EKONOMSKA ISTRAŽIVANJA-ECONOMIC RESEARCH
ISSN 1331-677X print

2013 Volume 26(1): 101-114

A DECISION MODEL FOR PHARMACEUTICAL MARKETING AND A CASE STUDY IN TURKEY

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ARTICLE INFO

Article data:
- Received: 27 December 2011
- Accepted: 20 July 2012

JEL classification: C02, C44, M31, I11

Keywords:
- Marketing
- Decision making
- Pharma industry

ABSTRACT

The choice of the appropriate product for the portfolio of a pharmaceutical company in terms of its strategy and long term commercial value is a sophisticated multi-criteria decision problem in pharma economics. This paper provides a systematic method for licensing in pharma industry and proposes a Fuzzy AHP based decision model for the decision makers in pharmaceutical industry to assess potentials of different products for license-in that may be proper for their portfolio. An application of the proposed model is also performed for a pharmaceutical company in Turkey.

Reference to this paper should be made as follows: Toker, D. ; Tozan, H.; Vayvay, O. 2013. A Decision Model for Pharmaceutical Marketing and a Case Study in Turkey, *Ekonomska istraživanja – Economic Research 101-114.*

I. INTRODUCTION

Like other sectors of industry it's critical for pharmaceutical industry to sustain growth. Business Development is the key to success in today's highly competitive environment. Two key elements are shaping the pharmaceutical environment: declining Research & Development and customers' economics. Despite injection of huge funding, Research & Development productivity of pharmaceutical companies is declining. Main two reasons are: increased regulations and inability of pharmaceutical markets to shift to new technologies in product development. For the customer economic perspective, health expenses of countries are increasing every year and drug expenses constitute major part of health expenses. Aging population is the main driver in increased drug expense budget. Governments put cost containment majors like motivating cheapest drug or not reimburse the new drugs if it's not superior to existing therapies. All those burdens force pharmaceutical companies to find new eras to ensure their sustainability in the market (Radu, 2012). Business development is the most prominent enabler to find out external alternatives for new products when R&D machines of pharmaceuticals are limited to create new products. There are many business development activities such as product acquisition, technology acquisition, and whole company acquisition.

In the last ten years, number of global acquisitions increased. Even in Turkey mergers and acquisitions experienced in the last years such as: Zentiva, Czech company acquired Eczacıbası İlac in 2007, and Eastpharmaceutical acquired Deva İlac in 2006 and then Saba İlac in 2007.

Usually, companies begin their business development activities by product acquisitions or collaborations. A product can be transferred from one company to another if this transfer will create more value to both companies in terms of field force synergy or portfolio synergy but certainly, those are not the only aspects for products acquisition.

Generally, multi-criteria decision making approaches focuses on model human judgment/inference and implementing them into the decision models (Anagnostopoulos et al., 2008; Turgutet al., 2011). Although there are many studies about pharmaceutical industry in literature, studies about developing frameworks to assess potentials of various pharma products to be a candidate for license-in and fuzzy approaches in this perspective are narrow.

From this point of view, the aim of this study is to get a better understanding of business development opportunities in pharma market especially license-in alternative, to develop a framework to assess potentials of various pharma products to be a candidate for license-in; and also, to offers a valuable tool for managers to assess a new pharma product's potential for their portfolio developing a decision making model (DMM) using both analytic hierarchy process and fuzzy analytic hierarchy process (FAHP) based on Chang's extent analysis (Chang, 1996).

The rest of this study is organized as follows: In the section 2, general background regarding pharmaceutical industry in Turkey is given with challenges of the sector. In section 3, methodology used in the study; AHP and FAHP, is explained briefly. In section 4, the proposed DMM with determination of evaluative criteria for the assessment of potential license-in candidates and hierarchical structure of the model is described. And, a case study for identification of the best product to license-in for the selected Turkish pharmaceutical company is included. Finally, conclusions are given in the final section of the study.

