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Regulatory Privatisation, Social Welfare Services and its Alternatives

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ABSTRACT

The strategy of price liberalisation and privatisation had been implemented in Sudan over the last decade, and has had a positive result on government deficit. The investment law approved recently has good statements and rules on the above strategy in particular to pharmacy regulations. Under the pressure of the new privatisation policy, the government introduced radical changes in the pharmacy regulations. To improve the effectiveness of the public pharmacy, resources should be switched towards areas of need, reducing inequalities and promoting better health conditions. Medicines are financed either through cost sharing or full private. The role of the private services is significant. A review of reform of financing medicines in Sudan is given in this article. Also, it highlights the current drug supply system in the public sector, which is currently responsibility of the Central Medical Supplies Public Corporation (CMS). In Sudan, the researchers did not identify any rigorous evaluations or quantitative studies about the impact of drug regulations on the quality of medicines and how to protect public health against counterfeit or low quality medicines, although it is practically possible. However, the regulations must be continually evaluated to ensure the public health is protected against by marketing high quality medicines rather than commercial interests, and the drug companies are held accountable for their conducts.

Keywords : Sudan, Healthcare, Medicines, Regulatory authorities, Pharmacy Management.

INTRODUCTION

The World Health Organisation (WHO, 2009) has defined drug regulation as a process, which encompasses various activities, aimed at promoting and protecting public health by ensuring the safety, efficiency and quality of drugs, and appropriateness accuracy of information (WHO, 2009). Medicines regulation is a key instrument employed by many governments to modify the behaviour of drug systems. The regulation of pharmaceuticals relates to control of manufacturing standards, the quality, the efficacy and safety of drugs, labelling and information requirements, distribution procedures and consumer prices (Sibanda, 2004). To assure quality of medicines, in most countries registration is required prior to the introduction of a drug preparation into the market. The manufacturing, registration and sale of drugs have been the subject of restricts regulations and administrative procedures worldwide for decades (Lofgren, and Boer, 2004). Nobody would seriously argue drugs should be proven to be 100% safe. No set of regulations could achieve that

goal, because it is impossibility and all drugs carry some risk (Lexchin, 1990).

Stringent drug regulation was introduced across many countries in the 1960s following the thalidomide disaster, and had since been embraced by the industry as a commercial essential seal of safety and quality (Lofgren, and Boer, 2004). In spite of the measures, many countries, especially developing ones face a broader range of problems. In several developing countries drug quality is a source of concern. There is a general feeling there is a high incidence of drug preparations, which are not of acceptable quality (Shakoor, Taylor, and Behrens, 1997). For example, about 70% of counterfeit medicines were reported by developing countries (Helling-Borda, 1995). Reports from Asia, Africa, and South America indicate 10% to 50 % of consider using prescribed drugs in certain countries may be counterfeit (Rudolf, and Bernstein, 2004). For instance, in Nigeria fake medicines may be more than 60 -70% of the drugs in circulation (Osibo, 1998), and 109 children died in 1990 after being administered fake Paracetamol (Alubo, 1994). In Gambia the drug registration and control system resulted in the elimination of 'drug peddlers' and certain 'obsolete and harmful' drugs, as well as a large decrease in the percentage of brand and combination drugs (Jallow, 1991). The percentage of drugs failed quality control testing was found to be zero in Colombia, but 92% in the private sector of Chad (WHO/DAP, 1996). Hence, it is very difficulty to obtain an accurate data. The proportion of drugs in the USA marketplace are counterfeit is believed to be small - less than 1 percent (Rudolf, and Bernstein, 2004). (Andalo, 2004) reported two cases of counterfeit medicines found their way into legitimate medicine supply chain in the UK in 2004.

Poor quality drug preparations may lead to adverse clinical results both in terms of low efficacy and in the development of drug resistance (Shakoor, Taylor, and Behrens, 1997). Regulations are the basic devices employed by most governments to protect the public health against substandard, counterfeit, low quality medicines, and to control prices. Thus, thorough knowledge of whether these regulations produce the intended effects or generate unexpected adverse consequences is therefore critical. The World Health Organisation (WHO) undertook a number of initiatives to improve medicines quality in its member states and promote global mechanisms for regulating the quality of pharmaceutical products in the international markets. But, there are not any WHO guidelines on how to evaluate the impact of these regulations. There are numerous reports concerning drug regulations (Ratanwijitrasin, Soumerai, and Weerasuriya, 2001), but the published work on the impact of these regulations on the quality of medicines moving in the international commerce has been scarce. Findings from most published studies lack comparable quantitative information that would allow for objective judging whether and by how much progress on the various outcomes have been made by the implementation of the pharmaceutical regulations. To ignore evaluations and to implement drug regulation based on logic and theory, is to expose society to untried measures in the same way patients were exposed to untested medicines (Ratanwijitrasin, Soumerai, and Weerasuriya, 2001).

