Atsumi & Sakai Newsletter
JAPAN
NEW YORK
LONDON
FRANKFURT
BRUSSELS
HO CHI MINH
July 2026
No.LFS_006

Legal Regulation of Foods and Cosmetics and Practical Compliance

Introduction: Starting from a Single Case

"We want to import and sell a lip balm made from naturally derived ingredients." "We want to develop a supplement using organic raw materials." "We want to launch a skincare brand that is popular in Korea here in Japan." What do these three inquiries have in common? It revolves around the question: "Which legal category does this product fall into?" Put another way, the issue is whether the product qualifies as a drug, a quasi-drug, a cosmetic product, or a food product, and what legal regulations apply to each as a result.

Misclassifying a product can lead to a failure to obtain required approvals or additionally to violations of the rules on advertising expressions, and in some cases to product recalls or a halt in sales. To better explain this issue, we will use the following fictitious case as our starting point to survey the overall landscape of the laws and regulations that relate to foods and cosmetics.

Scenario | Company A: Expanding "NATURA ROUGE" into Japan

Company A is a Korean skincare brand headquartered in Seoul. Its lip balm "NATURA ROUGE", formulated with a natural red pigment extracted from beetroot and a natural moisturizing ingredient α, has become a hit product in Korea as a "natural cosmetic", with total sales exceeding 500,000 units.

In July 2026, Company A decided to enter the Japanese market. Its CEO, Mr. B, was considering whether the same approach used in Korea could be used in Japan, drawing on his experience in Korea. But he does not have sufficient knowledge or information about Japanese laws and regulations.

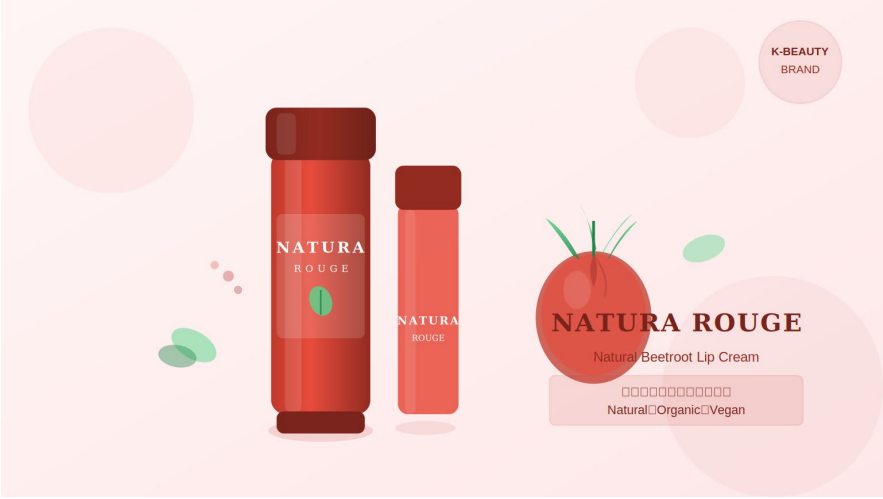

Figure: Image of the "NATURA ROUGE" product (fictitious) — a lip balm formulated with natural beetroot pigment

Mr. B's actions and the potential hidden issues

Mr. B takes the following four actions. We explain each in turn below.

(1) Measure ①: He tried to store and ship the product in the warehouse as-is, with its Korean-language container labels.

(2) Measure ②: He posted a Japanese-language advertisement on Instagram (using messaging such as "Heals chapped lips!" "Soothes inflammation and repairs cracks" "#crack-treatment").

(3) Measure ③: He provided the product free of charge to Japanese beauty influencers and requested posts without a "PR" disclosure.

(4) Measure ④: He posted a video on social media recommending oral ingestion, promoting it as an "edible lip balm."

1. Classification Basics: The Difference Between Cosmetics, Quasi-Drugs, Drugs and Foods

To understand Mr. B's measures, we first need to better understand the concept of "classification." Even where products appear identical, the laws applicable to such products can be completely different depending on the effects claimed and how the product is intended to be used. This newsletter assumes a scenario similar to Company A's case, namely, the importation into Japan and domestic sale of products manufactured overseas. Accordingly, the "Main approvals / notifications" and "Main requirements" in the table below are organized on the assumption that the relevant business involves import and sale. Please note that the required procedures may differ where a business manufactures the product itself domestically or outsources manufacturing to a third party.