II. GENERAL BACKGROUND OF TURKISH PHARMACEUTICAL MARKET

The Turkish pharmaceutical market registered sales of $10 billion in 2008, growing at 11.5% over the previous year (Business Insight, 2008). The Turkish pharmaceutical industry grew with Compound Annual Growth Rate (CAGR) of 23.5% over 2004-2008. This strong growth mainly driven by growing economy, increased healthcare expenditure, rising consumer spending on

drugs and recent healthcare reform initiatives that have improved access to medicine. With a population of 76.8 million in 2009 and rising consumer spending on drugs and healthcare improvements, Turkey could reach to sales of $16 billion by 2014 (Riley, 2008; Wesley, 2009)

According to Turkish Pharmaceutical Market Outlook to 2014, the key health care reforms which were introduced in the country can be summarized as follows (Datamonitor, 2009; Riley, 2008):

- Drug regulation:

Turkey's aspirations to enter the European Union (EU) have been the driving force for recent changes in pharmaceutical regulations. Major reforms impacting the pharmaceutical industry include implementation of patent legislation in 1995, creation of generics law in 1996 and establishment of a reference pricing system in 2004

Reforms have made the healthcare system more efficient, improved access for the population, synchronized with EU standards. At the same time, Turkey's growing economic consistency has brought in foreign investment into the pharmaceutical sector

- Data exclusivity and patent protection:

Patent law adopted in 1991 but this law covers patent applications submitted since 1995. Drugs registered prior to 1995 were not protected. Data exclusivity and patent protection law was introduced in January 2005, and it is valid for six years from the initial registration of the drug in the EU. This data protection would be valid but limited to patent term.

- Reimbursement:

A new reimbursement system was introduced in Turkey in February 2005 and revisions were made in the following years. Currently over the counter (OTC) medicines were not reimbursed by government. According to the current system, cheapest medicine plus %15 was reimbursed.

- Pricing:

Reference price system was introduced in 2004. Drug prices were determined based on prices in reference EU countries (Portugal, Spain, France, Italy, and Greece). For original products without generic, lowest reference price is taken; whereas for originals with generics and generic products %66 of lowest reference price is taken.

- Bio-equivalence testing for generics:

Generic product manufacturers applying for a product approval in Turkey are required to submit bio-equivalence data. Furthermore, generics that are already registered were mandated to submit a bio-equivalency certificate by December 2005.

- Top 10 pharmaceutical companies in Turkish market:

Currently with around 300 companies, the leading 10 companies of them represent 48% or $4.8 billion of the market in 2008 (IMS Health, 2010). Novartis led the Turkish pharmaceutical market with $763 million in 2008, and Abdi Ibrahim was the second in line registering $585 million in sales. Global major players other than Novartis, namely Sanofi-Aventis, Pfizer, GSK, Bayer and Astra-Zeneca were among the top 10 players. Besides local companies, İbrahim, Bilim, Sanovel have strong presence among the top 10 list, with market share of 13.5% in 2008.

The largest therapeutic segment in the Turkish market was anti-invectives', which recorded $1.8 billion sales in 2008. The anti-infective category in Turkey was led by the cephalosporin which are used in treatment of bacterial infections.

Alimentary tract and metabolism was the second largest therapy area in Turkey with $1.9 billion sales in 2008, capturing 14.5% market share. The leading drug class within this therapy area was proton pump inhibitors which are used to reduce the production of acid in the stomach.

The third biggest therapy area was cardiovascular disorders with $1.4 billion sales in 2008. Antihypertensive and antihyperlipidemia drugs are the largest in this area (IMS Health, 2010)

Turkish pharmaceutical market is highly fragmented with top 10 products capturing 7.1% of the entire market. GSK's Seretide remained the leading brand in 2008 with $108 million sales. The product helps in the relaxation of bronchial smooth muscles, providing relief in these respiratory disorders. Novartis's Foradil Combi which is the sixth product in the market is a big threat against Seretide. Another set of products which exist in top 10 are those used in the management of cardiovascular disorders. Novartis' hypertension management brand Co-Diovan and Pfizer's Lipitor are the biggest brands in this area.

