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EBHPME 2020; 4(3): 197-208 pISSN: 2538-5070

EBHPME

ORIGINAL ARTICLE

Evidence Based Health Policy, Management & Economics
Health Policy Research Center, Shahid Sadoughi University of Medical Sciences

Evaluation of Transparency to Improve Good Governance in Pharmaceutical Regulatory Sector of Iran

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ARTICLEINFO

Article History:
Received: 7 Jun 2020
Revised: 28 Jul 2020
Accepted: 29 Aug 2020

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ABSTRACT

Background: Improving good governance in the pharmaceutical sector is a valuable priority for improving access to essential medicines. Transparency as a means for good governance was the focus of this study. The objective was to evaluate different sectors of the pharmaceutical regulatory sector of Iran from the aspect of transparency. Awareness of the current situation may assist policymakers in making the right decisions.
Methods: The aim of this methodology was to present only quantitative measurement but to gather qualitative information as well. The study was carried from November 2016 to July 2017. The questionnaires of the assessment instrument, which the World Health Organization (WHO) produced for measuring transparency in the public pharmaceutical sector, was used. The interviewees were among managers and staff at different levels of the Food and Drug Administration (IFDA) of Iran and its clients.
Results: Medicines registration and distribution of medicines' scores in the 10-point rating system means that they are minimally vulnerable to corruption. Besides, medicine promotion control and procurement of medical products got an acceptable score, which means that they are marginally vulnerable to corruption. On the other hand, qualitative findings and observation of the evidence presented by key informants proved the sufficient legal capacity for transparency in almost all sections. The controversial issue was the 'conflict of interests,' which was not anticipated in some cases.
Conclusion: It is valuable to know if Iran's medicine regulatory sector is transparent In order to improve good governance, transparency should be maximized in all sectors, and this is possible by implementing mechanized actions and online tools.

Key words: Pharmacy administration, Drug and narcotic control, Evaluation, Pharmacoeconomics, Iran

Citation

This paper should be cited as: Herandi Y, Nikfar Sh, Bouzarjomehri H, Abdollahiasl A. **Evaluation of Transparency to Improve Good Governance in Pharmaceutical Regulatory Sector of Iran.** Evidence Based Health Policy, Management & Economics. 2020; 4(3): 197-208.

[Downloaded from jebhpme.ssu.ac.ir on 2026-11-22]

[DOI: 10.18502/jebhpme.v4i3.4166]

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Introduction

Several reasons explain the significance of transparency in the pharmaceutical sector. Firstly, greater transparency facilitates the transition to safer, more productive, and more humane healthcare (1). Secondly, the lack of transparency always gives the impression that something is being hidden (2) and reduces public trust. Besides, the pharmaceutical sector is highly vulnerable to be corrupted(3), which can be prevented through transparency. Lack of transparency in this sector wastes resources and reduces the availability of essential medicines. Therefore, it put public health at risk (4). All the functions should be free from unethical practices to assure that patients have the necessary medicine and that the medicine is safe, of satisfactory quality, fairly priced, and free of undue commercial influence (5). Furthermore, corruption reduces the credibility of the health profession and vanishes public trust (6), but transparency can help to reduce corruption (7). Ultimately, transparent and strong pharmaceutical systems can leadto improving the access to pharmaceuticals (8).

Promoting good governance in the pharmaceutical sector necessitates a long-term strategy (9). One way to promote good governance is to improve transparency. One of the most important actions that can improve transparency is to measure it. Therefore, the World Health Organization (WHO) has provided a tool for measuring transparency in eight sections of the pharmaceutical sector to promote good governance (5). Some countries, like Bolivia, Cambodia, Indonesia, Jordan, Kenya, Kuwait, Malaysia, Oman, Pakistan, Palestine, Philippines, Syria, and Thailand, have measured the transparency level in their pharmaceutical sector due to this assessment tool (9-12).

Utilizing this assessment instrument can help the countries to identify vulnerable aspects which may lead to corrupted and unethical practices (13). Thus, any shortage or strength is recognized for future studies or actions(14). As there is no published study on this issue in Iran, the present study intends to assess four sections of Iran's pharmaceutical sector from the perspective of transparency.