Classification	Main approvals / notifications	Main requirements	Disease-related claims	Advertising / labeling restrictions
Food (general food)	In principle, no product-specific approval is required (although business permits/notifications may be required separately)	Compliance with food-hygiene and labeling standards	Not permitted	Function claims are not permitted (except under the health-function foods system)
Health-function foods (Foods with Function Claims, etc.)	Permit system (Foods for Specified Health Uses) / notification system (Foods with Function Claims) / no specific procedure (Foods with Nutrient Function Claims)	Scientific grounds of the business operator (systematic reviews, etc.)	Not permitted (some exceptions)	Function claims based on scientific substantiation are permitted
Cosmetics	Marketing authorization + product notification + foreign manufacturer notification, etc.	Ingredient checks (negative/positive lists), Japanese-language labeling and full-ingredient labeling, etc.[1]	Not permitted	Claims are limited to the 56 designated efficacy

[1] For cosmetics, quasi-drugs and drugs alike, a marketing authorization holder that ships products to the domestic market must have systems in place for quality control (GQP Ordinance) and post-marketing safety management (GVP Ordinance).

Classification	Main approvals / notifications	Main requirements	Disease-related claims	Advertising / labeling restrictions
				claims for cosmetics[2]
Quasi-drugs (medicated cosmetics, etc.)	Marketing authorization + product-specific approval + foreign manufacturer accreditation/registration, etc.	Submission of materials on formulation and the safety of active ingredients; manufacturing/quality control in accordance with the approved scope, etc.	Permitted within a limited scope	Efficacy claims may be made within the approved scope
Drugs	Marketing authorization + product-specific approval + foreign manufacturer accreditation/registration, etc.	Submission of test data on efficacy and safety; manufacturing/quality control in accordance with the approved scope, etc.	Permitted	Claims are limited to the approved efficacy

"Prevent," "Cure" and "Repair" Are Different Things

The expressions "Heals chapped lips!" and "Soothes inflammation and repairs cracks" in the advertisement described in Measure ② above would constitute "claims of drug-like efficacy" aimed at treating disease. A product using such expressions is deemed to be, in substance, advertising an unapproved drug, in violation of Article 68 of the Pharmaceuticals and Medical Devices Act (PMD Act) (prohibition of advertising drugs before approval). Such claims may also be subject to Article 66 of the same Act (prohibition of exaggerated advertising) as constituting exaggerated efficacy claims. Even for a "product sold as a cosmetic," using this type of expression would still constitute a violation.

Correspondence Between Lip Balm Expressions and Classification

Cosmetic → Efficacy claims permitted only within the 56 items

"Gives moisture to the lips," "Protects the lips," "Prevents dryness of the lips," "Prevents chapped lips," etc.

Quasi-drug (medicated lip balm) → May claim efficacy within the approved scope

May claim it has efficacy such as "Prevents cracking" or "Prevents dryness" within the efficacy scope approved for such product → requires formulation of active ingredients and product-by-product approval.

Drug-like expressions → Selling/advertising without approval is prohibited (PMD Act Arts. 66 and 68)

"Cure," "treat," "repair," "soothe inflammation" → fall under expressions which are aimed at treating disease.

The "Edible Lip Balm" (Measure ④) also raises Food Regulation Issues

Because Mr. B posted on social media that "the beetroot ingredient contained in the lip balm is also effective when taken orally", a separate problem arises. Even when promoting oral ingestion as a food,

[2] The scope of cosmetic efficacy claims is limited to 56 designated items (Notice PSEHB No. 0721-1 of July 21, 2011); expressions exceeding these are regulated as quasi-drugs or drugs.

claiming drug-like efficacy such as saying it "suppresses inflammation" or "rejuvenates the skin" would violate Article 68 of the PMD Act (advertising of an unapproved/unauthorized drug).

