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Quasi Drugs: Review and Approach as Cosmeceuticals

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ABSTRACT:
Quasi-drugs havespecific pharmacological activity but are restricted in use to particular conditions.The drugs (occupy a special category) in between pharmaceuticals and cosmeceuticals. These quasi-drugs are different than cosmeceuticals in various ways.Cosmeceuticals have no legal requirements First of all there are no legal norms to call a product, which leads to any problems.The Ministry of Health, Labour, and Welfare in Japan are recognized and licensed quasi-drug products to get formulated.

Keywords: Quasi-drugs, cosmeceuticals, pharmaceuticals.

I. INTRODUCTION:

Quasi Drugs are Cosmeceuticals products widely known in Japan and South Korea. There is a small difference between cosmetics and drugs because of that they can be known as quasi-drugs. As their applications are not as suitable as drugs; South Korea's Ministry of Food and Drug Safety (MFDS) and health authority (HA) have differentiated them under the category of skin care cosmetics eg. Skin whitening or antiacne products. This Quasi-drugs are divided into two types.

Group 1	Group 2
Wet wipes which are used for facial hygienic product	Smell and odor inhibitors like mouth fresheners, antiperspirants, bath products, teeth whitening products, etc.
The material which is used for the production of surgical masks	Externally used hair care and skin care products.
Materials thatare used for the treatment of wounds and for the protection of affected area contains various types of bandages like crepe bandage, gauze,elastic bandage, etc.	Without nicotine Productsfor human beings who smoke.
Products used for menstrual hygiene purposes like sanitary pads and tampons.	Some disinfectant products which externally used on humans.

The approval process forQuasi-drugs:

The information required for the marketing approval for a quasi-drug is the same as that forapproval ofa new drug product.This information must include the information on the quality and controls of the raw materials, the manufacturing process of quasi-drugs, their stability data, storage conditions of quasi-drugs, expiry date of quasi-drugs, quality control specifications, etc. Quasi drug data was submitted to the health authority (HA) for the approval of the product. After that safety and efficacy data of the product must be evaluated and will be submitted to the National Institute of Food and Drug Safety

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Evaluation (NIFDS) and the Cosmetics Evaluation Division (CED). Finally, the product details were transferred to the Medical Products Safety Division, Regional Food, and Drug Safety after safety and efficacy evaluation of the quasi product for further approval.

All raw ingredients of the quasi-drugs are compulsorily mentioned from a monograph of the Pharmacopoeia of Japan and meet all specified criteria. They must have an active ingredient that is declared and the active ingredient is used in the dosage form that was approved previously for other quasi products, nearby 8 months takes place for the marketing authorization.

If the dose of the active ingredient is higher than the previously approved dose of the active ingredient from the quasi dosage form, at that time additional data from the nonclinical studies evaluated for the stability, safety, and efficacy of the drug must need to be provided which requires minimum up to 2 years.

2 weeks are required to complete all specified amendments required for the market authorization after getting the product approval of the quasi drug for every simple or minute modification and for any major changes or modifications it takes approximately 8 months of time span.

As compared to the cosmetic products, quasi-drugs were extensive for pre-marketing, and the marketing of quasi-drugs is the same as cosmetics they were sold without any prescription and without any restrictions in case of their distribution. Quasi-drugs have restrictions regarding volume, the quasi-drug products are not allowed to be sold in a volume of more than 100 ml in total volume.

The differences between the quasi-drugs and cosmetics:

According to the law of Japanese pharmaceutical affairs, "cosmetics" are the products used mainly for cleansing and moisturizingpurpose. And cosmetics products have very few ranges of acceptable and claimable effects.

And at the other side, the "Quasi-drugs" are the products that contain the raw or key ingredients which show the recognized effects like skin correction and skin whitening effects, and because of this sellers make openly efficacy claims for quasi-drugs.

So, the "cosmetics" and "quasi-drugs" are these officially recognized active ingredients is the biggest difference between these.

The difference between drugs and Quasi-drugs is that Drugs or pharmaceuticals are meant for giving relief and healing and producing correction effects on human beings. Quasi-drugs have some kinds of limitations like how much quantity of key ingredients will have to be added in the formulation. Because of that, they are not as adverse as actual drugs.

Pros and coins of Quasi-drugs:

Even though Quasi-drugs have their upsides, so they indeed have their downsides also, and because of that not everyone wants to formulate the quasi-drugs.

Pros of Quasi-drugs include:

1. **Quasi-drugEnable the seller to make any specific claims** – eg.

In the case of any shampoo, a quasi-drug will be sold under the claim like "these products prevent dandruff and itching" and in the case of cosmetic products they should claim like "these products decrease the intensity of dandruff and itching".

2. **Not required to display the full list of ingredients**-

In the case of Quasi-drugs, there is no need to mention the details of ingredients present in the formulation while in the case of cosmetic products you should have to mention all the ingredients listed on the packaging of the product. Also, quasi-drugs have the freedom to mention the ingredients without the concentration, while in the case of cosmetic products it's compulsory to mention the list of ingredients having a concentration of 1% or more than this.

Coins of Quasi-drugs include:

1. **High costs and long time for development –**

In order to be sold as quasi-drugs, every formulation needs to get approval, and the time required for the approval process is approximately 6 months to 8 months. And it also requires more cost to get the necessary test approval for getting the final approval of the product.

2. **Nonflexible Quasi drug formulations –**

Which ingredient can be added and which is not in quasi drug formulation for that purpose strict guidelines were followed and also the concentration of all ingredients which are present in quasi drug formulation has been determined by

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using those guidelines only. So this can be made differentials with the quasi product formulations.

II. CONCLUSION:

Quasi-drugs is a very acceptable concept to formulate. even if this concept if difficult to market in foreign markets, according to all the above information this is more important to get understand the need and approach of the quasi-drugs and cosmetic market in Japan and South Korea.

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