

# Critical Effects of Regulation on Thailand's Cosmeceutical Development Process: Human Placenta Extract

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## Abstract

Cosmeceutical is one of the most profitable businesses in Thailand. Many companies have been trying to develop their products to capture business value from market. They have developed many products under the classical product development model. However, more than 50 % of products failed and were not allowed by food and drug administration bureau (FDA) to be launched. The purpose of this study is to find critical effects of cosmeceutical development in work place. Participatory action research technique was applied in the study. The results showed that classical model was inappropriate for cosmeceutical development. Instead, companies should contribute regulation study that parallel with the process of development, especially in the stage of scoping, which will reduce development cost. The study contributes new process to develop cosmeceutical, which will be Thailand's standard process in the future.

## Keywords

Cosmeceutical product, Human placenta extraction, Product development process, Regulation.

## I. Introduction

The strong increasing growth rate of cosmetic industry has attracted many companies to become players in this field, causing cosmetic products to develop rapidly [1]. In this serious competitive condition, the best way to improve product is to apply the "make it real" concept. "Clear and cover", the old objective of cosmetic has changed to "reduce, repair and recover", which has become the original idea of cosmeceutical. Cosmeceutical, physiologically active cosmetic, combines between drug and cosmetic, is used as a cosmetic which has some physiological and pharmaceutical effect on skin appearance [2]. However, cosmeceutical only acts as a cosmetic. It does not prove any physiological effect as drugs. This could lead to misconception and wrong belief toward customers [3]. Among myths of cosmeceutical, many companies have launched cosmeceutical between the grey zones of regulation. There is no specific regulation for cosmeceutical, only drug and cosmetic acts that control it. Regulation is used, selected and adapted on a case by case basis. Thailand is similar to the other countries, it has no cosmeceutical acts. Companies have to either select "Drugs" or "Cosmetic" in order to register and follow the regulation chosen. Certainly, most companies would choose the cosmetic path to reduce cost; investment, including time to market [4]. However, cosmetic is limited to claim as "cleansing" and "Beauty" product but it cannot be addressed as "physiological effect" on product's form and use. Although development of cosmeceutical can be applied with classical product development process but there are some steps that are changed and rigid by regulation. This study aims to find effect of regulation on cosmeceutical development process by participatory action research that will propose to be the other phase for product development model.

## II. Cosmeceutical: Drug VS Cosmetic

Thailand's regulation system classifies products by the aim of using as a compilation of laws on food and drugs.

"Drugs" mean [5]

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

"Cosmetics" mean [6]

... (1) articles intended to be used by applying, rubbing, massaging, sprinkling, 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;...

Drugs are not limited for use by indication until there is some evidence to support, including root of administration; oral, intravenous, intramuscular, etc. Cosmetics, nevertheless, are different. Cosmetics have specific objectives as stated above and are allowed for external use only.

For Thailand's cosmeceutical, consideration to claim a product's properties is a critical step to run business. There is a phrase that, "high risk high return". In this case, high investment in drug development will establish monopoly power to companies and will also make high profit.

## III. Product Development Process

There are many ways to develop product that are suitable for each product's type. The most popular model for development incremental product is 'Stage-Gate™' model, which was proposed by Robert G. Cooper [7]. The model was composed by Stage; set of parallel activities undertaken by people from different functional areas within the companies, and Gate; decision point [8] (see fig. 1).

The model is used for general products but not for health related product that have many complication requirements by regulation. Then we should construct suitable model for them.

## IV. Cosmetic Development Process

For cosmeceutical development, companies have to choose path to development, drugs or cosmetic, for follow registration's procedure (see fig. 2).

