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Research Article

Explore the Challenge in Medicines Registration Process in Ethiopia: Qualitative Phenomenological Study

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Abstract

Background: Medicines are essential part of any healthcare system. Limited access to medicines undermine in healthcare systems. Ethiopian Food, Medicine and Healthcare Administration and Control Authority had been mandated to ensure quality, safety and efficacy of medicines nonetheless medicines registration process contributes to the availability of quality and safe medicine in Ethiopia. 80% of medicines used in Ethiopia were imported from abroad; in this regard, medicines registration process should be effective and avoid unnecessary delays in Ethiopia.

Objective: The main aim of this study was to explore the challenges of medicines registration process in Ethiopia.

Methods: Qualitative phenomenological study design was employed. Purposive sampling technique was used to select study participants until saturation point of themes reached. Key informant interviews and focus group discussion were used to collect data using unstructured questionnaires. The data were analyzed by thematic content analysis technique.

Results: In the present study different challenges were identified and explored; among these challenges: limitation on Ethiopian medicine registration guideline; inadequate human resources and prolonged medicine registration process. Hence, it results delayed the medicine registration process. Another challenge were dossier related challenges such as most local manufactures and medicines importers were lack of skilled about common technical documents required for medicine dossier submission and which is the most challenge identified for medicine registration process in Ethiopia.

Conclusion: In this study various challenges for medicine registration process were identified and explored. Hence, the Ethiopia Food, Medicine and Healthcare Administration and Control Authority should developed strategy for effective medicine registration process.

Keywords: Challenges; EFMHACA; Guideline; Medicines Registration

Abbreviations

AMRHI: African Medicines Registration Harmonization Initiative; CTD: Common Technical Document; EFMHACA: Ethiopian Food, Medicine and Healthcare Administration and Control Authority; FGD: Focus Group Discussion; WHO: World Health Organization; SRA: Stringent Regulatory Authority; TCA: Thematic Content Analysis.

Introduction

Medicines are defined as any substance or mixture of substances used in the diagnosis, treatment, mitigation or prevention of disease for human being [1]. Medicines are fundamental to any healthcare system. However, inadequate access to medicines undermines the healthcare system [2]. To this point, providing access to medicines has long been the challenge in African countries and also the impact of medicines registration policies in these countries poses the challenges for pharmaceutical companies to registered their medicines and to facilitate the medicines registration activity the recent AMRHI (African Medicines Registration Harmonization Initiative) has increased the focus on the need for harmonization [3].

Ethiopia has been putting tremendous efforts in implementing the national medicine policy of 1993 and health sector development programmed. Since the last two decades and during this period, Ethiopia has made huge strides to improve access to safe, quality and efficacious medicines to the Ethiopian public [4]. Despite the impressive progresses made, the Ethiopia Medicine Healthcare and Administration and Control Authority (EFMHACA) still confronted with new and increasingly complex challenges such as the

infiltration of illegal medicines to the Ethiopian medicine market, shortages of critical medicines, limited number of approved quality medicines and long waiting time for registration were some of the challenges [4].

In Ethiopia, no Medicine shall be produced locally, imported and put in use unless it is duly registered by the executive organ and after being tested for its safety, efficacy and quality [1]. Challenges in medicines registration were the problem often mentioned by medicine importers and local manufactures in Ethiopia. Nevertheless, 80% of Medicines were imported from abroad through Medicine and Medical Equipment importers while to increased access for medicines more 200 medicines and medical equipment importers available in Ethiopia [5].

Poor for medicines dossier assessment, cost of current good manufacturing practice inspection and quality testing procedures did not keep pace with the increasing demand of the pharmaceutical industries for registration of their medicine in African country and to overcome those challenges, the EFMHACA has set a strategy to expedite medicine market authorization [4]. In this view, the medicine registration process needs to be effective and it should be avoided unnecessary delays in order to increase the number and variety of medicines registered in Ethiopia.