As to the advertising and labeling of foods, in addition to the PMD Act, Article 65 of the Health Promotion Act (prohibition of markedly false or exaggerated labeling), Article 5 of the Premiums and Representations Act (prohibition of misleading representations of superiority), and the Food Labeling Act (mandatory labeling; the health-function foods system) apply in overlapping fashion. Use of the "Foods with Function Claims" System—which allows businesses to lawfully indicate functions relating to the maintenance and promotion of health—requires notification to the Consumer Affairs Agency and the preparation of scientific evidence. However, the Foods with Function Claims System is intended to indicate functions for the maintenance and promotion of health, not involving the treatment of disease, for "persons not suffering from disease". Accordingly, drug-like efficacy claims used by Mr. B, such as that it "suppresses inflammation" or "rejuvenates the skin," fall outside the scope of the System in the first place, regardless of whether a notification has been made. If Company A wishes to claim in the future some functionality for the beetroot ingredient, the proper path would be to consider making a notification that it is a Food with Function Claims within a scope that does not stray into drug-like efficacy.[3]

2. Labeling Regulation of Cosmetics: The Problem with Measure ①'s Label

Mr. B attempted to ship the product with its Korean-language container labeling intact. However, this is problematic in that this means the label lacks the items that are required to be included on containers under Article 61 etc. of the PMD Act and the Japanese-language full-ingredient labeling based on the full-ingredient labeling notice. To ship a foreign cosmetic to the Japanese market, the items listed below must be stated in Japanese on the container or wrapping. Note that, quite apart from the labeling problem, Mr. B was also in violation of the PMD Act in that he tried to ship without even obtaining the cosmetics marketing authorization and manufacturing license in the first place. We explain the overall picture of licenses and notifications in the next section.

① The name or designation and address of the marketing authorization holder

② The name (the sales name in the notification)

③ The manufacturing number or manufacturing symbol

④ Ingredient names: all ingredients labeled in Japanese (per the Japan Cosmetic Industry Association's ingredient labeling name list, etc.) in order of formulation quantity

⑤ The expiry date (where necessary, e.g., for cosmetics whose properties/quality may change within 3 years of manufacture or import under appropriate storage conditions).

[3] Following a 2024 incident involving red-yeast-rice (*beni-koji*) products, the Foods with Function Claims system was heavily revised. Under the amended Food Labeling Standards of August 2024 (effective September 1, 2024), notifying businesses must collect information on suspected health damage (based on a physician's diagnosis) and promptly report it to the authorities; conduct manufacturing control based on GMP for tablet/capsule-type foods; and self-assess compliance annually and report to the Commissioner of the Consumer Affairs Agency (some GMP requirements have transitional measures running until the end of August 2026). A notification is not a one-time procedure: adopting an ongoing post-notification system for safety management and information provision is essential. In addition, new notifications on or after April 1, 2025 require the use of new forms (Forms 1-7), and updates to sales status and self-inspection reports are handled through the notification database, so the system adopted must be designed with periodic post-notification updating and reporting in mind.

In addition, under the Fair Competition Code on the labeling of cosmetics, there are further mandatory labeling obligations such as providing the category name, content volume, country of origin, and contact information.

Key Point | Relabeling with a Japanese Label Requires a Manufacturing License

The act of relabeling a Korean-language container with a Japanese label falls under “manufacturing” (the packaging/labeling/storage process) under the PMD Act, and requires a cosmetics manufacturing license (in the packaging/labeling/storage category).

If someone is “merely purchasing and reselling a product that has already been lawfully shipped to the domestic market in Japan”, no license is required; but note that a license becomes necessary at the stage where the label is altered.

Overview of the Licenses and Notifications Required to Import and Sell Cosmetics

It was also problematic that Company A tried to ship the products without obtaining the necessary licenses and notifications in the first place. To import a foreign cosmetic and ship it to the Japanese domestic market, the following items are required.

(1) Cosmetics marketing authorization (Prefectural Governor): Required to ship cosmetics to the domestic market. This requires the appointment of a general marketing manager, a quality assurance manager, and a safety management manager (the "three officers"). The three officers are required to have a system enabling them to perform their duties effectively; some local governments require them to be full-time regular employees. It is necessary to confirm in advance the practices of the prefecture to which the application is made.

(2) Cosmetics manufacturing license (Prefectural Governor): Required where manufacturing acts including packaging, labeling and storage are performed (two categories: "general" and "packaging/labeling/storage").