Materials and Methods

The present survey was conducted using the method suggested by the World Health Organization (WHO). This assessment was intended to give a picture of the level of transparency and vulnerability to corruption in the procedures and structures of eight functions of the pharmaceutical sector, namely registration of medicines, licensing of the pharmaceutical business, an inspection of establishments, medicine promotion, clinical trials, selection of essential medicines, procurement of medicines and distribution of medicines. However, all of them are crucial government functions, but only medicines registration, medicine promotion control, procurement of medical products, and distribution of medicines were evaluated in this study.

The aim of this methodology was to present only quantitative measurement but to gather qualitative information by interviewing key informants (KIs) using a set of questionnaires. Due to the assessment instrument, semi-structured interviews were conducted from November 2016 to July 2017. The interviewees were among managers and staff at different levels of the Food and Drug Organization of Iran and its clients, since this organization is the pharmaceutical regulatory department of Iran. The interviews were arranged by calling the KIs and they were prepared with the questions and also assured about the confidentiality.

Four types of questions were used. Although, only two types were used to score the level of transparency for each function, and they were given equal weight in the final scoring. The third type allowed the comparison of existing legal provisions or administrative structures and procedures with their level of application. The last type used open-ended questions to seize

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[DOI: 10.18502/jebhpme.v4i3.4166]

additional information.

In the first type of questions, which assessed the knowledge of KI about availability of documents, the ″yes″ answer implied the existence of a document and was equal to value of 1, and the ″no″ answer implied the document does not exist and was equal to value of 0. A value of 1 revealed low vulnerability to corruption. The value of 0 presented high vulnerability to corruption.

The second type of question involved a set of criteria or sub-questions. Eachcriteria required a binary answer (yes/no). Repeatedly, a ″yes″ was equal to value of 1, and a ″no″ was equal to a value of 0. ″D.K.″ (Do not Know) implied that the KI did not know the answer. The final score for each indicator was the total of ″yes″ responses divided by the total number of valid answers.

In this type of rating, the score for each indicator was between 1 and 0. If the majority of answers of a KI was "D.K.", then this KI was regarded as invalid and was excluded from the final scoring.

The third type of questions examined KIs′ perceptions, which provides important insight into the transparency level of each sector.

Using the Likert scale, the questions began with a statement, and then, the KI was asked whether they strongly agree - agree- is undecided - disagree or strongly disagree.

The last type of questions were open questions which requested additional information in general from KIs. The answers to these questions were not used in scoring the functions. However, they were valuable qualitative information, since they could confirm findings from other types of questions (5).

Scoring

After completing the interviews, a score was calculated for each of the functions. This scoring was done due to the first and second types of questions. The average rating for each indicator was calculated by adding all the rates, then dividing the total by the number of valid answers.

In the next step, the sum of average ratings was divided by the number of indicators in each function so that the percentage of indicators rated as 1 was obtained. Subsequently, the result was converted to a 0 to 10 scale.

Using the WHO assessment instrument (The underlying hypothesis of this instrument is the reverse relationship between transparency and vulnerability to corruption), degrees of vulnerability to corruption are described in Table 1 (5).

As a reflexivity declaration, two authors, Associate Professor ShekoufehNikfar and Assistant Professor Akbar Abdollahiasl hold positions at the Food and Drug Organisation of Iran. However, they were not the assessors of this evaluation and had anonymous access to the answer sheets.

The authors declare that they have complied with the principles of the Helsinki Declaration.

Table 1. Degrees of vulnerability to corruption

Score	0.0—2.0	2.1—4.0	4.1—6.0	6.1—8.0	8.1—10.0
Vulnerability to corruption	Extremely vulnerable	Very vulnerable	Moderately vulnerable	Marginally vulnerable	Minimally vulnerable

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Results

When the saturation point was reached due to the goal of the study, no more interviews were taken. The number of interviews for each sector is demonstrated in Table 2.

