

Challenges and Opportunities: Human Placenta Extract Product Development in Thailand

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Abstract

There have long been products with human placenta extracts (HPE) which have been made profitable in business in many countries such as Japan, Korea and India. In Thailand, however, the use of HPE is a hot issue because of ethical reasons and problems of information insufficiency. This article proposes analysis of opportunity and challenge in developing products from HPE in Thailand. Trends and Population shifts are opportunities for HPE product develop, when demographic changes, it is changing market need. The Challenges of product develop from HPE in Thailand as selective market, it is challenge to choose a market that affect business success, we have found three pathway for product development, pharmaceutical industries, spent high cost and time to product development but the outcome pays off considerably. Cosmetics industries, there are many researches identified cost and time less than pharmaceutical industries. Cosmeceutical industry, it is gray market but attractive, barrier of market is low. Knowledge is another challenge, because business got benefit from patent in a proper time. It's challenge of knowledge from business R&D. For this study provide to understanding of Right place and Right time, in the case of HPE development in Thailand, the right time both challenge and opportunities.

Keywords

Human Placenta Extract, Challenges, Opportunities, Product Development.

I. Introduction

The placenta is an organ connecting between the developing fetus and the uterine wall to allow nutrient uptake, gas exchange, and waste elimination by way of the mother's blood supply. With the belief for more than 2,000 years that the placenta, particularly human placenta, is an elixir, nowadays the human placenta extract is a basis of cell therapeutic, which has created a trend of wide use as in the form of drugs and cosmetics. The stem cell is only a part of the placenta, apart from that there are other chemical compounds which are medicinal or therapeutic for many diseases. More than 5 growth factors, for example, are found in the placenta [1]. Today, the advance of technology – whether it is synthetic chemistry, nano-scale engineering or biological technology – causes the possibility of developing products from human placenta extracts to be more secure and more effective in results. The human placenta extracts have been used in Japan as injection, oral medicine, and supplementary food for health and beauty. About researches on human placenta extracts, plenty can be found on well-known search engines such as Google which provides a search service called “Google patent beta”; for the key phrases “human placenta extracts”, it shows 13,200 results in total. The same search on the website “Free patent online” shows 25,871 results related to the patent of human placenta extracts. With regard to the products in the market around the world, it is

found that Japan has approved injections of human placenta extracts into human beings, for example the product named “Melsmon” for menopausal disorder and failed lactation, or “Laennec” for those with liver disorders. Although the human placenta is known as an important source for growth factors, in Thailand there are limitations and regulations of the Thailand Food and Drug Administration, which are a crucial obstacle for the development of human placenta use here. Nonetheless, the problems concerning the use of human placenta in various products are still argued until now.

II. Challenges

A. Industries

A drug is a substance meant for the diagnosis, treatment, cure or prevention of disease or illness of human beings or animals; it also affects health, structure or bodily function of human beings or animals [2]. As a drug has a direct affect on the human body, there must be systematic verifying procedures and researches to ensure the utmost safety and efficiency of drug. Thus, when considering the process of drug development, we can see that, despite the finding of a new substance in every 1,000 compounds in each company, only 30 compounds can be active in an effective way. And only 1/10 of those effective compounds is brought into clinical trials, finally only one compound can enter the market in a commercialized form [3]. Consequently, the duration of improving a new drug is concerned with many procedures which can be roughly divided into 7 steps as follows

Step 1: Preclinical Research

Step 2: Investigational New Drug (IND) Application

Step 3: Phase I Trials

Step 4: Phase II Trials

Step 5: Phase III Trials

Step 6: New Drug Application (NDA)

Step 7: Approval (Post market testing)

Normally, the average duration of drug research and development from finding a new compound to being approved for commercial in the market in the USA is equal to 14.2 years; and the cost of development is averagely at 897 million US dollars. Moreover, this cost will increase along the course of time and each process of production [4,5]. At any rate, the overall image of the drug industry needs tremendous money in the investment and an extensive time. But as the saying “high risk, high return”, this is actually the characteristic of this industry.

Cosmetics refer to substances used to apply, scrub, rub, sprinkle, spray, put on, steam, scent or with any other ways on a part of the body for cleanness or beauty; or used to enhance the appearance, including skin treatment products but not limited to ornament and cloth which are external of the body [6]. The FDA emphasizes the importance concerning safety and contamination of cosmetics less than those of drug. This

