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RESEARCH ARTICLE

Regulatory Harmonization of East African Communities: A Study on Selected Pharmaceutical Industries in Ethiopia, 2023

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Abstract

Background: The East African Community (EAC) has been implementing the Medicine Regulatory harmonization (MRH) program among its member states for almost ten years in order to harmonize technical requirements and standards for medical product regulation.

Methods: A qualitative and qualitative study design was employed in this study from twelve pharmaceutical industries. Using semi structured interview guides with adaptable probing techniques were used for data collection in qualitative parts and self-administered survey questionnaires were used for quantitative parts. A total of twelve study participants were involved in the qualitative study, and forty three study participants were involved in the quantitative study.

All transcribed interviews were subjected to thematic analysis and the descriptive data were analysed by SPSS 22 version. Descriptive data was presented in frequency and percentage, while qualitative results were presented in themes and subthemes.

Results: The results of the current survey suggest that regulatory harmonization of the Ethiopian pharmaceutical industry with the East African Community (EAC) is very weak, even if a formal and regular framework exists. Collaboration, harmonization, joint dossier reviews, and inspections of manufacturing sites; reliance; and cooperation are key factors for building trust and capacity among national regulatory medicine authorities (NMRAs).

Conclusion: There is considerable goodwill on behalf of national pharmaceutical industries that the MRH effort could be initiated by the Ethiopian government to join the EAC and be strengthened for the benefit of the public and the region. Quality management systems and information management systems are necessary tools for improving the efficiency of regulatory processes.

Keywords

Africa, East, Ethiopia, Harmonization, Industry, Pharmaceutical

Abbreviation

AU: Africa Union; EAC: East African Community; EFDA: Ethiopian Food and Drug Administration; EPHARM: Ethiopian Pharmaceutical Manufacturing plc; IDIs: Indepth Interviews; GMP: Good Manufacturing Practice; NMRAs: National Regulatory Medicine Authorities; PMPA: Pharmaceutical Manufacturing Plan for Africa; SPSS: The Statistical Package for Social Science; WHO: World Health Organization

Background

Harmonization of supervisory requirements has many components, including ensuring favorable purchasing environments to help early procedures for medicinal commodities, advancing contest and adeptness, and lowering unnecessary replicas of dispassionate testing. Africa comprises 15% of the world's population but bears 25% of the global disease burden [1]. Africa's excessive disease burden and intense loss of life from preventable and correctable afflictions are incredibly resulting from insufficient wellbeing orders, refrain monetary and personnel, further to country of missing something wished or standard of and unaffordable treatments which might be of properly high-satisfactory, careful, and efficient.

Lack of access to high-quality pharmaceutical products, effective treatments, and affordable

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treatments is partially caused by constrained local pharmaceutical drug products based on the demand base and weak remedy supervision structures. In 2005, the Heads of State and Government of the African Union (AU) announced the expression of the Pharmaceutical Manufacturing Plan for Africa (PMPA), accompanying the view of heartening Africa's potential to supply tremendous and less expensive treatments as a way to step forward power and enterprise-associated consequences [1]. Harmonizing the definitions of novelty can enhance the location of the latest therapies, underrate costs, and prepare drug increase and authorization processes. The international burden of illnesses has existed at the upward push for the final diverse decades [2].

Preventing, treating, and preventing afflictions further from the blended threat elements can provide good healthcare. The myriad of all-encompassing health-demanding situations may be mentioned as one catalyst for novelty in healthcare [3]. Factors to a point converting affected person needs, decided and popular wellbeing problems, monetary restraints, regarding info adjustments, and risky practical country sides call for alternate fitness control to beautify affected person effects.

