Iranian Journal of Pharmaceutical Sciences
2018: 14 (3): 36-48
www.ijps.ir

Original Article

Selecting Reference Countries in External Reference Based Pricing: The Case Study of Iran

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Abstract

Most countries are using some kinds of pharmaceutical policies, like external reference-based pricing, to control the costs of medicines. This policy could be implemented in different ways and there is no systematic method for selecting reference countries. In this study, we tried to identify and classify the factors affecting the selection of reference countries in Iran .Delphi method was employed to elicit experts' opinion in pharmaceutical sector on the parameters affecting the choice of reference countries. Members of the panel were experts in the field of policymaking, manufacturing, distribution, and importation of medicines, insurance companies, and academics who were more familiar with the purpose of the research. Panels were run in three rounds. The results of this study reveal that the impact of pharmaceutical, economy, and health sectors characteristics has been more effective, in selecting reference countries. Health insurance coverage was the most important index among all the different sectors. Other important indexes included pharmaceutical pricing system, mechanism of drug registration, gross national income (GNI) per capita, health expenditure per capita, health expenditure (share of GDP) and the out-of-pocket health expenditure. To have an efficient pharmaceutical external reference-based pricing, it is important to select reference countries with more similar important parameters. Obviously, any change in these parameters has to be considered and adjusted during the time.

Keywords: External reference, Pricing, Delphi method, Selecting countries, Pharmaceutical, Iran.

1. Introduction

Pharmaceutical costs account for the importance of healthcare costs, and these costs are rising faster than overall health spending such that in OECD countries, pharmaceutical expenditure per capita grew by more than 50% between 1995 and 2005 [1]. Similarly, Iran pharmaceutical market in recent years has been grown in volume and value (see figure 1), such that in 2010, sales in volume and in

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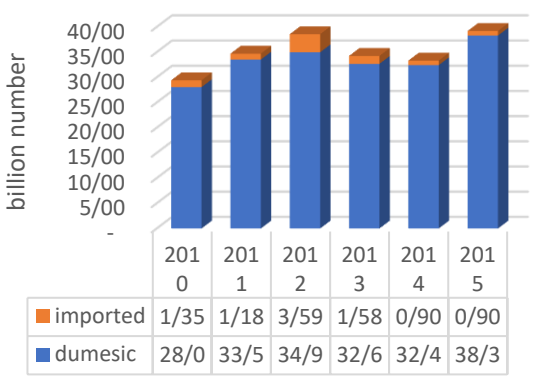
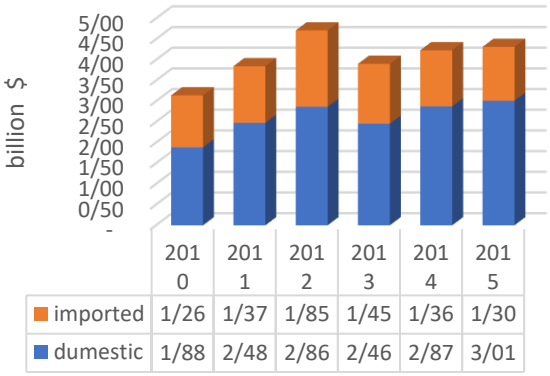
Cite this article as: Rahimi F, Rasekh H, Abbasian E, Peiravian F, Selecting reference countries in external reference based pricing: The case study of Iran, 14 (3): 36-48



A: volume



B: value

Figure1. Iran pharmaceutical market (2010-2015).

value have been 29.41 billion pharmaceutical unit and $3.14 billion, respectively; but the figures for 2015 have been 39.2 billion pharmaceutical unit and $4.31 billion, respectively. In this period of time, the average numerical growth of the pharmaceutical market of Iran has been 7% and the average monetary growth in this market has been 7.4% (total growth 32.87 and 38.13%, respectively in 6 years). For better understanding, it could be useful to have data for domestically manufactured and imported medicines separately. Statistics show that the number of imported medicines has changed from 1.35 billion units in 2010 to 0.9 billion in 2015. However, the total market value of imported drugs has been $1.26 billion dollars in 2010 and $1.3 billion dollars in 2015. During a certain six-year period, the average growth of domestic pharmaceutical productions in volume has been 34 and 2.74% in value (total growth 178.9 and 13.68% in 6 years). Furthermore, the average growth of imported medicines in volume has been 2, and 1.47% in value (total growth 8.14 and 7.33% in 6 years). This trend has raised some concern regarding the financial stability of the Iran's public health system and application of different policies to control pharmaceutical market [2].

