COSMETICS & QUASI-DRUGS
ISSUES AND RECOMMENDATIONS
The Ministry of Health, Labour and Welfare (MHLW) released a model template for ordinary quasi-drug application documents in 2013, and a Q&A notice for quasi-drug applications in 2014 to clarify their evaluation policy.

In addition, the Ministry also published 25 raw material specifications on already approved excipients.

These actions helped to improve the transparency of the quasi-drug review system.
The MHLW also released a new pricing policy to charge higher evaluation fees for quasi-drugs which contain new active ingredients to enable the hiring of more evaluators.

Thanks to these improvements, a shortening of the evaluation period can be expected.
Reform the Quasi-Drug Approval System

RECOMMENDATIONS

- The MHLW should establish clear processes for the periodical updating of lists of approved active and excipient ingredients and for expansion of raw material specifications on excipients, in order to increase the transparency of the quasi-drug review system.

- The MHLW should allow the use of excipients in cosmetics without restrictions or limits, as long as there are no special notes regarding safety or usage restrictions for each ingredient.

- The MHLW should establish approval standards for all quasi-drug categories to expand the number of quasi-drugs evaluated by the prefectural authorities. This would help shorten the new product evaluation period. We also recommend that the MHLW establish a system to review the standards periodically.
HARMONISE QUASI-DRUG & COSMETIC INGREDIENTS
The fluoride concentration levels permitted in oral care products in Japan are not aligned with the higher levels permitted in other developed countries.

Japan permits a maximum of 1,000 parts per million (ppm) of fluoride in toothpaste sold as a quasi-drug, while concentrations of fluoride of up to 1,500 ppm are permitted in Europe.

Japan does not accept fluoride in mouthwash products although mouthwash with fluoride concentrations of 226 ppm is sold at drugstores and supermarkets throughout Europe and the United States.
The use of fluoride to prevent dental cavities has been shown to be effective and safe in scientific studies conducted around the world.

Moreover, the EU and Japan maintain different rules governing which ingredients are allowed in cosmetics, expressed respectively in terms of negative and positive lists.
Harmonise Quasi-drug & Cosmetic Ingredients

RECOMMENDATIONS

- Japan should revise the Medicated Dentifrice Approval Standard by raising the fluoride concentration allowed in toothpaste sold as a quasi-drug to 1,500 ppm and in mouthwash sold as a quasi-drug to 226 ppm.

- Japan should resolve the inconsistency between Japan and the EU in the maintenance of positive and negative lists for all quasi-drug and cosmetic ingredients.
PROMOTION OF SELF-MEDICATION ADVISORY ROLE OF PHARMACISTS & GENERAL PRACTITIONERS
Self-medication is the selection and use of medicines by individuals to treat recognised illnesses or symptoms.

It includes the use of non-prescription medicines sold over the counter (OTC) and as quasi-drugs.

If more people were to visit general practitioner doctors and pharmacists for advice and use OTC and quasi-drugs to manage minor health problems on their own, then specialist doctors at major hospitals would have more time to focus on other patients with more serious conditions.

This would improve health and help reduce total healthcare spending.
RECOMMENDATIONS

- Japan should promote self-medication where it is safe and appropriate to do so by creating financial incentives for patients and pharmacists.
EXPANSION OF EFFICACY CLAIMS FOR COSMETICS & QUASI-DRUGS
A scheme for specifying the efficacy of cosmetics was presented in the “Notification on Enforcement of Pharmaceutical Affairs Law” in 1961.

Subsequently, 55 efficacy claims were defined for cosmetics in the “Notification on Revision of the Scope of Efficacy Claims for Cosmetics” issued in 2000.

In 2011, the efficacy claim of “making fine wrinkles due to dryness less noticeable” was added to the list.

Yet the scope of efficacy claims approved in Japan is still narrower than in other countries, which hinders the entry of foreign-made cosmetics based on the latest research and technology to the market.
Expansion of Efficacy Claims for Cosmetics & Quasi-Drugs

RECOMMENDATION

- Japan should expand and harmonise the scope of positive efficacy claims for cosmetics and quasi-drugs with the EU, including the claim of “preventing photo-ageing caused by exposure to ultra violet light.”

- To align with EU regulation, the MHLW should abolish the efficacy claim list and allow companies to communicate product efficacy within the definition of cosmetic based on verifiable data.
ELECTRONIC NOTIFICATION FOR COSMETICS & QUASI-DRUGS
Foreign cosmetic companies seeking to import cosmetics and quasi-drugs into Japan must submit two different notifications with significant duplicate information.

The MHLW requires paper-form submission of an Import Notification for all cosmetics to be imported for sale in Japan, prior to any of the import-designated products proceeding through Japan Customs.

The reviewed notification must also be submitted to Japan Customs at the time of the customs clearance processing.

This procedure is time-consuming and duplicative.

In many other countries in the world companies are allowed to use an electronic notification system.
The MHLW should simplify the Import Notification procedures for importing foreign-manufactured cosmetics and quasi-drugs by establishing an electronic system for the import notification process. It should be designed in such a way that not only will the current burdensome paper-based notification process be eliminated, but the number of necessary supporting documents can be reduced.
ELIMINATION OF NON-TARIFF BARRIERS FOR COSMETIC AND QUASI-DRUG IMPORTS
Once a partial change request has been approved for a cosmetic or quasi-drug, no previously approved versions are allowed through the customs quality check and onto the market.

Given the difficulty in predicting approval timing and shipping time, sea freight importers expecting a partial change request approval must hold large amounts of current stock in Japan to guarantee a stable supply.

To avoid these extra costs, many importers avoid partial change requests.

YEARLY STATUS REPORT: No Progress
They instead apply for approval of partial changes as if relating to completely separate products.

This forces companies to maintain multiple approvals for products that appear identical to the end-customer.
Elimination of Non-Tariff Barriers for Cosmetic & Quasi-Drug Imports

RECOMMENDATIONS

- After partial change approvals are granted, there should be a grace period during which the previous version of imported products can continue to undergo customs quality checks and be sold.
ESTABLISHING OF ALTERNATIVES TO ANIMAL TESTING
Cosmetic and quasi drug manufacturers are still expected to submit safety data based on animal testing in Japan and validated alternatives are limited.

The use of alternatives to animal testing was officially recommended in a February 2011 MHLW Administrative Circular.

MHLW guidance on replacing the skin sensitisation test took effect in May 2013, corresponding to Organisation for Economic Co-operation and Development (OECD) guidelines 442A and 442B.

Establishing of Alternatives to Animal Testing

RECOMMENDATIONS

- Japan should accelerate the establishment of validated alternatives for animal testing of ingredients and products based on safety endpoints that are harmonised with those used in the EU.

- Japan should abide by its international commitment to protect humans, animals and the environment.