Innovation is especially important to growth longevity, high satisfaction of history, state of affairs alternatives, affordability of state of affairs, and the performance of healthcare arrangements [3]. The impact of the Orient African Community EAC drug supervisory settlement power on the capability of inner treatments supervisory instrumentalities, with a dedicated attempt to something enrollment and exam systems [1]. By the first decade of the new millennium, the desire for technical harmonization and system optimization in regulating drug treatments had been identified throughout the African continent. On the other hand, such harmonization and optimization could assist in incentivizing drug treatment producers to sign up for their pharmaceutical purchases in African countries with the aid of lowering the complexity of the software system [4].

A wide variety of factors, inclusive of coverage guidelines and financing, play a vital role in figuring out the right of entry to pharmaceutical products in Sub-Saharan Africa. In practice, safety and productivity monitoring standards have been linked to the validation and availability of new remedies. This should be similar in all situations, given the apparent differences in states and races involved [5]. Many improvements are planned for joint product assessment and Good Manufacturing Practice (GMP) inspection. For example, in line with the roadmap, in 2019, the initiative will jointly handle product changes and updates in response to frequent requests from pharmaceutical companies operating in the EAC [6]. All countries, except the Sub Saharan countries, have regulatory bodies or departments within the Ministry of Health that deal with issues related to the regulation of pharmaceuticals [7]. The World Health Organization (WHO) reports that many of the continent's medical product regulatory agencies are underfunded, impacting the availability of medicines to the population. It accounts for a significant portion of the global disease burden [8]. Almost 60% of international manufacturers failed to follow GMP in recent years, preventing them from receiving marketing authorization [9].

Research has shown that reluctance by pharmaceutical companies to register their products in African markets is one of the main factors slowing access to medicines [10].

Research and development of novel medical products and technology, as well as investments in the production, distribution, and sale of pharmaceuticals, are made possible by the efficient and effective regulation of medical products. Consequently, patients and the community as a whole benefit socially and financially from these [11-13].

Due to the limited resources that African regulatory bodies have available, it is crucial to determine if harmonization activities bring value or deplete resources. According to these evaluations, corporations' general impressions of the pilot program were favorable, and it appeared that it might increase the effectiveness of the participating regulators. Hence, countries are not required to adopt the regulatory decisions that have been taken in another country when the NRMA receives evidence dossiers that are identical. On the other hand, countries like Ethiopia are at the observer stage and are not joining the EAC.

Methods

Study setting, design and period

A mixed method design using quantitative and qualitative data to get information from fourteen pharmaceutical companies in Addis Ababa, Ethiopia. At present, there are thirteen human medicine manufacturers, one veterinary vaccine manufacturer, and 38 medical supply and device manufacturers actively operating and licensed by the Ethiopian Food and Drug Administration (EFDA) [14,15]. Accordingly, a total of 12 pharmaceutical companies have been involved in this study .Namely; Addis Pharmaceutical Factory, Africure Ethiopia Plc, Cadila Pharmaceuticals (Ethiopia) PLC, East African Pharmaceutical PLC, Ethiopian Pharmaceutical Manufacturing Plc (EPHARM), Glowcare Pharmaceutical Manufacturing PLC, Kilitch Estro Biotech Plc, Pharma cure Pvt. Ltd. Co., Human Well Pharmaceutical Ethiopia, Julphar Pharmaceutical PLC, Sino-Ethiopia Associate (Africa) PLC, and Sansheng Pharmaceutical PLC. This study was carried out from March 30 to April 30, 2023.

Study population

All of the participants in a research study who meet the specific criteria set forth are referred to as the target population. The study's target participants were Ethiopian pharmaceutical industry workers and managers in twelve Pharmaceutical Industries.

Sample techniques

For quantitative data, the survey method was employed by the researchers. Forty-Eight employees (four from each manufacturer) of the pharmaceutical industry who are working in pharmaceutical company were selected to participate in this study. for which a purposive sampling technique was employed. Purposive sampling techniques were applied for qualitative research design. Participants were senior manager, plant manager, production managers and quality assurance. The questioners were distributed to key informant workers in the pharmaceutical industries.

Additionally, key informants from the supporting departments were also purposefully sampled for the study. The selected interviewees were expected to answer the semi-structured questionnaires.

