of substandard, counterfeit and low quality medicines.

Several institutions, such as WHO, the United Nations Office on Drugs and Crime, and the United States Institute of Medicine, have turned their attention, with varying degrees of effectiveness, to the problem of dangerously poor quality medicines (Institute of Medicine 2013). While substandard medicines are found everywhere in the world, it is the poorest countries with the weakest capacity for drug regulation and quality control that suffer the most.

Everyone agrees that poor quality medicines are undesirable, but not everyone agrees on how to define them. It is clear that iatrogenic harm arises from at least two distinct, concurrent problems: (i) medicines that are accidentally or negligently ‘‘substandard’’ as a result of various failures in manufacturing, handling, regulation, or some combination of these, and (ii) medicines that are deliberately ‘‘falsified’’, neither being of the correct standard nor being properly registered through a country’s regulatory authority, and that call out for criminal law measures to suppress. In all cases, the result is a potentially dangerous medicine, whether occasioned by criminal activity, accident, or negligence (Attaran et al 2012).The inadequacy of the current definition of substandard medicines enables many manufacturers to sell poor quality medicines with no risk to be sanctioned, just because these products have been registered by National Medicines Regulatory Authorities (NMRAs) with limited capacity. The current status quo furthers the interests of companies with poor technical capacity or with poor ethics, but it certainly does not serve the interests of the patients.

If the number of wholesalers steadily increases and the current marketing of cheap medicines in the private sector continues regardless of their safety, efficacy and quality (i.e. without confirming by evidence that these medicines are therapeutically equivalent to their innovators), Sudanese will deliberately denied access to innovative medicines marketed all over the globe. Experiences show that countries with the smallest number of suppliers to the market tended to have lower failure rates (Binagwaho et al 2013). FMOH needs to guarantee

sustainable progress towards quality medicines that are supplied by the NMSF and replicate the NMSF's experience in the private sector. However, the public health organizations are driven by price, “the cheaper the better”. NMSF has a clearly defined quality assurance policy. NMSF has the technical knowledge to assess the quality of the medicines but often faces pressure from the stakeholders, such as NHIF, to buy medicines of the lowest possible price. The NMSF's interest in meeting customers need may conflict with its quality assurance policy.

The responsibility for ensuring the marketing of safe, effective and quality medicines at affordable prices lies with NMPB. Like NMRAs elsewhere, the first priority for NMPB, is to protect populations from the harm caused by poor quality, unsafe medicines. The objective is to keep these harmful and low quality products off the market. Factors that compromise quality, safety, and efficacy include substandard active and inactive ingredients, poor manufacturing practices, improper packaging, transport, and storage. While many factors can compromise the quality, safety, and efficacy of medical products, what allows these products to get on the market and into the hands of consumers has a straightforward root cause, the inadequate capacity of NMRS (Chan 2011). Building this capacity is the best solution to the problem. The WHO approach to address the problem in developing countries is the same as that used successfully by wealthy nations to protect their populations. That is, strict regulatory control of medicines on the market, strict enforcement of quality standards, and diligent pharmacovigilance. Nothing suggests the need for a double standard (Chan (2011).

Besides their direct negative effect on patients and their families, poor quality drugs harm health workers and services, pharmaceutical companies, governments, and economies by increasing medical care expense for patients, and by reducing credibility of the healthcare system (Nayyar et al 2012). For example, a recently published book (Arie 2012) claims that half of all drugs on the French market are useless, some can be harmful, and the state is wasting up to US$20 billion a year paying for them. The authors reported that 5% of the drugs on the French market are potentially dangerous and that, despite those facts, 75% are paid for by the social security system (Arie 2012).