III. RESEARCH METHOD

In this study AHP and fuzzy AHP methods are used as decision support tool individually. In this section AHP and fuzzy AHP methodologies are explained briefly

A. Analytical Hierarchy Process

AHP is one of the most widely used multi-criteria decision making tools (Kahraman et al., 2008, Tozan, 2011). The method was introduced by Saaty in the 1970s. It is basically a mathematical theory for deriving ratio scale priority vectors from positive reciprocal matrices with entries built up by paired comparisons (Saaty et al., 1998; Vijayvargiya et al., 2010, Turgut et al., 2011).It is also a decision making tool that helps the decision making process by decomposing a complex problem into a multi-level hierarchical structure including objectives, criteria, sub-criteria and alternatives (Saaty, 1995; Sharma et al., 2008, Turgut et al., 2011; Zolfani et al., 2012).

The procedures of the AHP can be summarized with the following steps (Saaty, 1995; Lee et al., 2008; Shin et al., 2007; Turgut et al., 2011; Tozan, 2011; Yanar et al., 2012):

- Define the unstructured problem and state clearly the objectives and outcomes.
- Break down the complex problem into a hierarchical structure with decision elements (criteria, detailed criteria and alternatives).After the hierarchical structure is determined, the relative importance of the elements in each level is prioritized. The preference between each pair of elements can verbally be expressed as "equally important, moderately more important, strongly more important, very strongly more important, and extremely more important" with the scale illustrated in Table 1 (Saaty, 1980; Turgut et al, 2011; Tozan, 2011).
- Apply pair wise comparisons among decision elements and form comparison matrices. Use the eigen value method to estimate the relative weights of the decision elements. λmax ; the principal eigen value of the matrix; is determined via the following mathematical relation; $AW= \lambda maxW$ (Turgut, 2011).
- Control the consistency property of matrices to ensure that the judgments of decision makers are consistent.
- Add the relative weights of decision elements to obtain an overall rating for the alternatives.

TABLE 1 - FUNDAMENTAL SCALE USED IN AHP

Intensity of Importance	Definition
1	Equal Importance
2	Weak or slight
3	Moderate importance
4	Moderate plus
5	Strong importance
6	Strong plus
7	Very strong or demonstrated importance
8	Very, very strong
9	Extreme importance

Source: Saaty, 1995; Turgut et al, 2011.

B. Fuzzy Analytical Hierarchy Process

On the contrary human judgment process, crisp methods separates the elements of decision sets in to two basic groups as members (certainly belonging the set) and nonmembers (certainly not belonging the set) which mainly arises from their mutually exclusive structure. And this limitation enforces the decision maker to set a clear-cut boundary between the alternatives (Kahraman et al., 2008; Turgut, 2011, Tozan, 2011). But as the nature of decision making contains vagueness and uncertainty, generally it is very hard to set clear boundaries between the decision alternatives. As fuzzy set theory introduced by Zadeh (1965) has the ability to deal with ambiguous (or not well-defined) conditions (Kahraman et al., 2008) and use approximate rather than precise reasoning (Saaty et al., 2007), it handles this sophisticated decision making process with its brilliant capability of data processing using partial set membership functions (Turgut, 2011; Tozan, 2011).

As the pair-wise comparison in conventional AHP cannot take into account vagueness/uncertainty and the pair-wise comparison is established using a nine-point scale, it fails to capture whole uncertainty associated with the mapping of one's perception to a number. Therefore, fuzzy logic is used in the pair-wise comparison to deal with the deficiency of traditional AHP which is referred as fuzzy AHP (FAHP).

In this paper Chang's extent FAHP is selected and used due to the simplicity of the method. In Chang's extent FAHP; after the hierarchical structure of the model is contracted as defined in section 3.1, objects and goal set are constituted for obtaining extent analysis values for each object. When the analyze is finished; via normalization, the normalized weight vectors can be determined which also indicates solutions for the problematic (Chang, 1996;Tabari et al., 2008; Cakir et al., 2010; Turgut, 2011; Yanar et al.; 2012).

