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Copyright© 2013-19 IJDRA**Research Article****Customers' Perceptions on Pharmaceutical Regulatory Service Quality in Ethiopia****Kidanemariam G/Michael Beyene ^{a*}, Heran Gerba Borta ^a, Deribe Assefa Aga ^b, Mesafint Abeje Tiruneh^c**^aEthiopian Food, Medicine and Healthcare Administration and Control Authority, Addis Ababa, Ethiopia^bEthiopian Civil Service University, Addis Ababa, Ethiopia^cBethzatha General Hospital, Addis Ababa, Ethiopia**Abstract**

Introduction: Service quality is a unique and abstract concept that is difficult to define and measure. It is an overall customer judgment that results from the comparison between service expectations and perceptions. There is no information on customers' perception of pharmaceutical regulatory service quality in Ethiopia. Hence, this study aimed to assess customers' perception of the Ethiopian Food, Medicine and Healthcare Administration and Control Authority's pharmaceutical regulatory service quality.

Materials and methods: Cross-sectional study design was conducted from March 30 to May 30, 2017. Using simple random sampling technique, 131 respondents were included in the study. Structured questionnaire adapted from the SERVQUAL model was used to collect the data. Paired sample t-test and descriptive statistics were used for data analysis.

Results: The study found out that pharmaceutical regulatory service quality was low. Negative service quality gaps were observed in the five service quality dimensions and overall service quality. The widest service quality gap was in reliability and the narrowest gap was in the tangibility and assurance dimensions. The perception and expectation mean scores were 1.897 ± 0.61 and 3.433 ± 0.559 respectively.

Conclusions: Only 21.4% of the customers perceived that there was good service quality in the Authority while 78.6% claimed as poor. The study showed that there are service quality gaps in the pharmaceutical regulatory services. Hence, managers should look into the unmet needs and expectations or low perceptions of customers; and formulate effective strategies to ensure provision of better service quality.

Keywords: Pharmaceutical regulatory service quality, Customer, SERVQUAL, Ethiopia

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1. Introduction

Service can be defined in different ways depending on its usage. According to Kotler and Keller, service is an intangible act or performance that one party is willing to offer to another. The generation and consumption of service take place simultaneously since it cannot be stored for future use. (1) Another similar definition given by Grönroos states that service is a process that consists a series of more or less intangible activities that, but not necessarily always, takes place an interaction between customers and employees; service providers' physical resources and systems. (2)

Service features are specific to the service type. The service characteristics are (i) services are processes that consist activity (ies) (ii) services are produced and

consumed simultaneously, and cannot be stored and (iii) the customer participates as a co-producer in service production processes. (2) This implies that service should be defined by providers considering its inherent characteristics (i.e., intangibility, heterogeneity, perishability, and inseparability) to acknowledge how service quality is perceived by customers. (3)

Quality is an important factor that affects business performances. It is explained with respect to ways of doing business and commitment to customers. Quality is defined as the totality of a product or service features and characteristics that bear on its ability to satisfy an implied need. It is the ability of any service that can meet customers' expectation. (4) Quality can and arguably associate with achieving or exceeding expectations, meeting requirements that customers had not stipulated,

but once offered become everyone's expectation. (5) Furthermore, service quality evaluation is a process through which a customer compares its expectations and perceptions of the services to be received. (6)

Service quality: Both the technical and functional, is a cornerstone strategy in the success of service providers. It is a factor for survival, growth, and persistence of organizations as well as tackling challenges related to competition. (7) To have competitive advantages, service organizations' managers shall provide excellent services to their customers. (8,9)

Service quality is a unique and abstract concept that is difficult to define and measure though controversy exists. Most authors define service quality as the extent to which a service meets customers' need or expectation. It is the difference between customers' expectation for service and his/her perception for the same service. (8) It is the ability of an organization to meet or exceed customers' expectation. (10)

In today's rapidly changing global economy, doing business has become more difficult. Customers keen organizations strive to redesign and reshape their services to endure the global competition they are facing for survival. (11-13) Service providers are concerned about the service quality management and its association with performance measurements. (14) In today's globally competitive environment, delivering quality service is considered as an essential strategy for success and survival. (3,15)

