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**A COMPARATIVE VIEW ON COSMETICS REGULATION IN JAPAN AND
CANADA**

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ABSTRACT

The global cosmetics business has been rapidly expanding, and also a dramatically increasing in the world wide giving a means for a person to alter his or her look while also making the product instantly recognizable and appealing. The majority of people use cosmetics and personal care items on a daily basis to maintain their health, improve their well-being, and increase their self-esteem. Cosmetics, which include antiperspirants, perfumes, make-up, and shampoos, as well as soaps, sunscreens, and toothpastes, are necessary at all phases of life and provide significant practical and emotional advantages. The regulations in the Japan and Canada include approval process, Registration, Labelling and claims and also the premarket requirements. So for these require adequate regulations require while manufacture, labelling and transport which differ from country to country. In these regulations the Canada doesn't require the premarket approval or requirements or clearance for the cosmetics but the premarket clearance for cosmetics is require in the Japan.

Keywords: Cosmetics, Registration, Labelling, claims and Premarket requirements

INTRODUCTION

Cosmetics are made up of a range of chemical ingredients that come from both natural and manmade sources. Cosmetics serve a variety of functions. Cleanse and protect the body or skin using those

intended for personal care and skin care. Makeup may be used to cover defects, highlights natural features (such as the eyebrows and eyelashes), add colour to a person's face, and even change the look of

the persons face altogether to appear a new person, creature or item. Cosmetics can also be used to provide a nice aroma to the body.

Cosmetics are being utilized by females at an earlier and earlier age, particularly in the US. Many brands have responded to this growing demand by releasing flavored lipsticks and glosses. The societal repercussions of cosmetics usage have received a lot of attention in the media in recent years.

JAPAN:

Regulatory authority for cosmetics in Japan:

Under the Pharmaceutical and Medical Devices Law, the Ministry of Health, Labour, and Welfare (MHLW) regulates cosmetics in Japan. Cosmetics are supported by some subsidiary laws, standards, and guidance papers produced by the Ministry of Health, Labour, and Welfare (MHLW).

The Pharmaceuticals and Medical Devices Agency (PDMA) performs on-site and document-based inspections assess adverse effect reports and examine international procedures' and importer's applications.

Cosmetics (in the broad sense of beauty goods/ products) are legally divided into two categories in Japan: cosmetics and quasi-drugs. The rules that govern each group are somewhat different.

Cosmetics:

Articles with mild action applied to the human body for cleaning, beautify and increase the attractiveness to change the appearance or to maintain good skin and hair by rubbing sprinkling or other methods are termed as cosmetics in Japan.

Cosmetics are further divided into six categories in the Japanese market.

Perfume and eau de cologne: Perfume and eau de cologne are both perfumes and eau de cologne.

Makeup cosmetics: Foundation creams, lipsticks, eye makeup, and other cosmetics are examples of makeup cosmetics.

Cosmetics for the skin: Skin lotions, essences, skin milk, cleaning creams, and other products are available.

Hair color, shampoo, hair treatment, and other hair care items

Sunscreen, shaving cream, and other specialty cosmetics

Soaps for cosmetics: Soaps for cosmetics [1, 5].

Quasi drugs:

These products/ goods have minor side effects on the human body, and the MHLW classifies them accordingly on their characterization. Deodorants, depilatories, hair growth treatments, hair colors, bath products, dentifrice, perm, and straightening products, as well as

medicated cosmetics, are all examples of quasi-drugs.

Anti-itch or anti-dandruff shampoos

Products to get rid of freckles

Products for oily skin

Shaving creams

Anti-sunburn or "snow burn" products are available.

Anti-acne creams

Antimicrobial products

Skincare products to avoid chapping and harshness

It's difficult to tell the difference between cosmetics and quasi-drugs. The distinction is made by variations in the product's effects, nature, and the number of components used application technique and appearance.

Cosmetics and quasi-drug ingredients must adhere to Cosmetics and Japanese Standards of Quasi-drug Ingredients, for

the most part. Each category has its own set of rules, with the criteria for quasi-drugs being more stringent [1, 4].

REGISTRATION OR APPROVAL PROCESS OF COSMETICS:

The Approval process of cosmetics in Japan:

Ingredients analysis:

Marketing license holders are solely responsible for ingredient safety issues. When contemplating selling goods/products in Japan, the authority advises them to perform components analysis to guarantee compliance with Japanese cosmetic ingredient rules, however, the analysis is not required and no relevant reports must be submitted before marketing. However, if their items are proven to be hazardous, relevant reports will be reviewed.