MATERIALS AND METHOD

The present policy of the national health–care system in Sudan is based on ensuring the welfare of the Sudanese inhabitants through increasing national production and upgrading the productivity of individuals. A health development strategy has been formulated in a way that realises the relevancy of health objectives to the main goals of the national development plans. The strategy of Sudan at the national level aims at developing the Primary Health Care (PHC) services in the rural areas as well as urban areas. In Sudan 2567 physicians provide the public health services (554 specialists, 107 medical registrars, 1544 medical officers, 156 dentists, and 206 pharmacists (Gamal and Omer, 2008)). Methods of preventing and controlling health problems are the following:

- Promotion of food supply and proper nutrition.

- An adequate supply of safe water and basic sanitation.
- Maternal and child health-care.
- Immunisation against major infectious diseases.
- Preventing and control of locally endemic diseases, and
- Provision of essential drugs.

This will be achieved through a health system consisting of three levels (state, provincial and localities), including the referral system, secondary and tertiary levels.

Pharmacy management should be coordinated and integrated with other various aspects of health. The following are recommended:

- Community must be the focus of benefits accruing from restructures, legislature to protect community interest on the basis of equity and distribution, handover the assets to the community should be examined; and communities shall encourage the transfer the management of health schemes to a professional entity.
- The private sector should be used to mobilise, and strengthen the technical and financial resources, from within and without the country to implement the services, with particular emphasis on utilisation of local resources.
- The government should provide the necessary financial resources to guide the process of community management of pharmacy supplies. The government to divert from provision of services and be a facilitator through setting up standards, specifications and rules to help harmonise the private sector and establish a legal independent body by an act of parliament to monitor and control the providers. Government to assist the poor communities who cannot afford service cost, and alleviate social-economic negative aspects of privatisation.
- The sector actors should create awareness to the community of the roles of the private sector and government in the provision of health and pharmacy services.
- Support agencies assist with the financial and technical support, the training facilities, coordination, development and dissemination of health projects, and then evaluation of projects.

Health and Pharmacy Systems

The health system in Sudan is characterised by heavily reliance on charging users at the point of access (private expenditure on health is 79.1 percent (WHO, 2004)), with less use of prepayment system such as health insurance. The way the health system is funded, organised, managed and regulated affects health workers' supply, retention, and the performance. Primary Health Care was adopted as a main strategy for health-care provision in Sudan and new strategies were introduced during the last decade, include:

- Health area system.
- Polio eradication in 1988.
- Integrated management of children illness (IMCI) initiative.
- Rollback malaria strategy.
- Basic developmental need approach in 1997.
- Safe motherhood, making pregnancy safer initiative, eradication of harmful traditional practices and emergency obstetrics’ care programmes.

The strategy of price liberalisation and privatisation had been implemented in Sudan over the last decade, and has had a positive result on government deficit. The investment law approved recently has good statements and rules on the above strategy in particular to health and pharmacy areas. The privatisation and price liberalisation in healthy fields has to re-structure (but not fully). Availability and adequate pharmacy supplies to the major sectors. The result is that, the present situation of pharmacy services is far better than ten years ago.

The government of Sudan has a great experience in privatisation of the public institutions i.e., Sudanese free zones and markets, Sudan telecommunications (Sudatel) and Sudan airlines. These experiences provide good lessons about the efficiency and effectiveness of the privatisation policy. Through privatisation, government is not evading its responsibility of providing health-care to the inhabitants, but merely shifting its role from being a provider to a regulator and standard setter. The drug financing was privatised early in 1992. Currently, the Federal Ministry of Health (FMOH) has privatised certain non-medical services in hospitals such as catering services, security and cleanings.

The overall goal of the CMS ownership privatisation is to improve access to essential medicines and other medical supplies in order to improve health status of the inhabitants particularly in far states (e.g., Western and Southern States).

Establishment of alternative ownership for the CMS can be achieved by selling the majority of shares to the private sector. This will achieve the following objectives:

- High access to essential medicines of good quality and affordable prices to the states' population and governments.
- Efficiency and effectiveness in drug distribution system to avoid the serious pitfalls and incidences that reported during the last ten years in the CMS.
- Equity by reaching all remote areas currently deprived from the formal drug distribution channels.
- Improvement of the quality and quantity of delivery of medicines to the public health facilities.