## V. Effect of Regulation on Product Development Process

Under cosmetic act B.C. 2535, cosmeceutical development process modified from cosmetic development (see fig. 3). The process consists of 3 key activities; raw material control, root of administration concern and product claim

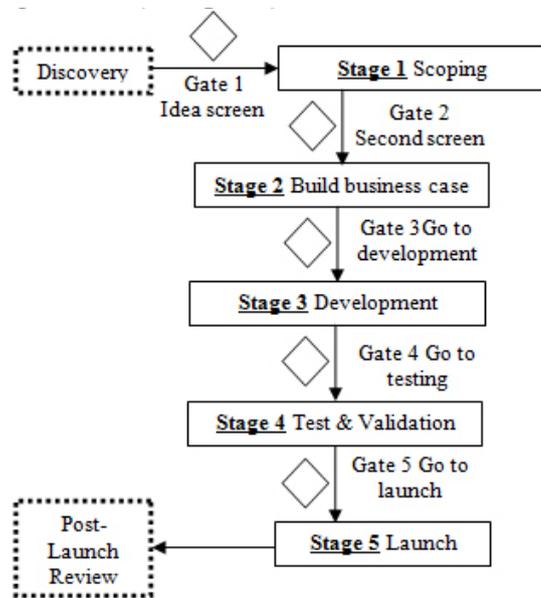


Fig. 1: Modified Stage-Gate™ model

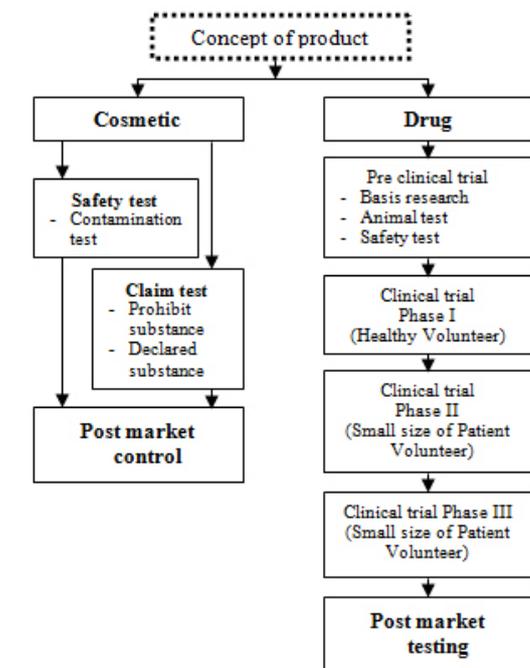


Fig. 2: Development process of cosmetic and drug.

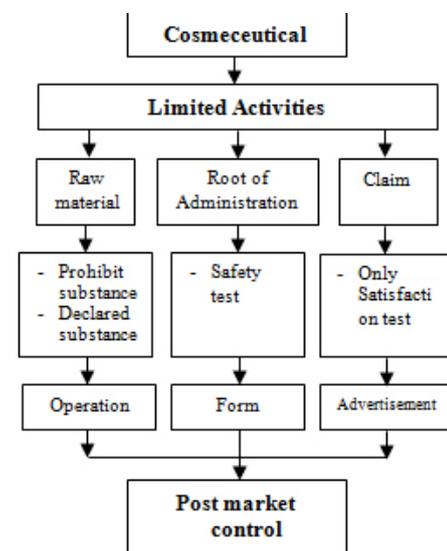


Fig. 3: Cosmeceutical development process

## VI. Human Placenta Extract Development

Cosmeceutical is physiological effect cosmetic. In this study, we generated ideas about dermatology effects and screened out by the literature review. We had “Anti-aging” and “Personal medicine” concept; stem cell, scaffold and growth factor, however, only growth factor can be used in cosmeceutical. For therapeutic use, growth factors are manufactured from biotic-engineering technique and are used as cocktail therapeutic; mixed growth factor. The conservative development process was able to develop only one kind of growth factor at a time and yet still expensive. Then, we surveyed the other sources of growth factor by reviewing the literature and confirmation by bio-technology expert. We have found that human placenta is the best source of growth factor; rich and cheap. After that, we evaluated resources assessment by hospital administrator, steak holder and lawyer with an in-depth interview. The result has shown high probability to acquire human placenta from public hospital with its mother’s allowance. Meanwhile, we reviewed and selected technology to extract growth factor from human placenta. The technology is confirmed by technicians and laboratory experiments.