Among the interviewees were chief executive officers (CEOs) of distribution companies, officers of social security organizations, heads of Food and Drug Organization in some cities, assistant professors and associate professors of Tehran University of Medical Sciences and Shahid Beheshti University of Medical Sciences, heads of departments within Food and Drug Organization, owners of drugstores, CEOs of pharmaceutical companies and employees of the procurement department of Food and Drug Organization. Table 3 indicatesC the total score obtained from interviews for each section.

In the 10-point rating scale, the total score for the medicine registration section is 8.5, which means it is minimally vulnerable to corruption or is at a maximum transparency level. Total scores for other sections demonstrate that they are marginally vulnerable to corruption or are at almost a good transparency level.

However, the qualitative information obtained in this study and the evidence observed by the assessor were more valuable to make a reasonable conclusion about transparency capacities in the pharmaceutical regulatory sector of Iran. Most of the interviewees agreed that gifts or benefits do not influence the decision-making of medicine registration officials, and all of them strongly agreed that the medicines registration committee meets regularly. All of the KIs agreed that decisions of the tender committee are considered in the procurement process, and the members of the committee are chosen according to specific criteria and the procurement system of Iran, transparently. Most of the KIs agreed that port clearing is done smoothly without any bribery or gift-giving for facilitating the process, but KIs did not approve that leakages in the medicine distribution system of Iran are very rare. Key informants had different opinions about developing legal provisions by consulting all the interested groups. Promotional and advertising materials require a pre-approval before becoming public. Civil society/ nongovernmental organizations improved the control of medicine promotion, and sanctions are applied in case of a breach.

More details of the findings, which describe the strengths and weaknesses of the system in each sector, is demonstratedin the following tables.

Table 2. Number of Interviews for each sector

Sector	Medicines registration	Medicine promotion control	Procurement of medical products	Distribution of medicines	Total
Number of interviews	5	5	4	7	21

Table 3. Total score for each sector

Section	Medicines registration	Medicine promotion control	Procurement of medicines	Distribution of medicines
Total score (in the 10-point rating scale)	8.5	6.8	6.7	7.8

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Table 4. Medicines registration

Key informants' answers Questions	KI 1	KI 2	KI 3	KI 4	KI 5	Average	Standard deviation
1. Is there an up-to-date list of all registered pharmaceutical products available in the country?	1	1	1	1	1	1.00	0.00
2. If such a list exists, does it provide a minimum level of information?	0.85	0.71	1	1	1	0.91	0.13
3. Are there written procedures for applicants on how to apply for registration of medicinal products?	1	1	1	1	1	1.00	0.00
4. Are there written procedures for assessors on how to assess applications submitted for registration of medicinal products?	0.83	1	1	0.83	0.83	0.90	0.09
5. Is there a standard application form publicly available for the submission of applications for registration of medicinal products?	1	1	1	1	1	1.00	0.00
6. Are there written guidelines' set limits on how and where medicines registration officers meet with applicants?	1	1	1		1	1.00	0.00
7. Is there a functioning formal committee responsible for assessing applications for registration of pharmaceutical products?	1	1	1	1	1	1.00	0.00
8. Are there clear written criteria for selecting the members of the committee?	1	0.8	1	1	0.8	0.92	0.11
9. Is there a written document that describes the composition and terms of reference of the committee?	0.75	0.62	1	1	0.57	0.79	0.20
10. Are there written guidelines on conflict of interest (COI) concerning registration activities?	0.66	0	0.85		0.42	0.48	0.37
11. To what extent do you agree with the following statement: "The members of the registration committee are systematically and objectively selected based on the written criteria in force in your country"? (See question 8)	Agree	Agree	Agree	Agree	Agree		
12. Are there clear and comprehensive guidelines for the committee's decision-making process?	0.75	0	0.75		0.12	0.41	0.40
13. Is there a formal appeals system for applicants who have their medicine applications rejected?	1	1	1	1	0	0.80	0.45

