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A Comprehensive Study on Quasi-Drugs Regulations in Japan and South Korea

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ABSTRACT

Cosmeceuticals, often known as quasi-drugs, are a distinct class of goods that fall in between cosmetics and medications; they are especially well-known in South Korea and Japan. These chemicals are used for minimal therapeutic actions, preventive, or hygiene, or they have mild pharmacological effects. The regulatory frameworks in South Korea and Japan distinguish quasi-drugs from complete pharmaceuticals and cosmetics by requiring particular safety, labeling, and approval requirements. The definitions, regulatory differences, and instances of quasi-drugs in both nations are examined in this review. The creation and marketing of products including medicated shampoos, sanitizers, anti-hair loss agents, and mild disinfectants are made possible by the nuanced classification, which increases customer alternatives for hygienic and preventive use while maintaining oversight to guarantee product safety and effectiveness.

Key words: Quasi-drugs, Cosmetics, Active ingredients, Marketing authorization, GMP (Good Manufacturing Practice), Medicated products

INTRODUCTION:

Brazil defines perfumes, cosmetics, and personal care items as blends of natural and synthetic substances that are applied externally to the mouth's mucous membranes, lips, teeth, hair, nails, and skin, among other body parts. The primary purposes of these products include cleansing, imparting scent, enhancing their aesthetic appeal, addressing body odors, and preserving or enhancing their optimal condition.

In India, " Cosmetic products encompass a wide array of items, including creams, perfumes, lotions, skin cleansing agents, and products within the realm of decorative cosmetics. The term cosmetic originates from the Greek term "kosmtikos," denoting "capable of organizing and adorning.

In Japan and South Korea, cosmetics are frequently referred to as "quasi-drugs." Because of their modest differences, cosmetics and pharmaceuticals are frequently referred to as quasi-drugs. The South Korean Because their applications are not as suitable as those of pharmaceuticals, the Ministry of Food and Drug Safety (MFDS) and the Health Authority (HA) have categorized them as skin care cosmetics, such as skin whitening or antiacne products. Quasi-drugs fall into two groups.

Table 1: Classification of Quasi-Drugs

GROUP 1	GROUP 2
Wet wipes are a type of face hygiene product.	mouth fresheners, antiperspirants, bath treatments, teeth-whitening products, and other odour and scent blockers.
The substance that is utilized to make surgical masks	products for skin and hair care that are used externally.
Bandages of many kinds, including crepe, gauze, elastic, and others, are among the materials used to treat wounds and protect the afflicted area.	Products without nicotine for human beings who smoke
Menstrual hygiene products, such as tampons and sanitary pads.	Certain disinfection products are applied externally to people.

THE JAPANESE DEFINITION OF QUASI DRUGS :

- Products known as quasi-drugs are used in Japan to treat and prevent mice, flies, mosquitoes, fleas, and other pests, as well as to promote hair growth or remove hair and avoid heat rash, soreness, nausea, and other discomforts.
- Products that fall between medications and cosmetics are referred to as quasi-drugs.
- The Pharmaceuticals and Medical Devices Act (PMD Act), formerly known as the Pharmaceutical Affairs Law, governs them.
- The product information and labelling for every product should be in Japanese.
- Although they are subject to less stringent regulations than pharmaceuticals, they nonetheless need Ministry of Health, Labour and Welfare (MHLW) approval before being on sale.

EXAMPLES:

- Medicated shampoos and toothpastes
- Hair growth tonics
- Anti-dandruff products
- Disinfectants
- Deodorants with bactericidal action
- Vitamin supplements (for specific uses)
- Some skin lightening products (with active ingredients)

KEY REGULATORY FRAMEWORK:

In Japan, selling cosmetics or quasi-drugs requires adherence to a number of laws:

1. Take steps to guarantee the quality, safety, and efficacy of pharmaceuticals, medical devices, cellular and regenerative treatment, gene therapy, and cosmetics products: This statute lays out the fundamental requirements for all cosmetic items.
2. **Standards for Cosmetics**: formulated rules outlining permissible components and labelling procedures.
3. Law targeting unreasonable premiums and false or misleading advertising prohibits deceptive claims and advertising around cosmetics.
4. Law regulating products that may contain high-pressure gas.
5. Standards of fair Competition promote integrity in marketing approaches.
6. The Narcotics and Psychotropics Control Act governs the utilisation of specific substances in cosmetics. These regulations ensure that all cosmetics meet stringent safety standards before being given to consumers..

LICENSING REQUIREMENTS:

- To get both a manufacturing and marketing license, importers need to designate a Responsible Person. Good Vigilance Practices (GVP), Good Manufacturing Practices (GMP), and Good Quality Practices (GQP) must all be followed in order to ensure the safety and quality of the product.
- **Manufacturing License**: need for Japanese product labelling, storage, and packaging.
- **Marketing License**: essential for product promotion, sales, distribution, and importation into Japan.