This analysis is carried out on samples by MHLW-designated "testing and inspection facilities," which are owned or hired by

manufacturers/importers. The following objects will be put to the test: Preservatives,

Absorbents for UV light,
Anti-oxidants,
Heavy metal genres,
Colorants for the Japanese legal colors index
Ingredients that are prohibited
pH, viscosity, specific gravity, bacterial count, patch testing, stability tests, and other tests may be conducted as well. Because there are so many testing elements, the MHLW provides a confirmation checklist for manufacturers/importers.

Obtaining the Necessary Licenses:

The next stage is to get the required permits from the appropriate regulatory bodies, such as a Cosmetic Manufacturing License and a Cosmetic Marketing License.

For cosmetics Manufacturing and Marketing License the validity is 5 years
Foreign manufacturers must be first recognized by the MHLW as "Accredited Foreign Manufacturer." Holders of a marketing license are required to follow a set of guidelines known as the Marketing License Standards.

Good Quality Practice (GQP) is a set of guidelines for maintaining product quality.

Good Vigilance Practice (GVP) is a set of guidelines for implementing proper safety management measures.

Good Quality Practice (GQP) and Good Vigilance Practice (GVP):

Marketing license holders must assess their production management and quality control of cosmetics to be marketed as part of the GQP. A processes manual is used as a reference for registering product deliveries, gathering information on product quality, processing faulty items, recalling products from the market, and so on. This standard seeks to ensure that the license holder's products are of high quality.

Additionally, as required by the GVP requirements, marketing license holders must develop systems capable of delivering and maintaining correct information in response to consumer enquiries, as well as a monitoring system that manages customer complaints about product quality and product recalls. This necessitates the gathering of data on product safety from competent authorities, professional groups, producers, merchants, consumers, researchers, and others. Following a review of this data, marketing license holders may take remedial action, such as recalling items from the market or altering package warning and cautionary labels, if considered required (for example, the risk of adverse consequences produced by the products). Furthermore, the license holder must notify the MHLW within 30 days if they become aware of any information suggesting that one of the cosmetic items may have a negative effect.

Notifications:

Manufacturers must submit cosmetic marketing notification after acquiring permits but before beginning marketing or

importation, while importers must submit cosmetics (foreign manufacturer, importer) notification in addition to the marketing notification.

Table 1: Notification for Cosmetics in Japan

Notification	Administrative agency Responsible
Marketing notification for cosmetics	The prefecture that issued the cosmetics marketing license is the same prefecture that issued the cosmetics marketing license
Notifications for cosmetics (foreign producer, importer)	Pharmaceuticals and Medical Devices Agency, Japan (PMDA, Tokyo)

If a list of full components from the importer's supplier or manufacturer cannot be acquired, the two notices must be accompanied by a record of the testing and inspection findings verifying the product does not include any banned ingredient combinations instead [1].

Labeling and Claims:

Cosmetic labels must be in Japanese, and the outside box of cosmetics must include complete ingredient labelling in Japanese. Unapproved claims of functioning or efficacy, as well as labelling using deceptive language, are banned.

The Japan Cosmetic Industry Association (JCIA) has created a Japanese version of the "List of Cosmetic Component Label Names," which may be used to comply with the PMDL's requirement that all ingredient names be listed on the label. Companies can use the document to standardize ingredient names in Japanese. Companies can use the document to standardize ingredient names in Japanese [2, 6].

Quasi drugs:

These products/ goods have minor side effects on the human body, and the MHLW classifies them accordingly on their characterization. Deodorants, depilatories, hair growth treatments, hair colors, bath products, dentifrice, perm, and straightening products, as well as medicated cosmetics, are all examples of quasi-drugs.

The Approval Procedure:

Note1: Cosmetics and quasi-drugs have comparable application procedures for marketing and manufacturing licenses. The criteria for quasi-drugs, on the other hand, are more stringent.

Note2: There are three types of quasi-drug manufacturing licenses:

Manufacturing that is sterile

Labeling, packaging, and storing

Generally speaking (except the above categories)

The second category does not include repackaging (converting quasi-drugs in bulk to cosmetics in tiny containers or

bags). All three types of licenses can be obtained by a single company.

Note3: Because imported quasi-drugs must be stored for testing at Customs, the importer's subsidiary or entrusted storage business must get a manufacturing license (packaging, labeling and storage).