The above objectives are expected to:

- Increase geographical and economic access to essential medicines in all states (i.e., in both rural and urban areas) to reach at least 80% of the population (currently less than 50% of population have access to essential medicines).
- The tax collection from the new business becomes more efficient and will increase after privatisation. The tax revenues could be used to finance other health-care activities.
- If the government reserves some shares (not more than 50%) in the new business, then its shares' profit could be used to finance free medicines project in hospitals outpatients' clinic, and other exempted medicines e.g., renal dialysis and haemophilic patients treatment.

Privatisation of public pharmaceutical supplies

The term privatisation has generally been defined as any process aims to shift functions and responsibilities (totally or partially) from the government to the private. In broader meaning, it refers to restrict government's role and to put forward some methods or policies in order to strengthen free market economy (Aktan, 1995). Privatisation can be an ideology (for those who

oppose government and seek to reduce its size, role, and costs, or for those who wish to encourage diversity, decentralisation, and choice) or a tool of government (for those who see the private sector as more efficient, flexible, and innovative than the public sector) ((Kamerman et al., 1989), and (Gormley, 1991)). (Scarpaci, 1991) contends that "the invisible hand of the market is more efficient and responsive to the consumer needs and the public administrative budgets consume large portion of tax monies that could otherwise be used for service delivery". The emphasis is on improving the efficiency of all public enterprises, whether retained or divested.

Privatisation may take many forms including:

- The elimination of a public function and its assignment to the private sector for financial support as well as delivery (police, and fire departments, schools, etc.). Opponents characterise this as "load-shedding" (Bendick, 1989).
- Deregulation is the elimination of government responsibility for setting standards and rules concerning goods or services (Gormley, 1996 and 1997).
- Assets sales are the selling of a public asset (city buildings, sports stadiums) to private firms.
- Vouchers are the government provided or financed cards or slips of paper that permit private individuals to purchase goods or services from a private provider (food stamps) or circumscribed list of providers (Kettl, 1995).
- Franchising is the establishment of models by the public sector that is funded by government agencies, but implemented by approved private providers.
- Contracting is the government financing of services, choice of service provider, and specification of various aspects of the services laid out in contracts with the private-sector organisation that produces or delivers the services.
- User fees are the public facilities such as hospitals maximise their income or finance some goods from private sources, either through drug sales or other services. This kind of privatisation is applied in Sudan since early 1990s, as the health financing mechanism (especially for medicines).

In Sudan, the government has decided to distance itself from direct involvement in business, and thus to divest most of its interests whether in loss or profit making public enterprises. The public reform programme was set firmly in the context of the broader reforms, which were introduced in 1992. It had become clear the previous policies had delivered very disappointed results. This reform based on the transfer of activities vested with the government institutions to the private sector. It signalled the government intention to reduce its presence in the economy, to reduce the level and scope of public spending and to allow market forces to govern economic activities. Privatisation also forms part of the government strategy of strengthening the role of the private in the development to achieve the vision of the 25 years strategy in which the private sector will be the engine for economic growth. The privatisation started in 1992 by liberalization of local currency, foreign exchange transactions, internal and external trade, prices and health services (e.g., user fee as a mechanism of drug financing and other services). This reform had led to greater reliance on individual initiative and corporate accountability rather than on government as a decision-maker in business matters.

The privatisation policy goal is to improve the performance of the public sector companies. So, they can contribute to the growth and the development of the economy by broadens ownerships, participation in management, and stimulation domestic and foreign private investment. The following are the primary objectives, which have been defined in the government's policy statement on public sector reform:

- Improve the operational efficiency of enterprises that are currently in the public sector by exposing business and services to the greatest competition for the benefit of the consumer and the national economy.
- Reduce the burden of public enterprises on the government's budget by spreading the shares' ownership as widely as possible among the population.
- Expand the role of the private sector in the economy (permitting the government to concentrate on the public resources) on its role as provider of basic public services, including health, education, social infrastructure, and to compact the side effects of the privatisation.
- Encourage wider participation of the people in the ownership and management of business.