THE CONTENTS OF JAPAN'S QUASI-DRUG REGISTRATION DOSSIER:

The registration dossier for quasi-drugs submitted to PMDA contains the following information:

1. The application

2. Ingredients, quantity, and purpose list

3. An explanation of the production procedure

4. Dosage and usage

5. Effectiveness and functionality

6. Shelf life and storage techniques

7. Methods of specification and testing

OVERVIWE OF THE REGULATORY PROCESS:

The regulatory procedures for cosmetics and quasi-drugs include the following steps:

The formula is reviewed to ensure it complies with Japanese rules and is safe. Making ingredient lists in INCI (International Nomenclature of Cosmetic Ingredients) and Japanese forms is part of this.

Review of Labels and statements: making sure that product labels follow the law and that statements on packaging are backed up by proof.

The Pre-Approval Document Getting Ready for Quasi-Drugs: To do this, a lot of information on the product's origin, specs, testing methods, safety details, and efficacy must be gathered.

The evaluation process for quasi-drugs can take up to six months since they require more documentation.

THE PROCEDURE FOR REGISTERING AND NOTIFYING QUASI-DRUGS IN JAPAN

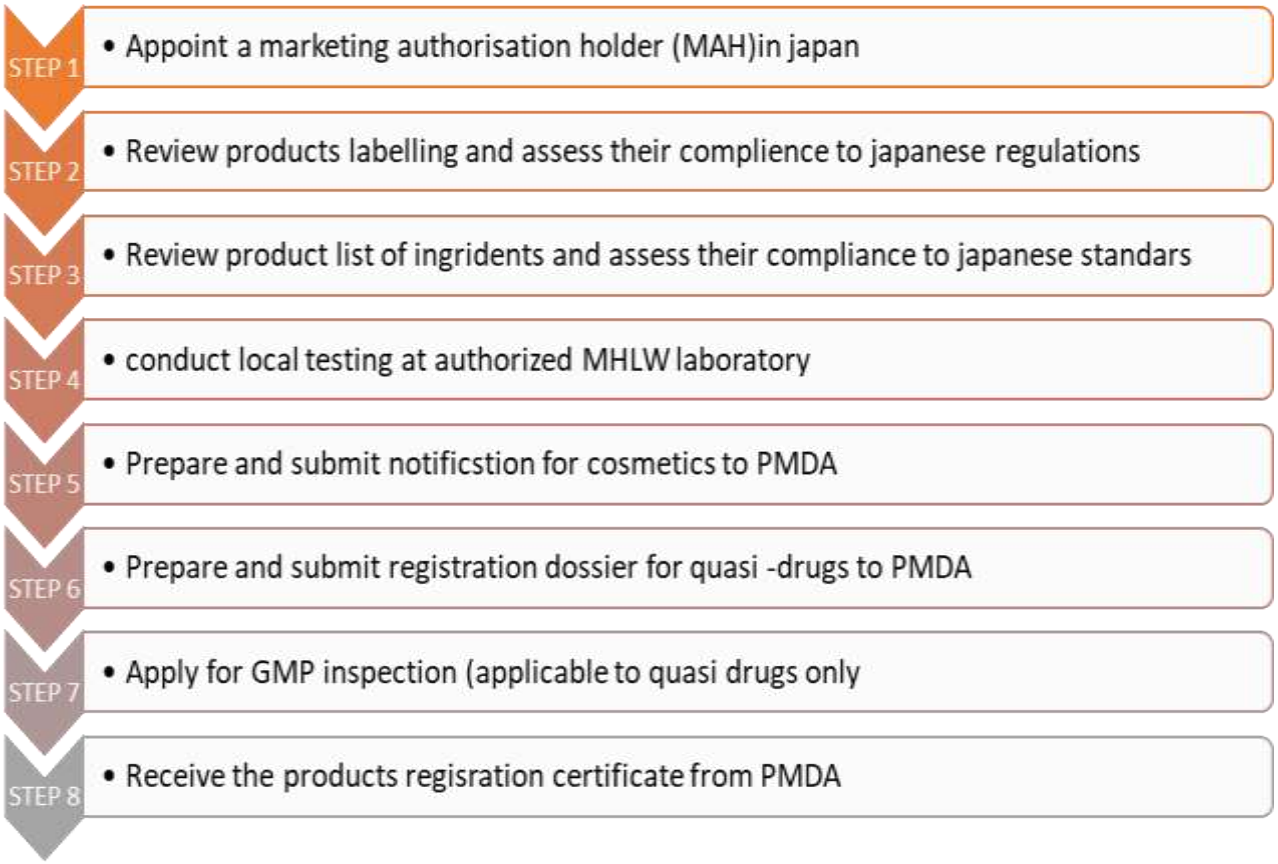

Figure 1: Registration and Notification Process of Quasi-Drugs In Japan

THE APPROVAL PROCESS FOR QUASI-DRUGS:

