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Original Article

From generic scheme to brand-generic scheme: Have new policy influenced the efficiency of Iranian pharmaceutical companies?

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ABSTRACT

Objective: Brand-generic scheme was implemented in Iran to improve the competition in the pharmaceutical market. In this study, we aim to assess if this policy had any positive effect on efficiency of Iranian pharmaceutical companies.

Methods: We used data envelopment analysis to evaluate the relative efficiency of pharmaceutical companies during 1999-2008. The Wilcoxon matched-pairs signed-rank and sign tests were used to assess the difference between mean technical efficiency of companies before and after implementation of the new policy.

Findings: Although the Wilcoxon matched-pairs signed-rank tests did not show any significant differences in favor of the new policy in terms of both relative and pure (managerial) technical efficiency for included companies (P = 0.079 and 0.07, respectively), but the one-sided sign test indicated that only relative pure (managerial) efficiency has been improved after this policy (P = 0.031).

Conclusion: The "brand-generic scheme" does not seem to be a successful policy to improve efficiency level and prompt competition in pharmaceutical companies in Iran. To achieve this aim, consideration of infrastructural requirements including transparent and non-discriminating laws and regulations to support competition, the competitive pricing policies, the presence of international companies in the market, and full privatization of companies had to be also deeming by policy makers.

Keywords: Data envelopment analysis; efficiency; Iran; pharmaceutical

INTRODUCTION

Pharmaceutical industry in Iran has experienced two main policies during past decades. First, in 1981-2 years after Islamic revolution - The "generic scheme" was implemented by Ministry of Health as a plan under Iranian National Drug Policy[1] to support accessibility to medicines for the population.[2] In this scheme, all pharmaceutical companies (most of them were state-owned) were obligated to produce and market their products only by generic names and with a unique price determined by government for the same products of all companies.[3] Pharmaceutical industry enjoyed especial support of government including lower currency rate (than the free market) to the companies for importing pharmaceutical ingredients as well as expedients, packaging materials, and technologies.[4] This scheme although had some gains especially in terms of accessibility

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and affordability[5] and also gradual development of domestic infrastructures including human resource,[6] but raised concerns about quality of domestic medicines and lack of innovation most probably associated with uncompetitive environment of the market, therefore, many experts believed that this scheme was only beneficial during the Iran-Iraq war period (1980-1988). In the postwar period, new pharmaceutical manufacturing sites had been established, and the old ones reconstructed (totally more than 70 companies), in which the old policy could not be appropriate anymore due to the enhancement in capacity of production and need for sale competition. To make the pharmaceutical market more competitive, the "generic-brand scheme" was introduced in 2000[7] and enforced during 2002-2004 in which companies could differentiate their products by a distinctive generic-brand name from the other companies'. This new strategy has shown promising achievements at the "industry level" including considerable growth of market and more investment in it.[8,9] In this study, we aim to explore the positive and negative consequences of this policy at the "company level." As there are many evidences supporting the association between competition and efficiency improvement[10-12], in this research we took efficiency as a proxy for the existence of competition in the market and with this basic approach in mind, we evaluated whether or not this new policy had any positive effect on efficiency of Iranian pharmaceutical companies.

METHODS

To evaluate the efficiency of Iranian pharmaceutical companies and compare it before and after implementation of the new policy, we used data envelopment analysis (DEA). DEA is a nonparametric method based on linear programming, for calculation of relative technical efficiency among organizations or firms which are called decision making units (DMUs).[13] In DEA, an efficiency frontier would be built based on multiple inputs and outputs using linear programming methods and then investigated DMUs would be categorized as efficient or non-efficient based on being on or under the frontier, respectively.[14] It means that DMUs which are on the frontier are producing either maximum outputs for a set of inputs or minimizing inputs for a set of outputs. For each DMU, two technical efficiency measures including the relative technical efficiency or constant return to scale technical efficiency (crste) and pure technical efficiency or variable return to scale technical efficiency (vrste)-sometimes is called managerial efficiency-would be estimated and presented by scores between 0 and 1, in which 1 means that a DMU is relative efficient. Then the scale efficiency of each DMUs would be calculated by dividing crste to vrste and using that, they would be categorized to increasing return to scale (irs), decreasing return to scale and constant return to scale (crs). Accordingly, a DMU is called irs, if a proportionate increase in its input ends up with a greater increase in its output.