Data collection methods and data quality control

After a thorough assessment of the literature, the investigator created a structured questionnaire. A systematic questionnaire was created by analyzing relevant research findings on the topic covered in the caption. Originally prepared in English then translated into the local language (Amharic) then back to English to ensure reliable information. Four numerators who had graduated from university were recruited and trained about the purpose of the study; how to approach respondents; how to obtain written consent for 1 day. An interviewer-administered questionnaire was used. An anonymous, structured questionnaire that was administered by an interviewer was employed to obtain a high response rate. During the creation of the questionnaire, data collecting, and data input, the data quality assurance system was altered. The survey was pretested, objectively based, rationally ordered, free of scientific jargon, and non-leading.

Data analysis

All indicators involving the availability and pertinent information of the national policies, laws, regulations, provisions, legal frameworks, level of autonomy, references, and regulatory standards, Good Manufacturing Practice (GMP) guidance and procedures, and the stage of various modules' implementation were subjected to data analysis and interpretation. Quantitative data was entered and coded using Epi Info version 7 and exported to the Statistical Package for Social Science (SPSS version 22). Qualitative data analysis began. Qualitative information was gathered through interviews. Then the researchers translated and fully transcribed all of the Amharic recorded material for the talks and telephone interviews. The acquired data were verbatim transcribed and translated, and then the qualitative data were analyzed. These categories produced the themes. The data analysis was presented in the form of tables, graphs, and percentages from the descriptive statistics.

Result

Sociodemographic characteristics of the respondents

A total of 43 employees out of 48 samples from the twelve human medicine manufacturers participated and answered the self-administered questionnaire, yielding a 90% response rate. 34 (79.1%) of the total respondents were men. In terms of educational standing, more than two-thirds of the study participants possessed a first degree. The respondent's mean age and SD were 15.97 ± 5.7 years, and their working experience ranged from 5 to 27 years. According to their position in the pharmaceutical business, more than half of the study participants were from quality assurance departments, as shown in Table 1.

Pharmaceutical company product manufactured

Table 2 suggests that 35 (81.3%) answered that their pharmaceutical corporation produced dry

Table 1: Socio-demographic characteristics among employees in pharmaceutical industry in Ethiopia, 2023.

Variable	Frequency (n = 43)	Percentage (%)
Sex		
Male	34	79.1
Female	9	20.9
Educational status		
BSc/BPharm	29	67.4
MBA	14	32.6
Current Position /Work place in the company		
Production Manager	4	9.3
General/Admin	12	28.0
Quality Control	2	4.65
Quality Assurance	23	53.4
Marketing	2	4.65
Total working experience in years		
5-10	7	16.3
> 10	36	83.7
Working experience Pharmaceutical industry in years		
1-5	26	60.4
> 5	17	39.6

Table 2: Pharmaceutical company product manufactured and having pipelines.

Variable	Frequency	Percentage (%)
Product manufactured		
Cephalosporin, Capsule products	8	18.7
Dry powder, tablet, ointment and injectable products	35	81.3
Number of manufacturer pipe lines have		
1-5	33	23.3
6-10	10	76.7
Types of pharmaceutical product		
OTC	2	4.7
Prescribed product	17	39.5
Both	24	55.8

Table 3: Document review questions related to regulatory harmonization in Ethiopian pharmaceutical industries, 2023.

Variable	Frequency (n = 43)	Percentage
Does your company benefit from joining the EAC and IGAD harmonization scheme?		
Yes	39	90.7
No	4	9.3
Do you recommend Ethiopia to join the EAC medicine registration harmonization now?		
Yes	39	90.7
No	4	9.3
Do you have harmonized guidelines for product registration in EAC and IGD region?		
Yes	14	32.6
No	29	67.4
Do you think that Ethiopia as a country will be a loser if joined EAC?		
Yes	12	27.9
No	31	72.1
Do you have a ready CTD dossier for some of your products?		
Yes	29	67.4
No	14	32.6
Do you have the capacity and all infrastructure to apply for the EAC?		
Yes	39	90.7
No	4	9.3

powder, tables, ointment, and injectable products. The local pharmaceutical manufacturing organizations particularly produce indispensable medicines. More than half of the respondents stated that their pharmaceutical organizations produced OTC and prescribed products. Regarding pharmaceutical manufacturers having pipelines, the majority of pharmaceutical organizations have up to five pipelines.