IV. Proposed DMM and an Application in a Turkish Pharmaceutical Company

A. Proposed DMM

As stated before, the goal of the proposed model is to determine the best fit product for the portfolio of the pharmaceutical company in terms of its strategy and long term commercial value. Criteria and sub criteria are determined via questionnaire technique applied to specialists working in pharmaceutical market and profound discussions with experts; especially with the top management of various pharmaceutical companies. After criteria are identified, they are also

checked for relevance with a focus group consists of current and ex business developers. Then a pilot survey is conducted to a sample group of marketing managers and final questionnaire including 46 questions for all possible pair wise comparison of criteria are prepared. The summary of study methodology is illustrated in figure 1.

Main criteria to choose best product are determined as:

- Medical characteristics
- Marketing characteristics
- Commercial attractiveness
- Company fit
- Time to market

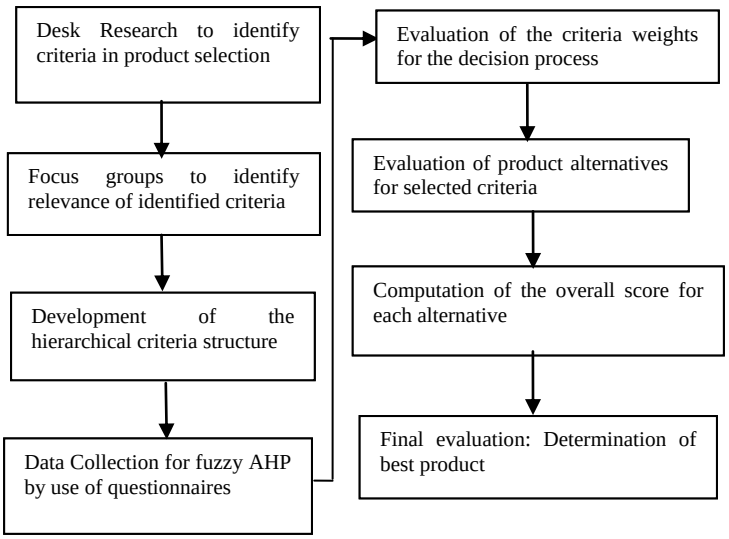

FIGURE1. METHODOLOGY

Source: Authors

Each of main criteria is decomposed into sub-criteria, for example medical attractiveness has following sub-criteria: Superiority to other molecules, meeting an unmet medical need and no of clinical trials conducted and planned.

Similarly, company market share in a related area, company know how in therapeutic area, existence of related sales force in the company are listed under "Company fit".

Seven sub-categories were included under "marketing characteristics": Turkish market size, Turkish market growth, no of competitors in Turkish market, generics impact in Turkish market, expected pipeline product in the same therapeutic area, global market size, and global market growth.

Also, commercial attractiveness includes 3 sub-criteria: Potential attractiveness, potential profitability, expected rate of return.

The last main criteria "time to market" contained 4 sub-criteria: deal easiness, registration easiness, reimbursement easiness, and predicted years to launch.

B. An Application in a Turkish Pharmaceutical Company

The application of the model is implemented in a multinational pharmaceutical company operating in Turkey. The company has a Business Development department mainly focusing on in-licensing opportunities. The aim of the company; which is to assess in-licensing opportunities in a systematic way, is performed using the proposed model. Three potential products with the following characteristics are A, B, and C are compared.

Product A: Niche product in high priced Therapeutic Area like oncology, respiratory

- High market size
- Very high market growth
- High profitability
- Targeted physicians: Specialties like oncologist, endcronologs

Product B: Consumer lifecycle products like food supplements, dermocosmetics,

- Weight loss products
- Promoted by small pharmaceutically teams and trade channel activities
- Paid out of pocket
- High market growth
- High profitability

Product C: Mass chronic products in hyperlipidemia, hypertension, depression

- Promoted by large FF teams
- Medium market growth
- Medium profitability
- Targeted physicians: Specialties like cardiologists, neurologists