Although the various policies are designed differently, their main purpose is to control pharmaceutical public expenditures through demand (quantity) and supply (price) [1]. External reference pricing (ERP)[1] is one of the most common tools for controlling pharmaceutical spending by authorities. This method has been used in 22 European and non- European countries such as Brazil, Oman, South Africa, Japan, Canada and

[1]Is equal to External price referencing, International price referencing ،International reference pricing ،International price comparison ،International price benchmark ، External price benchmark ،External price linkage and International price linkage.

Australia [3, 4]. Iran uses different policies in pharmaceutical pricing including ERP for majority of imported and cost-plus approach for most of the local manufacturing medicines so as to control medicines costs [2].

ERP refers to a system where the price or prices of a drug is utilized in one or several countries to elicit reference or benchmark price aiming at price setting and/or product price negotiation in the given country [5]. Different methods of implementation and basket selection in various countries distinguish the comparison of prices of drugs in different countries [3]. Countries should utilize ERP as a method for negotiating or benchmarking the price of drug, and also as a part of a more general strategy in combination with other methods to regulate the prices of drugs [6].

Few published information is available on the criteria and processes of selecting a country as reference in reference-based pricing system [5]; this is while most studies deal with the evaluation of reference systems and their effects. These studies investigate ERP system [7-10] or the effect of ERP on the consumption of drugs and their demand [4, 11, 12], price of drugs [4, 12-14], drug expenditures [4, 12], health consequences [4, 8, 15, 16], competition of generic enterprises [8, 10, 14, 17], and the pharmaceutical industry [1, 7, 15, 18, 19]. Literature studies

Table1. Factors and indexes.

Factors	**Indexes**
Economical	GNI per capita, PPP, $[1]
	Inflation, CPI[2] (annual %)
	Exchange Rate Fluctuations[3]
Social, cultural and political	Population Ages[4]
	Income group[5]
	Same Region/ Neighbor Countries[6]
	Human Development Index (HDI) [7]
	Corruption Perceptions Index[8]
Health	Health Expenditure per capita[9]
	Total Health Expenditure as a % of GDP[10]
	total Health Expenditure as a % of total public expenditure[11]
	% Out of Pocket Health Expenditure[12]
	% Health insurance coverage[13]
	Similarity in health policy goals[14]
Pharmaceutical	Reference/Non-reference Based Pricing[15]
	Registration and pharmacoeconomics analysis[16]
	Procurement by Government or Insurance[17]
	mark-ups [18]
	Lowest Price [19]
	Access to prices from websites[20]
	Manufacturer's country of origin[21]

[1] GNI per capita based on purchasing power parity is gross national income (GNI) converted to international dollars using purchasing power parity rates.

2[1] Inflation as measured by the consumer price index reflects the annual percentage change in the cost to the average consumer of acquiring a basket of goods and services that may be fixed or changed at specified intervals, such as yearly.

[3] Official exchange rate refers to the exchange rate determined by national authorities or to the rate determined in the legally sanctioned exchange market.

[4] Total population between the ages 0-14, 15-64 and >65 as a percentage of the total population.

[5] Economies are divided into four income groupings: low, lower-middle, upper-middle, and high, based on GNI per capita.

[6] It refers to the geographic proximity of the countries from either neighbors or presence in a similar area.

[7] HDI is a summary measure of average achievement in key dimensions of human development: a long and healthy life, being knowledgeable and have a decent standard of living.

[8] The public sector management and institutions cluster includes property rights and rule-based governance, quality of budgetary and financial management, efficiency of revenue mobilization, quality of public administration, and transparency, accountability, and corruption in the public sector.

[9] Total health expenditure is the sum of public and private health expenditures as a ratio of total population

[10] The share of total health expenditure is the sum of public and private health expenditure to Gross Domestic Product.

[11] Public health expenditure consists of recurrent and capital spending from government (central and local) budgets, external borrowings and grants (including donations from international agencies and nongovernmental organizations), and social (or compulsory) health insurance funds.

[12] Out of pocket expenditure is any direct outlay by households, including gratuities and in-kind payments, to health practitioners and suppliers of pharmaceuticals, therapeutic appliances, and other goods and services whose primary intent is to contribute to the restoration or enhancement of the health status of individuals or population groups. It is a part of private health expenditure.

[13] Percentage of total population covered by total public and primary private health insurance, by government/social health insurance, and by primary private health insurance.

