

A Survey on Research Methodology to Evaluate the Technological Capabilities of Iran's Current Pharmaceutical Industry to Provide a Model for Accelerating the Transition to Biopharmacology

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Abstract

Research plays an important role in evaluating an issue or problem or performing a technological activity. We aimed to present a research methodology to assess the technological capability and its influencing factors in the developed and developing countries in biopharmaceutics. Accordingly, we studied the methods that could be used for evaluating and presenting a model in such countries. In this qualitative study, we assessed independent variables and their effect on dependant variables in developed and developing countries. Then, the studied indices were considered as standards. The study ultimately concludes with a qualitative assessment of the pharmaceutical industry and a quantitative assessment of the current status of this industry in Iran. By comparing the current condition of this industry with the obtained standards, the amount of under development in this field was determined and analyzed. With respect to the novelty of this study's methodology, our findings are hereby presented to be reviewed by experts in this field.

Keywords: Technological Capability, Influencing Factors, Biopharmaceutics, Developed and developing countries.

1. Introduction

Field studies show that pharmaceutical and biotechnological companies in Iran do not use the existing potentials in this field with respect to certain variables (Mani & Halimi, 2011). These variables include the molecular biology revolution, innovation, laws, regulations and necessities, international business environments, research settings, and international development (Mani & Halimi, 2011). Only a few private biotechnological companies have manufactured biosimilar products (Business Monitor International, 2012). Moreover, pharmaceutical companies are still manufacturing generic drugs and no research and development has been done for manufacturing innovative products. Most of these companies still desire to obtain the license for producing currently available medicine from multinational pharmaceutical companies. As a result, important potentials in revolutionizing the pharmaceutical industry and developing biopharmaceutical products have been neglected.

Of the \$ 3.2 billion worth Iran's drug market in 2009, only \$300 million was spent on biotechnological products; of which only \$50 million was related to national generic brands and the rest was related to imported brands (Food and Drug Deputy, Ministry of Health, 2009) (Business Monitor International, 2012). This is while, according to the pharmaceutical statistics report, 10% of the \$751 billion worth the global pharmaceutical market in 2007 was related to the production of biotechnological pharmaceuticals (Business Monitor International, 2012). Despite the general governmental support of biotechnological development, only \$50 million (less than 1.5%) worth of Iran's drug market is spent on biotechnological production. Also, this amount is mostly spent on biosimilar products not on creating new molecules (Food and Drug Deputy, Ministry of Health, 2009) ((Business Monitor International, 2012).

Iranian pharmaceutical companies have not clinically tested any new molecules yet, while newly established American biotechnological companies have created 2900 new molecules, of which 633 molecules are in different clinical testing stages for obtaining the Federal Drug Association's approval (Gallaher & Petrusa, 2007). Currently, poor and limited potentials exist in some Iranian biotechnological companies. However, it seems that failure to actively approach the achievements of the biotechnological revolution and the lack of sufficient interactions and collaborations has led to the current setbacks in this area (Pharmaceuticals & Biotech Industry Global Report, 2011). These approaches could consist of merging companies, considering new regulations such as trade-related aspects of intellectual property rights or foreign direct investment, and interacting with the World Trade Organization (Pharmaceutical Research and Manufacturers of America, 2011).

Considering the current under development, we will study the different aspects of global developments in pharmaceutical-biotechnological industries. We will also assess the facilities and limitations of Iranian pharmaceutical-biotechnological industries to match them with the developments of developed and developing countries in this field (Germany Trade and Invest. (2011). We aimed to identify the effective and influential variables in biopharmaceutics to accelerate the transition from the current pharma-

ceutical industries to biopharmaceutics. Accordingly, the practical and theoretical models in this study can help identify the current situation. It can also help find effective national and international factors that could enhance the country's technological capabilities in order to overcome the current under development and reach global standards. Our findings can be beneficial for researchers as well as policy makers in pharmaceutical industries.

2. Aim of the study

2.1 The ideal aim:

Enhancing public health through identification and assessment of the effective factors in improving the technological capabilities in the pharmaceutical and biotechnological industry in Iran considering the global development of biopharmaceutics

2.2 General aim:

The identification and assessment of the effective factors in improving the technological capabilities in the pharmaceutical industries in Iran to shift from the current pharmaceutical production to biopharmaceutical production.