The use of herbal drugs for the prevention and treatment of various health ailments has been practice in Ethiopia and generally it is believed that the risk associated with herbal drugs is very less, but reports on serious reactions are indicating to the need for development of effective marker systems for isolation and identification of the individual components and standards for herbal drugs are being developed worldwide but as yet there is no common consensus as to how these should be adopted [6].

Traditional medicines and plant-based remedies are widely used in Africa and it has been estimated that 80% of the African population relies on traditional forms of medicine to meet their healthcare needs [7]. Thus, traditional medicines were playing an important role in Ethiopian society. Besides, knowledge about the extent and characteristics of traditional healing practices and practitioners is limited and has frequently been ignored in the national health system [8].

Statement of the problems

Access for medicines was remains a challenge in African countries and medicines registration policies in these countries are the challenge for pharmaceutical companies wanting to register their medicines [3]. Africans medicine regulatory have lack of human resource and skills; and capacity to perform their functions adequately [9]. Very little data were available regarding pharmaceutical companies experiences in registering and supplying medicines in Africa [9].

More than a third of the world's population has no access to essential drugs and more than half of this group of people lives in the poorest regions of Africa and Asia. In addition, several factors determine the accessibility of drugs in developing countries [10]. For many years, African medicines regulatory authorities have relied on stringent regulators in developed countries on novel pharmaceutical products such as vaccines [11].

The demand for safe, effective and affordable medicines is therefore largely depends on imported medicines. It is estimated that around 79% of all pharmaceuticals in Africa are imported. This significantly increases health expenditure and leaves people vulnerable to interruption of the supply of medicines [12].

Many developing country medicine regulatory have not been able to respond effective medicines registration system and some of their problems are: lack of effective legislation, quality manufacturing capacity, adequate human resources; inadequate time for medicine registration [13]. Another challenges in medicine registration process are, lack of adherence to medicines registration guidelines in different country and it prolonged the medicine registration time or rejection of the dossiers [14].

There were significant differences in the length of time taken for registration of medicines applications among various drug authorities. The average evaluation period is between three to six months in developing countries while emerging countries like middle income countries Russia, Brazil, China, India and Thailand it took 12-18 months [15]. The Kenya pharmacy and poison Bored has provisions for fast-track medicine guidelines and which state that fast-track submissions have a product approval time of up to three months whereas regular medicine applications approval expected between six months to one year [16].

In Ethiopia, shortages of critical medicines, limited number of approved quality medicines and long waiting and the time settled for registration is one of the challenges [4]. Nevertheless, in Ethiopia, there is no previous study conducted that clearly show the challenges for medicines registration process. However, about 80% of medicines are imported from abroad and registration process contribute to the availability, quality, safe and efficacious medicinal products in the country. Thus, the aim of this study is to explore evidence on the challenges of medicines registration process in the Ethiopian Food, Medicine and HealthCare Administration and Control Authority.

Till now, Ethiopia did not registered traditional medicine while it has been estimated that 80% of the population in the developing countries rely on traditional medicines for their primary health care needs. But there is limited information to traditional medicine practices in the country and this study identified the challenge why

not the EFMHACA did not registered traditional medicine as well as identified the challenges in medicine registration process in Ethiopia and findings might help in strengthen strategies within Ethiopian medicine registration system to meet its client service charter.

Methodology

Study setting and period

The study setting was at Ethiopian Food; Medicine and Healthcare Administration and Control Authority, which is located in Addis Ababa. The mandates of the authority: Registration of Medicines, Licensing and Inspection of Health professionals, pharmaceuticals and food establishment's and health institutions.

To apply the mandate, the authority developed citizen charter and medicine registration process should be based on this citizen charter. In the citizen charter of the authority set the precondition that should be fulfilled by the medicine importers and manufactures.

For local medicine manufactures; for new medicine registration the required time was one and half a month and not more than three days for re-registration of a medicine. Although, the registration process was for new medicine importer the time set by the regulatory was from two days up to three months. This study was conducted from February 2018 to September 2018.

Study design

Qualitative phenomenological study design was conducted.

Study participants

Study participants were professionals from medicine registration departments of EFMHACA, professionals from importers, local manufacturers and traditional medicine healers.