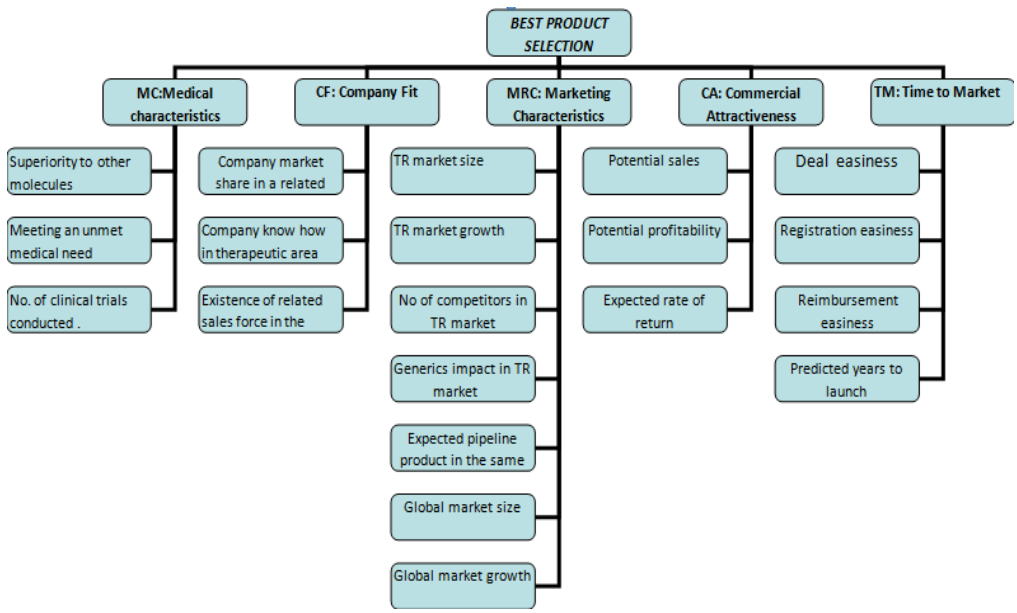

FIGURE2. PROPOSED MODEL

Source: Authors

In the study for fuzzy AHP, the decision makers utilize the linguistic set W as illustrated in Table 2 (Saaty, 1994).

TABLE 2 - THE SCALE USED FOR FUZZY AHP

Verbal Judgment	Fuzzy Scale
Equal	(1 , 1, 1)
Weak	(2 / 3, 1 , 3 / 2)
Fairly Strong	(3 / 2, 2 , 5 / 2)
Very Strong	(5 / 2, 3 , 7 / 2)
Absolute	(7 / 2 , 4 , 9 / 2)

Source: Saaty, 1994

For determining the values for the application a Visual C# based program. The results are illustrated with the following tables.

According to these results, pharmaceutical companies should find products with high commercial attractiveness which means products with high price, profitability and rate of return. Specialty area products such as oncology, respiratory or niche areas like growth hormones, Gaucher disease products which are seen in a very small population are candidates for high price. If targeted specialty doctors are not very crowded like oncologists, endocrinologists, algologists, the investment needed to promote the product is minimal and it enables high profitability.

TABLE 3 - WEIGHTS OF CRITERIA

Criteria	Sub-criteria	Relative Weight	Global Weight
Medical Characteristics	Superiority to other molecules	37%	7%
	meets an unmet medical need	63%	12%
	No. of clinical trials conducted and planned	0%	0%
		100%	18%
Company Fit	Company market share in related market	34%	4%
	Company know & how in TA	34%	4%
	Existence of related FF team in the company	32%	4%
		100%	13%
Marketing Characteristics	TR (Turkish) market size	17%	3%
	TR market growth	20%	4%
	No of competitors in TR market	17%	3%
	Generics impact in TR market	20%	4%
	Expected pipeline product in the same therapeutic area	6%	1%
	Global market size	13%	3%
	Global market growth	7%	1%
		100%	20%
Commercial Attractiveness	Potential sales	34%	11%
	Potential profitability	34%	11%
	Expected rate of return	32%	10%
		100%	32%
Time to Market	Deal easiness	7%	1%
	Registration easiness	25%	4%
	Reimbursement easiness	47%	8%
	Predicted years to launch	21%	3%
		100%	16%