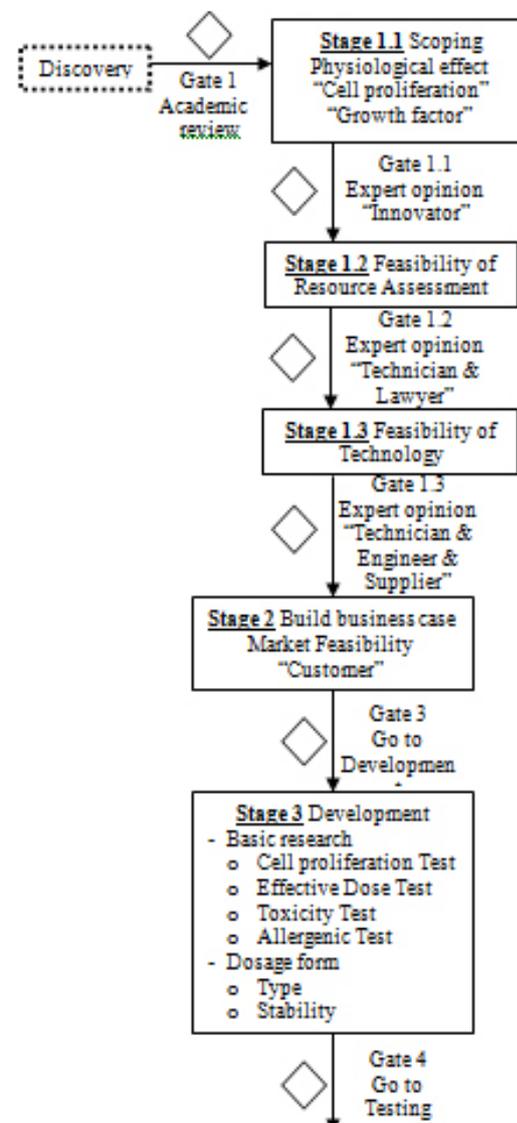


Fig. 4: Cosmeceutical development model

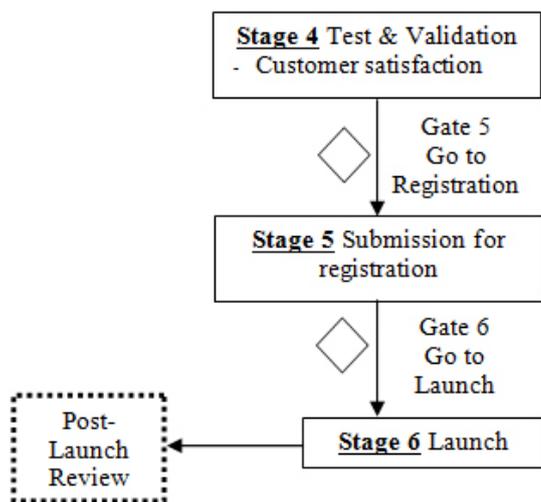


Fig. 5: Cosmeceutical development model (cont.)

For “build business case”, we surveyed customers’ needs and their satisfactions, both on recent products and our product’s concept. Customers include end user, doctor and investor. The results have shown their satisfaction trends to be highly positive. Most end users wanted to test product without FDA approve, with less than 10% concerned about its properties. For medical doctor, dermatologist and anti-aging, they had a consensus to use the product for recovering skin properties and recommending it to cosmetic clinic over treatment clinic. Investors, related business owners, were interested in the product and recommended some technology that could scale-up the manufacture. However, investors showed concerns on supply issue as they needed to make certain that the supply would not run out of the market.

For “Development”, we constructed many researches to confirm the product properties, cell proliferation test, effective dose test, toxicity test, allergenic test and product stability test. The results confirmed that our product claim. We finally got a variety of products; cream, serum, lotion and injection of selection and for development. Some potential products could not develop under the cosmetic regulation, before the register process, products are required to get tested by regulation and guideline of FDA.

## VII. Conclusion and Discussion

Cosmeceutical development process is affected by regulation. Firstly, regulation affected the scoping process, although we could generate many ideas but we were limited under the cosmetic acts, the prohibit substance and the root of administration. Secondly, it affected the source of materials from an allowance source. Lastly, it affected on the product’s claim, cosmeceutical only claim on evident base and cannot claim on physiological effect. The other effects include the limited of advertisement and communication channel.

The study has shown that cosmeceutical manufacturers should select their path to develop products, either drug or cosmetic, then follow its registration procedures. Idea generation should be merged with regulation study in the stage of scoping idea to reduce development cost.

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