In pursuing the primary objectives the privatisation policy aims to transform the performance of most significant enterprises in the public sector and ensure liquidation of all viable and non-viable public enterprises as soon as possible through commercialisation, restructuring and divesture. Public sector reform efforts are thus aimed at reducing government dominance and promoting a larger role for the private sector, while improving government's use of resources. Movement towards those goals in some countries is supported by components of a structural adjustment loan, which helped initiate the programme and establish the legislative and institutional base. Opponents argue, the original objectives of state ownership were to ensure the corporate sector of the economy was in national hands rather than being controlled by either foreign investors or the minorities that enjoyed business dominance upon independence. A further objective was to use investment in state firms to accelerate development in a situation, in which private sector was reluctant to take risks.

Medicines legislation framework in Sudan

The availability of medicines in Sudan is controlled on the basis of safety, quality and efficacy. Thus, the government effects control in accordance with the Pharmacy, Poisons, Cosmetics and Medical Devices Act 2001 and its instruments. The Federal or State Departments of Pharmacy (DOP) and directives issued orders. The primary objective of both Federal and States' Departments of Pharmacy is to safeguard public health by ensuring all medicines and pharmaceuticals on the Sudan market meet appropriate standards of safety, quality and efficacy. The safeguarding of public health is achieved largely through the system of medicines' registration and licensing of pharmacy premises.

The first Pharmacy and Poisons Act was enacted in 1939. This Act had been amended three times since then. In 2001 amendments, cosmetics and medical devices were also brought under its purview. Thus, the name was changed to Pharmacy, Poisons, Cosmetics and Medical Devices Act (hereafter the Act). The Act regulates the compounding, sale, distribution, supply, dispensing of medicines and provides different levels of control for different categories e.g., medicines, poisons, cosmetics, chemicals for medical use and medical devices.

The Act makes provision for the publication of regulations and guidelines by the Federal Pharmacy and Poisons Board (FPPB), the pharmaceutical regulatory authority and its executive arm - the Federal General Directorate of Pharmacy (FGDOP). The FGDOP regulates mainly four aspects of medicines use: safety, quality, efficacy and price. Traditionally, governments in many countries, particularly developed nations have attempted to ensure the efficiency, safety, rational prescribing, and dispensing of drugs through pre-marketing registration, licensing and other regulatory requirements (Ratanwijitrasin, Soumerai, and Weerasuriya, 2001). When applying to register the

medicine manufacturers and importers are required to furnish the FGDOP with a dossier of information including among others, the indication of the medicine, its efficacy, side effects, contraindication, warnings on usage by high risk groups, price, storage and disposal (MOH, 2001).

The role of FGDOP includes among others:

1. Regulation and control of the importation, exportation, manufacture, advertisement, distribution, sale and the use of medicines, cosmetics, medical devices and chemicals;
2. Approval and registration of new medicines - the Act requires FGDOP should register every medicine before be sold or marketed. Companies are required to submit applications for the registration of medicines for the evaluation and approval;
3. Undertake appropriate investigations into the production premises and raw materials for drugs and establish relevant quality assurance systems including certification of the production sites and regulated products;
4. Undertake inspection of drugs' whole and retail sellers owned by both public or private sectors;
5. Compile standard specifications and regulations and guidelines for the production, importation, exportation, sale and distribution of drugs, cosmetics, etc.
6. Control of quality of medicines: This will be done by regular inspection and post-marketing surveillance;
7. Licensing of pharmacy premises (i.e., pharmaceutical plants, wholesalers and retail pharmacies);
8. Maintain national drug analysis laboratories for the pre- and post- marketing analysis of medicines;
9. Coordination with states departments of pharmacy to ensure the enforcement of the Act and its rules and directives.

Public sector medicines supply system

In Sub-Saharan Africa countries (Sudan is not an exceptional) discussions about medicine distribution system reform have concentrated on ways to improve sustainability and quality of access to essential medicines. These discussions also include debate on the impact of privatisation of public drug supply organisations on effectiveness, efficiency, quality and cost of medicines in the public health facilities, as well as on the respective role of the public and private sectors (Leighton, 1996).

Until the mid 1980s, governments in Africa assumed responsibility for providing drugs to the inhabitants in some countries such as Mali and Guinea. The private distribution of all drugs including aspirin was illegal (Vogel et al., 1989). In many countries e.g., in Sudan there were two parallel government distribution systems. The public health network of hospitals and health centres were gratuitously distributed drugs. In the public sector pharmacies, the drugs were sold to the public at subsidised prices.

