

Commercialization Process of Biopharmaceuticals Development

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Abstract—Considering the changes of pharmaceutical industry in interaction with biotechnology and the significant role of biopharmaceuticals in the treatment of special diseases, investigating the commercialization process will play an important role in rapidly offering the products to market. The aim of this study is introducing the process of commercialization of biopharmaceuticals. The methodology of this research was based on literature review and deduction of related scientific papers and reports. Because of the important role of biopharmaceuticals in industry and their increasing commercial success, we need to focus on factors which can assist the reduction of costs and quick deliver. The results of this research indicate that there are various factors which can affect the success of biopharmaceuticals commercialization.

Index Terms—Biopharmaceuticals, biotechnology, commercialization, new product development.

I. INTRODUCTION

During the last decades biotechnology science has been proved as a source of new technologies in drug industry [1]. Researchers have attributed commercial application of biopharmaceuticals into two main elements. The essence is with the high risk of drug producing process that highly emanates from uncertainty derived from immunity. Generally for this reason drug industry must follow scientific international laws that affect development, production and drug marketing. Moreover, development and commercialization of one drug is a long and difficult process that can last 9 to 12 years without any guarantee in its commercial success [2].

In Finland biotechnology is a growing industry and there are various companies in this field. Remarkable general investment on research, innovations and biotechnology has been spent. But there is an important problem in biotechnology field. Although this country has proper researching activities in international standard stage, commercialization of these researches could be better. Process of converting ideas into final product requires a lot of time and energy; moreover all ideas don't always fructify. So,

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commercialization is a present topic in this industry [3]. Regarding the revolutions of this industry in interacting with biotechnology science accomplishments and due to the importance that biopharmaceuticals have in curing special disease in society, studying commercialization process of biopharmaceuticals and determining important factors that affect this process have significant role in reducing its expenses, faster presentation of a product to the market and adjusting products with patient needs. The goal of this article is studying commercial process of biopharmaceuticals and determining important challenges in commercialization of pharmaceuticals. Research method in this study was retrospective and the information related to it has been taken from scientific authentic sites such as Science direct and Emerald.

II. COMMERCIALIZATION PROCESS

Innovation is a process that involves idea to commercialization i.e. transition of idea or invention to market as a new product, process or service from a process that includes stages such as idea generation, research and development, product development and marketing of new products or service. In fact innovation is a commercial and scientific application of ideas or inventions [4]. Commercialization process determines success of entering a product to the market. A product may fulfill technical predictions, but commercialization fails.

Rope states that commercialization time maybe acceptably different in various products, and it depends on business groups, product types, range of novelty, customer groups, market condition, sources and company strategies [5].

According to Asian and Pacific Center for Transfer of Technology (2005) commercialization includes a set of activities that is able to acquire idea, set them to achieve their growth, develop technologies resulting from research, prototype producing, deploy developed technologies, develop a new process or improve existing processes, supply product to the market, create sales situation and new infrastructures (6).

III. DEVELOPMENT AND COMMERCIALIZATION OF BIOPHARMACEUTICALS PROCESS

Biotechnology is a technique that utilizes organisms in order to create or change in products, quantitative improvement of plants or animals and changing microorganism's features for special applications [7]. According to this definition utilizing organisms abilities especially microorganisms is one of biotechnological application. Other applications of biotechnology in

pharmaceutical section are drugs with rDNA technology, interferon, vaccines, etc.

Process of developing new drugs in biopharmaceutical field doesn't have many differences with the other sectors of pharmaceutical industry. But in drug discovery in industrial method, treatment is used as a basis for drug development, and in biopharmaceuticals this process begins with recognition of genes related to a special disease [8]. Process of developing new drugs in biopharmaceuticals field, combines technical and scientific researches in order to achieve commercialization of a new drug. So process of developing a new drug includes three stages of research/discovery, development and commercialization [9].

Research discovery stage includes three parts of recognizing genes connected to disease, recognition and authentication of aim proteins that result in disease and recognizing new molecules that prevent disease [10]. Usually in this stage for invention registry applications filing is necessary in order to limit future competition in technical field. After discovery stage, there is development stage which includes preclinical and clinical tests. In preclinical test stage, tests accomplish on animals in order to measure the poisonousness of a drug. After preclinical tests Investigational New Drug Application (INDA2) is filled to determine the immunity and usefulness proofs. The regulatory authority is responsible for confirming the application before entering the product development into the next phase.

Clinical tests are divided into three stages. In the second phase, usefulness and technical side effects will be investigated on 100 to 300 patients. Also, in the third phase long term effects of drugs will be examined on 1000 to 6000 patients in order to compare the new drug with available treatments and pharmaceutical formulations [8]. These phases occur respectively and each phase cannot start without succeeding of the previous phase. It should be noted that among these phases, the third phase requires the most time and expense to itself. If clinical tests pass on successfully new drug application (NDA) will be filled. The regulatory authority fills this application. If the confirmation of drug market received too, entering into the market could be started [8], [9].