In summary, the quality of medicines is not uniform worldwide, but largely depends on the level of income (Newton et al 2010) and regulation (Editorial2012; WHO 2010a; Nishtar 2012) in the country of destination. Substandard medicines have remained insufficiently or not addressed, despite being a widespread problem,

highly prevalent in resource-poor settings (Caudron et al 2008; Newton et al 2010) and at least as dangerous as counterfeits. Even if surveys on quality are not generally conducted according to harmonised methods (Newton et al 2009), there is evidence that poor-quality medicines are widespread in poor countries, with serious and often undetected consequences for individuals and for public health.

4.13 Management of Medical Devices

Health technologies are essential for a functioning health system. When used within the context of a robust health system, medical devices in particular are crucial in the prevention, diagnosis, and treatment of illness and disease, as well as patient rehabilitation. Through such a system, medical devices can be effectively allocated based on the needs of a particular population (WHO 2011c). As health facilities expand and there is an increase in the number of medical devices they require to provide quality health care, a need to manage health care technology more effectively and efficiently becomes evident (WHO 2011d). The World Health Assembly adopted resolutionWHA60.29 and acknowledged the need "to contain burgeoning costs by establishing priorities in the selection and acquisition of health technologies… on the basis of their impact on the burden of disease, and to ensure the effective use of resources through proper planning, assessment, acquisition and management" (WHO 2007).The lure of technology is strong, but the cost-effectiveness, real need, and likely usefulness of many innovative technologies are questionable. For example ultrahigh-field-strength MRIs, robotic assisted surgical systems, and proton radiation therapy have uncertain additional benefits and high financial costs (ECRI 2010, CTAF 2008). With the increased emphasis on the importance of effective diagnostic laboratory services to the public health in Sudan, this section focuses particularly on strategies that maximize the value for money spent by the government and individuals to provide and to receive laboratory services respectively.

4.13.1 Selection, Quantification and Procurement

According to WHO (2011d), today, there are more than 10,000 types of medical devices available. The selection of appropriate medical equipment always depends on local, regional or national requirements. Factors to consider include the type of health facility where the devices are to be used, the health work force available and the burden of disease experienced in the specific catchment area. It is therefore impossible to make a list of core medical equipment which would

be exhaustive and/or universally applicable. Solutions to allow for greater standardization would be most beneficial and help to encourage universal use of "generic" diagnostic tools, which in turn could lead to standardized procurement practices, which has many potential advantages. As already mentioned in this report, this concept could apply to medical devices in general, not just to diagnostics. "Generic", "compatible", "standarized" and "interoperable" equipment could lower costs make training more efficient, make consumables easier to find, and facilitate the creation of generic technical specifications for procurement.

The WHO (2010b) states that choosing a medical device is complex and requires a transparent process based on reason, evidence and assessment of prioritized public health needs. Poor choices lead to inappropriate use or non-use of medical devices and a waste of resources. Barriers to rational choosing of a medical device include fascination with technology, aggressive marketing, high costs and inadequate information about the device (WHO 2010b). Possible solutions include improving access to information for decision-making and increasing the role of the biomedical engineer or similar experts.

4.13.2 Use of Medical Devices: laboratory testing and imaging

The demand for laboratory tests has expanded rapidly. It has been estimated that around 70% of all medical decisions are influenced by laboratory test results. Reasons cited for such increase in the use of laboratory tests include financial incentives, a fear of litigation, weak training of recently graduated doctors, and increased patient expectations. As tests have become easier to request, concerns about an increase in inappropriate use have arisen. The unnecessary requesting, as well as wasting valuable resources directly, can lead to further downstream costs, such as additional investigations. The avoidance of unnecessary procedures not only reduces costs but also the anxiety of incidental findings. For example, over-utilisation of imaging is a substantial problem. It accounts for typically 10% of health expenditure in the UK and literature estimates of internationally inappropriate imaging are about 40% (Hadley et al 2006). On the other hand, it is possible that the underuse of tests may also represent waste (Maughan and Ansell 2014). The diagnostic tests should not be performed if the results will not change management (Qaseem et al 2012). For example, chest radiography 4 weeks after diagnosis of pneumonia in a patient who has responded clinically to treatment will not affect management because resolution of radiographic abnormalities may take as long as 6 to 8 weeks. In this situation,