Sampling procedure and sample size

The participants were selected based on the criteria to meet the research objectives and purposive sampling technique was employed to select the study participants. The required sample size for this research was determined with saturation point.

Data collection methods and procedure

The respondents were from medicine registration and licensing department, medicine quality control and customer service departments of EFMHACA as well as from medicine importers; local human medicine manufacturers; traditional medicine healer in the country and the data were collected until the saturation point reached.

Data were through in-depth interview and focused group discussions. To collect the data, in-depth interview types of data collection method was used from medicines and medical equipment importer to Ethiopia whereas local human medicine manufactures and traditional medicine healers were participated on focus group discussion.

A pretested open-ended unstructured interviewed and discussion guide was prepared in English. After obtaining consent from participant's in-depth interview was conducted by used unstructured questioners and for the participant's asked question in natural manner and listening the participant's response attentively, asking probing questions and probes based on the responses provided. Each session of in-depth interview was last from 60-90 minutes.

The seconded types of data collection methods was focus group discussion and official letter and cell phone call was done to informed the study participants to come at EFMHACA hole office for FGD. One hour orientation was given for study participants by principal investigators about the objective of the study before focused group discussion conducted.

Six data collectors were recruited and three focus group discussions were conducted with medicine and medical equipment importer; local human medicine manufactures and participants reply were recorded and notes was taken during the interviews and focus group discussion by note taker.

Data quality assurance

In the in-depth interview part of data collection was done the principal investigator and posing question in natural manner, listen the participant's response attentively, asking probing questions and probes based on the responses provided was the main way of in-depth interview data collection quality assurance. During data collection of the in-depth interview, the interview guide was coded based on the first letter of their first, second and third name of the participant and finally numbering of the questionnaire done. In addition to that, on the consent form participants should put their signature after deciding to be part of the study.

On the focused group discussion type of data collection the objective of the research was presented for the participant and homogenous group was assigned for the discussion. The participant responses reporters at a time were taken and volunteer response recorded and finally it was taken as data for the research purpose. It was kept tall the data with the principal investigator.

Trustworthiness of the study

For ensuring the reliability of the study, credibility, dependability, transferability and conformability was used. The credibility was achieved by the use of frequent debriefing sessions and triangulation. In order to address the dependability the processes within the study was reported in detail and thereby enabling a future researcher to repeat the work.

Transferability achieved via sufficient thick description of the phenomenon under investigation to allow readers with proper

understanding of it and thereby enabling them to compare the instances of the phenomenon described in the research report. Conformability was achieved by triangulation, keeping an audit trail, detailed chronology of research activities and processes.

Data processing and analysis

Data collection and analysis were conducted simultaneously. We did the write-ups and was taken a time to prepare a contact summary before write-up, which involves reviewing the main concepts, themes, issues, questions seen during interview and data collected during FGD. We transcribed all notes, audio record and following the transcription, the data were analyzed by thematic content analysis technique and then data were broken down into discrete parts, closely examined and compared for similarities and differences i.e. themes and sub themes were developed from the data.

Ethics

Ethical clearance was obtained from Woldia University and it approved by EFMHACA Research Ethics Committee. After all ethical clearance was granted, invitation letter was distributed to local medicine manufactures, medicines and medical equipment importers for FGD. The letter explained the purpose of the study with the right of participants and participants were assured they can withdraw from the FGD during data collection and written consent asked in all case.

Sessions were arranged in a private, quiet and convenient place for study participants and the privacy of study participants was fully respected during data collection and dissemination of results too. The identity of in-depth interviewee participants' was change to un-identity to be ethical. The tape record and transcript was kept in a safe place and remained confidential.

Operational definition

- **Medicine Manufacture:** A company that carries out operations such as production, packaging, repackaging, labeling and relabeling of pharmaceuticals.
- **Market Authorization:** An official document issued for the purpose of marketing or free distribution of a product after evaluation of safety, efficacy and quality.
- **Bio-equivalence:** Two pharmaceutical products are bioequivalent if they are pharmaceutically equivalent or alternatives and their bio-availabilities (rate and extent of availability), after administration in the same molar dose, are similar to such a degree that their effects can be expected to be essentially the same.