Source: Author's calculation

Marketing characteristics is the second important factor in choosing the best product. Although it involves seven different sub criteria, most critical ones are Turkish market growth (%20), generics impact (%20), Turkish market size (%17), no of competitors (% 17), other factors has less importance e.g. expected pipeline (%13), global market growth (%7), global market size (%6). For a high potential product candidate Turkish market size and market growth is very critical, if a product is not exist in Turkey looking to global data for the product's market

size and growth may give a good indication, however deep dive analysis should be done to understand major contributor markets in the world. Europe can be a good indicator for Turkey regarding to illnesses experienced and reimbursement rules conducted. Certain types of illnesses are specific to some countries like AIDS in Africa, Hep C in China, India.

Medical characteristics is the third important determinant with sub categories of superiority (%37) to other molecules , unmet medical need (%63). If a product is first in its class , and cures a disease which was not be able to cured by other products , it is obvious that this product will have a very high potential. If a product is differentiated from existing therapies with its medical features such as efficacy, efficiency, life expectancy; this product will be far beyond of other molecules

Time to market is the fourth prioritized aspect in choosing a product for the portfolio. Reimbursement easiness (% 47) , registration easiness (%25) and predicted years to launch (% 21) are drivers of this category. Bringing a new product to the market is a very long process due to extensive R&D and elongated registration and reimbursement steps. This process takes 10 years on the average. If a product is differentiated from existing ones in terms of medical characteristics or low price, registration and reimbursement could be faster, and this creates advantage of realizing sales earlier which is very valuable for any company.

The last criterion in product selection is company fit. Existence of market share, know-how and related field force of the company for the product category determinescompany fit. As can be understood from lowest score of this criteria, if a company sets a target of acquiring new products for the portfolio, that company can build all necessary muscles like field force, Key Opinion Leader's relationship, marketing expertise for this new product. If these capabilities have already been existed within the company it shortens the time necessary for the uptake of the product, and it enables cost saving for the product.

Once all the relative weights have been calculated, a composite weight for each product (A, B and C) is determined. This is achieved by aggregating the weights over the hierarchy for each decision choice. The weights from top of the hierarchy to down for each product are multiplied, and then sum those products over all different pathways to that product. The result is single weight value for each product. The combination of weights for sub criteria and alternatives to determine priority weights for main evaluation criteria is given in the Table 4.

B. Results of the Application

The dimension specific scores shown in table 3 provide managerial insights for strengths and weaknesses of each product. Managers can give attention and evaluate the possibility of increasing low scores by investing on that product, so that this product may be a candidate for the portfolio.

The results indicate that product alternative A is the first choice of the case company with %57 overall score, whereas product B and C has scores of %15 and %28 respectively. The high score of A comes from both it's commercial attractiveness (%18) and medical characteristics (%17). Time to market (%9) and marketing characteristics (%8) are second tier factors, and company fit (%5) is the last factor for prioritizing product A as a best alternative.

Since the product A is a niche product with very high price, and it's market is big and growing fast it's potential sales is expected to be very high. Main two expense items for a product is field force and marketing expense. For product A, field force expense will be low, since the product will be promoted to small no of specialties, although marketing expense per Dr is expected to be high, overall marketing expenses will be reasonable due to size of targeted

doctors. Small field force and reasonable marketing expense together with high priced will lead to high profitability and high rate of return.

Unmet medical need attribute of Product A brings high medical score to the product. This attribute differentiates product A from other alternatives which is really a very critical aspect for a product's success. If a product is a first product in its area and meets a medical need which was not addresses by any other product before, this product will very well accepted by doctors, regulatory authorities for fast registration and reimbursement.

Unmet medical need attribute of product A may expedite reimbursement and registration processes and this may lead to fast launch of product.