2.3 Specific aim:

Presenting a model for policy making in Iran's pharmaceutical industry to accelerate the transition to biopharmaceutics

2.4 Practical aim:

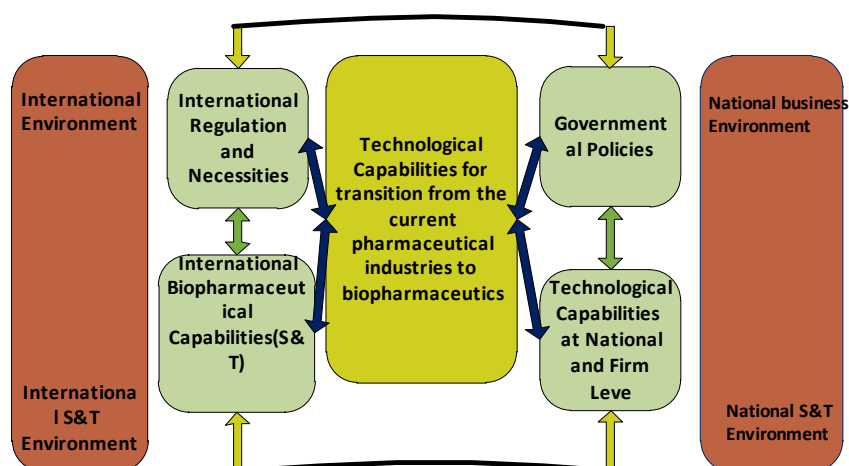
The use of this model by policymakers in the governmental and private sectors of pharmaceutical and biotechnological industries so that they could present suitable strategies to related biopharmaceutical firms

3. A conceptual model and the parameters of a comparative study Conceptual model

3.1 Model:

It is a theoretical model derived from the research literature. This model has been used as the basis for assessing the current situation in Iran's biopharmaceutical industry. Therefore, the strengths and limitations of this industry are identified based on amount of consistency between the current situation in our country and the obtained model. The inconsistencies show the current gaps and limitations which require suitable approach in order to be modified, enhanced, and developed. All these issues will be discussed in the form of an integrated set of strategies and solutions. Figure 1 shows the set of critical success factors (CSF) in technological capabilities and their mutual effect on each other. This model shows that these key factors (dependent variables) interact with each other and also with technological capabilities (dependent variable). In fact, this model also represents the relationship between these variables (dependent and independent) in national and international environments for comparative studies based on the conceptual framework presented in the model.

Figure 1: Conceptual Model of the Relationship between Variables

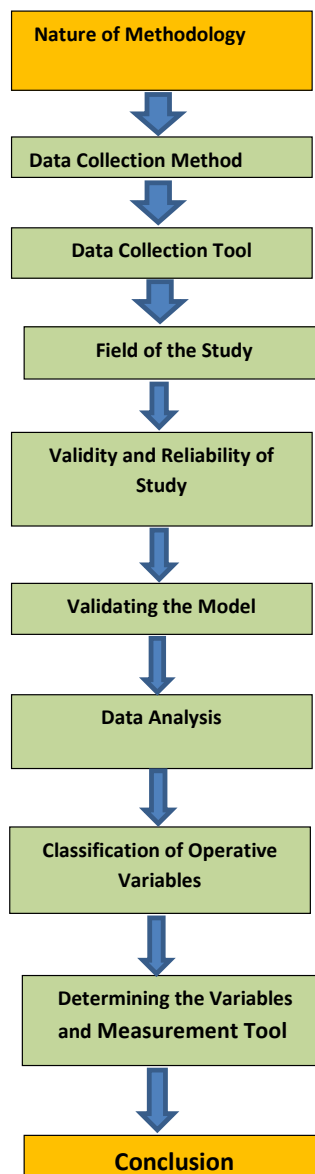


3.2 Parameters of a comparative study

Table 1 shows the general concepts illustrated in (Fig. 1) more specifically in order to be compared. This table is designed in a format that compares the technological capabilities in national and international environments using the measurable sub-varia-

bles. Some of these variables are quantitative while others are quantitative. The effects of independent variables on dependent ones (technological capabilities) have been shown. Therefore, it is easier to assess and validate this model in a statistical population and perform a comparative study. The flowchart regarding the different stages of the study is shown in (Fig. 2).