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Key informants' answers Questions	KI 1	KI 2	KI 3	KI 4	KI 5	Average	Standard deviation
14. To what extent do you agree with the following statement: "Gifts and other benefits that are given to the officials in charge of medicines registration does not influence the final decisions"?	Strongly agree	Disagree	Strongly agree	Agree	Disagree		
15. To what extent do you agree with the following statement: "The registration committee meets regularly and keeps minutes for its meetings"?	Strongly agree	Strongly agree	Strongly agree	Strongly agree	Strongly agree		
16. In your opinion, what types of unethical behavior are common in the registration system in your country?	▪ Lack of unity of procedure in the decisions of the Construction and Entry Commission, ▪ Lack of transparency about the conflict of interest, ▪ Existence of unrelated people behind the scenes of companies						
17. If you were in a position of the highest authority, what would be the first action that you would take to improve the registration process in your country?	Inscribing instructions to the Construction and Entry Commission						
Total score						0.85	

Table 5. Medicine promotion control

Key informants' answers Questions	KI 1	KI 2	KI 3	KI 4	Average	Standard deviation
1. Is there a provision in the medicines legislation/regulations covering medicine promotion and advertising?	1	1	1	1	1.00	0.00
2. Do the provisions on medicine promotion and advertising include explicit mentioning of the following forms of promotion?	0.55	0.85	0.7	0.9	0.75	0.16
3. Is the pre-approval of promotional and advertising materials officially required?	0		1	0.87	0.62	0.54
4. Do the provisions foresee an enforcement mechanism on promotion and advertisement of medicines, and stating the sanctions in cases of violation?	1	1	1	1	1.00	0.00
5. Is there a formal complaints procedure to report unethical promotional practices?	0.25		0.75		0.50	0.35
6. Is there a service or committee responsible for monitoring and enforcing the provisions on medicine promotion?	1	1	1	1	1.00	0.00
7. Are there clear criteria for selecting the members of the service/committee?			1	0	0.50	0.71

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Key informants' answers Questions	KI 1	KI 2	KI 3	KI 4	Average	Standard deviation
8. Is there a written document that describes the composition and terms of reference of the service/committee?			1	0	0.50	0.71
9. Are there written and publicly available Standard Operating Procedures (SOPs) guiding the services responsible for pre-approving or monitoring medicine promotion and advertising?	0		1	1	0.67	0.58
10. Are there written guidelines on conflicts of interest (COI) concerningthe control of medicine promotion activities? If so:	0	0	1	0	0.25	0.50
11. To what extent do you agree with the following statement: "The legal provisions on medicine promotion have been developed in broad consultation with all interested parties"?	Disagree	Disagree	Strongly Agree	Agree		
12. To what extent do you agree with the following statement: "Pre-approval of promotional and advertising materials are systematically obtained before they are made public"?	Disagree	Undecided	Agree	Agree		
13. To what extent do you agree with the following statement: "Civil society/nongovernmental organizations have a great influence on improving the control of medicine promotion in your country"?	Strongly disagree	Disagree	Disagree	Strongly agree		
14. To what extent do you agree with the following statement: "Sanctions foreseen in the provisions on medicine promotion are systematically applied when there is a breach"?	Agree	Disagree	Agree	Disagree		
15. In your opinion, what types of unethical behavior are common in the medicine promotion area in your country? – Involving health professionals and health institutions in general – Involving regulatory office staff and committee members responsible for controlling medicine promotion	Inductive demand, Unusual gifts, Demolishing rival medicines, Informal relationships of specialists and companies, Lack of sufficient education for medical representatives, Conflict of interest					
16. If you were in a position of the highest authority, what would be the first action that you would take to improve the medicine promotion process in your country?	Launching an independent monitoring section					
Total score					0.68	

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Table 6. Procurement of medicines