Knowing the importance of selecting variables as inputs and outputs in DEA, a panel from the experts in the pharmaceutical industry (financial managers and manager directors) was performed, and all variables which could be accessible from financial statements of the companies were evaluated by them. Finally, "total assets" and "capital stock" as inputs and "net sales" and "net profit" as outputs were selected to be included in the analysis. The inclusion criteria for selecting pharmaceutical companies as DMUs were: (1) Finished product manufacturer; (2) listed in Tehran stock exchange (TSE) for accessing to reliable disclosed financial statements; (3) having available data from 1999 to 2008 (5 years before and after policy enforcement) as the time period of study. The exclusion criteria included active pharmaceutical ingredients producers, contract manufacturing companies, and also importer firms. Considering these inclusion and exclusion criteria, 21 companies were included in our analysis. The data of each company were extracted from the "balance sheet" and "profit and loss statement" and also other financial statements of each company in TSE database[15] for the fiscal years 1999-2008.

The relative technical efficiency, pure technical efficiency, and scale efficiency of each company, was calculated applying input-oriented DEA using deep 2.1 for each year before and after new policy by assuming all included companies in vrs positions separately. Input-oriented is defined as how much input quantities could be proportionally reduced without changing the output quantities, and output-oriented refers to how much output quantities can be proportionally increased without changing the input quantities. The geometric mean efficiency score of each company for 5 years before and after 2004 were calculated, and the statistical significance of the difference between mean technical efficiency of companies before and after policy was tested by related samples Wilcoxon signed-rank test. We also used a one-sided sign test to evaluate if the technical efficiency of pharmaceutical companies has improved after new policy using R 2.15.2.[16] To evaluate the situation of pharmaceutical companies in terms of efficiency, their relative efficiency was calculated for fiscal year March 2010-March 2011 separately.

RESULTS

The relative efficiency for all years before and after policy was measured and then the geometric mean of efficiency scores for each company before and after new policy was calculated [Table 1]. It shows that 14 out of 21 investigated companies have experienced some improvements in terms of mean relative technical efficiency (crste) after new policy implementation and also for 14 companies this improvement was observed in terms of mean relative pure technical efficiency (vrste). Furthermore, 12 companies have experienced improvements in both of them.

To evaluate the statistical significance of differences between relative and pure technical efficiencies before and after new policy, a nonparametric Wilcoxon matched-pairs signed-ranks test was conducted [Table 2] which indicated that about both the mean relative technical and mean pure technical efficiency, the null hypothesis (no statistically significant difference between before and after policy) could not be rejected

Table 1: Geometric mean of relative technical efficiency of pharmaceutical companies in fiscal years before and after brand-generic policy implementation (2004)

Firm	Before new policy			After new policy		
	Crste	Vrste	Scale	Crste	Vrste	Scale
A	0.696169	0.818568	0.850429	0.866883	1	0.866883
B	0.50461	0.647625	0.779516	0.911129	0.925755	0.984172
C	0.603749	0.686572	0.879495	0.787777	0.868285	0.907161
D	0.832825	0.843844	0.987172	0.980276	0.996992	0.982962
E	0.726992	1	0.726992	0.767356	1	0.767356
F	0.705356	0.747839	0.943279	0.623458	0.645014	0.966555
G	0.917435	0.927687	0.988864	0.76981	0.976626	0.788431
H	0.686152	0.824141	0.832003	0.875025	0.904591	0.967604
I	0.686286	0.713876	0.960788	0.478631	0.540354	0.886154
J	0.385819	0.490342	0.786476	0.738803	0.843891	0.875475
K	0.922203	0.953768	0.966766	0.711472	0.775808	0.917504
L	0.80145	0.920256	0.870899	0.825432	0.940536	0.87763
M	0.717826	0.941875	0.761884	0.696145	0.792435	0.87901
N	0.688574	0.753876	0.913225	0.870839	0.909688	0.957264
O	0.712227	1	0.712227	0.666482	1	0.666482
P	0.505218	0.685325	0.737385	0.917893	0.946036	0.970267
Q	0.591447	0.868099	0.681523	0.995357	1	0.995357
R	0.755999	0.792766	0.953432	0.589205	0.655905	0.898189
S	0.451267	0.678088	0.66525	0.604954	0.710709	0.850987
T	0.507691	0.761379	0.666922	0.565018	0.846538	0.667361
U	0.533742	0.580395	0.919578	0.582859	0.686385	0.849333