[14] There are three goals of any health care system and of policies to influence that system: (1) to maximize the quality of health care available, (2) to minimize total national expenditures on health care, and (3) to achieve equitable distribution of the benefits of quality health care and of the burden of costs.

[15] In general, it refers to the use of reference pricing system as one of the main methods of medicine pricing or non-use of this system in pharmaceutical pricing.

[16] Legal obligation to perform pharmacoeconomics studies for drug registration or the absence of such this requirement in the country.

[17]Which one is in charge of drugs procurement: the government or insurance organizations.

[18] It points to regulation of mark-ups in the pharmaceutical supply and distribution chain.

[19] Given the country has the lowest drug prices in the basket of reference countries.

[20] Ease of access to the latest price information in the country through its official website.

[21] In relation to the pricing of any pharmaceutical product in addition to reference countries, manufacturer country add to basket of countries.

have revealed that factors like economic similarities and geographical proximity have greater role in selecting reference pricing countries in Europe [3, 5, 6, 8, 20-23]. Other parameters for selecting reference countries include: same region, the availability of price information, country of origin, economic status, socio-economic similarities, health care organization, pharmaceutical pricing system, similar burden of disease, neighboring countries, health status, population structure, epidemiological situation, pricing process etc.[3, 5, 6, 21, 24, 25].

Given that less attention has been paid in previous literature to the method of selecting pricing reference countries, we tried in this research, to use the Delphi method to identify factors affecting the selection of such countries. In fact, at this time, Iran's reference-pricing countries include Spain, Greece, Turkey and the country of origin, but there is no evidence that these countries has been selected appropriately. Based on literature

review and expert opinions, four general categories were considered as the most important criteria in this study: Economical, cultural and political factors, factors related to the health sector, and those related to pharmaceutical sector. Some indexes were determined for each of these factors and the level of importance of factors and indexes were questioned in Delphi expert panel.

2. Materials and Methods

Delphi method is a systematic approach for obtaining the opinions of a group of experts on a matter or item, and it is implemented in two or several rounds [26, 27]. In this survey, which was based on experts' opinion, at each round, respondents were provided with the results of the previous survey as feedback. The purpose of utilizing Delphi technique was to reach consensus on the subject-matter of the research. Consensus on a subject-matter can be reached if a certain percentage of votes are within the specified range [28]. One application of Delphi method is to identify, rank, and prioritize the factors affecting the topic of research, namely to reach consensus on the relative importance of the research variables [29] used herein to rank various factors and determine the relative significance of indexes for selecting pricing reference countries .

The main challenge of this study was to determine the percentage and range of consensus, so that there are various consensus criteria in different researches: a criterion suggests that consensus can be achieved by having 80% of subjects' votes fall within two categories on a seven-point scale, and with 70% of votes fall within three categories and above in a 4-point Likert scale or an average of at least 3.25. The other criterion states that using percentages is not enough, and it is more reliable alternative to measure the stability of repeated and successive responses [30].

Central tendency (mean, median and mode) and dispersion (standard deviation and interquartile range) are the most important statistics utilized in Delphi method so as to provide information on the collective judgment of respondents [31]. Overall, the use of median and mode is more common, and the average is used in many studies at the same time. If the scale used in Delphi studies is not identified at equal distances, the responses are measured using the average. Nevertheless, using median when using Likert scale is more common [30].

Interquartile range (IQR) also assesses the degree of agreement as a dispersion index. IQR 0 or 1 is necessary for an item to reach a consensus. In other words, at least 75% of participants have to agree, disagree, strongly disagree or strongly agree. IQR equal to 2 or more in some items implies that at least 75% of participants neither agree nor disagree [27].

The modified Delphi method was used because the basic information about the subject matter in this study was accessible and usable [30], and the closed- ended questions were designed in the form of a questionnaire.

After forming a team for implementation, guidance and supervision of Delphi method, Delphi panel members were identified and selected. Experts with sufficient expertise and

experience on the subject matter participated in Delphi studies. In addition to ability, participants also had to have interest and commitment to the topic, spend enough time to study, respond to questions and engage consistently in all the rounds. In order to improve the participation of panel members during their stay in Delphi courses, it was suggested that a person-to-person (e.g. "snowball") method should be used so that participants can accept invitation more easily (and stay longer) [32]. Given that the researchers planned to select the items with scientific and practical information on the pricing of drugs for the objective of the research, purposive sampling method was then used. The quota number of all members was determined based on their employment in Iran Food and Drug Administration (IFDA), pharmaceutical companies and insurance organizations, and then panel members were selected in each category as a snowball.