Result

Characteristics of the study participants

Thirty seven study participants were involved in this study. Of the total, 19 study participants' were participated in-depth interviewee. Seven study participants were from the medicines registration and licensing directorate and customer services directorate of EFMHACA. Other study participants were from medicine and medical equipment importers regulatory affaire professional. Male study participants accounted the highest percentage. Furthermore, three focuses group discussions that contained six experts at each section were conducted.

Themes content

In this study, one major theme and three sub-themes were developed from the content analysis. The main theme was: the challenges that contributed delay of medicine registration in Ethiopian and the three sub-themes were: guideline related; human resources related and dossier related challenges.

Guideline related challenges

Most of the study participants both in FGD and in-depth interview explained that the Ethiopia medicine registration guideline of 2014 G.C edition has limitations and the summary results are presented below. "….such as all Medicines that used by humans evaluated by the 2014 G.C edition guideline" (participant #1).

Majority of the study participants were agreed that further medicine registration guidelines with product specific should require such as guideline for bio-therapeutics, bioequivalent medicine and biological medicine registration. Study participant #1 said that "… there was lack of guidelines for medical devices for post marketing surveillance to assure the effective performance of medical devices after registration and to assure the safety and quality of medical equipment's. There were no good manufacturing practice guidelines in Ethiopia to ensure the safety and quality of medical devices such as synovial fluids, HIV test kite, Hepatitis test kite and malaria rapid diagnosis kite".

Majority of the study participants agreed that "...the medicines registration guideline of Ethiopia is not clear and risk-based; because medicines such as over the counter drug (OTC) were treated as very important medicine like prescription medicines". "…Because of this, the number of medicines registered in Ethiopia was smaller than other countries such as Kenya: the number of medicines registered in Ethiopia was around 3,800 while it was around 10,000 in Kenya" (participant #19). Another participant #3 explained that, the Ethiopian medicines and medical device registration guideline was a copy of ICH and WHO, which is difficult to fulfill the guideline requirements to register our medicinal products. "…it is better to put the most important document as requirement in the guideline"....She further argued that there is no need to put certificate of pharmaceutical product as a requirement for registration of medicine".

Lack of skilled human resource

In both in-depth interview and FGD, most of the study participants forwarded that for medicine registration process knowledgeable and skillful human resources are mandatory EFMHACA. "The salary for medicine dossiers assessors was too small and the

attrition rate of well experienced experts was so high, and this is another challenge in medicine registration process" (participants #4). "Even though local medicine manufactures and medicine and medical equipment importers have regulatory affair managers that facilitate the registration process, these managers lack the necessary knowledge and skill in dossier compilation that are submitted to the regulatory, and because of this the dossiers submitted to EFMHACA were asked further information" (Participant #11).

Another participant #9 also explained that "…Medicine dossier assessors in Ethiopia lack the required skill on new medicine registration process. Since some dossiers that were submitted to the EFMHACA require special knowledge and skill for statically interpretation such as bioequivalent part of the dossiers. Furthermore, the authority did not harmonize with any other country's regulatory authority for experience sharing. In addition to this, the time set for medicine registration process was not sufficient to evaluate the dossier".

Dossier related challenges

Most of the study participants explained that dossier related problems were the huge challenges in medicine registration process in Ethiopia, and EFMHACA partially outsourced the dossier evaluation process for one public university to avoid delays. However, the university has no accreditation to evaluate the dossiers, and information exchange between the university and EFMHACA is time consuming. "…Most local manufactures as well as medicine and medical equipment importers have no knowledge and skill about CTD based medicines dossiers document submission, and this was the most challenging part in medicine registration process" (Participant #16). He also added that "...Submission of medicine dossier via hard copy for registration purpose is another challenge in Ethiopia and some of relevant documents should be submitted in soft copy such as stability study report whereas the rest should be submitted as requirement of hardcopy".