Crste=Relative technical efficiency or constant return to scale technical efficiency from crs DEA, Vrste=Pure technical efficiency or variable return to scale technical efficiency from vrs DEA, Crs=Constant return to scale, Vrs=Variable return to scale, DEA=Data envelopment analysis

Table 2: Comparison of mean technical efficiency of companies before and after brand-generic policy implementation (Wilcoxon matched-pairs signed-rank test)

Sign	Crste			Vrste		
	Observed	Sum ranks	Expected	Observed	Sum ranks	Expected
Positive	7	65	115.5	5	62	114
Negative	14	166	115.5	14	166	114
Zero	0	0	0	2	3	3
All	21	231	231	21	231	231
		Unadjusted variance: 827.75			Unadjusted variance: 827.75	
		Adjustment for ties: 0.00			Adjustment for ties: 0.00	
		Adjustment for zeros: 0.00			Adjustment for zeros:−1.25	
		Adjusted variance 827.75			Adjusted variance: 826.50	
		Z=−1.755			Z=−1.809	
		P>|z|=0.0792			P>|z|=0.0705	

Crste=Relative technical efficiency or constant return to scale technical efficiency from crs DEA, Vrste=Pure technical efficiency or variable return to scale technical efficiency from vrs DEA, Crs=Constant return to scale, Vrs=Variable return to scale, DEA=Data envelopment analysis

(P = 0.08 and 0.07). The one-sided sign test [Table 3] also indicated that although the null hypothesis (the median of crste and vrste are the same before and after policy) could not be rejected for crste (P = 0.09), but it could be rejected for vrste (P = 0.03).

The relative and pure technical efficiency of each company in fiscal year 2010-2011 was then calculated which is represented in Table 4. It shows that three out of investigated companies could be categorized as being in crs and 50% of them in irs. It also indicates that only about one-third of included companies (7 out of 21 companies are on the efficiency frontier) could be considered as relative efficient in terms of pure technical efficiency but this proportion is much less in terms of relative technical efficiency (only 3 out of 21 companies are on the efficiency frontier).

DISCUSSION

The results of this study imply that the policy reform from "generic scheme" to "brand-generic scheme" probably could not be considered as a successful plan in terms of improving relative technical efficiency of pharmaceutical companies. However, it has probably some positive effect on their pure technical efficiency (or managerial efficiency). The result of analyzing the situation of investigated companies was also consistent with the former analyses as it indicated that the current situation of pharmaceutical companies in terms of managerial efficiency is better than in terms of relative technical efficiency; however, in neither of them the situation was desirable.

Implementing the new policy was expected to improve competition and efficiency of pharmaceutical companies but the result of this study could not show this hypothesis. One reason for the current undesirable efficiency could be that the new policy has not been enough for making the pharmaceutical market very efficient. Some other infrastructural requirements including nondiscriminating laws supporting competition, the competitive pricing policy, the presence of international companies in the market, and full privatization of companies had to be also considered by policy makers to approach their goal. As an example, the current pharmaceutical pricing model in Iran has lead the companies to compete each other on giving more financial incentives to pharmacies to sell their products[17] which reduces their profitability and negatively affects their efficiency. A study has shown that pharmaceutical companies have also not been successful in using the potentials of branding.[18] The studies on related industries have indicated that these basic infrastructures could be facilitated during accession to World Trade Organization.[19,20] New interpretation of the general policies on "Article 44" of constitution of Islamic Republic of Iran which has been declared for implementation less than one decade ago follows efficiency as a principal aim to be achieved by focusing more on privatization of domestic state-owned industries as an important step for that aim.[21]

This study was faced with some limitation including a limited number of companies included in the analysis. We only evaluated 21 out of more than 70 Iranian pharmaceutical manufacturers due to the possibility to access the reliable financial data for them. Considering the company selection process of this study, the results might not be generalizable to the whole pharmaceutical industry of Iran. We had also some limitation regarding input and output selection. Some valuable data including companies' investment on Research and Development, marketing, and human resource and also data about export to international markets were not disclosed anywhere and accessible.