TABLE 4 - WEIGHTS OF CRITERIA FOR EACH PRODUCT

	Product A	Product B	Product C
Medical Characteristics	**17,1%**	**0,0%**	**1,3%**
Superiority to other molecules	5,5%	0,0%	1,3%
Meets an unmet medical need	11,6%	0,0%	0,0%
No of clinical trials conducted and planned	0,0%	0,0%	0,0%
Company fit	**4,8%**	**2,9%**	**5,4%**
Company market share in related market	1,6%	1,2%	1,7%
Company know & how in TA	2,0%	0,7%	1,7%
Existence of related FF team in the company	1,2%	1,0%	2,1%
Marketing Characteristics	**8,0%**	**4,2%**	**7,8%**
TR (Turkish) market size	1,0%	1,0%	1,5%
TR market growth	1,7%	1,0%	1,3%
No of competitors in TR market	0,9%	1,0%	1,4%
Generics impact in TR market	1,7%	0,5%	1,8%
Expected pipeline product in the same therapeutic area	0,5%	0,3%	0,4%
Global market size	1,6%	0,0%	0,9%
Global market growth	0,6%	0,4%	0,5%
Commercial Attractiveness	**18,3%**	**5,4%**	**8,6%**
Potential sales	5,6%	2,1%	3,3%
Potential profitability	6,0%	2,2%	2,8%
Expected rate of return	6,7%	1,1%	2,5%
Time to Market	**8,9%**	**2,3%**	**4,9%**
Deal easiness	0,4%	0,3%	0,4%
Registration easiness	2,1%	0,8%	1,1%
Reimbursement easiness	4,8%	0,3%	2,4%
Predicted years to launch	1,6%	0,8%	1,1%

Source: Author's calculation

Product A has low company fit score which means the company does not exist any product in the related therapeutic area, therefore it must build know how, field force and

relationship with doctors. However if the product is very potential one, it is logical for companies invest on that product even if they do not have any experience. Although the model has been illustrated for three alternative products, it is capable of comparing more than three products at the cost of complexity. Biasing of decision makers can be an issue. To avoid such situations, group decision-making techniques should be used. For example, brainstorming and sharing of ideas and insights often lead to a better understanding of the issues than would be possible for a single decision-maker.

IV. CONCLUSION

Finding external products for pharmaceutical companies becomes increasingly important in today's complex environment. Increased regulations, inefficiencies in R&Ds, cost containment pressures of governments pushes pharmaceutical companies create new product alternatives. Business Development activities such as choosing best products through in-licensing evolve very importantly in companies. This study introduced a systematic way for choosing the appropriate external product for a pharmaceutical company. A case study for identification of the best product to license-in for the selected Turkish pharmaceutical company is also performed and three pharmaceutical products ranked according to the proposed model.

With the aid of the methodology used a complex multi-criteria decision-making problem is simplified. Subjective judgments are quantified, which is necessary to evaluate different alternative products. Another advantage of this methodology is that it not only supports group decision-making but also enables us to document the various considerations in the process of decision making. The selection process involves the determination of quantitative and qualitative factors to select the best possible product. Decision-makers face up to the uncertainty and vagueness from subjective perceptions and experiences in the decision-making process. Multi-criteria decision systems need experts in different areas. Fuzzy theory can be used in many decision making areas like that. Fuzzy AHP approach seemed to be particularly effective in reducing the uncertainty in the determination of the relative weight given to the different criteria and in determining the impact of each alternative provider on the attributes considered.

Further studies can be performed using other decision making techniques such as fuzzy TOPSIS and PROMETHEE for the proposed DMM.

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MODEL ODLUČIVANJA U FARMACEUTSKOM MARKETINGU I SLUČAJ TURSKE

Sažetak: Odabir prikladnog proizvoda za portfolio farmaceutske kompanije u smislu strategije I dugoročne komercijalne vrijednosti je sofisticirana problematika baziranana mnoštvu kriterija u farmaceutskoj ekonomiji. Ovaj rad donosi sustavnu metodu za licenciranje u farmaceutskoj industrijii predlaže „fuzzy" AHP bazirani model odlučivanja za one koji u farmaceutskoj industriji donose odluke kako bi odredili potencijal raznih proizvoda koji bi mogli biti pogodni za njihov portfolio. Predloženi model je primijenjen na jednoj farmaceutskoj kompaniji u Turskoj.

Ključne riječi: marketing, odlučivanje, farmaceutska industrija