Another study participant #10 said that "…The medicine importers submit bioequivalent medicine dossiers to the regulatory. Nevertheless, EFMHACA does not inspect current good manufacturing practices and hence challenges during dossier evaluation by EFMHACA dossier assessors".

FGD with local medicine manufactures and medicine and medical equipment importers

Majority (N=12) of the FGD participants agreed that, "the medicine registration guideline is the direct copy of WHO and other European Country Medicine Regulatory, so that, it is difficult to implement in our country. This result is similar with the response of in-depth interview participant #3 who explained that, the Ethiopian medicines and medical device registration guideline was a copy of ICH and WHO which is difficult to fulfill the guideline requirements. The team also agreed that the submitted dossiers to EFMHACA were incomplete and further information asked by the regulatory".

Another challenge explained by the FGD participants was documentation problem. "….Documents submitted to the EFMHACA disappears, and even there is no accountability as no evidence is given whether the Authority received or not the document. The FGD team concluded that formerly the customers who asked the responsible persons at EFMHACA used to get response. However, currently, it is difficult to get answer for their question. In general, the performance of the current medicine registration system is not as effective as the previous one".

FGD team agreed that there is a challenge "…..in exchanging information between customers and the EFMHACA customer service directorate. Most of the directorate staff have lack of knowledge in handling customers, as well as in dossiers pre-screening skill and because of this there is poor communication even among EFMHACA staff members; no common understanding about the submitted dossiers between EFMHACA and customers".

In addition, the FGD team explained that "…information flow between the EFMAHACA and the customers is not clear, any amendment or variation on the medicine registration system is not announced for customers via official letter, website or notice board".

All participants agreed that "….meetings were the main challenge in Ethiopia for medicine registration process, and they said that if there were meetings by the staff, somebody should delegate and give response on time for the customers".

Other challenges were discussed by the study participants at FGD about references standard to cheek the quality of the medicine "...for the same product with different strength. However, manufactures outside the country were not interested for this type of procedures and this made the medicine registration system time consuming".

In addition to this, the FGD team agreed that "…since the time given for quality control check is long and unclear, the reference standards submitted to the Authority were expired or lost".

Focus group discussion with traditional medicine practitioners

Participants from traditional medicine healers explained that "...Traditional medicine is one type of medicine commonly used by most Ethiopian population even though; there is no any registered traditional medicine in Ethiopian".

The Proclamation number 661/2009 part 9 of the country declared that any locally produced or imported traditional, complementary or alternative medicine may not be put into use unless evaluated and registered by the executive organ. Traditional medi-

cine practitioners explained "even if here is no registered traditional medicine by the EFMHACA, the medicines are being used by Ethiopians and the world at large".

Most of them maintained that, "...Traditional medicines were given by God and how the government of Ethiopia can register them. In addition to this, registration of traditional medicines is impossible, because in addition to the cost to assure safety, quality and efficacy, it would take more than 20 years".

Moreover, most (N=6) reported that, "…it is difficult to get registration certificate based on the current proclamation and regulation of the country. The proclamation should be modified based on the knowledge and skills of the traditional medicine healers of the country".

The study participants agreed that other challenges for traditional medicine registration in Ethiopia are the fact that "...There is no strong traditional medicine practitioners association, for that matter the practitioners have no sufficient scientific knowledge on traditional medicine. There is poor commitment from the Government to develop the profession; no guaranty for traditional medicine practitioners; no clear policy, strategy and guideline for traditional medicine registration in Ethiopia". They also added that "there is no special support from the government concerning manufacturing area and finance; there is also lack of regulation on how to work with the scientific community".

Discussion

The present study revealed that the 2014.G.C Ethiopian medicines registration guideline was the copy of ICH and WHO which was not easy to full fill the requirements as a result of Ethiopia medicine importers, manufactures for medicine registration and this was in line with other cross-sectional pilot study conducted in South Africa on 23 pharmaceutical companies indicated that countries specific regulatory requirements in Africa were a barrier to registered, supplying medicines to African countries [3]. In addition, the Ethiopian medicine registration guideline was not medicine specific rather general and based on this guideline, the EFMHACA faced challenge to register medicinal products such as bio-therapeutic medicines: insulin; biological medicine: vaccine of different strength.