Key informants' answers Questions	KI 1	KI 2	KI 3	KI 4	Average	Standard Deviation
1. Does the government use transparent and explicit procedures for the procurement of pharmaceutical products?	0.25	1	1	0.75	0.75	0.35
2. Is there written guidance for procurement office staff on the type of procurement method to be used for different types of products?	0	1	0	1	0.50	0.58
3. Is procurement done with an objective quantification method to determine the number of pharmaceuticals to be purchased?	0	1	1	1	0.75	0.50
4. Is there a formal appeals process for applicants who have their bids rejected?	1	1		1	1.00	0.00
5. Is there a tender committee (TC)? If so, are the key functions of the procurement office and those of the tender committee separated?	0	1	1	1	0.75	0.50
6. To what extent do you agree with the following statement: "Decisions of the tender committee are always taken into account in the procurement process"?		Strongly Agree	Strongly Agree	Agree		
7. Are there specific criteria for tender committee membership?		0.87	0.42	0.5	0.60	0.24
8. Are there written guidelines on conflicts of interest (COI) with regard to the procurement process?	0.12	0		0.44	0.19	0.23
9. To what extent do you agree with the following statement: "The members of the tender committee are systematically selected based on specific criteria (see question No. 7)"?		Strongly Agree	Strongly Agree	Agree		
10. Is there a computerized management information system used to report product problems in procurement?	0.57	1	1	0.57	0.79	0.25
11. Are there Standard Operating Procedures (SOPs) for the routine inspection of consignments?	0.75	1	1	0.5	0.81	0.24
12. Is there an efficient post-tender system in place to monitor and report on suppliers' performance to the tender committee?		1	1	0.33	0.78	0.39
13. Does the procurement office undergo regular audits?	0.2	0.5	1	0.16	0.47	0.39
14. To what extent do you agree with the following statement: "The procurement system in your country is operating transparently"?	Agree	Strongly agree	Strongly agree	Agree		
15. In your opinion, what types of unethical behavior are common in the procurement system in your country?	Favoritism and conflict of interest in limited cases					
16. If you were in a position of the highest authority, what would be the first action that you would take to improve the systems and processes of procurement?	Decreasing the supply time, Promoting human resources					
Total score					0.67	

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Table 7. Distribution of medicines

Key informants' answers Questions	KI 1	KI 2	KI 3	KI 4	KI 5	KI 6	KI 7	Average	Standard deviation
1. Is there a system in place that can expedite port clearing?	1	1		1	0	1	1	0.83	0.41
2. To what extent do you agree with the following statement: "port clearing is done smoothly, and there is no need for bribery or gift-giving to expedite the process."	Agree	Agree	Undecided	Strongly agree	Disagree	Undecided	Agree		
3. Is there an inspection system to verify that the medicines delivered from the port or directly from a supplier match those that were shipped from the supplier?	0.75	1	0.75	1	1	1	0	0.79	0.37
4. Is there a coding system used to identify government medicines?	1	1	1	1	1	1	1	1.00	0.00
5 Is there systematic and orderly shelving of products in warehouses or storerooms?	1	1	0.66	1	0.66	0.66	1	0.85	0.18
6. Is there a security management system in place to oversee storage and distribution?	1	1	0.83	1	0.66	0.66	1	0.88	0.16
7. Are there SOP for stock management at each level of the distribution system?	0	1	1	1	1	0	1	0.71	0.49
8. Is there an inventory management system at each level of the distribution system that provides information, as a minimum, on the following elements?	1	1	0.85	1	1	0.57	1	0.92	0.16
9. Are stock records reconciled with physical counts at least every three months by internal staff?	0	0	0	1	0	1		0.33	0.52
10. Are there independent audits of warehouses by external inspectors or auditors?	0	1	1	1	1	1	0	0.71	0.49
11. Is there a system (computerized or manual, historical or current) in place to track the movement of pharmaceuticals from a warehouse to a health	1	1	1	1	1	1	1	1.00	0.00

