Study of Regulation Approach of Growth Factor Product from Human Placenta in Thailand

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Abstract- Growth factors production are profitable business, in term of market values and medical values. Products from Human Placenta are broadly applied in clinical and cosmetic approaches in the world. However, either clinical or cosmetic are not applied in Thailand at the moment. Thailand’s Food and Drug Associate does not clearly established the standard of processing for registered and operation which is the major problem to establish the business in Thailand. The research aims to find the optimal path way for product registration under Thailand’s law and regulation system.

Qualitative methodology used as in-depth interview for expert opinion and secondary data analysis for comparison of several acts under a complication of the laws on Food and Drug Associate.

The result showed that path of cosmetic approach was more appropriate than drug approached which are significantly reduce cost of investment and highly profitability. Nevertheless, human placenta is limited substance and should be supported by value of their applicant. In order to resolve the limitation of human placenta production and registration should be applied by the strategy of business development.

Keywords- Growth factor product, Human placenta, Thailand’s regulation system

I. INTRODUCTION

Growth factors (GF) are currently widely used in pharmaceutical cosmeceutical and cosmetic products. GF have many clinical biological effects to cell proliferation. The almost one of the GF effects were used in clinical practices and develop to commercial product are fibroblast growth factors (FGF). FGF was from many sources, both of natural; blood and some...
organ extraction and artificial; recombinant protein from bacteria. On the other alternative, human placenta, waste in hospital, is the richest human source of protein (Rosen, 1986) and may be useful GF on production scale (Tiollier et al., 1990). More than 5 GF were discovered, epidermal growth factor (EGF), α and β transforming growth factor (TGF α, TGF β), both of type 1 and 2 insulin -like growth factor (IGF-1, TGF-2), and FGF also (Uhlrich et al., 1992).

By the way, although human placenta is the most optimum resource for produce GF, but there are many limitation on Thailand’s food and drugs regulation system that is the barrier to establish the business in Thailand. This research aims to find the path of GF product development that will contribute business development in the future.

II. GROWTH FACTOR AND HUMAN PLACENTA

Growth Factor (GF) is the peptide molecules that function as growth stimulator/inhibitor and modulate differentiated function of cell (McKay, 1993). GF is classified by size and biological effect to several superfamilies and families; large peptide factor superfamilies, individual large peptide factors, small peptide factor families and individual small peptide factor.

Effect of growth factor, the first is nature of the activity. GF can stimulate or inhibit cell division, all or some stages. Cell differentiation and cell migration are effected by GF.

Growth factor (are several activities that were classified. There are many clinical biological of GF effects on cell activities as cell proliferation, cell division and cell differentiation.

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Human placenta, waste in hospital, is the richest human source of protein (Rosen, 1986) and may be useful GF on production scale (Tiollier et al., 1990). More than 5 GF were discovered, epidermal growth factor (EGF), α and β transforming growth factor (TGF α, TGF β), both of type 1 and 2 insulin -like growth factor (IGF-1, TGF-2), and FGF also (Uhlrich et al., 1992). For all properties of human placenta that make considerate to be source of GF production.

III. THAILAND’S REGULATION SYSTEM

Thailand’s regulation system classified products by aim of using as a compilation of laws on food and drug. “Drug” is aimed to treatment and diagnosis as drug act B.C. 2510, “drugs” means

(4) Substances intended to affect the health, structure or function of the human or animal body.

While “cosmetics” is aimed to cleansing, beautifying, or promoting beauty as cosmetics act B.C. 2535, “Cosmetics” mean:

(1) articles intended to be used by applying, rubbing, massaging, spraying on, dropping, introducing into, perfuming or by any other means to any part of human body for cleansing, beautifying, or promoting beauty, including skin-care products, but shall not include ornaments and clothing which are accessories outside human body;

Both of drug and cosmetic have the rigid pathway and almost different process to registration.

But GF is the unclear aim of product concept, GF are classified as “cosmeceutical product” that compose with drug’s and cosmetic’s aims. For the unclear procedure to registration, there are opportunities and threat to run this business. The standard procedure may contributed by the first mover.
but also high risk. The business should find pathway to reduce risk, low investment and time to market, but strong enough to barrier other competitors.

IV. RESEARCH METHODOLOGY

Qualitative approach was applied in this research. In-depth interview technique was use for fact finding from expert, secretary general of food and drug association (FDA), director of drug controlling department, director of cosmetic department, pharmaceutical and cosmetic expert of ministry of public health and secretary general of ethical committee of ministry of public health. Content analysis was used to analyst data.

V. RESULT AND DISCUSSION

There is no clearly criteria for GFs classification. We considerate to studying under regulation approach, drug and cosmetic, that have difference principle for identification.

Under “Drug” approach, the regulation have 2 critical point for consideration. The first is type of active ingredient, chemical or biological substance. That is the important for regulate standard operation process, product quality and infection control (agreement from expert of ministry of public health and representative of drug control department).

The second is the degree of novelty. Register must to declare that the product is new drug, new generic drug or generic drug. Each degree of product need difference evident level for submission. New drug, new to the world, are required the strongest evident especially clinical data. As the product is generic drug, just bio-equivalent (BE) is required for registration. Development of GF to be drug consumes time and high investment. In the other hand, drug patent will return highly profitability to the investor.

GF are classified as biological-substance and new drug. Then GF registration is required standard operation process, product quality, infection control and the strongest clinical evident. The basic research and preclinical data are included. There are not limit for submission but have to show the evident for proved “claim of product”.

![Diagram](image)

**Fig. 1** Development of GF under Drug approach

Under “Cosmetic” approach, FDA concern about product safety, product cleaning, bacterial contamination, and free from prohibit substance. The regulation set maximum concentration of contaminant, micro organism and prohibit substance for cosmetic product. For Cosmetic approach consume less investment and less restriction than Drug approach. As the result Cosmetic approach can gain profit within the short period of time.

Although, there are not specific regulations for GF but source of GF, human placenta is the prohibit substance for cosmetic product. (No. 413 of FDA announcement: cell, tissues or product from human origin) (most of expert and representative of FDA are agree) then disclosure GF origin can make easier registration process (suggestion from cosmetic expert). However, some product from human origin make to exceptional condition of the announcement by cosmetic committee of ministry of public health consideration. Then persuaded committee for agreement is an interesting alternative for
registration GF product from human placenta under cosmetic regulation. However way to acquire the human placenta must followed by principle of human right.

VI. CONCLUDING AND REMARK

For GF business development, we should invest on the optimal path way, less resource, time and money, which compensate long run for create value. Then the investment should separate to 3 phases. The first phase, GF product should use registration process of cosmetic which reduce cost and time to approve. Product’s claim about biological effects are not use for advertisement, but human placenta is the prohibit substance for cosmetic. In the second phases, business should support evidence which make human placenta is exceptional condition. At the same time, we should implement the basic research in order to support non clinical and clinical data for new drug registration. The last phase, GF should run both of cosmetic and drug parallel but should claim biological effected to drug and physical effected to cosmetic.

REFERENCES