the test incurs costs but provides no benefit to the patient (Qaseem et al 2012). Owens and others (2011) argue that it is important to note that the true cost of a test includes not only the cost of the test itself but also the downstream costs incurred because the test was performed. For example, an exercise stress test in an asymptomatic patient may result in a false-positive finding that leads to cardiac catheterization, with its attendant costs and risks, but with no proven benefit. Thus, a seemingly inexpensive test can result in substantial costs because of subsequent testing, treatment, or follow-up. In assessing the costs of a diagnostic test, these downstream costs and savings must be considered (Owens et al 2011). Doctors should discontinue the use of diagnostic tests that provide little or no benefit and can be classified as low value.

To tackle the wasteful use of tests, the FMOH and NHIF need to identify common clinical situations in which there are opportunities to both improve care and decrease expenditures by reducing the use of diagnostic tests that are unnecessary and do not improve patient care. Guidelines must be developed to ensure appropriate test requesting and to reduce the unnecessary repeat requesting of tests in both public and private health facilities throughout Sudan. To enhance doctors' compliance, the guidelines should be evidence-based and expert consensus opinions must be sought before launching. The guidelines could provide a sustained reduction in testing utilization through greater awareness of appropriate tests and reinforcement through educational messages during mentoring of young doctors and at clinical meetings.

4.13.3 Calibration and Maintenance of Medical Devices

Unlike pharmaceutical products, medical devices require calibration, maintenance, repair, user training, and decommissioning. Technical assistance to develop a well-functioning department for medical device within NMSF is highly needed. The well-functioning department will enhance affordability of medical devices and, as a result, increases health service coverage. The department also provides, through need assessment of medical devices, basis for priority setting and informed decision making and helps in the rational allocation of resources. It will cost-effectively address the issues of medical equipment inventory management, maintenance and computerized maintenance management systems.

Medical devices are considerable investments and in many cases have high maintenance costs. It is important, therefore, to have a well-planned and managed maintenance programme that is able to keep the medical equipment in a health

care institution reliable, safe and available for use when it is needed for diagnostic procedures, therapy, treatments and monitoring of patients. In addition, such a programme prolongs the useful life of the equipment and minimizes the cost of equipment ownership (WHO 2011e; WHO 2011f). Although spare parts and supplies to enable common items of equipment to be maintained and run should be kept routinely in stock, it is not cost effective to keep most items of new equipment in stock.

4.13.4 Summary

In summary, FMOH should develop a national list of medical and laboratory supplies and equipment, based on types of tests, treatments and interventions that are to be delivered at different levels of health care. Such a national list is useful to define priority items and help ensure that the most essential items are available where needed; to promote cost-effective use of scarce financial resources; to reduce the number of items through standardization; and to serve as the basis for training staff and technicians (MSH 2013). The sources of medical devices must be unified throughout the country to help in the availability of spare parts, maintenance and training of biomedical engineers to repair devices that run out of services.

5. Conclusion

There are a number of key issues driving policymakers' concerns about the viability of the health care systems, including the increased cost of pharmaceuticals and other evolving technologies, the growing needs of aging populations, the impact of chronic diseases, and a significant workforce crisis (WHO 2006b). Solutions to these issues will not come easily. However, what is clear internationally is that pharmacists can be key participants in the management of health care costs through their contribution to the informed and appropriate use of medications in the community. For example, in the United States, qualified pharmacists are allowed to work within a defined protocol to assume responsibility for performing patient assessments, ordering laboratory tests, and selecting, initiating, monitoring, and adjusting drug regimens.

In Sudan, there are no specific procedures in place regulating doctors' prescribing and encouraging the use of generic products. Prescribing patterns have never been properly monitored. To date, Sudan National Formulary has been issued (SNF 2013) but this does not include any cost-effectiveness considerations regarding the management options. It has been proposed that prescribing

by protocol can lead to containment of medicine costs, improving access to medicines (Chi 2000), reduction of medical practitioner visits and integration with medication reviews (Aldous 2003).

