

The impact of the pharmaceutical regulations on the quality of medicines on the Sudanese market: Importers' perspective

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Abstract

The Pharmacy and Poisons Act (2001) and its provisions established the Federal Pharmacy and Poison Board (FPPB). All the authorities of implementation of Pharmacy and Poisons Act were given to this board. This article provides an overview of the impact of the pharmaceutical regulations on the quality of medicines on the Sudanese market from the perspective of the pharmacists working with drug importing companies. The information necessary to conduct the evaluation was collected from 30 pharmacists who are the owners or shareholders in medicines' importing companies. The participants were selected randomly. Although the majority (89%) of respondents considered the medicines on the Sudanese market are generally of good quality, the current pharmaceutical regulations have some loopholes. The design of the research may be considered inadequate with regard to selection process. However, the author believes that it provides enough evidence that the current Pharmacy and Poisons Act-2001 and its regulation should be enforced. The overall set-up including the Act itself needs to be revised.

Keywords: *Quality of medicines, drug importers, the Act, regulatory authorities, counterfeits medicines.*

Introduction

The World Health Organisation (WHO) 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⁽¹⁾. 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⁽²⁾. To assure quality of medicines, in most countries registration is required prior to the introduction of a drug preparation into the market.

The manufacture, registration and sale of drugs have been the subject of restricts regulations and administrative procedures worldwide for decades. Nobody would seriously argue drugs should be proven to be 100% safe. No set of regulations could achieve that goal, because it is impossible and all drugs carry some risk⁽³⁾.

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⁽⁴⁾. 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⁽⁵⁾. WHO⁽⁶⁾ 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⁽⁷⁾. For example, the percentage of drugs that failed quality control testing was found to be 92% in the private sector of Chad⁽⁸⁾. It has been estimated that up to 15% of all medicines sold across the world are fake⁽⁹⁾. About 70% of counterfeit* medicines were reported by developing countries mainly in Africa and Asia⁽¹⁰⁻¹²⁾. Reports from Asia, Africa, and South America indicate that 10% to 50% of prescription medicines in certain countries may be counterfeit⁽¹³⁾. For instance, in Nigeria where fake medicines may be more prevalent in circulation (60% - 70%) than genuine medicines⁽¹⁴⁾, 109 children died in 1990, after being administered fake Paracetamol⁽¹⁵⁾. 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⁽¹⁶⁾. 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%⁽¹³⁾. Within the UK, Andalo⁽¹⁷⁾ reported that two counterfeit medicines found their way into the legitimate medicine supply chain for the UK during 2004.

Poor quality or counterfeit medicines may lead to low efficacy, adverse clinical results, treatment failure or death at the individual level and to public health problems by encouraging drug resistance. In the long term they may result in the waste of limited resources⁽¹⁶⁾. 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, and to control prices. 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⁽¹⁸⁾.

The 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 aren't any WHO guidelines on how to evaluate the impact of these regulations thorough knowledge of whether these regulations produce the intended effects or generate unexpected adverse consequences is therefore critical. There are numerous reports concerning drug regulations, 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 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⁽¹⁹⁾.

In Sudan, 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, these regulations must be continually evaluated to ensure the public health is

* Products that are deliberately and fraudulently mislabelled with respect to identity and/or source

protected by marketing high quality medicines rather than commercial interests, and the drug companies are held accountable for their conducts.

Aims and objectives

The main purpose of this article is to determine and analyse the opinion of a group of pharmacists who are the owners or shareholders in Sudanese medicine importing companies and their perception concerning the effects of the government's new Pharmacy, Poisons, Cosmetics and Medical Devices Act on the quality of medicines in Sudan. To achieve this purpose the following questions would be answered:

- Do the Sudan pharmacy legislations prohibit marketing of low quality medicines?
- What is the impact of the transfer of veterinary medicines registration system to the Ministry of Animal Resources after the approval of the Pharmacy and Poisons Act 2001?
- Does pre-marketing analysis of medicines help to detect the counterfeit medicines?
- Does importation of non-registered[†] medicines by the government and non- governmental organisation exacerbate the problem of low quality medicine if any?