During the 1990s, Sudan initiated a number of initiatives to establish drug-financing mechanisms as part of the health reform process and decentralised decision-making at a state level. In 1992 when a law was passed, medicines were not anymore free-of-charge (i.e., privatised) in public health system. The aim of the government is to increase equitable access to essential medicines, especially at states' level. As a result the Central Medical Stores, which was responsible for medicines supply system of the public health facilities, became an autonomous drug supply agency, and renamed as

the Central Medical Supplies Public Corporation (CMS) and operated on cash-and-carry basis. It was capitalised and an executive board was installed. Since that time, it implied the states and federal hospitals have to buy their own medicines, other medical supplies. They organised their own transport means and distribution to their primary health-care facilities and hospitals. In addition, all hospitals became financially autonomous entities and had to organise their own medicines procurement system.

The public drug supply system has not been working throughout Sub-Saharan Africa including Sudan. There are serious shortages or no medicines at all, particularly in rural areas. A study in Cameroon found the rural health centres received only 65% of the stock designated for them, and 30% of the medicines arrived at the centres did not reach the clients. The loss rate after arrival in hospitals was estimated at 40% (Stephens, 1982). In Sudan, Graff and Evarard (2003) who visited the country on a WHO mission reported, "Although the cash-and-carry system took off well, but lack of sufficient foreign exchange hampered the CMS procurement activities and resulted in low stock levels of all medicines and even stock out of life-saving products. Hospitals had to purchase the medicines from elsewhere and often had to buy from private sector. Overall hospitals' budgets were tied to allocate drug budget and sales income was not sufficient to cover the purchase of needed medicines supplies. This resulted the medicines were not available most of the times. The in- or outpatients with their prescriptions were directed to the private pharmacies. In 2003, Khartoum Teaching Hospital-the biggest hospital in Sudan (not far than 5 km away from the CMS) had medicine stock of only LS 83,000 (US$ 31). This would not fill one prescription for an anaemic patient as a result of renal failure. This is a common practice that patients or their relatives are given prescriptions to buy any pharmaceutical supplies that are needed including drugs and other disposables from private sector pharmacies.

Many ministries of health, services' providers and researchers have identified many characteristics that lead to poor performance in Africa public drug supply systems. These characteristics include:

(1) Absence of competition:
Competition is the best way to ensure the goods and services desired by the consumer are provided at the lowest economic cost. Given the customers (i.e., public health facilities) freedom of choice enables market forces to provide sustained pressures on companies to increase efficiency. Privatised companies generally operate in a competitive market environment.

(2) Insufficient funding:
For example in Sudan with exception of Khartoum, Gezira and Gedaref states, all the states have no enough funds to establish efficient drug supply system. In spite of being profit-making organisation, the CMS failed to avail such funds during the past 14 years.

(3) Inefficient use of available resources:
The CMS since it was established in early 1990s working as a profit-making organisation. Due to the absence of privatisation the CMS engaged in an instalment of repackaging joint venture pharmaceutical factory in 1999 and recently announced its commitment to build a pharmaceutical city with not less than US$ 20 million, despite the lack of life-saving medicines in the public health facilities. Such amount could be sufficient to establish a reliable supply system for all states of Sudan. The lack of prioritisation is a typical symptom and sign of most public organisations.

(4) Poor management:
There are a number of constraints inherent in operating government drug supply service.
These constraints comprise:

(a) Civil servants are hired, rather than persons with business experience and skills. Managers confront different challenges in public setting. They are not easily hired or fired. The lack of accountability results from the lack of shareholders, who would be free to remove incompetent administrators.

(b) Even if the services can recruit outside of civil service, the wages are often too low to attract experienced managers. In addition, the managers do not share in dividends or other monetary activities as do private managers and incentives for doing well are often attenuated in a bureaucracy.

(c) There are cultural and structural conditions that promote corruptions including enormous pressure of wages earners to support an extended family and a strong incentive to more than their fixed government wage, traditional gift giving practice and a proprietary view of public offices (Van der Geest, 1982).

Privatisation of the CMS's ownership

The public sector drug supply institutions have not succeeded (CMS is not exceptional) so far in organising a reliable and regular essential drug supply for the public health facilities (Huss, 1996). One of the most criticisms of the public drug supply system generally in Africa and particularly in Sudan, is how badly they are internally managed. There are those who agree the greater amount of real pharmaceutical resources could be made available to the public health- care system and the access to essential medicines could be significantly increased, if managerial efficiency of the system improved (Akin, 1987). Given the limitation of the public sector - due to constraints inherent in operating a government drug supply organisation even after autonomous experience - and the stabilised role of the private sector organisations such as private pharmaceutical sectors organisations (rapid increase in importing companies, manufacturers and pharmacies). Telecommunications, e.g., Sudatel is one of the obvious solutions of choice for the government pharmaceutical policy would be to privatise the ownership of the CMS to the extent possible.