Strict price controls for pharmaceutical products have been successful in reducing relative prices by more than a half. However, pricing policies appear not to be enough for containing total expenditures. Marketing of new products that offer modest therapeutic gain relative to cost is facilitated by the lack of pharmacoeconomic cost- effectiveness criteria in Sudan registration and pricing systems. The cost-effective criterion is also absent in the development of the national list of essential medicines and NHIF selection of medicines. There are no effective regulations and incentives that promote cost-effective prescribing behaviour by physicians.

The government must take concrete legal and technical steps to ensure the quality of the drug supply chain in public and private sectors. The improvement of the country's supply chain and drug surveillance systems, combined with equity-oriented strategies for increasing geographic and financial access to high quality drugs through the public sector, will play an important role in the cost containment of medicines in Sudan.

The inappropriate use of medicines might also be a consequence of the behaviour of doctors and promotional efforts of drug industry (Väänänen et al 2007). One strategy to increase value for money that is spent on pharmaceuticals is to improve quality use of medicines through clinical pharmacy services in hospitals. This strategy has been implemented in many developed countries (Pedersen et al 2011; Musing 2013) and being embraced by many developing countries (Pande et al 2013).

This proposal demonstrates the variety of strategies and measures used internationally to foster value for money that has been spent on medicines and medical devices. Each measure is applied somewhat differently across countries, usually in combinations of strategies. While the evidence of improvement mostly comes from high-income countries, the applications of these strategies in developing countries, in general, and in Sudan, in particular, is possible. Choices exist but application of the full range of strategies may depend on the country specific context. In developing effective pharmaceutical strategies to increase value for money, governments from developing countries need to bear in mind the key question of who is paying for medicines. The pursuit of these

strategies may require a comprehensive health system reform. Such reform must include strong legal systems and establishment of supportive administrative and professional agencies. Maintaining, strengthening and enforcing the legal system are a necessary and ongoing adjunct to the development and implementation of strategies to enhance value for money that is spent on medicines. This needs to include pharmaceutical sector regulation, competition and anticorruption law to create a level playing field to ensure a healthy competitive generic market given the clear advantages of pricing through competition over direct price regulation (Nguyen et al 2015). Leadership and strong political commitment is needed to facilitate the implementation, monitoring and evaluation of the strategies that aim to increase the value of money spent by governments, health care providers, payers and patients.

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Appendix 1: Strategies to maximize Benefits from expenditure on Health Technologies

	Strategies	Key Words	Number of Publications
1	Generic Medicines	Generic medicines; costs; savings; off-patent	22
2	Pharmacoeconomics	Pharmacoeconomics; Cost-analysis; value for money	9
3	Selection of Medicines	Essential medicines; brand;	5
4	Pricing of Medicines	Cost control; prices; expenditure; affordability	3
5	Rational Use of Medicines	Uses; rational; prescribing; dispensing	20
6	Improving Medication Adherence	Adherence; medication; concordance	38
7	Prohibiting Unethical Medicine Promotion	Promotion; pharmaceutical industry; ethical promotion	8
8	Reducing Medication Errors and Adverse Drug Reactions	Medication errors; pharmacovigilence; prescription-only-medicines	13
9	Combating Self-Medication: the Challenge of Health System	Self-medication; over-the-counter;	19
10	Clinical Pharmacy Services	Clinical pharmacy; pharmacist prescribing;	33
11	Pooled Procurement	Pooled procurement; tenders;	9
12	Safety, Efficacy and Quality of Medicines	Counterfeit medicines; safety; quality;	24
13	Management of Medical Device	Medical devices; health technology	13
Total			216