First round: Based on existing literature, we defined indexes for each of the economical, socio-cultural, and political, health and pharmaceutical factors and so we developed the initial questionnaire. Respondents were asked to prioritize economical, socio-cultural and political, health and pharmaceutical factors and, in addition, specify the importance of the indexes in each category from very high to very low. The closed-ended questions were utilized for developing the questionnaire so as improve response [32]. The questionnaire was emailed to 50 researchers and influential people in the pharmaceutical industry; 32 of them gave answers to the questions (response rate = 64%). After analyzing the first questionnaire and talking to experts, some of the indexes were changed and/or excluded. Finally, the following indexes were selected for all the four factors:

Second round: Panel members in the second round of the study were as follows: seven members from IFDA, three from insurance organizations (social security and health organization), three CEOs of manufacturing companies, three CEOs of importation companies, and three CEOs of drug distribution companies. In addition to their technical knowledge about the research topic, they had a close relationship with drug pricing problem. After being present at work and a little explanation of the research topic, the team members, the purpose of the study and their willingness to participate in this round and subsequent round, the questionnaire was given to the panel members. Meanwhile, the results of the first round were indicated briefly in various parts. On average, each questionnaire took about 30 minutes to complete. Also all panel members agreed that the next round could be held electronically.

Third round: Electronic questionnaires were designed and the access link was sent to members via email. Various methods including email reminders, SMS, personal reminders, mass media, etc. were used to increase the participation of all members of the previous round. At the end of three months, most of the participants (17 out of 19 with a response rate of 89%) responded to the questionnaires. Given that the results of second and third rounds indicated consistency

of responses, the study ended in this round based on the criteria found in different texts.

3. Result and Discussion

The validity of the content of a questionnaire is usually determined and confirmed by experts in the subject matter. Cronbach's alpha coefficient was utilized to investigate the reliability of this questionnaire. This coefficient was closely associated with internal consistency of questions and its value was theoretically between zero and one. In this study, the coefficient value was 0.87, which confirmed the reliability of the questionnaire.

All indexes selected in each round had an average greater than 3 which indicates their relative importance. However, as mentioned earlier, central indexes and dispersion of judgment criteria are taken into account in Delphi method. According to various citations to these criteria in various articles, we chose to use them in this study as a basis for simultaneous decision-making. To justify this, it can be said that since each of these indexes point to one aspect of the distribution of votes, we accept a result, as a consensus, that has been assigned acceptable values in all of these indexes.

According to the results in all rounds, the highest priority was given to factors of pharmaceutical, economical, health, and socio-cultural and political sectors, respectively. In the third round, the average for determining the priority of these factors was as follows: 2.0 for pharmaceutical sector; 2.1 for economic sector; 2.3 for health sector; and 3.1 for socio-cultural and political sector (1: first priority – 4: last priority).

3.1. Economical

Of the three indexes in this category, GNI per capita adjusted by the purchasing power parity, obtained a good rank in all rounds in each of the three central indexes and the two dispersion indexes. Consequently, the importance of this index was accepted by the panel members unanimously. The index of exchange rate fluctuations could not obtain a good rank among all indexes in the third round although it was favorable considering the three indexes in the second round (see Table 2).

3.2. Social, Cultural and Political

Despite the importance of cultural and social factors according to experts' opinion in the first round, no factor in this category could be assigned acceptable values in central and dispersion indexes. Among these factors, "income group" was assigned better values

Table 2. Economical indexes and their ranking.

Economical:	**round 2**					**round 3**				
	mean	Median	Mode	QIR	SD	mean	median	mode	QIR	SD
*GNI per capita, PPP, $**	4.3	4.5	5.0	1.0	0.9	4.0	4.0	4.0	0.3	0.9
Inflation, CPI	3.6	3.5	3.0	1.0	0.9	3.3	3.0	4.0	2.0	1.0
Exchange Rate Fluctuations	3.5	4.0	4.0	1.0	1.2	3.3	3.5	4.0	2.0	1.3
** :mean≥4 , median≥4 , mode≥4 & QIR≤1*										

Table 3. Social, cultural and political indexes and their ranking.