Advantages of private agencies

There are many arguments in favour of privatisation of public institutions. Advocates of this method claim privatisation have the following advantages (Savas, 1987; Hartley, 1986; De Hoog, 1984; Moore, 1987; and Ascher, 1987).

- Privatisation is efficient and effective because it fosters and initiates competition. The competition among firms drives the cost down. Empirical studies clearly prove the cost of the services provided by the government is much higher than when the services are provided by private contractors. For example CMS's declared mark-up on cost (35%) amounted to 2.3 times the private mark-up (15%). In addition, private sector pays taxes, customs and other governmental fees (CMS exempted).
- Privatisation also provides better management than the public management. Because decision making under privatisation is directly related to the costs and benefits. In other words, the privatisation fosters good management because the cost of the service is usually obscured.
- Privatisation would help to limit the size of government at least in terms of the number of employees. On the other hand, it is a fact that overstaffing is common in publicly owned enterprises.

- Privatisation can help to reduce dependence on a government monopoly, which causes inefficiencies and ineffectiveness in services.
- Private sector is more flexible in terms of responding to the needs of citizens. Greater flexibility in the use of personnel and equipment would be achieved for short-term projects, part-time work, etc. Bureaucratic formalities are very common when government delivers the service. Less tolerance and strict hierarchy in bureaucracy are the reasons of the inflexibility in publicly provided services.

Medicines supply system

The Act, for the first time in Sudan has given the responsibility of veterinary medicines to separate committees. The Ministry of Animal Resources took the law "in hand", and started the registration of veterinary medicines and the licensing of the veterinary medicines premises. The conflict in the shared authorities between the Ministry of Health and the chairman of the FPPB lead to the freezing of the Board since October 2002. The FGDOP continues in the process of medicines registration, inspection of the pharmaceutical premises and the licensing as before establishment of FPPB.

The Act also obliges the states' governments to take all steps necessary to ensure compliance with marketing of registered medicines in licensed premises. But, the weaknesses of the regulatory infrastructure and lack of political commitment at state levels, the leakage of low quality, unregistered medicines to those states are highly suspected. This left the door widely opened for informal marketing of medicines particularly in far states. The states regulatory authorities should take the advantage of the legal authority granted by the Sudan constitution and the Pharmacy, Poisons, Cosmetics and the Medical Devices Act 2001 to enforce the regulations and increase the frequency of the inspection visits to drug companies and retail pharmacies.

Experience has shown the poor regulation of medicines can lead to the prevalence of substandard, counterfeit, harmful and ineffective medicines on the national markets and the international commerce. The Sudanese pharmaceutical legal framework was described as one of the strictest pharmaceutical system in the region. One of the great loopholes in this system was found to be the increased number of non-registered medicines-governmental sources such as the Central Medical Supplies Public Organisation (CMSPO) and not-for-profit non-governmental Organisations (NGOs). Respondents were hopeful the double standard of rules enforcement would be lifted after the new national unity government take over, arguing the current situation in which public organisations (such as the CMSPO) sell non-registered medicines to the private pharmacies could enhance trading of counterfeit medicines and create unfair competition environment.

One of the respondent reported, *"It is disturbing, in spite of the existence of appropriate legislation, illegal distribution of medicines by the CMSPO. The CMSPO continues to flourish, giving the impression the government is insensitive to harmful effect on the people of medicines distribution unlawfully, and some are of doubtful quality"*. During the past three years the CMSPO started to sell unregistered medicines to the private pharmacies. The CMSPO practice (he added) *will undermine the inspection and medicines control activities and ultimately jeopardise the health of the people taking medication.*

Not surprisingly all respondents strongly agreed the increased number of sources of non-registered medicines will lead to entrance of low quality medicines. This result is inline with the WHO recommendation, which encourages the regulatory authorities and state members` government to register all medicines before the marketing. The medicines imported by public sector organisations are not excluded (Bryman, 2004).

The FGDOP should define the norms, standards and specifications necessary for ensuring the

safety, efficacy and quality of medicinal products. The availability, accuracy and clarity of drug information can affect the drug use decisions. The FGDOP does not have a well-developed system for pre-approval of medicines labels, promotional, and advertising materials. The terms and conditions under, which licenses to import, manufacture and distribute will be suspended, revoked or cancelled. This should be stringently applied to public, private and not-for-profit NGOs drug supplies organisations.