After successful screening process, producing biopharmaceutical Products Company is an appropriate candidate for measuring findings. This phase typically lasts more than 10 years till necessary clinical studies are completed. Noting this point that a product could fail at any time during the test, and the project may end without commercial results, is very important. After measuring phase and if candidate product is tested successfully and without any reversed reaction, company is ready for commercialization. [10].

IV. CHALLENGES OF NEW DRUGS DEVELOPMENT

Commercialization stage is consisted of drug production and marketing. In this stage company must find commercial methods of producing a product and take an appropriate strategy for entering into the market. The commercialization stage usually starts at the end of clinical tests. Biopharmaceutical commercialization process confronts with

uncertainty and various technical and commercial risks in each stage. Moreover it is a long and expensive process as in average new drug development lasts 14 years [11].

Choosing partner is an inseparable part of biopharmaceutical business; because small companies with heavy R&D expenses are not able to create their international marketing networks. Usually newly founded companies in this field have copyright contracts and chose partners that have strong position in the market. After this stage, company must investigate to see whether selected partner has invested in product market or not.

Biopharmaceutical companies should have some drugs in the development process at the same time [12]. The companies which have only one product in their development process, due to several risks in this process, are more vulnerable but it should be noted that research and development of some drugs alone has roughly multi billion dollars costs for the companies [8]. However, having many goods in the process of new drugs can't be desirable. Because the investors may be concerned about unsuitable results and debit in the next stages. As a result, financial support of new drug development is a risky activity for drug companies [12].

Based on recent studies, most proportion of patents in this field is related to US which were roughly 58.3% between 1931-2013. Furthermore, North American organizations have allocated 2/3 biotechnology drugs to themselves comparison with Asia and Europe organizations. Eli Lilly and Genentech were the dominant companies in biotechnology patents [13].

Biopharmaceuticals Industry created 28.8 % job positions rather than other industries such as computers.

Supplying the financial resources for development of biopharmaceuticals and passing the valley of death is very needful like other industries. In the sector of R&D, the valley of death is the location between market and laboratory research that many novel ideas like biopharmaceuticals may fall in and waste or can cross this place through suitable decisions.

In the most cases, this distance is due to lake of financial resources for growing new ideas and proving their products to the market. Biopharmaceutical companies supply most of their capital from private sector [14]. Financial resources in the process of new drugs development can be provided by some sources; for example: friends and relatives, initial investment of co-founders, angels and, venture capitals. These sources are explained in Table I [15]-[17].

Intellectual property rights can help companies to prevent the propagation of counterfeit drugs. These kinds of drugs not only reverse the intellectual property rights, but also due to toxic symptom of them, they have many risks for human's health. Thus, pharmaceutical companies should consider the issues of intellectual property in the initial process especially establishment phase [18], [19]. Patent is one of the important intellectual assets for pharmaceutical companies. Drug patents can cover the products which have long time development process [20].

V. KEY SUCCESS FACTORS OF BIOPHARMACEUTICALS COMMERCIALIZATION

Because of multiplicity of pharmaceutical products and

obligation of companies to compliance with the standard laws of drug producing, process of producing new pharmaceutical products are very risky, expensive and time consuming, noting key factors in success of commercialization of these drugs is very important, because if biopharmaceutical products fails after the process, expenses and sources of company would have been wasted. In studying these factors, success factors are divided into two main groups of internal and external success factors. Internal success factors include products, networks and condition of firms and external factors consist public infrastructure and policies [21].

Summary of the other success factors of biopharmaceutical commercialization is shown in Table II.

TABLE I: SOURCE OF FINANCING IN THE PROCESS OF NEW DRUGS DEVELOPMENT

Source	Explanation
Initial investment of co-founders / Friends and relatives	Initial investment of co-founders and friends and relatives like other industries can provide preliminary resources for establishment of company and supply the required facilities.
Angels	Angels especially in the private sector obtain the initial resources and also, there are experienced people among them who can invest roughly 5-15% of these resources for the risky business.
Venture capitals	Venture capitals are professional managers who can administer the financial resources for other investors such as pension funds.

TABLE II: SUMMARY OF KEY SUCCESS FACTORS OF DRUG COMMERCIALIZATION

Success factors	Domain	Author - year
excellence in invention, excellence in production technology, continuous development after patent, advertisement, exclusive production, human resources, enough infrastructure for internal and external demands	Commercialization of drug	Lee,2002 [22]
Method of production, product quality, Advertisement: marketing, propaganda and public communication, Accreditation Choosing appropriate partner	Commercialization of biopharmaceuticals	Lemmetynen, 2001 [2]
Ability of staff, Commercialization and Product management, Risk management , Kind of drug		Gustafsson, 2000 [23]

VI. CONCLUSION

Production path of a new drug is a long, complicated and expensive. Regarding to the long new drug producing cycle, being costly and also high risk of these products, this field requires more investigation about determining effective factors on commercialization of these products. This study

proposes that commercialization process must be considered along with the innovating process from the beginning of idea generating stage, and noting customer needs and cooperation between different parts of organization are key items in succeeding of this process.

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