The customer expectations from private and government organizations are changing from time to time. The government service provision and quality requirements are changing with customer value propositions. Customers are rational decision makers on the service quality they receive. Service quality becomes critical for reputation and viability. (16) However, service quality in public organizations is slow and is exacerbated by difficulties in measuring outcomes and understanding customer expectations. (17)

In recent decades, service quality has become an issue for managers in the service sector. This is due to increased customers demand for higher quality services. (16) Effective service quality management entails accepting customer's perceptions and expectations as the main factor in determining service quality. (2,18)

As service has unique inherent nature, measuring service quality is much elusive than measuring the quality of physical products. (14) Bearing in mind that medicine regulation is a governmental function that serves societal objectives to protect and promote public health, measuring the effectiveness of service quality provisions is of utmost importance. (19)

Ethiopia is not immune to the influence of global competitive situation and the dynamic change in customer dimensions. (20) The service sector was under increasing pressure to demonstrate customer centered quality services that continuously improve the service sector performances. In recognition of this, the Ethiopian government has undergone some changes in the public organizations. (21) It has been committed to access and

quality service provisions for increased productivity and efficiency. A strong focus has been given to improve the service quality in the health sector (20,21) particularly the regulatory services (21, 22) but a lot remains to improve the regulatory service quality. It is a high time to pay attention to services quality at all levels of the regulatory system. (22,23) In addition, regulatory service quality is a hazy and undemonstrated area in the health sector. Besides, there are claims and complaints about poor quality service provisions in the regulatory authority. (23) However, in Ethiopia, there are no empirical studies on pharmaceutical regulatory service quality. The findings of this study will provide information to policymakers and relevant stakeholders to develop strategies and put appropriate interventions to improve the regulatory service quality. Therefore, this study aimed to assess customers' perception of pharmaceutical regulatory service quality and associated factors in EFMHACA. More specifically, the study aimed to assess the perceived service quality by examining the discrepancy between customers' expectation and perception.

2. Materials and methods

Study area and period

The study was conducted in Addis Ababa, Ethiopia from March 30 to May 30, 2017. Addis Ababa is the diplomatic capital of the African Union and the capital city of Ethiopia. It has ten sub-cities and 116 districts. (24) The total population of Addis Ababa is about 3.2 million of which 52.6% are females. At the time of the study, the city had eight pharmaceutical manufacturers and 210 pharmaceutical importers. (25) EFMHACA, previously called Drug Administration and Control Authority, was established by the Council of Ministers Regulation No.189/2010 mandated to regulate food, medicine and healthcare services. It is the national regulatory authority under the Ministry of Health. During the study period, EFMHACA had eight technical and eight supportive directorates, seven branch offices and 18 entry and exit port offices operating in different parts of the country. (26)

Design

Cross-sectional study design was used among pharmaceutical importers in Addis Ababa, Ethiopia.

Sample size and sampling procedure

The sample size was determined using a single population proportion formula by considering 50% proportion at 95% confidence interval, 5% marginal error and 10% non-response rate. The final sample size was 149 pharmaceutical importers. Simple random sampling technique was employed to select the study participants. All pharmaceutical importers available in Addis Ababa were listed, and table of random numbers was used to randomly draw the required samples. From the study population, 131 pharmaceutical importers were selected for the study. The respondents were technical managers or regulatory affair experts working in the pharmaceutical importers who have frequent contact with EFMHACA.

Data collection tools, procedures, and quality assurance

The data were collected using a self-administered structured questionnaire. Before the actual data collection, the self-administered structured questionnaires were pre-tested on 5% randomly selected pharmaceutical importers who were excluded from the study, and necessary amendment was made. Four experienced pharmacists were recruited for data collection, and one-day training was given to data collectors on the study objectives, data collection procedures, data collection tools, respondents approach, data confidentiality and respondents' right before data collection date.