The predominant view, shared between the medicines' importers is the current pharmacy legislation to some extent satisfactory and managed to prohibit the marketing of low quality medicines. The recent post-marketing study carried by the National Drug Quality Control Laboratories, suggested the power of the current regulation is overestimated (WHO, 1991). The finding of this article indicates the application procedures of the current measures to ensure the quality of medicines should be revisited. The technical complexity of regulations, political, commercial and social implications, makes necessary a degree of mutual trust between concerned stakeholders (i.e., suppliers, doctors, pharmacists, consumer representatives and government agencies).

RESULT AND DISCUSSION

The study reveals the need for further research to find out how efficient the regulatory authorities at both federal and state levels are. The research also needed to discover whether or not counterfeit medicines are sold on the Sudanese market.

From the data obtained in this article some general inferences could be made:

1. The brad outlines remain intact, but preventing drug smuggling across national boarders (Sudan shares frontiers with 9 countries) is hard to police.
2. The enforcement of the Act and its regulation governing the manufacture, importation, sale, distribution and exportation of medicines are not adequate enough to control the illegal importation and sale of medicines in Sudan.
3. The splitting of the drug regulatory authority between two ministries and the marketing of unregistered medicines by public drug suppliers (namely the CMSPO, and RDFs), and NGOs undermine the quality of medicines and ultimately jeopardise the health of the people taking medication.

In the light of the findings the following recommendations could be useful at various levels:

1. There is an urgent need for government to implement the provisions of existing Act.
2. The government should adequately equip and fund the National drug Analysis laboratories to start active post-marketing surveillance.
3. A more spirited effort need to be made by FGDOP and the States' Departments of Pharmacy to ensure all the medicines on the pharmacies' shelves are registered and come from legal sources.
4. The states' departments of pharmacies are not in existence should be re-established and invigorated. They should be adequately funded to be able to acquire the necessary facilities for their operations.
5. The CMSPO should stop importation, manufacture and distribution of unregistered medicines. It should also cease selling the tenders' product to the private pharmacies. The latter practice undermines the inspection outcomes, because it makes inspectors task too difficult (i.e., cannot identify the source of medicine whether it is CMSPO or not).

Rational of the CMS privatisation

Even in the absence of broader adjustment context, however, it has long been clear the CMS reform is needed and indeed is not to avoidable. Patients, administrators (at both hospitals and ministries of health), doctors and other health-care professionals, the regulatory authority and others are being fully aware the performance of the CMS is so poor and ill people are really suffered even after the privatisation of medicines financing in 1992. Although it is profit-making organisation, neither the Ministry of Finance nor FMOH is getting proper or even any returns from the CMS. The Ministry of Finance after more than 14 years still have to inject annual money to cover the cost of certain budget lines such as free medicines projects. In addition, the following are main three justifications, which summarise the inefficiency of the CMS as a public organisation:

- There is a widespread dissatisfaction with the situation of pharmaceuticals in public facilities. For instance, 79% of the population pay for their medicines out of pockets (WHO, 2004). The access to essential medicines in Sudan is still less than 50% (Quick, 1997).
- Yet, the cost has been immense and it is continuing. There is no satisfactory estimate of the total capital invested in the CMS. Rather than receiving a sustained flow of dividends from its investments, the Ministry of Finance still financing the free medicines and certain diseases drugs. For example, in Khartoum State RDF, with small capital (US$ 2 million) - compared to the CMS big employed capital (more than US$ 20 Million) approximately 10 times that of the Revolving Drug Funds (RDF)- support Ministry of Health activities with two billion every year. In contrast, the CMS pays nothing to health services since it was established in 1992. Instead, the strong stream of dividends and tax revenues, which should support public spending on other health activities, is lost. Hence, it is the poor who suffer as a result.
- Violation of pharmaceutical regulation at the expenses of the public health by creating a big loophole in the pharmaceutical legal framework, which will inevitably leads to marketing of counterfeit medicines. This practice also suppresses the private sector (the government encourages it heavily to grow) by making inappropriate barriers to the private sector provision of drugs.

This is not to say the CMS has no future: there are substantial investment opportunities. Many can be turned around under new ownership and will succeed. It has been the experience of state enterprises worldwide that, in both socialist economies and in mixed economies, it is exceedingly difficult to remain competitive:

- If run by a board of public servants with multiple objectives and without real accountability to shareholders.
- The constraints from government on investment and other business decisions.
- If cut off by virtue of ownership from the latest technologies, marketing and management trends.