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 including orders (subordinate legislation), and directives issued by the Federal or State Departments of

[†] All medicines should be registered by the General Directorate of Pharmacy to get marketing approval. Each manufacturer or importer must present extensive information on the product (or products) submitted to allow Technical Standing Committee for drug registration evaluates the quality, safety, efficacy and price of medicines.

Pharmacy (DOP). 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⁽¹⁹⁾. 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⁽²⁰⁾.

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 that FGDOP should register every medicine before being 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 sales owned by both public or private sectors;
5. Compile standard specifications, 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.

Sudan medicines' quality measures

Registration of medicines

The FGDOP is responsible for the appraisal, and registration of all medicines and other pharmaceuticals for both human and veterinary use on the Sudan market. It is also responsible for the

verification of the competence of manufacturing companies, the manufacturing plants, the ability to produce substances or products of high quality before registering these companies and allowing them to apply for registration of their products in Sudan. When necessary, visits are conducted to those companies and their manufacturing units, to verify their compliance with good manufacturing practice recommended by WHO. The applicant for registration of pharmaceutical product must submit all prescribed data and the certificates required under the WHO certification scheme for a pharmaceutical product moving into international commerce, and any other information that is necessary for assuring the quality, efficiency and stability of the product through its shelf life ⁽²¹⁾.

Licensing of pharmacy premises

The licensing is a registration exercise to provide the DOP at state level (Federal level in case of local manufacturing plants) with the information necessary for the full implementation of the Act. Licenses are granted for a period of one year, and may be renewed at the end of December every year (applications to the relevant DOP before expiry of the current license).

There are three major licenses as follows

a) License A (Wholesaler License): License A authorises the holder to sell a registered medicine to a person who buys the medicine for the purpose of sale or supply to someone else under the direct supervision of a registered pharmacist or licensed medical doctor. Licensing of the wholesalers involves identification of the wholesaler and suitability of the premise. There are 175 wholesalers. The majority (162 wholesalers) are local agents for the goods manufactured from abroad. The rest are 13 "local manufacturer" wholesalers at Khartoum State (KS) and distribute the medicines to the whole country. Wholesalers

are inspected by the state DOP before license is granted and thereafter at least once per year.

b) License B (Retail Pharmacy License): Authorises the holder to sell a registered medicine to a patient on prescription or over-the counter basis under direct supervision of the registered pharmacist. The pharmacies are inspected before a license is issued and thereafter at least twice per year.

c) License D (Manufacturer's License): Manufacturing includes any process carried out in the course of making a medicinal product. A manufacturer's license covers all aspects- bulk drug, product manufacture, filling, labelling and packaging- under supervision of a registered pharmacist. There are 13 generic manufacturing sites in Sudan, mainly in Khartoum state. Each one is inspected by the Federal DOP. Good manufacturing practice (GMP) is the basis of the inspection. Effective control of quality requires a manufacturer possess, appropriate facilities with respect to premises, equipment, staff, expertise and effective well-equipped quality control laboratory. Normally, before a license is granted, an inspection of premises is made and Federal DOP takes this into account.

In Sudan there are two types of retail pharmacy:

Commercial private pharmacies: These are private establishments retailing registered drugs and medical supplies at a mark-up of 18%. The source of the drugs and pharmaceuticals is private wholesalers. In 2002, though unlawful, the Central Medical Supplies Public Organization (CMSPO) started to sell its non-registered medicines to the private pharmacies.

People's pharmacies: These are quasi-public establishments retailing drugs and medical supplies below the market prices to improve access and availability of pharmaceuticals. They were founded in the early 1980s as a pilot study for a drug cost recovery system. They differ from the private

commercial pharmacies, in having access to CMSPO drugs i.e., generic and large pack products, in addition to the brand products from the private wholesalers. Secondly, the peoples' pharmacies are only owned by public organisations (e.g., hospitals, peoples' committees, trade unions and Non Governmental Organisations (NGOs)). Mark-up on cost for drugs from CMSPO (35%), and from private drug wholesalers (profit margin is 10%). However, they have become commercialised now and operate in a similar way to private pharmacies. The total number of such pharmacies was approximately 200 in Sudan.