The current study also revealed that a number of dossiers that were submitted to the EFMHACA were more than the dossier assessors and this was one of the big challenges for medicine registration process in Ethiopia. This finding is comparable to study conducted [14] in Tanzania, which revealed that medicines registration authority had inadequate numbers of medicine dossier evaluators and has been observed to take longer time than the suggested in the Client Service Charters [14].

This study also showed that the EFMHACA developed strategy for outsourced the medicine dossiers evaluation activity for one government university in Ethiopia to facilitate the registration process. However, the university was not accredited by external body to evaluate the medicine dossiers and information exchange about evaluated medicinal document was one of the challenges and dossiers stayed for a long time without market authorization.

This study demonstrated that medicine dossier assessors in Ethiopia have lack of skill and knowledge on dossiers evaluation. Because some dossiers submitted to the EFMAHACA required special knowledge, skill regarding statically analysis of the dossiers such as skill for interpretation of the data example bioequivalent part of the dossiers. This study finding agreed among study done by [14] that the pharmacist in-charge in medicine registration process had limited knowledge on medicines registration concept and also in line with a study conducted in South Africa medicine regulators lacked the expertise to register biologic agents [3].

It is also showed that the medicine registration process in Ethiopia had no real and applicable time schedule for registration of medicine which was similar to study conducted in Pakistan that the major gaps for medicine access driven by weaknesses in medicine registration process [23].

The FGD team explained that the medicine registration performances in Ethiopia decreased from time to time with the evidence of medicines registration in Ethiopia were not based on citizens' charter of the country which was two month and less [24] in contrast with another study done in Tanzania [14] the average medicine registration time was 18 months.

In Ethiopia, medicine registration process was CTD based while the submitted dossiers for the EFMHACA were not based on this CTD format and because of this the authority asked further information about the medicine document. Consequently, it delayed the medicine registration process [25].

Traditional medicine plays an important role in Ethiopian society [8]. However, the FGD team that were participated at the study explained that up to now in Ethiopia there is no any traditional medicine registered by Ethiopian Food, Medicine Healthcare and Administration control Authority. Some of the reason identified were: traditional medicine healers had no sufficient scientific and document based knowledge on traditional medicines and their practices; the government of Ethiopian had poor commitment to develop the profession of traditional medicine practices; no motivation from the Ethiopian government for traditional medicine practitioners; no clear policy, strategy and guideline for traditional medicine registration process in Ethiopia. This study finding supported by another study [8] that knowledge about the extent and characteristics of traditional healing practices is limited and has

frequently been ignored in the national health system of Ethiopia and the requirements of the medicine regulatory are difficulties and although in the proclamation 661/2009 traditional medicine should be registered before used by Ethiopian community.

The other challenges explained by the study participants was document misplaced, disappeared and they were also added that they were afraid of the confidentiality of the document. Majority of the study participants said that meeting is the main challenge for medicine registration activity and especially experts at medicine registration and licensing directorate were main responsible for medicine registration process while most of the time they were in meeting and the customers did not get answered for their questions.

Conclusion

There are different challenges in medicine registration and these challenges are guideline related; human resources related and dossier related challenges. Based on these findings the Ethiopia Food, Medicine and Healthcare Administration and Control Authority should developed strategy for effective medicine registration process. Furthermore, it is proposed that EFMHACA management should deploy sufficient number of qualified personnel to undertake for effective medicine and medical equipment medicine registration.

Ethical Approval

Approval and permission were sought from Ethical Review Board of Woldia University.

Availability of Data and Materials

The datasets used and/or analyzed during the current study are available upon requesting the principal author.

Competing Interests

The authors have declared that no competing interests exist.

Author's Contribution

DF conducted the actual study and the statistical analysis. DF and BK were involved in developing the idea, designing of the study and the write up of the manuscript. All authors approved the submitted version of the manuscript.

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