The basic points are:

- Public sector boards and civil servants are not in touch with markets and commercial trends.
- Government-run companies have conflicting objectives that do not stress commercial accountability and thus jeopardise survival and commercial success.

Reform is a matter of practical necessity rather than ideology. For example, the government of Cuba has still committed to socialist policies, and has recently chosen for pragmatic reasons, to privatise its telephone company. The final pragmatic reason impelling the government towards swift public

sector reform is the resources are being misused.

Strategies to overcome the CMS privatisation obstacles

It is not surprising some obstacles and resistance from the CMS member of staff will confront this reform. The following strategies will help to overcome such resistance and obstacles:

- Consensus should be built by negotiation with relevant ministries, public and private sectors, and interest groups so that all "buy into" the process and negotiated the goals.
- Promotion research and development, demonstration and dissemination of information for the current situation. WHO mission 2003 Report will be of great value and expected outcomes with more focus on the patients after adoption of user fee policy.

The role of the FMOH

Private enterprise functions most efficiently if market forces are allowed to operate independently and completely unfettered. Nonetheless, some FMOH involvement is necessary to ensure the availability of proper use of good quality and affordable pharmaceuticals. So FMOH will continue its current responsibility for importing, licensing, inspecting and regulating the distribution system without any discrimination between different organisations including the new established business, facilitating the development of adherence to the national drug list in the public health facilities, encourage purchasing of registered medicines from the least cost reliable sources, quality control of medicines and maintenance of quality through out the system, and enforcement of price control system. The FMOH could also be involved in informing private distributors and the public about the appropriate use of medicines.

At the public health facilities, however, freedom-of-choice arguments that would justify a laissez-fair approach to private sector importing do not apply. There is the overriding merit-good aspects of medicines need, the related requisites of availability, cost-efficiency, and quality control. Some pharmaceuticals are more cost-effective than others. Therefore, the enforcement of a government-mandated essential drug list lowers the real resource cost of a given quantity of pharmaceuticals necessary for alleviation of common diseases. Standard treatment guidelines alleviate unsuitable medicating practices particularly over-medication, and reduce costs to consumers.

CONCLUSION

The CMS reform is stronger today than it was in the early 1990s when the reforms were started. There are many highly committed and able individuals throughout the public sector in the absence of the single-minded pursuit of commercial success. Also, in the long-term interest of employment growth and the public at large, narrower concerns have prevailed. Managements and boards are less able and less willing to impose accountability for results on themselves and their employees. Stock-out of life saving items is common, and sanctions for non-performance are often absent altogether. To overcome those common symptoms of all public owned enterprise, and achieve the strategic objectives of the FMOH by increasing the access of population to the essential medicines. The privatisation of the CMS's ownership is the best solution of choice. By resurrecting competition, which could be achieved mainly through privatisation of the CMS ownership, many of the mentioned pitfalls can be avoided. The new business should be responsible (of course without any kind of monopoly) for drug supply and distribution to the public health facilities on competition basis. The initial capital of the drug stocks for the different health facilities should be given by this new business by signing a clear agreement with interested states' ministries of health.

Recommendations

By resurrecting competition, which could be achieved mainly through privatisation of the CMS ownership, many of the mentioned pitfalls can be to avoided. The new business should be responsible (of course without any kind of monopoly) for drug supply and distribution to the public health facilities on competition basis. The initial capital of the drug stocks for the different health facilities should be given by this new business by signing a clear agreement with interested states' ministries of health.

The government may retain a special (or "golden") share ranging from 30% to 50% to protect a newly privatised business from unwelcome take-over on national security grounds, or as temporary measure, to provide an opportunity for management to adjust to the private sector. The special share requires certain provisions in the articles of incorporation of a company may not be changed without the specific consent of special shareholder. The presence of a special share is useful tool but is not intended to be a government straitjacket on the management. The management and not the government are generally responsible for ensuring the special share's provisions are observed (Omer, 1994; and Gibbon, 1996). In order to develop a free market in shares, special shares should be time limited as far as possible. The purpose of privatisation is to remove the government from ownership of the CMS. In some cases, especially where there are major uncertainties about the probable market of the business, for example, United Kingdom and other governments have sold their ownership interest gradually in several times over a period of years (Gibbon, 1996; Bryman, 2004; MOH, 2003; and Andalo, 2004).

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