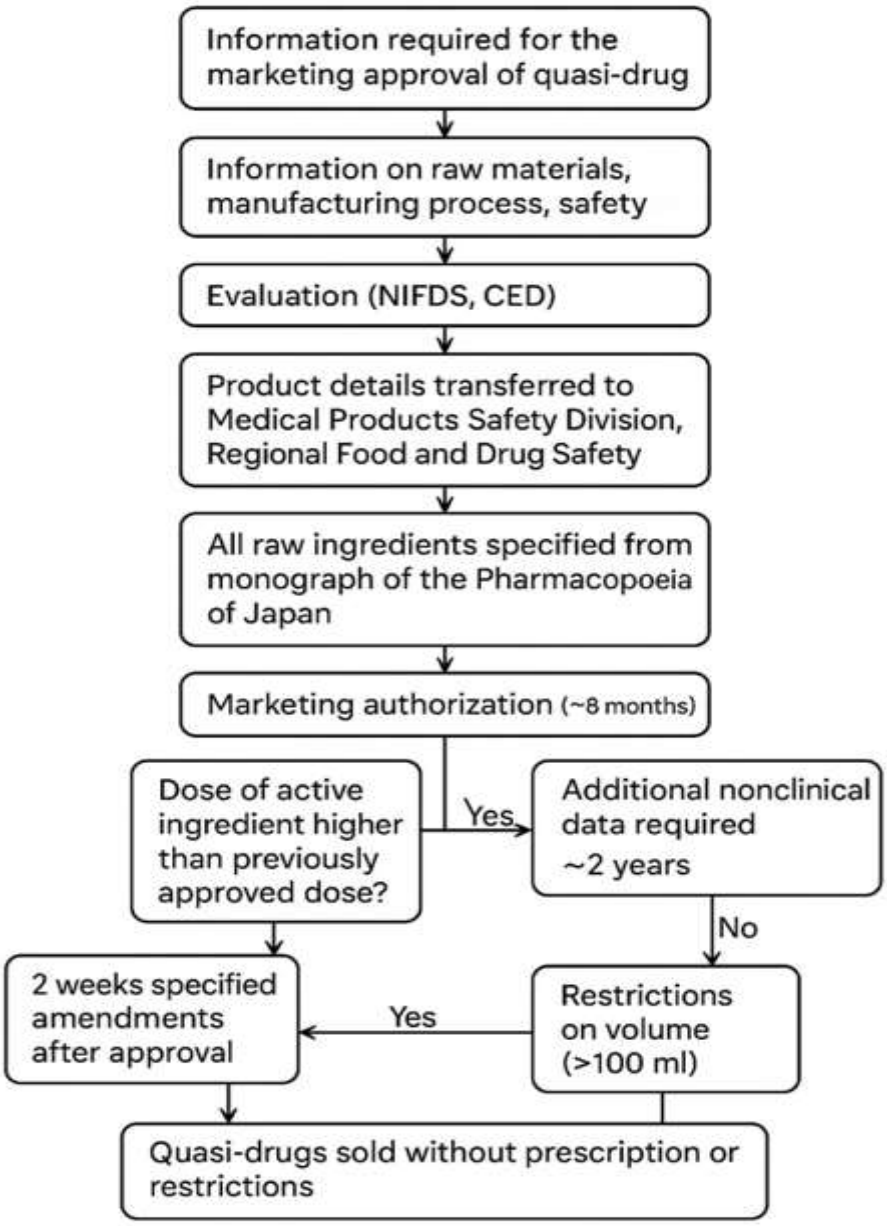

Figure 2: The approval process for Quasi-drugs

PMDA Charges

Table 2: PMDA Classification and Fees

PMDA Classification	**PMDA Fee (Yen)**
Cosmetics	337,300
Quasi-drugs	355,900

DEFINITION OF QUASI DRUGS IN SOUTH KOREA:

A product type governed by the Pharmaceutical Affairs Act in South Korea is known as a quasi-drug, or quasi-pharmaceutical. Substances that are not exactly pharmaceuticals but yet have moderate pharmacological effects or are utilized for preventative or sanitary reasons are known as quasi-drugs.

DEFINITION (as per the Ministry of Food and Drug Safety - MFDS):

A product is considered a quasi-drug if it:

- ❖ Lacks the potent therapeutic effects of a medication,
- ❖ Is employed for hygienic purposes, sanitization, or disease prevention,
- ❖ Or exhibits negligible pharmacological action.