Figure 2: Research Methodology Flowchart



3.3 Research methodology:

This study will use its own specific methodology based on the aims and the nature of the data (qualitative or quantitative). Therefore, this study will be a descriptive-comparative study using a conceptual framework.

3.4 Data collection method:

Systematic review of the existing literature based on a specific pre-determined protocol to identify the latest theories on the study variables. We will also search the existing documents in institutions and organizations (the statistical population) to gain technical, technological, and organizational information.

3.5 Data collection tool:

Data will be collected using structured questionnaire consisting of different sections about the research questions, variables, and the research problem, based on a comprehensive model and variables' operational table. For questions requiring an expert opinion, a questionnaire will be designed for exploratory interviews; which will include a guide for conducting the interview.

Table 1: Table of variables and their classification

Variables	Technological Capabilities (National Environments)				Technological Capabilities of Biopharmaceutics (International Environments)											
	National S&T Environment		National Business Envi- ronment		Infrastructure	Collaborations		International S&T Environment		Business Environment		Infrastructure and Legal Requirements		Collaborations		
Effective Factors (In- dependent variables) Technological Capabilities (Dependent Variables)	The facilities of Laboratory Network and Equipment		Technology Transfer Capabilities		Governmental Policies	World Trade Organization	Patent	Joint Research	Joint marketing	The facilities of Laboratory Network and Equipment		The cost of Research and Development		Research and Skilled Workforce		
	The cost of Research and Development		Private Investment and Venture Capital		Public Sector Investment		Private Investment and Venture Capital and Venture Capital		Technology Transfer		World Trade Organization		Patent		World Trade Organization	
	Researchers and Skilled Workers		Public Sector Investment		World Trade Organization		Patent		Joint Research		Joint marketing		Public Sector Investment		Private Investment and Venture Capital	
	Technology Transfer Capabilities		Private Investment and Venture Capital		Public Sector Investment		World Trade Organization		Patent		World Trade Organization		Joint Research		Joint marketing	
	The facilities of Laboratory Network and Equipment		Technology Transfer Capabilities		Governmental Policies		World Trade Organization		Patent		Joint Research		Joint marketing		The facilities of Laboratory Network and Equipment	
	The cost of Research and Development		Private Investment and Venture Capital		Public Sector Investment		Private Investment and Venture Capital and Venture Capital		Technology Transfer		World Trade Organization		Patent		World Trade Organization	
	Researchers and Skilled Workers		Public Sector Investment		World Trade Organization		Patent		Joint Research		Joint marketing		Public Sector Investment		Private Investment and Venture Capital	
	Technology Transfer Capabilities		Private Investment and Venture Capital		Public Sector Investment		World Trade Organization		Patent		World Trade Organization		Joint Research		Joint marketing	
	The facilities of Laboratory Network and Equipment		Technology Transfer Capabilities		Governmental Policies		World Trade Organization		Patent		Joint Research		Joint marketing		The facilities of Laboratory Network and Equipment	
	The cost of Research and Development		Private Investment and Venture Capital		Public Sector Investment		Private Investment and Venture Capital and Venture Capital		Technology Transfer		World Trade Organization		Patent		World Trade Organization	
	Researchers and Skilled Workers		Public Sector Investment		World Trade Organization		Patent		Joint Research		Joint marketing		Public Sector Investment		Private Investment and Venture Capital	
	Technology Transfer Capabilities		Private Investment and Venture Capital		Public Sector Investment		World Trade Organization		Patent		World Trade Organization		Joint Research		Joint marketing	
Technology Transfer Capabilities																
Production Capabilities																
Innovation Capabilities																
Commer- cialization Capabilities																

