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 e f cacy 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 reg] ᴰ ק ע Ẏ ˝ Ạ ⁵ medicine registration process in Ethiopia.

Conclusion:

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Received October 14, 2019; **Accepted** July 21, 2020; **Published** July 28, 2020

Citation: Fantaw D, Kefale B (2020) Explore the Challenge in Medicines Registration Process in Ethiopia: Qualitative Phenomenological Study. Epidemiol Sci 10: 383.

expedite medicine market authorization. In this view, the medicine registration process needs to be e ective and it should be avoided unnecessary delays in order to increase the number and variety of medicines registered in Ethiopia.

e 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 e ective marker systems for isolation and identi cation 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]. us, 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. Africans medicines regulatory have lack of human resource and skills; and capacity to perform their functions adequately. Very little data were available regarding pharmaceutical companies experiences in registering and supplying medicines in Africa [9].

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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 [19-22].

A pretested open-ended unstructured interviewed and discussion guide was prepared in English. A er 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.

e seconded types of data collection methods was focus group discussion and o cial letter and cell phone call was done to informed the study participants to come at EFMHACA hole o ce 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 rst letter of their rst, second and third name of the participant and nally numbering of the questionnaire done. In addition to that, on the consent form participants should put their signature a er 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 homog-
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*"….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 speci c 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 e ective performance of medical devices a er registration and to assure the safety and quality of medical equipments. ere were no good manufacturing practice guidelines in Ethiopia to ensure the safety and quality of medical devices such as synovial uids, 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*

Ethiopian population even though; there is no any registered traditional medicine in Ethiopian."

e 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 medicine 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 e cacy, it would take more than 20 years.*"

Moreover, most (N=6) reported that, "*…it is di cult to get registration certi cate based on the current proclamation and regulation of the country. e proclamation should be modi ed based on the knowledge and skills of the traditional medicine healers of the country."*

e study participants agreed that other challenges for traditional medicine registration in Ethiopia are the fact that "*... ere is no strong traditional medicine practitioners association, for that matter the practitioners have no su cient scienti c knowledge on traditional medicine. ere 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*". ey also added that "*there is no special support from the government concerning manufacturing area and nance; there is also lack of regulation on how to work with the scienti c community.*"

Discussion

e 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 ll 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 speci c regulatory requirements in Africa were a barrier to registered, supplying medicines to African countries. In addition, the Ethiopian medicine registration guideline was not medicine speci c 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 di erent strength.

e 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. is nding is comparable to study conducted 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.

is 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.

is 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 thel.agr

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cient number of quali ed personnel to undertake for e ective medicine and medical equipment medicine registration.

Declarations

Ethical approval

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

Availability of data and materials

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

Competing interests

e 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.

Acknowledgments

We would like to acknowledge EFMHACA sta s for their valuable contribution towards this project.

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