(3) Cosmetics marketing notification (Prefectural Pharmaceutical Affairs Division): Notify the sales name, manufacturing site, manufacturing method, etc. for each product. Changes require a change notification within 30 days.

(4) Foreign Manufacturer Notification (PMDA): When importing a cosmetic product manufactured overseas, it is necessary to notify the PMDA of information relating to the foreign manufacturer or foreign marketing authorization holder.

Even after obtaining these licenses, there is a continuing obligation to establish systems and retain records based on quality control (GQP Ordinance) and post-marketing safety management (GVP Ordinance). It is important to factor these into the company's business plan from an early stage and recognise that "obtaining the license is not the end of the matter."

3. Advertising Regulation of Cosmetics: A Deeper Look at the Problems with Measures ② and ③

(1) Scope of Efficacy Expressions (Measure ②: Instagram Advertisement)

The efficacy expressions permitted for cosmetics are limited to 56 specific items. The terms "heals," "soothes inflammation," "repairs" and "#crack-treatment" which are contained in the advertisement under Measure ② are all problematic expressions. When creating advertising copy, it is essential to carry out a prior check of the expression using a No-Go (NG) / OK table such as the following.

Scene / context	× NG expression	○ OK expression
Whitening / dark-spot care	"Prevents spots and freckles" (omitting the condition "caused by sunburn")	"Prevents spots and freckles caused by sunburn"
Aging care	"Improves wrinkles and sagging" / "Rejuvenates the skin"	"Makes fine lines caused by dryness less noticeable" / "Gives firmness to the skin"
Lips / moisturizing	"Cures cracks" / "Soothes inflammation" / "Solves lip trouble at its root"	"Prevents dryness of the lips" / "Gives moisture to the lips"
Ingredient promotion	"Ingredient XX repairs cells" (emphasizing a drug-like action)	"Contains ingredient XX" / "Formulated as a moisturizing ingredient" (stating the generic name and formulation purpose)
Hashtags	"#crack-treatment" / "#inflammation-care" (implying disease treatment)	"#lip-care" / "#moisture-lip" (expressions within the efficacy scope)

Note that an act qualifies as "advertising" under the PMD Act where it satisfies the following three requirements: ① there is a clear intent to attract customers (inducement); ② the specific product name being clear (specificity); and ③ being in a state perceivable by the general public (recognizability). Social media posts, product descriptions on e-commerce sites, and hashtags also become subject to advertising regulation where they satisfy these requirements.

Furthermore, the rules on how ingredients may be promoted were recently tightened. By a notice dated March 10, 2025 titled "Concerning the Special Highlighting of Specific Ingredients in Cosmetics"[4], for the first time in 40 years (since 1985), Japan's Ministry of Health, Labour and Welfare (MHLW) revised the treatment of special highlighting (making a specific formulated ingredient stand out—including framing, color changes, and also references to the ingredient name within the body text). Special highlighting is in principle not permitted because it may create a misleading impression that the ingredient is an active ingredient; it is permitted only exceptionally where certain conditions are met, namely: ① the formulation purpose is always stated alongside, and ② that the formulation purpose is an expression within the scope of the cosmetic's efficacy and formulation technology and is objectively substantiated. The revision also made changes such as that the formulation purpose needs to be clearly stated even for umbrella expressions such as "plant ingredients", for which the formulation purpose could previously have been omitted. Company A's "NATURA ROUGE" prominently features a natural beetroot pigment and a natural moisturizing ingredient α; when promoting these in the body of advertising copy etc., in light of this legislative revision it is necessary to state the formulation purpose (e.g., "formulated as a moisturizing ingredient") alongside objective grounds, and to avoid expressions that create the misleading impression of an active ingredient.

(2) Stealth Marketing Regulation (Measure ③: Influencer Requests)

Mr. B's act of requesting influencers to post without a PR disclosure risks violating the Stealth Marketing Designation that took effect in October 2023 (a designation under Article 5, item 3 of the Premiums and

[4] Notice of the Director of the Compliance and Narcotics Division, Pharmaceutical Safety Bureau, MHLW, *"Concerning the Special Highlighting of Specific Ingredients in Cosmetics"* (March 10, 2025, No. 0310-3).