Rational for the research

The drug distribution network in Sudan during the past few years was in a state of confusion. It consists of open market, drug vendors (known as home drug store), community (private) pharmacies, peoples' pharmacies, private and public hospitals, doctors' private clinics, NGOs clinics, private medicines importers (wholesalers), public wholesalers (i.e., Central Medical Supplies and Khartoum State Revolving Drug Fund) and local pharmaceutical manufacturers. It is a common phenomenon in far states (e.g., Western and Southern states) to see street sellers or mobile sellers (hawkers) sell cigarettes, perfumes, orange and astonishingly medicines that range from Paracetamol and Aspirin tablets to antibiotics and anti-malarial drugs including injections. The medicines are usually left under the sun, and such conditions could facilitate the deterioration of the active ingredients.

Community and Peoples' pharmacies are statutorily licensed by the states' departments of pharmacy. A superintending pharmacist, who is permanently registered with the Sudan Medical Council and licensed, oversees the pharmacy any time it is opened for business ⁽²⁰⁾. With such pharmacies there should not be any hazards of the sale of fake

drugs. Unfortunately, however there are many pharmacies working without qualified pharmacists. This study is significant because the people right to health include the right of access to a reliable standard of health care and assurance that, medicines received are not only genuine but also safe, effective, of good quality and affordable ⁽²²⁾. The Sudan government has designed various ways to protect the public against low quality medicines. It is expected to equip the departments of pharmacy especially in remote areas, poor states with material and trained staff to effectively perform duties.

A recent study on post-marketing surveillance revealed that 35% of public drug source and 16% of the private companies (registered products) samples obtained from different pharmacy shops failed to pass the quality test ⁽²³⁾. However, very few studies if any have been undertaken to evaluate the impact of the regulations put in place by the government long time ago.

This article should reveal strength and weaknesses of the legal pharmaceutical framework in Sudan from drug importers perspective. The findings of this investigation would be instructive to regulatory authorities in the developing countries. It also highlights how systematically the drug companies perceived the role of pharmacy regulations in assuring high quality of medicines and what suggestions (if any) they had to make in order to improve the regulatory framework.

Method

The survey was deliberately focussed on drug importers, as low quality medicines from informal sources will affect their business. A self-administered questionnaire of 14 close-ended questions and one open question was developed. The questionnaire was designed to address main six issues:

- The quality of medicines.

- The consequences of splitting of the regulatory authority functions between the Federal Ministry of Health (FMOH) and the Ministry of Animal Resources (MOAR).
- Views on the role of the recently established Federal Pharmacy and Poisons Board, and Pre- and Post-Marketing Surveillance.
- Decentralisation, and
- Increased number of suppliers of non-registered medicines.

The final version of the questionnaire had been tested (three pharmacists working with drug companies in Sudan were asked to fill the questionnaire and feed the author back whether there was unclear question or not). The questionnaire was tested to make sure all relevant issues were covered, pre-coded and adjusted before its distribution.

The questionnaire was distributed to all (40) participants (total number of drug importers companies were 175 in 2004) at a seminar held in July 2004. This seminar was organised by the FGDOP on the new proposal to limit (agree a ceiling for each item) the number of commercial brand product registered from each generic drug (the current situation is open). The owners and shareholders of drug companies were the participants. This was seen by the author as a great opportunity to collect data of the drug importers' perspective on the quality of medicines. Hence, the study participants were so busy and it was very difficult to devote a time to be interviewed by the author. In addition, the postal services in Sudan are poor (too slow and unreliable).

Before the beginning of the seminar, the participants were requested by the secretariat to complete the questionnaire and hand it back to the secretariat before departure. The participants were informed it is anonymous questionnaire. The reasons given to the participants for filling out the

questionnaire was to enable an academic research to assess the impact of the new Act on the quality of medicines. Finally, at the end of the seminar, the secretariat managed to get 30 questionnaires, representing 75% out of 40 distributed.

The information necessary to conduct this evaluation was collected from 30 pharmacists working with medicines' importing companies. Data gathered by the questionnaire were electronically analysed using Statistical Package for Social Sciences (SPSS) version 12.0 for windows.

Findings

In the absence of past baselines data, decisive conclusions should not be drawn from this article regarding the impact of the pharmaceutical regulations on ensuring good quality medicines. Nevertheless, the survey did serve to confirm the general impression about medicines of good quality on the Sudanese market.