Approval for Marketing

The purpose of marketing approval is to guarantee that each new drug's quality, effectiveness, and safety are all met. Domestic producers can apply to MHLW or the prefectural governments; however importers can only apply to MHLW. Both the importer and the holder of a domestic marketing license are required to fill out the application form for importers.

The MHLW requires that a foreign company planning to make quasi-drugs in another country and export them to Japan be accredited.

A Japanese marketing license holder who sells quasi-drugs made by a foreign company can submit an accreditation application on the company's behalf [1].

Labeling and Claims:

Quasi-drugs

A label including the names of particular components authorized by the MHLW is necessary for quasi-drugs. MHLW does not provide a list of permissible and banned claims for quasi-drugs. The effectiveness of quasi-drugs is determined by their active

components. Only after approval may the sponsor promote the product.

For example, a claim of whitening efficacy with a product that contains the active whitening component, or a claim of anti-acne efficacy with a product that contains an anti-acne active ingredient [2].

Premarket Requirements:

Pre-market approval was needed for any cosmetic product to be launched in Japan prior to the deregulation in 2001. Cosmetic goods are no longer subject to premarket clearance, as this obligation has been removed. Companies are only obliged to submit notification of the product's brand name prior to manufacturing or importing under the new laws. Cosmetics manufacturers and importers are also required to obtain a license issued by the government following an examination of the production facility. Every five years, this license must be renewed [3].

Fees for cosmetics in Japan:

Depending on the type of items you produce or import, the fees for the license as well as the processing of the papers may vary significantly. The entire list of service fees may be found on the Japanese website of the Bureau of Social Welfare and Public Health.

The following are some extremely rough estimates:

Product testing costs between 30000 and 70000 JPY.

Sending notifications for 5 goods/ Products costs 20,000 JPY, and customs clearance costs 5-10% of the invoice value.

20,000 JPY for designing label for 5 items

500 JPY for 100 labels to be printed

Inspection and labelling costs 70 JPY

The expense of importing quasi-drugs can go into the millions of yen [7].

CANADA:

Regulatory authority of Canada:

Cosmetics are regulated by Health Canada under the Federal Drug Act's Cosmetic Regulations. Cosmetic goods do not require prior clearance in Canada, but they must be notified once they are on the market. Non-Prescription Drugs or Natural Health Products may be present at the Cosmetic-Drug Interface.

Cosmetic Regulations:

Consumer Packaging and Labelling Act (CPLA) and regulations

- False and misleading statements, as well as a net weight declaration

Canadian environmental protection Act (CEPA)

- Cosmetic ingredients, both new and old [9, 10].

Cosmetics:

Cosmetics include deodorants and fragrances and are "made, marketed, or promoted for use in cleaning, enhancing, or

changing the complexion, skin, hair, or teeth." (Food and Drug Administration Act) [8].

Drugs:

A medicine is defined as a product that is "made, sold, or represented for use in the diagnosis, treatment, mitigation, or prevention of a disease, sickness, or abnormal physical state, or its symptoms," or "restoring, correcting, or modifying organic functioning in people or animals."

NHP (Natural Health Product):

A Natural Health Product (NHP) is a supplement manufactured from naturally occurring ingredients that is used to improve or maintain one's health. Plants, animals, microbes, and marine sources can all be used to create these products. Vitamins and minerals, herbal treatments, homoeopathic medications, traditional medicines (such as traditional Chinese medicine or Ayurvedic medicine), and probiotics are all examples of natural health products (NHPs).

Principles:

The following guidelines should be followed:

The major priority will be to preserve public health and safety in accordance with Health Canada's goals and the appropriate regulatory framework.

The Food and Drugs Act's definitions of "cosmetic" and "drug" must be followed.

A substance's risk does not automatically classify it as a cosmetic or a medication. The Food and Drugs Act's regulatory frameworks offer a layer of protection against the hazards of the various and different items covered by the definitions. In Canada, products are categorized based on two essential factors:

1. Product claims:

The suggested claims are the most important factor to consider when categorizing a product. On the product's labels, box inserts, or ads, a claim can be a word, sentence, picture, symbol, paragraph, or inference. These claims are combined to give a general idea of what the product accomplishes. Cosmetics cannot include products having a medicinal claim.

The product's composition is as follows:

2. The product's composition:

While the content of a product does not always determine its categorization, the existence of a component, or its concentration, may exclude the product from being classified as a cosmetic or a medicine. Monographs describe how a certain active component is utilized in non-prescription drugs and natural health products [10].