Representations Act). The Designation regulates representations that, notwithstanding are advertising, are not recognizable as advertising—that is, representations for which it is difficult for general consumers to determine that they are "a representation by a business operator". Social media posts and review posts are also covered, including representations that a company has a third party (such as an influencer) make at the company's request or direction.

As a recent enforcement example, in June 2026 Takamitsu Pharmaceutical Co., Ltd. received an order under the Premiums and Representations Act regarding its foods "Nobirun" and "Nobirun C". In that case, the company provided products to third parties free of charge and requested they make social media posts, and used the images of those posts on its own website and EC malls. However Takamitsu did not clearly indicate to general consumers that the posts were made at the company's request.[5]

Key Point | Stealth Marketing Regulation

- Posts requested from influencers must always clearly indicate “PR,” “advertisement,” or “promotion” etc.
- The same applies where posts are requested in return for providing free products or participation as a product monitor.
- Posts made by a company's own employees while pretending to be ordinary consumers may also be covered.
- Even without an explicit instruction, an act may become subject to regulation if the business operator is found to be “involved in deciding the content of the representation” (substantive involvement is the criterion). Violations are subject to an order under the Premiums and Representations Act (stealth marketing designation violations are not subject to a penalty; however, where the violating conduct includes a misleading representation of superiority or advantage, that conduct may become subject to a penalty payment order).

It is not uncommon for a single advertising expression to simultaneously violate both the PMD Act (exaggerated efficacy labeling) and the Premiums and Representations Act (misleading representation of superiority). It is necessary to check the perspectives of both statutes from the advertising-creation stage.

An overview of the measures imposed upon violation should also be discussed. For PMD Act violations, in addition to administrative measures such as imposing administrative business suspension orders, criminal penalties may also apply in egregious cases. Furthermore, the 2019 amendment to the PMD Act introduced, for violations of Article 66(1) (false or exaggerated advertising), a penalty payment order system equal to 4.5% of the sales amount of the relevant product (up to 3 years) (this became effective August 1, 2021). It should therefore be noted that there is a monetary sanction which extends beyond mere penalties. For violations of the Premiums and Representations Act, in addition to an order by the Consumer Affairs Agency, a penalty equal in principle to 3% of the sales amount of the relevant product may be imposed.[6] For example, from recent beauty/healthcare-related cases: in December 2025, a penalty payment order of nearly 6 million Japanese Yen was issued to M&M Inc. regarding the quasi-drug "Unwrinkle", on the grounds that it was labeled as if it could achieve wrinkle-improvement effects similar to cosmetic medicine and had the effect of eliminating wrinkles and improving sagging in various facial areas. Also in the food sector, in June 2025, a penalty payment order of just over 10 million Yen

[5] Consumer Affairs Agency, “Order under the Act against Unjustifiable Premiums and Misleading Representations against Takamitsu Pharmaceutical Co., Ltd.” (published June 29, 2026; last accessed July 1, 2026).
[6] Where a penalty payment order under the Premiums and Representations Act exists for the same case, an adjustment provision deducts the Premiums and Representations Act surcharge amount (3% of sales) from the penalty amount under the PMD Act.

was issued to Hahaha Labo Inc. regarding slimming-effect labeling and No.1 labeling on affiliate sites etc. for the Food with Function Claims "Merat".[7]

Conclusion

In this issue, using the story of attempts to expand the fictitious brand "NATURA ROUGE" into Japan as an entry point, we surveyed the overall picture of the classification issues, labeling regulation, and advertising regulation relating to cosmetics and foods.

From the next issue onward, we will delve into individual topics. We plan to cover such matters as the details of cosmetic efficacy expressions (specific criteria for the NG/OK line), the practice of import procedures for Korean cosmetics and equivalent, and the latest trends in the Foods with Function Claims System.

[7] Consumer Affairs Agency, "Surcharge Payment Order against M&M Inc. under the Premiums and Representations Act" (published December 2, 2025; last accessed July 1, 2026), and "Surcharge Payment Order against Hahaha Labo Inc. under the Premiums and Representations Act" (published June 30, 2025; last accessed July 1, 2026).

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