Appendix 2: Summary of strategies

	Description of Strategies	Prerequisites	By whom	Expected output	Expected outcome
1	Use of Therapeutically Equivalent Generic Medicines	1. Bioequivalence and other relevant studies 2. Contract Research Organizations	1. NMPB 2. Pharmaceutical companies (manufacturers and importers) 3. NMSF	1. Therapeutically equivalent generic versions of the innovators	1. Safe and effective treatment 2. Cheap medication
2	Pharmacoeconomics	1. Cost-effectiveness research 2. Expert committees	1. NHIF 2. NMPB 3. NMSF	1. Registration of quality, cost-effective medicines; 2. Reimbursement of cost-effective medicines; 3. Purchasing of cost-effective drugs.	1. Low-cost effective medicines; 2. Enhanced affordability 3. Savings to the payers
3	Selection of medicines	1. National list of essential medicines 2. Evidence-based approach	1. GDOP 2. NHIF 3. NMSF	1. Short list of medicines 2. Regular availability 3. Reduced inventory costs 4. Low demand for hard currency	1. Improve adherence to medication 2. Rational use of medicines
4	Control of medicines price	1. Enforcement of regulations	1. NMPB 2. Drug companies	1. Acceptable prices 2. Reduce demand of hard currency	1. Enhanced affordability 2. Increased access 3. Improved adherence
6	Improving of adherence to medications	1. Training 2. Formularies 1. Standard treatment guidelines 2. Health education	1. NHIF 2. GDOP 3. Health professional unions	1. Patients take their treatment as prescribed by doctors	1. Reduced costs 2. Adverse reactions avoided
7	Prohibiting unethical promotion by pharmaceutical companies	1. Enforcement of regulations 2. Price control	1. SMC 2. NMPB 3. Professional unions	1. Rational use of medicines 2. Reducing waste 3. Decrease cost 4. Improving adherence	1. Better treatment outcomes at lowest cost possible
8	Reducing medication errors and adverse drug reactions	1. Training 2. Workload 3. Formularies 4. Standard treatment guidelines	1. FMOH 2. Hospitals 3. NHIF 4. SMC	1. Reducing hospitalization 2. Improving adherence 3. Reducing costs	1. Better treatment outcomes at lowest cost possible
9	Combating self-medication	1. Enforcement of regulations 2. Classification of medicines according to their safety 3. Health education	1. NMPB 2. FMOH 3. GDOP	1. Restricted use of medicines	1. Better treatment outcomes 2. Reduced costs
10	Clinical pharmacy services	1. Recruitment of specialized pharmacists 2. Training	1. FMOH 2. NHIF 3. SNMSB 4. SMC	1. Trained clinical pharmacists 2. Accurate prescribing 3. Rational use of medicines 4. Monitoring of patient medication	1. Safe medication 2. Less medication errors 3. Improved adherence
11	Pooled procurement	1. Enforcement of regulations 2. Political commitment	1. FMOH 2. NMSF 3. NHIF 4. States 5. Other public organizations	1. Low cost medicines 2. Same quality medicines in public health facilities	1. Best value for money
12	Safety, efficacy and quality of medicines	1. Enforcement of regulations 2. Training	1. FMOH 2. NMPB 3. NMSF 4. NHIF 5. Drug companies	1. Marketing of safe, effective quality medicines 2. Combating counterfeit, substandard or nonregistered medicines	1. Effective treatment 2. Reduced cost 3. Improved adherence
13	Management of medical devices	1. Well established department at NMSF 2. High quality medical devices 3. Well trained biomedical engineers and users 4. Standard treatment guidelines	1. FMOH 2. NHIF 3. NMSF 4. SMC 5. NMPB 6. Professional unions	1. Quality medical devices and lab reagents 2. Accurate diagnostic tests	1. Effective treatment 2. Reduced costs 3. Improved adherence

NMSF = National Medical Supplies Fund; FMOH = Federal Ministry of Health; GDOF = General Directorate of Pharmacy; NHIF = National Health Insurance Fund; NMPB = National Medicines and Poisons Board; SMC = Sudan Medical Council; SNMSB = Sudan National Medical Specialization Board

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