Regulatory harmonization in Ethiopian pharmaceutical industries

As can be seen from Table 3 below, 90.70% of the respondent's pharmaceutical industries said they will benefit from becoming members of the EAC and IGAD schemes. The majority of the respondents preferred to advocate that Ethiopia join the EAC remedy registration harmonization now. More than two-thirds of the participants said that their pharmaceutical agencies have no harmonized suggestions for product registration in the EAC and IGAD regions. However, 72.1% agree that Ethiopia will now not be a loser if it joins the EAC. Moreover, the descriptive evaluation indicated that their pharmaceutical industries have the capability and infrastructure to follow the EAC.

Qualitative Result

Sociodemographic characteristics of study participants

A total of 12 interviews were conducted for this study. 11 (91.6%) of the study participants were males, and more than half of the study participants had bachelor-level training. Regarding the role of working experience in the pharmaceutical industry, 8 (66.6%) of the total study participants had much less than 4 years of working experience, as shown in Table 4 below.

The IDI participants explained the regulatory harmonization of pharmaceutical industries in Ethiopia. Thematic analysis identified three main themes in the areas: Current R&D capacity, opportunities, and challenges for involvement in R&D. Detailed descriptions of the findings under each theme are presented below (Table 5).

Determinant factors related to apply pharmaceutical marketing harmonization

This theme describes the situation in Ethiopia with respect to pharmaceutical marketing harmonization. There are many factors affecting the decision to apply for pharmaceutical authorization in East Africa and intergovernmental authority development. The majority of the study participants agreed that there are still many problems with regulatory harmonization in the pharmaceutical industry in Ethiopia.

As the male production manager said:

> "The first thing is that the local manufacturers don't fulfill the need for medicines in their own countries. The second factor is the administrative issues for completing the task." (IDIs)

Table 4: Socio-demographic characteristics of study participants in local in qualitative Study in Ethiopia, 2023.

Variable	Frequency	Percentage
Sex		
Male	11	91.6
Female	1	8.4
Educational status		
BSc/BPharm	7	58.3
MBA	5	41.7
Current Position in the company		
Production Manager	2	16.6
General/Deputy Manager	7	58.4
Plant Manager	1	12.5
Quality Assurance Manager	1	12.5
Market Manager	1	
Total working experience in years		
7-10	3	25.0
> 10	9	75.0
Working experience pharmaceutical industry in years		
1-4	8	66.6
> 4	4	33.4

Another male technical manager added that:

> "high demand for foreign currency in Ethiopia and high demand for our products in the regions of the country and the need for marketing integrity are the main challenges for the pharmaceutical company in Ethiopia." (IDIs)

Mechanisms for a pharmaceutical company getting market authorization

On the other hand, prior authorization can cause unnecessary delays in treatment. The prior authorization process typically involves communicating with the pharmaceutical company and filling out forms that may be specific to that particular pharmaceutical product. The majority of the study participants argued that there are certain procedures to get market authorization.

As the male market manager said:

> The company plans to follow all available marketing authorization procedures to introduce its products, i.e., ECA/IGAD, joint assessment lines, and WHO lines" (IDIs).

Methods of regional free trade agreements like the EAC

A market economy is an economic system in which decisions regarding investment, production, and distribution to consumers are guided by the price signals created by the forces of supply and demand. The major characteristic of a market economy is the existence of factor markets that play a dominant role in the allocation of capital and the factors of production. Most of the study participants argued with this statement.