Social, cultural and political:	**round 2**					**round 3**				
	mean	median	mode	QIR	SD	Mean	median	mode	QIR	SD
Population Ages	3.2	3.0	3.0	1.0	0.8	3.3	3.0	3.0	1.0	1.0
Income group	3.8	4.0	4.0	1.0	0.8	3.4	4.0	4.0	1.0	0.9
Same Region/ Neighbour Countries	3.3	3.0	4.0	1.0	0.9	3.1	3.0	3.0	1.3	0.8
HDI index	3.3	3.0	4.0	1.0	0.9	3.2	3.0	4.0	1.3	1.0
Corruption Perceptions Index	3.5	3.5	3.0	1.0	1.1	3.1	3.0	3.0	2.0	1.2
** :mean≥4 , median≥4 , mode≥4 & QIR≤1*										

Table 4. Health indexes and their ranking.

Health:	**round 2**					**round 3**				
	mean	Median	mode	QIR	SD	mean	median	mode	QIR	SD
*Health Expenditure per capita**	4.2	4.0	5.0	1.0	0.9	4.0	4.0	4.0	0.5	0.8
*Total Health Expenditure % of GDP**	4.2	4.0	5.0	1.0	0.8	4.0	4.0	4.0	0.5	0.7
total Health Expenditure % of public	3.9	4.0	4.0	0.0	0.7	3.6	4.0	4.0	1.0	0.8
*Out of Pocket Health Expenditure**	4.2	4.0	5.0	1.0	0.9	4.0	4.0	4.0	0.0	0.8
*Health insurance coverage**	4.6	5.0	5.0	1.0	0.6	4.5	5.0	5.0	1.0	0.8
Similarity in health policy goals	3.8	4.0	5.0	2.0	1.0	3.6	4.0	4.0	1.0	0.9
** :mean≥4 , median≥4 , mode≥4 & QIR≤1*										

(the acceptability of 4 out of 5 indexes), and this may be justified because this index was close to economic sector. Overall, according to table 3 there was no consensus on the importance of social, cultural, and political factors.

3.3. Health

Greater consensus on the importance of the health sector was achieved, such that health insurance coverage was obtained with an average of 4.5 and 4.6, a median of 5, a mode of 5, an interquartile range of 1 and a standard deviation of 0.6 and 0.8, and for panel members, it was identified as the most important of these factors (See Table 4). Thereafter, health expenditure per capita, total health expenditure (% of GDP), and out of pocket health expenditure were three important factors in the health sector of which there was a consensus.

3.4. Pharmaceutical

In the pharmaceutical sector, considering the priority of this sector among the four others in this study, two factors were identified as important by the panel members despite the fact that 7 factors indicated the importance of these sectors. According to table 5, the two factors included using reference pricing or not, and the registration system based on pharmacoeconomic analysis or not were important. The interesting point in these results is that the drug manufacturing company was identified as the less important factor; nevertheless, the drug price in the

Table 5. Pharmaceutical indexes and their ranking.

Pharmaceutical:	**round 2**					**round 3**				
	Mean	median	mode	QIR	SD	mean	median	Mode	QIR	SD
*Reference/Non-reference Based Pricing**	4.2	4.5	5.0	1.0	1.0	4.2	4.0	4.0	1.0	0.9
*Registration and pharmacoeconomic analysis**	4.1	4.0	4.0	1.0	0.7	4.0	4.0	4.0	0.3	0.9
Procurement by Government or Insurance	3.6	4.0	4.0	1.0	0.7	3.6	4.0	4.0	1.0	0.8
Mark-ups	3.7	4.0	3.0	1.0	0.9	3.6	4.0	4.0	1.0	0.9
Low Prices	3.4	3.0	3.0	1.0	1.0	3.4	3.0	3.0	1.0	1.0
Access to prices from websites	3.8	4.0	4.0	1.3	1.2	3.3	3.0	3.0	1.3	1.1
Manufacturer's country of origin	3.3	3.5	4.0	2.0	1.2	3.1	3.0	3.0	1.0	0.9

** :mean≥4 , median≥4 , mode≥4 & QIR≤1*

manufacturing country is used in Iran for pricing [5].