89% of respondents considered the medicines on the Sudanese market are generally of good quality. Although 55% of the study population either strongly agree (21%) or agree (34%) with the statement that the drug legislations in Sudan prohibit marketing of low quality medicines, 35% believe that the transfer of authority to recently established Federal Pharmacy and Poisons Board (FPPB) will undermine quality assurance system of medicines. However, 38% of the participants thought that the replacement of FGDOP by FPPB will improve the medicines quality control system.

Only one-fourth of respondents were not very confident in current systems and safeguard to ensure the quality of medicines. 69% of respondents were somewhat confident in FGDOP ability to regulate and monitor quality of medicines. The majority (79%) of respondents agree with the statement "decentralisation of licensing and inspection of pharmaceutical premises will improve the pharmaceutical control".

After the approval of the Pharmacy and Poisons Act 2001, the Ministry of Animal Resources (dominated by veterinarians) took the responsibility of registration of veterinary medicines and the licensing of the whole and retail sellers of veterinary medicines. As expected, 91% of respondents thought, the splitting of drug registration between the MOH and the MOAR weakens the medicines control, compared with only 9% who thought that the arrangement would improve the quality of medicines. One of the respondents added: "*The splitting of the drug authority between MOH, which according to the Sudan constitution is fully responsible for the public health and MOAR, will create contradiction in lines of commands and public health would be compromised*". 84% of respondents agreed with the statement "*This new arrangement could cause conflict between two regulatory authorities*".

93% of participants either strongly agree (73%) or agree (20%) that the increased number of non-registered medicines distributors will facilitate the marketing of low quality medicines. When asked about updated requirements of medicines registration, only 25% of respondents thought the updated requirements are not sufficient to prevent marketing of low quality medicines. Nearly three-quarters (71%) agreed that the pre-marketing surveillance is not enough to ensure the quality of medicines. The law regulating medicines was judged by the respondents as generally adequate (68%).

Discussion

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 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, in view of 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 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 that 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. However, one of the great loopholes in this system was found to be the increased number of non-registered medicines by public foundations, such as 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 that the current situation, in which public organisations 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 public organisations 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*'. For example, 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.*

It is not surprising that all respondents strongly agreed that the increased number of sources of non-registered medicines will lead to entrance of low quality medicines. This result is in line with WHO recommendation, which encourages the regulatory authorities and state members' governments to register all medicines before the marketing. The medicines imported by public sector organisations are not excluded ⁽²⁴⁾.

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 should be stringently applied to public, private and not-for-profit NGOs medicine supply organisations. The predominant view, shared among the medicines' importers is that the current pharmacy legislation is to some extent satisfactory and managed to prohibit the marketing of low quality medicines. However, the recent post-marketing study carried by the National Drug Quality Control

Laboratories, suggested the power of the current regulation is overestimated⁽²²⁾. The findings of this study indicate that the application procedures of the current measures to ensure the quality of medicines should be revisited. The technical complexity of regulations, and its political, commercial and social implications make necessary a degree of mutual trust between concerned stakeholders (i.e., suppliers, doctors, pharmacists, consumer representatives and government agencies).

Conclusion and Recommendation

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 is 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 broad outlines remain intact, but preventing drug smuggling across national borders (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 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 Quality Control

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 pharmacy that 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. CMSPO should stop importation, manufacture and distribution of unregistered medicines. It should also cease from selling the tenders' product to the private pharmacies. The latter practice undermines the inspection outcomes, because it makes inspectors task too difficult (i.e., can not identify the source of medicine whether it is CMSPO or not).

Limitations

The selection of one group of stakeholders and ignorance of the rest (such as CMSPO, retail pharmacies, drug manufacturers, NGOs, consumers organisations, policy-makers, regulators, police, customs, doctors, other health care professionals, and health professional unions, etc.), means great caution must be exercised in any extrapolation to a country level statistical analysis, and percentage given must be regarded as rough estimates.

The sample chosen is indicative rather than fully representative and has been sized to be feasible in the time and resources available for the author. However, the sample is thought to be sufficient to allow valid statistical analysis. Establishing the reliability and validity of measures are important for assessing their quality⁽²⁵⁾. The mentioned time and resources constraints did not allow the author to test the reliability and validity of the research instrument.

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