EXAMPLES:

- Sanitizers and disinfectants (for hands, surfaces)
- Medicated toothpastes and mouthwashes
- Anti-hair loss shampoos
- Menstrual pads and panty liners
- Cooling patches and heat patches
- Insect repellents or anti-itch creams (with mild active ingredients)

REGULATORY NOTES:

- ➢ Before being on sale, quasi-drugs need to be registered with the MFDS.
- ➢ They are exempt from the strict clinical trial regulations that apply to whole medications.
- ➢ Nevertheless, given their intended use, they still need to adhere to safety, labelling, and efficacy standards.

QUALIFICATIONS FOR NOTIFYING OR REGISTERING FOR QUASI-DRUGS:

Depending on its properties, a quasi-drug must either be approved or notified by the RFDS or MFDS before going on sale in South Korea.

Table 3: Qualification criteria for RFDS or MFDS Approval

Classification of products	Quasi drugs requiring to notification	Quasi drugs requiring to authorization
Criteria for eligibility	• Items included in South Korean pharmaceutical compendia and other compendia that are approved by MFDS • Goods for which MFDS prescribes test procedures and specifications • Goods that adhere to the production guidelines of MFDS formally notifies quasi-drugs	If goods are being evaluated for efficacy and safety: • When a product has a new excipient that hasn't been used locally • When combining substances that aren't intended as inhalable additives • Items that contain active substances,The formulation, efficacy, the volume (or concentration for liquid forms),method of use,and quantity are the same as those previsouly approved and exmpted from saftey and formulation evalution in the korean study Air agent either oxygen • Human body applications of mosquito bite repellents • Electronic smoking craving
Reviewing Health Authority	(RFDS) Regional Office for Food and Drug Safety	The Ministry of Food and Drug Safety (MFDS) and the Regional Office of Food and Drug Safety (RFDS)

MFDS TIMELINE AND FEES:

Table 4: MFDS Timeline and Fees

	Type of assessment	**Timeline**	**Fee (KRW)**	
			Online assessment	**In person assessment**
Quasi drugs subject to registration and approval	● Specifications and test methods ● Safety and efficacy	70 days	904,000	999,000
	● Specifications and test methods	55 days	402,000	444,000
Quasi drugs subject to Notification	● oversight review	Ten days	100,000	110,000
	● Standards for product quality and the procedures used to assess them, as required by Good Manufacturing Practice (GMP).	40 days	401,000	443,000
	● Standards for product quality and the procedures used to assess them, as required by Good Manufacturing Practice (GMP).	Three months	1,203,000	1,330,000

THE DIFFERENCES BETWEEN THE QUASI-DRUGS AND COSMETICS:

Table 5: The differences between the quasi-drugs and cosmetics:

Aspect	**Quasi-Drugs**	**Cosmetics**
Definition	Products with mild pharmacological action; between cosmetics and pharmaceuticals	Items that enhance appearance, encourage attractiveness, clean, or beautify
Key Ingredients	must include MHLW-approved active substances.	Do not require pharmacologically active ingredients; focus on general safety
Purpose/Function	avoiding symptoms (such as heat rash, hair loss, and nausea), cleanliness or a moderate therapeutic impact	Cleaning, fragrance, look, and moisturizing are examples of superficial care.
Regulatory Approval	requires documentation, pre-market approval, and registration.	Follows a simpler notification process; no pre-market efficacy review
Allowed Claims	may provide mild therapeutic, preventative, or hygienic benefits (e.g., whitens, stops dandruff).	Can only claim beautifying or conditioning effects (e.g., softens skin, adds shine)
Examples	Deodorant, whitening cream, anti-dandruff shampoo, depilatory, and medicated toothpaste	Standard moisturizer, lipstick, perfume, and shampoo

Aspect	Quasi-Drugs	Cosmetics
Sales Channels	available at pharmacies, grocery stores, and convenience stores	accessible and able to be sold anywhere
Regulatory Body (Japan)	Japan's Ministry of Health, Labor, and Welfare	Japan's Health, Labor, and Welfare Ministry
Approval Time	longer (many months) because the active ingredient and efficacy are being assessed	shorter (weeks) because it concentrates on documentation and safety inspections of ingredients.

CONCLUSION:

In South Korea's and Japan's health and beauty industries, quasi-drugs are important from a practical and regulatory standpoint. As defined and governed by their individual national authorities, quasi-drugs fall somewhere between cosmetics and pharmaceuticals, giving consumers access to goods with mild therapeutic or preventative effects without having to go through the stringent requirements of pharmaceutical licensing. Their specialized regulatory scrutiny guarantees that product development strikes a balance between safety, effectiveness, and innovation. As the demand for preventive healthcare and personal hygiene products rises, the importance of clear quasi-drug regulations and their international harmonization is likely to grow, making them an essential topic for industry professionals and policymakers alike.

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Conflict of interest:

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