REQUIREMENTS FOR REGISTRATION:

The procedure for registering cosmetic products varies by nation. As a result, it's

critical to be aware of all the distinctions and to be well-versed in the appropriate country's cosmetic regulations.

To achieve product conformity and effectively register your items, you must first understand the regulatory requirements.

The most essential criterion is that cosmetics marketed in Canada be made, prepared, preserved, packed, and kept in hygienic circumstances, making them safe for customers to use.

A cosmetic product must not represent a risk to consumers when used as intended. The product's safety must be decided, but the legislation does not specify how the product's safety must be verified and shown; this is the product manufacturer's duty.

Health Canada has a lengthy list of substances that cosmetic products should not include, can only contain up to a particular maximum concentration, or can only contain under specified conditions, as well as the warnings that must be shown regarding their usage. The Cosmetic Ingredient Hotlist is the name given to this list. This list, however, only includes substances that were employed on purpose; it does not include accidental ingredients.

COSMETIC NOTIFICATION FORM:

Each new cosmetic product supplied in Canada must be informed to Health Canada

within 10 days, as stated by section 30 and 31 of the Cosmetic Regulations under the Food and Drugs Act, by completing a Cosmetic Notification Form (CNF). It includes not only new products, but also any modifications that influence the CNF, such as formulation changes, product name changes, sale discontinuance, or changed business name, location, or contact information. The producer or importer should update and resubmit the CNF to Health Canada in each of these situations.

- The product's brand and name
- Date of the product's initial sale in Canada (actual or predicted)
- Information about the product (application, form, function, components, and concentrations)
- The notifier contact information
- Manufacturer and/or Canadian importer contact information (notice that at least one of the firms for whom contact information is supplied must be located in Canada). If the maker is not from Canada, the Canadian importer's information must also be given.)
- Photographs and other documentation (needed only if the product presents an avoidable hazard according to the Cosmetic Regulation or Cosmetic Ingredient Hotlist)

Check the Cosmetic Ingredient Hotlist, which provides lists of prohibited and restricted substances for use in cosmetics in Canada, before notifying your product.

If any of the ingredients in your product warrants warning statements, it's critical to include the product label (as a separate document) with the notification form [11, 12].

Pre-market requirements:

Pre-market clearance is not required for cosmetics in Canada. Health Canada, on the other hand, requires that cosmetic items be disclosed after they have been launched. The Cosmetic Notification Form is used to notify Health Canada about cosmetic goods (CNF) form to the appropriate authorities within 10 days of the product's release. The CNF is an online form that is completed by the manufacturer, a Canadian importer, or a notifier working on behalf of the manufacturer or importer, such as a consultant. The CNF gives information on the product, its ingredients, as well as the maker and distributor to Health Canada [3].

Labeling:

A cosmetic product's inner and exterior labels must include:

- Identification of the product should be both in English and French
- The manufacturer's or distributor's name and address; and

• A statement of net amount and any relevant warnings or directions in English and French [12].

Fees:

No fee required for the cosmetic notification process [13].

Table 2: Comparative study of cosmetic regulations in Japan and Canada

Content	Japan	Canada
		
Authority	Ministry of Health, Labour, and Welfare (MHLW)	Health Canada
Rules/ Acts	Pharmaceutical and Medical Devices Law	Federal Drug Act's Cosmetic Regulations
Premarket approval	Required	Not required
Validity	5 Years	No specific validity time is not given to the cosmetics in Canada
Post marketing requirements	N/A	Required
Fees	<ul style="list-style-type: none"> • Product testing costs between 30000 and 70000 JPY. • Sending notifications for 5 goods/ Products costs 20,000 JPY, and customs clearance costs 5-10% of the invoice value. • 20 000 JPY for designing label for 5 items • 500 JPY for 100 labels to be printed • Inspection and labelling costs 70 JPY 	No fees is required for cosmetics notification process

CONCLUSION:

In now-a-days the cosmetics play an important role in the world for both male and females to appear their look more beautiful. There is a lot of difference in the regulations of the cosmetics in Canada and Japan. According to Japan regulations it should compulsorily get the prior approval requirements for cosmetics before entering into the marketing but these prior approval requirements or clearance not required for the Canada regulations. The main aim of this article is to know about the regulations of cosmetics in Japan and Canada.

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CONFLICT OF INTEREST:

There is no conflict of interest.

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