As participants in this panel were influencers and policy makers of drug sector, especially the pricing of drugs, and they are representatives from the Iran food and drug administration, insurance companies and pharmaceutical manufacturer, importers and distributers, their consensus means the importance of these factors regardless of any prejudice to the status of experts. This consensus is considerable despite the incompatibility of the panel members in their field of activity in the pharmaceutical industry. As it became evident from the relevant tables, the consensus on the importance of these indexes was obtained in the first priority (pharmaceutical sector), pharmaceutical pricing systems in place (ERP or not) and the similarity of legislation system (the necessity and/or unnecessity of the pharmacoeconomic analyses), respectively. The results were similar in both rounds and the opinion of the panel members was established. Therefore, generally it can be concluded that the type of pricing system of the country in question and the drug registration mechanism were more important than the other indexes of pharmaceutical sector. These two factors were also considered important in the studies of Alexandra Cameron, et al. (2013), Kanavos, P., E. Nicod, et al. (2010) and Docteur, E. (2008). However, while access to price information, countries of origin and low prices were important in the studies of Alexandra Cameron, et al. (2013), Espin, J., J. Rovira, et al. (2011) and Kanavos, P., E. Nicod, et al. (2010), in our study, their importance has not been confirmed. Also in the economic sector, the similarity of countries in terms of national income adjusted by purchasing power parity was more important. All studies in this field emphasized the economic similarities and the study of Kanavos, P., E. Nicod, et al. (2010) referred to the importance of the similarity of the GDP and purchasing power which is in line with the findings of this study. Health sector involved more important indexes, so that the type of insurance coverage, per capita health spending, health spending share of GDP, and the out-of-pocket health expenditure were known as important. The studies of Kanavos, P., E. Nicod, et al. (2010) and Docteur, E. (2008) also demonstrate that

health costs, health care resources, and reimbursement policy are influential in the selection of reference countries. Unfortunately, none of the cultural, social, and political indexes were considered important, However, geographic proximity in many studies (as mentioned in the introduction) and population, age distribution and same region in Alexandra Cameron, et al. (2013), Kockaya, G. and P. Kılıc (2012) and Docteur, E. (2008) studies were considered important.

Thus, countries entering Iran basket should also use reference pricing system and there must be regulations for registration of medicine as the same way as in Iran. The economic sector, as the second priority, became important with GNI per capital, PPP. In addition to indicating the national income per capita of countries, this index shows the purchasing power as well: all countries whose national income per capita is close to 16,590 dollars (according to the latest data available on the World Bank website[2] in 2013) may be considered as reference pricing countries in Iran [33].

In health sector as the third priority, more indexes became important. The similarity of insurance coverage has become important because drug pricing is close to reimbursement system which influences the affordability and accessibility of drugs. Hence, this should be taken into account when determining prices by reference country, whether or not there is a similarity between their reimbursement system and that of Iran. Health expenditure per capita was another index in health sector, about the importance of which there has been consensus for selecting a reference country. According to the statistics published by the World Bank, the per capita health expenditure in 2013 and 2014 are 414.7 and 350.74 dollars[3], respectively for Iran. Therefore, the countries that will be selected as reference pricing should be placed in the same area of health expenditure. Total health expenditure % of GDP was another important index which revealed the share of health expenditure of the GDP in a country. In 2013 and 2014, this share was 6.49 and 6.89, respectively. The reference country in Iran should have a share similar to Iran in this regard. The last index selected for health sector was out of pocket health expenditure which indicated the share of health expenditure paid directly by individuals. In Iran, 47.06 and 47.80% of health expenditure were out of pocket paid by people in 2013 and 2014, respectively [33]. The similarity of such share in the reference-based pricing country was confirmed by the panel members.

4. Conclusion

ERP is a price control tool for managing the prices of medicine and a mechanism for pricing in pharmaceutical industry. The point in this system is to determine countries which are a basis for pricing. There is no study

2 http://beta.data.worldbank.org/indicator/NY.GNP.PCAP.PP.CD?end=2014&start=2013

3 http://beta.data.worldbank.org/indicator/SH.XPD.PCAP?end=2014&start=2013

available on the ways of identifying reference countries [34] and this paper seeks to find a solution for selecting reference countries for Iran and, for this purpose, the opinions of entities aware of pricing in a Delphi study were obtained. Although these criteria were determined for Iran by using the opinion of local experts, they can also be evaluated in other countries especially those with similar pharmaceutical markets. The selection of reference countries is just one step in implementing ERP, and sources of price data in reference countries, the clear continuing process in case of unavailability of related prices and adjustments to calculate discount and discounted price are issues that should be taken into consideration for more efficient use of the system [5, 6]. In addition, countries have to use external reference pricing as a way to negotiate or benchmark the price of medicine and as part of a broader strategy in combination with other methods to regulate the price of medicine [6]. Nevertheless, this method alone will not be efficient.

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