As the male technical manager said,

> "It is highly useful for pharmaceutical companies to have such an agreement to sell their products. Free trade for African countries is for technology transfer. Also, it creates a big market interconnection, so for this reason, it has a high impact to register for market authorization." (IDIs)

Challenges for regulatory harmonization of the pharmaceutical industry

Participants from the pharmaceutical industry argued that the government sees regulatory harmonization in the pharmaceutical industry as another aspect of its agenda. According to participants, the lack of foreign exchange is a major problem in the Ethiopian economy in general. Despite the government's special treatment

Table 5: Qualitative themes of IDIs.

THEMES	Determinant factors related to apply pharmaceutical marketing harmonization
	Mechanism of pharmaceutical company getting market authorization
	Methods of regional free trade agreement like EAC?
	Challenges for regulatory harmonization of pharmaceutical industry

of the pharmaceutical sector, it remains difficult to obtain the necessary foreign currency for the timely purchase of raw materials and consumables. There is no specific focus on regulatory harmonization activities, so each request for such activities takes a similar amount of time as a registration activity. A further challenge to regulatory harmonization in the pharmaceutical industry is the fact that many factories are operating below capacity.

As the male general manager reflected his idea:

> "A problem we have had over the last five years has prevented us from producing the products in our portfolio. The obvious reason is the lack of foreign exchange. Another is that we may not even be able to manufacture medicines to meet patient demand. Another is that the Ethiopian pharmaceutical industry has paid little attention to the concerned bodies." (IDIs)

Discussion

Medical product regulation is based on laws and policies pertaining to medicines. All EAC member nations have laws pertaining to pharmaceuticals, however they differ in terms of their main regulatory roles, legal requirements, and operational procedures, according to a comparative analysis of the region's legislation. These may have an impact on the market's capacity to obtain necessary, high-quality, safe, and effective medications [16]. Because of the EAC's expertise with regulatory harmonization, regulatory science has improved due to the rigorous review process and consequently higher quality requirements than those of national procedures. Consequently, there has been less effort duplication and a decrease in the total regulatory load [16-19].

The public health benefits from harmonization processes as well, since they promote frank technical discussions and strengthen national authorities' ability to quickly evaluate priority medications and weed out subpar or unsafe products through the sharing of ideas and experiences among regulators from various nations [20]. Socioeconomic advancement and the promotion of investment in the pharmaceutical sector depend on sound, efficient, effective, and transparent regulatory structures [21].

Many corporations are now reluctant to employ the joint product evaluation approach until efficiency improvements are made, despite the fact that some nations have demonstrated to be faster than others in providing marketing approval of items following the regional review process [18]. Many people are frustrated by the length of time it takes to obtain the real marketing permission, particularly for smaller, less desirable markets, even though it has been claimed that regional procedures have unexpectedly higher quality criteria than national procedures [18]. Therefore, in order to achieve the goal of harmonization, improvements must be made to the current EAC procedures.

Conclusion

The results of this study suggest that regulatory harmonization in the Ethiopian pharmaceutical industry is very weak. There is considerable goodwill on the part of national and international pharmaceutical manufacturers that the MRH effort could be successful. Great progress has been made in implementing the EAC MRH, but more efforts are needed. The EAC Free Trade Agreement does not promote free trade in pharmaceuticals. Because pharmaceuticals still require import and export approval from each country.

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Authors Contributions

All authors made significant contributions to the work reported, whether in conception, study design, data analysis, or interpretation. Final approval of the version to be published, agreement on the journal to which the article has been submitted, and agreement to be accountable for all aspects of the work.

Ethics Approval

The studies involving humans were approved by Lead Innovation Growth Success (LIGS) University, Hawaii, USA. Institutional Research Ethics Review Committee (IRERC). The studies were conducted in accordance with the Ethiopian Food and Drug Authority's legislation and institutional requirements. The study participants provided their written informed consent to participate in this study.

Consent for Publication

All authors read and approved the final manuscript.

Conflict of Interest

The researchers declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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