Data collection was done using the internationally renowned SERVQUAL five-dimension model. The original SERVQUAL 22 items were modified to suit the study relevant to the regulatory services. The SERVQUAL-type questions used in the pharmaceutical regulatory services was constructed by refining and paraphrasing in both wording and contextual applications as appropriate for this study. The questionnaires were designed in a five-point Likert scale format ranging from a "strongly disagree" with scale point 0 to a "strongly agree" with scale point 4. The instrument included 23 items for expectations and the same for perceptions. Thereby, the data were collected using the modified questions. The questionnaire included three parts. The first part related to customers' socio-demographic characteristics and the second part included 23 items each about customers' expectation and perception: four questions related to tangibility, five questions related to responsiveness, five questions related to reliability, four questions related to assurance and five questions related to empathy. A total of 149 questionnaires were distributed among the study participants.

Data management and analysis

Data were entered using the EPI-INFO version 7.2.1.0 statistical package and exported to SPSS version 23.0 for analysis. The collected data were checked for consistency and completeness before any attempt to data entry and analysis. Besides, discriminant validity was undertaken to test how well the measured variables represent the constructs based on procedures recommended by Hair et al. (2009). (27) Accordingly, the average variance extracted was greater than the correlation squared for each of the factors/constructs in pairs, hence discriminant validity is established. Descriptive statistics were used to measure respondents' socio-demographic characteristics, their expectation, and perception scores. To determine service quality gap, the mean scores of perception were subtracted from the mean scores of expectation. The relation between the dependent variable and independent variables was analyzed using sample paired t-test. The mean scores for the overall quality and its dimensions were calculated. The overall quality were dichotomized into poor quality (< 75%) and good quality (>75%). Multicollinearity among the independent variables was checked.

3. Results

Socio-demographic characteristics of the respondents

Of the 149 respondents, only 131 respondents have completed the questionnaire and used for further analysis, which is 88% usable response rate. The reasons for non-response might be time constraint and fear of giving sensitive information. The majority, 85 (64.9%) of the study participants were males, and 48 (36.6%) were aged above 35 years old. Hundred and twenty-eight (97.7%) respondents had a first degree and above, and more than three-fourth (98.5%) were pharmacists. More than half of the study participants (52.7%) were technical managers and almost half (45.8%) had less than five years of work experience (Table 1).

Table 1 Socio-demographic characteristics of study participants in Addis Ababa, 2017 (n=131).

Characteristics	Frequency (n)	Percentage (%)
Sex		
Male	85	64.9
Female	46	35.1
Age		
≤30	39	29.8
31-35	44	33.6
>35	48	36.6
Level of education		
TVET	1	0.8
Diploma	2	1.5
First degree and above	128	97.7
Profession		
Pharmacist	129	98.5
Druggist	2	1.5
Position level		
Technical Manager	69	52.7
Regulatory Affair Expert	62	47.3
Work Experience		
≤5 years	60	45.8

6-10 Years	49	37.4
>10 Years	22	16.8

Constructs reliability

Cronbach's Alpha Coefficient was measured to check the data reliability and internal consistency, and coefficients higher than 0.6 were considered as acceptable. (27,28) Values ranging from 0 to 1 with

higher values indicate greater reliability. The overall Cronbach's Alpha Coefficient for perception was 0.93 and for expectation was 0.96. The reliability of scale showed that the study is free from random error. The Cronbach's Alpha Coefficient indicated that there is acceptable reliability between all items (Table 2).

Table 2 Cronbach's Alpha scale for expectations and perceptions of the study participants, 2017 (n = 131)

Variables	Number of items	Expectations, α	Perceptions, α
Tangibility	4	0.811	0.794
Reliability	5	0.884	0.856
Responsiveness	5	0.842	0.741
Assurance	4	0.844	0.732
Empathy	5	0.842	0.827
Overall Cronbach's Alpha		0.96	0.93

Regulatory service quality dimensions

The perception mean scores were low. The lowest score predominantly came from customers' perception whereby it ranged from the lowest 1.23 to the highest

2.57 for each questionnaire statements. For customers' expectation, the mean score ranges from the lowest 3.14 to the highest 3.72 for each questionnaire statements. The expectations mean score was 3.433 ± 0.559 , and the perceptions mean score was 1.897 ± 0.61 (Table 3).