opens an opportunity for manufacturers to create products and access the market of human placenta extracts. In fact, is this possible? Human placenta extracts are not allowed to use in drugs in many countries such as USA, UK, Austria, Canada, and those of EU, because it lacks of support for safety and performance data. Since 2008, all products with human placenta extracts, including the use of the extracts in cosmetics are not authorized by the government of the USA, even though it appears that this kind of cosmetics is still for sale on many websites. In spite of the fact that the Federal Food, Drug, and Cosmetic Act (FD&C Act) has not defined “cosmeceutical”, this product can be drug, cosmetic or even both. Then, the sense of “cosmeceutical” slips through the law. The term is broadly used in the industrial sector to describe products which are medicinal or drug-like therapeutic, as it occurs in Thailand as well. However, the regulations vary in the main cosmetic markets such as in the USA, Japan or the EU [7]. In USA, cosmeceutical products are categorized as “OTC drugs” which are strictly controlled even more than other cosmetic products, but they can still be found for sale without prescription from a doctor or pharmacist, and in general stores. For Japan, the cosmeceutical products are called “quasi-drugs”, as PAL has defined it as the products which are specifically used and insignificantly affects the body, but not for diagnosis and treatment or prevention of disease whatsoever. These products have an effect on the body and by definition cannot be ‘cosmetics’, but they are neither formulated nor regulated as ‘OTC drug’ products. Some cosmeceuticals are naturally derived or some are synthetic. Active ingredients in cosmeceutical products are naturally derived or some are synthetic [8]. What are the active ingredients? The active ingredients in drugs are medicinal; on the contrary, the inactive ingredients are not, but they help to better absorb the active ingredients into the body. In both cases, these ingredients are exactly “active,” acting a specific function upon application or ingestion. How’s important? It is extremely important because the active ingredient in cosmetics is the main factor causing differences according to the properties of such compound. In this matter, the difference between cosmetics and cosmeceutical products are the main active compound; this latter in cosmeceutical products directly affects the skin structure and it is also therapeutic [9]. It is different from the cosmetic products that are only intended to be used to cleanse the body, beauty, and skin care. Active ingredients in cosmeceutical products can classify by different application, for example, ingredients that may reduce water loss from the skin and wrinkle reduction in anti-aging products. Thus, a new active ingredient will create an innovation of product; the same goes for the case of cosmeceutical products with human placenta extracts.

B. Knowledge

According to Peter Drucker (1993), innovation is an important tool of the entrepreneur. The challenge in business competition is the marketing opportunity. The reason is because no one knows exactly when the right time is to launch the products into the market, or when the company should begin a research or an improvement of knowledge for the future market. Besides, there are other factors: technology always changes, as well as the consumers’ need; the competitor introduces a new product into the market; or the environment changes. These are the reasons why no one can decides when the right time is; thus, it is difficult to make this decision while the situation is not stable. The decision to develop the products also needs to be

done quickly even without sufficient information [10]. Many entrepreneurs continue to spend money and time on studies and development even though they are not successful to bring those products out to the market. But what these entrepreneurs gain is skills which they can use as an intellectual property. The concept of intellectual property extends beyond creative effort and encompasses aspects of commercial reputation. Whether one is talking about a new product or new publication they all involve creative effort and as such are the results of intellectual activity on the part of individuals of something new. Intellectual property may therefore be seen as the product of the application of knowledge and skills. To overcome this potential loss to society, the law provides legal recognition of the ownership of the products of creative [11].

The active ingredient is the important key of cosmeceutical product, which can be presented to consumers in terms of its efficacy. It is firm that cosmeceutical products are neither drugs nor cosmetics; therefore, they can be presented with that efficacy. Also, they claim to be able to improve skin texture, increase skin radiance, decrease wrinkling and others, based on a variety of ingredients [12].

This crucial form of cosmeceutical improvement leads to the growth of researches and developments (R&D) regarding active ingredients. When the R&D has a high growth rate, the entrepreneurs can increase their knowledge from these R&D, and sometimes they can make profitable of it as a patent. It’s challenge of knowledge from research and develops.

III. Opportunities

A. Trends

The trend of technology opens to a big opportunity [13]. The regenerative medicine is a trend for future products [14], in particular, those for health, including all products to take care of the body and to maintain its beauty. The consumers these days need a fast and effective result; this is the need that has been changing. The survey result of consumers’ behavior finds that, according to them, the product must have an affect after being used. For example, anti-wrinkle products must in a short time decrease wrinkles; or, teeth whitening products must quickly whiten or brighten teeth [12].

The changing behavior causes that business has to look for new materials of production. The concept of natural extracts directly influences cosmetic products. The marketing plan and public relations are also changed; clinical information and scientific result are communicated to the consumers. The packaging resembles more and more to that of general drugs. All things considered, the cosmeceutical market in Thailand now has an increased growth rate, especially about anti-aging skin care products, whitening products and other customized cosmetics.

B. Demographic

The demographic change also affects the economy, particularly the baby boom of anti-aging products. A baby boom is a demographic phenomenon taking place during the World War II. It is the period when many countries in the world, including Thailand, encouraged increasing population, hence, the increased birth rate back then. Nowadays, Baby Boom is the big population in the world. Once there is a demographic change, the economy and the society will also change. In Thailand, it is found that there are about 25 million people of 31-55 years of age [15]; this is a good sign of developing products to be

in line with the market. For instance, the healthcare industry is an industry which is directed affected by this demographic change although it is not happening today but in the near future. New strategies will be created and modified to overtake the continually changed society. Technology is also developed to support the society with the increased aged people. Furthermore, the demographic change has an affect on the marketing opportunity as the consumers' need changes with the decreased fertility while we are entering the aging society. For this reason, products concerning health and quality of life can become a significant business opportunity. This indicates that the demographic change and technology change are able to build a good business opportunity.