Data envelopment analysis has been used in policy analysis in many areas including the pharmaceutical industry[22,23] but we could not find it being used as a method to evaluate the effect of a new policy.

Table 3: Test equality of matched pairs to evaluate the improvement of technical efficiency after brand-generic policy implementation (one-sided sign test)

Sign	Crste		Vrste	
	Observed	Expected	Observed	Expected
Positive	7	10.5	5	9.5
Negative	14	10.5	14	9.5
Zero	0	0	2	2
All	21	21	21	21
	One-sided tests H_o: Median of crste2 - crste1=0 versus H_a: Median of crste2 - crste1>0 Probability (# negative ≥ 14)=Binomial (n=21, x ≥ 14, P=0.5)=0.0946		One-sided tests H_o: Median of vrste2 - vrste1=0 versus H_a: Median of vrste2 – vrste1>0 Probability (# negative ≥ 5)=Binomial (n=19, x ≥ 14, P=0.5)=0.0318	

Crste=Relative technical efficiency or constant return to scale technical efficiency from crs DEA, Vrste=Pure technical efficiency or variable return to scale technical efficiency from vrs DEA, Crs=Constant return to scale, Vrs=Variable return to scale, DEA=Data envelopment analysis

Table 4: Technical efficiency of investigated pharmaceutical companies in fiscal year 2010-2011

Company	Crste	Vrste	Scale	RS
A	0.711	1	0.711	irs
B	0.951	0.962	0.988	drs
C	0.542	0.747	0.726	irs
D	1	1	1	crs
E	0.504	0.61	0.827	drs
F	0.572	0.587	0.975	irs
G	0.843	1	0.843	drs
H	1	1	1	crs
I	0.379	0.494	0.767	irs
J	0.953	1	0.953	irs
K	0.671	0.77	0.87	irs
L	0.728	0.819	0.888	drs
M	0.79	0.79	1	crs
N	0.752	0.767	0.981	drs
O	0.432	1	0.432	irs
P	0.808	0.809	1	crs
Q	1	1	1	crs
R	0.713	0.773	0.922	irs
S	0.637	0.682	0.933	drs
T	0.802	0.926	0.865	irs
U	0.682	0.831	0.821	irs

Crste=Relative technical efficiency or constant return to scale technical efficiency from crs DEA, Vrste=Pure technical efficiency or variable return to scale technical efficiency from vrs DEA, Crs=Constant return to scale, Vrs=Variable return to scale, DEA=Data envelopment analysis, RS=Return to scale, Irs=Increasing return to scale, Drs=Decreasing return to scale

This study is also the first assessment on the implementation of "brand-generic scheme" in Iran and could be used by policy makers in managing pharmaceutical industry as an important component of health system. Other studies to evaluate the effects of this and also other related policies using the methods and outcomes other than DEA and efficiency seem to be necessary for supplying information needed for evidence-based policy making.[24]

According to the results of this study, although implementation of "brand-generic scheme" has ended up with a significant increase in mean pure (managerial) technical efficiency of pharmaceutical companies, but the relative technical efficiency did not change significantly and also the relative efficiency of investigated companies is not currently in its desirable position. This issue could be probably associated with other obstacles including pricing policy and the absence of international companies in Iranian pharmaceutical market which are not still addressed by policy makers.

AUTHORS' CONTRIBUTION

AHM: Study design and manuscript writing, MV: Study design and data collection, MY: Study design Analysis, SY: Data collection, consultation with experts, analysis, HZ: Data collection, analysis, manuscript writing, SN: Supervising on all study process, checking the manuscript, AK: Study idea, supervising on all study process.