Table 3 Item wise expectations, perceptions and service quality gap in each dimension of the study participants, 2017 (n=131)

Statements	Expectation	Perception	P-E
	Mean \pm SD	Mean \pm SD	Mean \pm SD
Tangibility			
1. Have modern technology	3.72 \pm 0.611	1.76 \pm 1.126	-1.954 \pm 1.386
2. Physical facilities and materials are visually clean and appealing	3.65 \pm 0.655	2.13 \pm 1.011	-1.519 \pm 1.255
3. Employees are well dressed and neat in appearance	3.25 \pm 0.86	2.26 \pm 0.882	-0.992 \pm 1.106
4. Have up-to-date requirements or laws	3.54 \pm 0.777	2.22 \pm 1.062	-1.321 \pm 1.217
Reliability			
5. Show sincere interest in solving customer's problems	3.53 \pm 0.758	1.92 \pm 1.093	-1.603 \pm 1.492
6. Perform the service right the first time	3.25 \pm 0.931	1.61 \pm 0.873	-1.641 \pm 1.331
7. Provide services at the promised time	3.46 \pm 0.834	1.24 \pm 0.884	-2.221 \pm 1.366
8. Maintain error-free and fast retrieval of records	3.37 \pm 0.768	1.23 \pm 0.899	-2.145 \pm 1.348
9. Consider customers' suggestions and comments	3.46 \pm 0.825	1.89 \pm 1.01	-1.565 \pm 1.463
Responsiveness			
10. Inform customers when services will be performed	3.57 \pm 0.657	1.90 \pm 0.96	-1.672 \pm 1.280
11. Easy communication at EFMHACA	3.61 \pm 0.742	1.90 \pm 1.101	-1.710 \pm 1.378
12. Provide prompt services to customers	3.20 \pm 0.898	1.27 \pm 0.869	-1.924 \pm 1.316
13. Always willing to listen and help customers	3.53 \pm 0.778	2.02 \pm 0.928	-1.519 \pm 1.236
14. Readily do not respond to customers request	3.21 \pm 0.839	2.17 \pm 1.104	-1.038 \pm 1.475
Assurance			
15. Employees behavior able to instill confidence in customers	3.44 \pm 0.795	1.85 \pm 0.912	-1.580 \pm 1.252
16. Assure customers' confidentiality	3.53 \pm 0.705	2.07 \pm 0.95	-1.462 \pm 1.234
17. Employees are courteous	3.44 \pm 0.766	2.22 \pm 0.88	-1.214 \pm 1.222
18. Knowledge and skill to answer customers' questions	3.58 \pm 0.690	2.03 \pm 0.976	-1.550 \pm 1.217
Empathy			
19. Have convenient working hours	3.46 \pm 0.862	2.57 \pm 1.023	-0.885 \pm 1.311
20. Give individual and personal attention to all customers	3.39 \pm 0.770	1.77 \pm 0.933	-1.618 \pm 1.255
21. Employees are caring to deal with customer's requests	3.40 \pm 0.688	1.95 \pm 0.919	-1.450 \pm 1.172
22. Employees have customers best interests at heart	3.14 \pm 0.951	1.76 \pm 0.869	-1.382 \pm 1.356

23. Employees understand customer's specific needs	3.27±0.795	1.92±0.945	-1.359±1.345
Overall quality gap	3.43±0.559	1.897±0.61	-1.536±0.051

The expectations mean score was higher than the perceptions mean score in all service quality dimensions. The highest expectation mean score belonged to responsiveness dimension (Mean=17.09±3.080), and the lowest mean score belonged to assurance dimension (Mean=13.98±2.445). In the perception, the highest mean score belonged to empathy (Mean=9.97±3.610), and the lowest mean score belonged to reliability (Mean=7.89±3.807) (Table 4).