Row	Name of Variables	Role of Variables	Type of Variables	Definition of Variables (Scientific and Operational)	Measurement Tool	Measurement Unit
1	Technology Transfer Capabilities	Independent	Qualitative	The Definitions Mentioned in the section 1	-	(Weak, Average, Good, Excellent)
2	Production Capabilities	Independent	Qualitative		-	
3	Innovation Capabilities	Independent	Qualitative		-	
4	Commercialization Capabilities	Independent	Qualitative		-	
Variables of National S&T Environment						
1	Laboratory facilities and Equipment	Independent	Quantitative	Based on Square Meters and the Number of Suitable Laboratory Equipment	Questionnaire and Field Test	Square Meter and Numbers
2	Costs of Research and Development	Independent	Quantitative	Based on the Budget and Research and Development Environment	Questionnaire and Field Test	Annual Budget in RIALS
3	Research and Skilled Workforce	Independent	Quantitative	Based on the Number of Research and Skilled Workforce in the Field of Biopharmaceutics	Questionnaire and Field Test	Person
Variables of National Business Environment						
1	Regulations	Independent	Qualitative	The Bill Passed, Current Regulations Suitable for Development in the field of Biopharmaceutics	Questionnaire and Field Test	Exist/Not Exist
2	Investment in Public and Private Sector	Independent	Quantitative	Based on Statistics on Public Investment in Pharmaceutical Biotechnology	Questionnaire and Field Test	The Amount of Investment in Rials
Political Infrastructures of the Government						
1	Outlook	Independent	Quantitative	Documents	Questionnaire and Field Test	Exist/Not Exist
2	Policy Making campaigns	Independent	Quantitative	The Number of Existing and Active campaigns	Questionnaire and Field Test	Exist/Not Exist

3.6 Field of the study:

Experts in the pharmaceutical industry, leading companies and countries in the biopharmaceutical industry as well as Iranian pharmaceutical companies and institutes.

3.7 Validity and reliability:

The questionnaire will be validated by experts, professors and specialists in this field. After validating the questionnaire based on the obtained ideas and performing the pilot study, a comparative study will be done. This comparative study will aim to obtain a conceptual model regarding the assessed indices in the biopharmaceutical industry of leading countries as illustrated in the Table 2.

3.8 Validating the model:

Based on the conceptual model (Fig. 1), each dependent variable is the resultant of several independent variables. The results obtained from the comparative study will indicate the different desired levels in the sample countries. Therefore, the different desired levels and the cut off points will be determined for each independent variable. Accordingly, the nominal qualitative variables such as presence or absence of regulations will be recorded in binary codes (0 and 1). With respect to quantitative variables such as number of skilled workers, etc., the desired levels will be divided into multiple categories for comparison.

The categories can be rated based on 2, 3 or 4 states like weak, average, good and excellent or other rating systems, which will be determined at the end of the study based on the distribution type of each variable. Then based on the obtained parameters from the model countries, the adapted and obtained model will be examined and validated in a case-control study using the models of under developed countries. This model will be the basis of practice in the current situation of the Iranian biopharmaceutical industry. Therefore, those items that correspond with the current status in Iran will be considered as the strengths and those that do not, as the gaps and limitations. After identifying the limitations and weaknesses, corrective, reinforcing, and developmental strategies need to be put in place. These strategies will be presented and discussed.

3.9 Data analysis:

Data will be analyzed using descriptive statistics (frequency distribution tables and graphs), deductive statistics (cross tables using proper statistical tests), and the Lisrel structural equation.

3.10 Classification of operative variables:

Figure 3 illustrates the qualitative and quantitative nature of the variables and the role determined for the dependent or independent variables. The measurement and data collection tool is also specified. In this figure the variables are divided into two groups: A) dependent variables that include technological capabilities required for development and transition from current technological capabilities in the biopharmaceutical industry to technologies based on biopharmaceutics and B) independent variables in the national environment.

Dependant variables include production, innovation, technology transfer, and commercialization. Independent variables in the national environment include the technological and scientific environment, the business environment, infrastructure and legal requirements, international collaboration (including the international technological and scientific environment, business environment, infrastructure and legal requirements, and collaborations). This figure is a road map that assists the survey section of our study. It also helps in preparing a valid and reliable questionnaire.

3.11 Variables and measurement instrument:

Table 2 illustrates the qualitative or quantitative nature of the operational variables and the their method of measurement

4. Conclusion

The research methodology presented in this proposal can help create a basis for evaluating the variables that affect technological capabilities in Iran's pharmaceutical industry in order to revolutionize themselves and better adapt with global biopharmaceutical developments. This methodology can be used as a model for evaluating technological capabilities in biopharmaceutics and their influential factors in the developed and developing countries. Moreover, this study is also beneficial for policy makers and planners in the transition from the current technological capabilities in the pharmaceutical industry to enhance biopharmaceutical technologies. Our methodology will also present a clear picture of the current situation and the method of transition to biopharmaceutics to pharmaceutical companies in general, and to knowledge-based companies specifically.

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