REFERENCES

1. Nikfar S, Kebriaeezadeh A, Majdzadeh R, Abdollahi M. Monitoring of National Drug Policy (NDP) and its standardized indicators; conformity to decisions of the national drug selecting committee in Iran. BMC Int Health Hum Rights 2005;5:5.
2. Cheraghali AM, Nikfar S, Behmanesh Y, Rahimi V, Habibipour F, Tirdad R, *et al.* Evaluation of availability, accessibility and prescribing pattern of medicines in the Islamic Republic of Iran. East Mediterr Health J 2004;10:406-15.
3. Cheraghali AM. Iran pharmaceutical market. Iran J Pharm Res 2006;1:1-7.
4. Basmenji K. Pharmaceuticals in Iran: An overview. Arch Iran Med 2004;7:158-64.
5. Davari M, Walley T, Haycox A. Pharmaceutical policy and market in Iran: Past experiences and future challenges. J Pharm Health Serv Res 2011;2:47-52.
6. Madani H, Shahhoseyni MH, Khamse A. Impact of generic plan on development of technology capability (in Farsi). Hakim Res J 2011;14:23-31.
7. Kebriaeezadeh A, Eslamitabar Sh, Khatibi M. Iranian Pharmaceutical Law and Regulations. Tehran: Razi Distribution Press; 2009.
8. Dinarvand R. A new pharmaceutical environment in Iran: Marketing impacts. Iran J Pharm Res 2003;2:1-2.
9. Dinarvand R. New national drug policy in Iran leading to expanded pharmaceutical market and extended access of public to medicines. Iran J Public Health 2009;38 Suppl 1:158-61.
10. Donald AH, Liu SG. The efficiency of firms: What difference does competition make? Econ J 1997;107:597-617.
11. Carlsson B. The measurement of efficiency in production: An application to Swedish manufacturing industries 1968. Swed J Econ 1972;74:468-85.
12. Bikker JA, Bos JW. Bank Performance: A Theoretical and Empirical Framework for the Analysis of Profitability, Competition and Efficiency. New York: Routledge; 2008.
13. Charnes A, Cooper WW, Rhodes EL. Measuring the efficiency of decision making units. Eur J Oper Res 1978;2:429-44.
14. Emamimeibodi A. Principles of Efficiency and Productivity Measurement [in Persian]. Tehran: Institute of Trade Studies and Research; 2004. p. 48-51.
15. TSE database website. Available from: http://www.rdis.ir/CMPAnnouncements.asp. [Last accessed on 2012 Sep].
16. R Core Team. R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria; 2012. ISBN 3-900051-07-0. Available from: http://www.R-project.org/. [last accessed on 2013 Jan].
17. Keshavarz K, Kebriaeezadeh A, Meshkini AH, Nikfar S, Mirian I, Khoonsari H. Financial perspective of private pharmacies in Tehran (Iran); is it a lucrative business? Daru Journal of Pharmaceutical Sciences 2012;20:62.

18. Amirshahi MA, Haghighinasab M, Habibi A, Ahmadiani A. A case study on branding in Iran pharmaceutical industry (in Farsi). Pejouhandeh 2009;14:99-107.
19. Hashemi Meshkini A, Kebriaeezadeh A, Dinarvand R, Nikfar S, Habibzadeh M, Vazirian I. Assessment of the vaccine industry in Iran in context of accession to WTO: A survey study. Daru Journal of Pharmaceutical Sciences 2012;20:19.
20. Rahimi M, Ahmadi P, Hoseini SH. Commercial effects of Iran's membership in the WTO in the drug industry (in Farsi). Hakim Res J 2011;14:73-7.
21. Azad S. The politics of privatization in Iran. MERIA 2010;14:60-71.
22. Chen X, Skully M, Brown K. Banking efficiency in China: Application of DEA to pre- and post-deregulation eras: 1993-2000. China Econ Rev 2005;16:229-45.
23. Hashimoto A, Haneda S. Measuring the change in R and D efficiency of the Japanese pharmaceutical industry. Res Policy 2008;37:1829-36.
24. Gray JA. Evidence based policy making: Is about taking decisions based on evidence and the needs and values of the population. BMJ 2004;329:988-9.

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