Regulatory service quality gap

The gap mean scores for each questions and the service quality dimensions were computed by subtracting the expectation mean scores from the

Table 4 Mean ± SD score for customer's perceptions, expectations, and service quality gap for each service quality dimensions, 2017 (n=131)

Dimensions of service quality	Expectation	Perception	Service quality gap score (P-E)
	Mean ± SD	Mean ± SD	Mean ± SD
Tangibility	14.16±2.310	8.36±3.218	-5.80±3.856
Reliability	17.07±3.411	7.89±3.807	-9.18±5.949
Responsiveness	17.09±3.080	9.26±3.492	-7.83±5.193
Assurance	13.98±2.445	8.16±2.767	-5.82±3.938
Empathy	16.66±3.200	9.97±3.610	-6.69±5.097

SD = Standard Deviation, P= Perceptions, E= Expectations

Factors associated with service quality

The difference between the regulatory service quality expectation and perception was negative since the perception mean score (Mean=1.897) was smaller than the corresponding expectation mean score (Mean=3.433). This negative gap was because all the perception scores were smaller than the corresponding expectation scores. However, this requires statistical proof to examine whether these gaps are truly significant

Table 5 Paired sample t-test and expectation and perception mean scores of customers, 2017 (n = 131)

Paired variables	Mean score		Paired Differences		t	P
	Expectation	Perception	Mean	Std. Deviation		
Tangibility	14.16	8.36	-5.8015	3.8559	-17.221	0.000
Reliability	17.07	7.89	-9.176	5.949	-17.653	0.000
Responsiveness	17.09	9.26	-7.832	5.193	-17.261	0.000
Assurance	13.98	8.16	-5.817	3.938	-16.908	0.000
Empathy	16.66	9.97	-6.695	5.097	-15.032	0.000

4. Discussion

The present study assessed customers' perception of EFMHACA's pharmaceutical regulatory service quality. This study found out that the pharmaceutical regulatory service quality was low. There was a negative regulatory service quality gap in all the five quality dimensions. The findings corroborated that customer expectations were much higher than customer perceptions. This was

perception mean scores. The findings indicated that there were negative service quality gaps in all the five SERVQUAL dimensions. The lowest service quality gap was in tangibility dimension (Mean= -5.80 ± 3.856), and the highest was in the reliability dimension (Mean= -9.18 ± 5.949). These showed that there was -1.536 an overall service quality shortfall (Table 4).

In this study, the regulatory service quality status of EFMHACA has categorized into poor and good services. The study showed that 90.1% of customers expected good service quality. However, 78.6% of the customers agreed that the regulatory service quality provided was "poor" and 21.4% was good service quality in the Authority.

or not. Paired sample t-test was used to check the statistical significance between the customers' expectation and perception. It was observed from the paired sample t-test that the gap between customer expectation and perception concerning EFMHACA's pharmaceutical regulatory service quality was statistically significant ($t = -19.047, p < 0.05$). There was a significant difference ($M = -35.321$) between customers' expectation (Mean=3.433) and perception (Mean=1.897) on the regulatory service quality (Table 5).

almost similar to studies conducted in Europe and Mauritius. (18,29,30)

This study revealed that the expectation means score regarding EFMHACA's pharmaceutical regulatory service quality was 3.433. This can be considered 'moderately high' which is similar to studies done in Iran and Bangladesh. (12,31,32) This is naturally because people generally have high needs and expectations for service quality. However, the

perceptions mean score concerning EFMHACA's pharmaceutical regulatory service quality was 1.897. The low perception means score indicated that the respondents might not experience appropriate regulatory service quality from EFMHACA. This might be because the authority could not manage its regulatory services as per the promise is given in the citizen charter.

The study showed that there was a negative overall pharmaceutical regulatory service quality gap in the five service quality dimensions. Customer expectations were beyond their perceptions on the EFMHACA's pharmaceutical regulatory service quality. The regulatory service quality gap between the perceptions and expectations was found to be -1.536. Besides, the perception mean scores in all the statements were smaller than the corresponding expectation mean scores, and the gaps were negative for all the items. This finding indicated that the respondents' perception did not match with their expectation. This was almost in congruence with studies done in Iran. (32,33)

The highest regulatory service quality gap was observed in reliability, responsiveness and empathy dimensions respectively, and the lowest service quality gap was in tangibility dimension followed by assurance dimension. This result was in line with studies done in Korea and Mauritius. (30,34,35) To the contrary, a study conducted in Greece reported that empathy produced the highest service quality gap followed by tangibility and assurance dimensions. Responsiveness and reliability were with the smallest service quality gaps. (16) This might be due to the differences in study design and setting. This was similar to studies conducted in Iran. (29,32,36) The negative regulatory service quality gaps showed that there were opportunities existed for the managers to improve its services.