C. Cosmeceutical products

The analysis of previous market of cosmetic products states that the market consists of many products with a high marketing value. These products are used in quotidian life to nurture, maintain and take care of the body. It also attracts the investors. However, there are plenty of competitors in this industry, and it can be easily accessed. Generally in an industry, the manufacturers must create a difference of their products to interest the consumers, the products should be ordered from the publicity. Now the cosmetic products are facing a change; they are focused on by the result which is similar to that of drugs. This gave birth to cosmeceutical products, which have become a new option for the investors because the start-up cost, time, and production process are from the same resources as the cosmetics, and only less than the pharmaceutical products. What is important for the cosmeceutical industry is to improve their products to have better active ingredients which give the consumers a better and faster result. At all events, the cosmeceutical products are developed relying on the strength of both drugs and cosmetics. About the active ingredients used by this industry, they can improve the products in both small and large companies, whether concerning pharmaceutical, biotechnology, natural products and cosmetics. Interesting is that all can develop their own cosmeceutical products by themselves. This is considered as an impact due to the knowledge of biotechnology and pharmacology, which also enables a rapid development of innovation, particularly such as the development of active ingredients to be used in the products in a safe and effective way, and to help improve the products with the lower investment.

IV. Conclusion

The Challenges of product develop from HPE in Thailand as selective market, it is challenge to choose a market that affect business success, we found three pathway for product development, pharmaceutical industries, spent high cost and time to product development but the rewards are high as well. Cosmetics industries, there are many researches identified cost and time less than pharmaceutical industries. Cosmeceutical industry, it is gray market but attractive, barrier of market is low. Knowledge is one part of the challenges, because business got benefit from patent in a proper time. It's challenge of knowledge from business R&D. An opportunity is timely and favorable juncture of circumstances providing a good chance for a successful. We are the identification and exploitation of previously unexploited opportunities. Finding a specific business opportunity with a combination of customer segment, technology and competencies, and application, new opportunities open up because need of customer had changed

from trends and demographic change or new technology lead new ways of accomplishing tasks. Opportunities also emerge from circumstances or experience. Often customers emerge from personal experience of a need or problem that cries out for solution. Another opportunities occurs from the discovery of capabilities can be applied to problem or need [13]. For this study provide to understanding of Right place (market) and Right time, in the case of HPE development in Thailand, the right time both challenge and opportunities, but knowledge and know how about product development from HPE very challenge when the opportunity arrives. When Opportunity Comes Knocking, Will You Be Ready?

V. References

- [1] Intrama, V., Karnchanatat, A., Bunaprasert, T., Vadhanasindhu, P., "Study of Regulation Approach of Growth Factor Product from Human Placenta in Thailand", Special Issue of the International Journal of the Computer, the Internet and Management, Vol.19 No.Sp1, June, 2011, pp. 17.1-17.4.
- [2] Drug Act B.C. 2510.
- [3] Janodia, M.D., Sreedhad, D., Ligade, V., Pise, A., Udupa, N., "Drug Development Process: A review", [Online] Available: <http://www.pharmainfo.net/reviews/drug-development-process-review>
- [4] "Greater Access to Generic Drugs: A Special Report From the FDA Consumer Magazine and the FDA Center for Drug Evaluation and Research", Fourth Edition, [Online] Available: <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143545.htm>
- [5] Willmann, J.K., Bruggen, N., Dinkelborg, L.M., Gambhir, S.S., "Molecular imaging in drug development", Nature Reviews Drug Discovery, Vol. 7, July, 2008 pp. 591-607.
- [6] Cosmetic Act B.C. 2535.
- [7] Vernon, J., Nwaogu, T.A., "Comparative Study on Cosmetics Legislation in the EU and Other Principal Markets with Special Attention to so-called Borderline Products", London: Risk & Policy Analysts Limited, 2004.
- [8] Kumar, S., "Exploratory analysis of global cosmetic industry: Major players, technology and market trends", Technovation 25, 2005, pp. 1263-1272.
- [9] Lintner, K., Mas-Chamberlin, C., Mondon, P., Peschard, O., Lamy, L., "Cosmeceuticals and active ingredients", Clinics in Dermatology, Vol. 27, 2009 pp. 461-468.
- [10] Ulrich, K.T., Eppinger, S.D., "Product design and development", 4th edn., 368 p. McGraw-Hill Higher Education, Boston, 2008.
- [11] Smith, D., "Exploring innovation", McGraw Hill Education-Europe, 2005.
- [12] Draelos, Z.D. "The cosmeceutical realm", Clinics in Dermatology, Vol. 26, 2008, pp: 627-632.
- [13] Dorf, R.C., Byers, T.H., "Technology Venture", International Edition, 2008.
- [14] Brandt, F.S., Cazzaniga, A., Hann, M. "Cosmeceuticals: current trends and market analysis", Seminars in Cutaneous Medicine and Surgery, Vol. 30(3), 2011, pp. 141-143.
- [15] Thailand National Statistical Office, 2011.



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