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Key informants' answers Questions	KI 1	KI 2	KI 3	KI 4	KI 5	KI 6	KI 7	Average	Standard deviation
facility, which provides the following information for medicines that have taken out of the warehouse?									
12. Does the health facility have an appropriate procedure for requesting medicines?	0	1	0.8	1	1	0	1	0.69	0.47
13. Are there appropriate written guidelines on transportation and delivery of the medicines from/to the warehouse?	0.5	1	1	1	1	1	1	0.93	0.19
14. Is there a well-functioning communication system for ordering, reordering, and complaints between the suppliers and the end-users?	0	0	1	1	1	0	1	0.57	0.53
15. Does a program exist for monitoring and evaluating the performance of the medicine distribution system?	0.42	0.85	0.57	1	0.85	1	0	0.67	0.37
16. Are sanctions imposed on individuals or agencies/companies for theft or corrupt practices associated with distribution?	0.33	0.66	0.66	1	0.33	0.33	1	0.62	0.30
17. Does the MS/health facility have appropriate procedures for the disposal of expired or spoiled medicines?	0.75	1	1	1	1	1	1	0.96	0.09
18. To what extent do you agree with the following statement: "there are very rare leakages in the medicine distribution system in your country."	Disagree	Undecided	Agree	Strongly agree	Agree	Disagree	Disagree		
19. If you were in a position of the highest authority, what would be the first action that you would take to improve the systems and processes of public sector medicine distribution in your country?	Completion of the T-TAC system, Revision of provincial share, Online access to the inventory of distribution companies, Employing NGOs to make changes, Quest for support from other administrations such as the Ministry of Roads and Urban Development or the Ministry of Industry								
Total score								0.78	

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[DOI: 10.18502/jebhpme.v4i3.4166]

Discussion

Assessing the level of transparency as a means of good governance was the focus of this study. To achieve this goal, the Food and Drug Organization, which is the pharmaceutical regulatory sector of Iran, was evaluated.

While interviewing the key informants, it was found out that all of the bureaucracies of this process are based on standard operating procedures (SOPs), which are published on the official website of this organization.The existence of laws and regulations discussed in the questionnaires of the WHO assessment instrument in Iran was the reason for the good points that all four sectors gained.The key informants repeatedly mentioned that utilizing online capacities to supervise the processes can lead to a more transparent system. On the contrary, lack of adequate modern legal provision, standard operation procedures (SOPs), written criteria for recruiting employees in certain committees were weaknesses of some other countries like Palestine (15). The most frequent weakness of Iran, which was expressed by key informants, was a conflict of interest in some responsible commissions. However, in the present assessment,the transparency level of all evaluated sectors was more satisfying than the other countries. The Gaza Strip report, compares the total score for each sector in the countries that assessed the transparency level of their pharmaceutical sector and can give a good comparing view of their positions (15).

Most of these countries had common strengths and weaknesses. For example, countries such as Laos, Malaysia, Philippines, and Thailand had clear guidelines for providing medicines, but none of them asked the members of the medicine registration and selection committees to complete the form of conflict of interest (6). Lack of transparency in the conflict of interest is also the common point of these countries with Iran. However, in Iran, the completion of a conflict of interest form for members of the relevant commissions is an obligation.

A remarkable point in the two reports of 2009 and 2006, as well as other similar reports (The Jordanian article in 2009 (4) and the Nigerian article in 2007 (16)), is the selection of a few areas of the eight WHO proposed areas for review, which represents that a great deal of time required for examining each of the eight areas. In this study, the areas of medicines registration, medicine promotion control, procurement of medical products, and distribution of medicines were evaluated. The other limitation of the study was restricting the interviewees to managers, employees, and costumers of the Food and Drug Organization of Iran.

Conclusion

To conclude, the four sectors were found to be transparent to a good degree due to the existence of written guidelines and SOPs in all sectors. Specially in medicine's registration and distribution of medicines which rated great scores and did not have significant legal gaps. The transparency can be maximized in these sectors by utilizing online capacities to follow up on the implementation of available instructions. It is also necessary to take steps toward the disclosure of conflicts of interest, in order to make the decision-making of the committees more transparent.

Acknowledgments

The authors would like to acknowledge the interviewees for their time and cooperation and to thank Transparency for Iran think tank group for their expert advice and encouragement and other people who helped throughout this study.

Conflict of interests

There was no conflict of interests in this study.

Authors' contributions

Bouzarjomehri H, Herandi Y, and Nikfar S designed research; Bouzarjomehri H, Herandi Y, Nikfar S and Abdollahiasl A conducted research; Herandi Y analyzed data; and Herandi Y and Bouzarjomehri H wrote manuscript. Herandi Y had primary responsibility for final content. All authors read and approved the final manuscript.

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[DOI: 10.18502/jebhpme.v4i3.4166]

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