In the current study, the mean score of expectations was higher than the mean score of perceptions of all the service quality dimensions. The highest expectations mean score belonged to reliability and responsiveness, and the lowest mean score belonged to assurance. In the perception, the highest mean score belonged to empathy, and the lowest mean score belonged to reliability. This was similar to a study conducted in Iran which reported that highest perception was in assurance dimension and highest expectation was in responsiveness and assurance dimensions.

The observed higher service quality gap in the reliability dimension might be due to the lack of service provisions at the promised time and lack of performing services right the first time. Moreover, the gap in maintaining error-free records, irretrievable and loss of applicants' documents were other reasons. This might be due to the lack of systems to trace and track internal procedures, poor information handling system and not abiding by the processing timelines set by the Authority. The higher service quality gap on responsiveness might be due to the fact that most employees were not willing to inform customers when the services will be performed and how the customers will comply with requirements; customers did not receive services promptly, and it was not easy for customers to communicate with employees.

The lack of appropriate explanations on what specific decisions made for the services requested by customers was another pitfall. These findings substantiated that the managers of the authority should provide the pharmaceutical regulatory services by ensuring accountability and transparency among its employees. Information on regulatory services and decisions made should be available and accessible to the customers. (19,37)

The lowest service quality gap was related to tangibility dimensions. This might be due to the fact that the authority's managers have relatively emphasized to physical aspects and infrastructures such as up-to-date regulatory requirements and laws, modern technology and up-to-date equipment and procedures; and enhancing visually clean and appealing physical facilities and materials. This finding is almost in line with studies conducted in Singapore and Malaysia. (38)

Service quality is the most common concerns of customers in service providers. Unless necessary care is given to customers, it may lead to a high risk for providers' viability. Service providers ought to take customer needs into account. The voices of customers are effective in quality improvement measures and provide managers with an opportunity for organizational learning and development. (39,40) EFMHACA's managers are encouraged to build trust with customers if they want to maintain their viability. To achieve competitive advantages, the managers must keep improving the service from time to time to make sure that level of service quality is at an optimum level and create an impact on customer's future behavioral intention.

Customers' feedbacks are essential elements in planning and policy-making that aids the managers in better and effective services management. Furthermore, the managers should provide training and behavioral change courses for all staffs to enhance their skills in communication, customer handling, information handling and timely service delivery.

5. Conclusion

The study showed that there are service quality gaps in the pharmaceutical regulatory services in all the service quality dimensions. The negative gap between expectations and perceptions indicated that customers' perception of the current situation is far lower than their expectations. Furthermore, the negative service quality gap was not similar in all the quality dimensions. The greatest pharmaceutical regulatory service quality gap belonged to reliability and responsiveness, and the lowest service quality gap belonged to tangibility and assurance dimensions. These challenging situations might jeopardize the viability of the authority's managers in protecting the public health.

Pharmaceutical regulatory service reform is needed across all the five service quality constructs. The Authority's managers should reform the delivery of its services considering the needs and expectations of customers. Improving the ability to perform the promised services dependably and accurately and

willingness to help customers and provide prompt service is not negotiable.

Implementation of quality management systems and regulatory information handling systems with automation support will pave the way to blossom the pharmaceutical regulatory service quality in the Authority. Proper planning and effective systems to implement customer service handling are also important to foster success in improving the regulatory service quality. The regulatory review processes, inspection and assessment results, and other regulatory decision results, aside from confidential information, should be publicly available. In addition, the estimated processing timelines set in the citizen charter should be followed. Otherwise the managers need to revise the processing times based on the best experiences.

6. Declaration

Ethics approval and consent to participate

The study was approved by Leadstar University College, and official permission was obtained from EFMHACA. Written consent was taken from study participants after telling the study objectives. All the respondents were voluntarily participated in the study and confidentiality of the study participants' related data was maintained by avoiding possible identifiers. Finally, the collected data were kept in a safe place and were accessible only to the research team.

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Availability of data and materials

The data set supporting the conclusions of this article are available in the manuscript.

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Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

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