EUROPEAN BUSINESS COUNCIL IN JAPAN
THE EUROPEAN (EU) CHAMBER OF COMMERCE IN JAPAN

COSMETICS & QUASI-DRUGS

ISSUES AND RECOMMENDATIONS

REFORM THE QUASI-DRUG APPROVAL SYSTEM

Reform the Quasi-Drug Approval System

YEARLY STATUS REPORT: Slight Progress

- In October 2016 and September 2017, MHLW's Evaluation and Licensing Division issued a notification concerning a "Partial Amendment of the List of Excipients for Quasi-drugs", and added maximum thresholds for the listed ingredients.
- In addition, a study of real examples of product approval processes was started in order to develop guidelines for examining medicated cosmetics related to medicated soap.
- However, to-date the guidelines have not been developed.

Reform the Quasi-Drug Approval System

YEARLY STATUS REPORT: Slight Progress

- In order to accelerate the speed of examination, the Pharmaceuticals and Medical Devices Agency (PMDA) created a checklist, planning to request submission of the checklist's cover sheet with any application made from April 2016 onwards.
- The burden on applicants was, however, a concern, and use of this list was revised in February 2017 and submission of the list is no longer required.
- In 2014, the PMDA began collecting information from businesses on the raw material specifications of excipients that had already been approved, and published this information as "Standards of Excipients for Quasi-drugs" (2014).

Reform the Quasi-Drug Approval System

YEARLY STATUS REPORT: Slight Progress

- The exercise was repeated in 2015 and again in 2016.
- However, almost no information was provided by businesses due to concerns about protection of their intellectual property and consequently the publication still covers only 27 ingredients.
- Although the quasi-drug review system has been improved, there is unfortunately no commitment in the above-mentioned notification to shorten the review period.

Reform the Quasi-Drug Approval System

RECOMMENDATIONS

- MHLW should shorten the review period for quasi-drugs for which review guidelines have been created and which are believed to be identical to already-approved quasi-drugs.

- A code should be assigned to standards for ingredients used in already-approved quasi-drugs, and this code should then be used in applications for approval of other quasi-drugs that share the same ingredients, to obviate the need for repeatedly reviewing the standards for those same ingredients. This would enhance efficiency and shorten the review period.

HARMONISATION OF QUASI-DRUG & COSMETIC INGREDIENTS

Harmonisation of Quasi-drug & Cosmetic Ingredients

YEARLY STATUS REPORT: Progress

- The EU and Japan maintain different rules governing the type and quantity of ingredients allowed in cosmetics and quasi-drugs.
- The effectiveness of fluoride in preventing tooth decay has been scientifically verified: it is important for the health of the mouth and the entire body and is therefore key to self-care.
- Japan used to permit a maximum of 1,000 ppm of fluoride in toothpaste sold as a quasi-drug as an approval standard, while concentrations of fluoride of up to 1,500 ppm are allowed in Europe.

Harmonisation of Quasi-drug & Cosmetic Ingredients

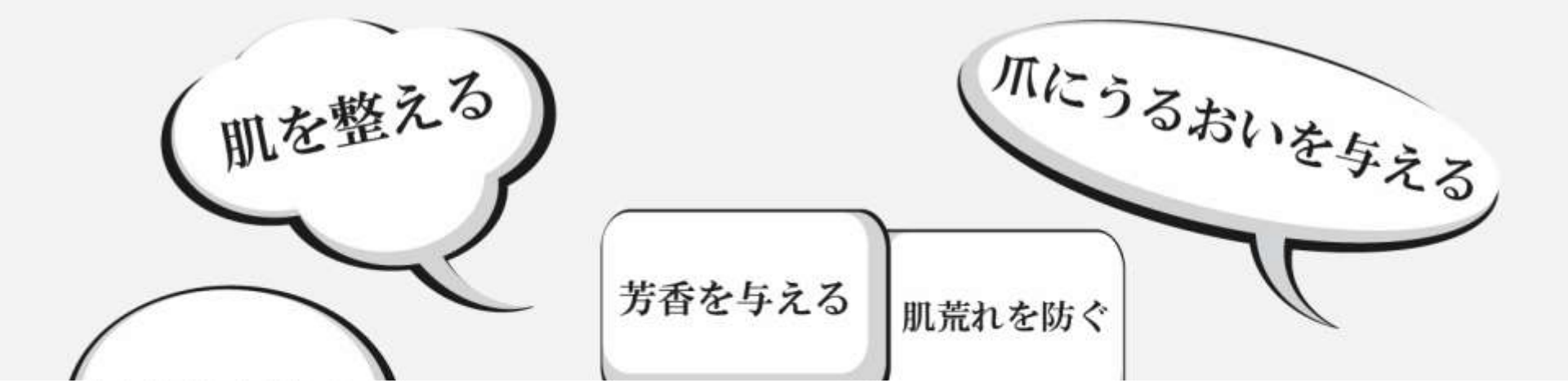
YEARLY STATUS REPORT: Progress

- In March 2017, MHLW approved the sale of products containing a maximum of 1,500 ppm fluoride, in line with the international standard (ISO) used in other countries.
- However, mouthwash with fluoride concentrations of 226 ppm is sold at drugstores and supermarkets throughout Europe and the United States, and while Japan approved the use of fluoride in mouthwash for general consumption in 2015, its use is limited to products sold as a drug requiring guidance.
- The EBC notes that the Japan Society for Oral Health suggested at an academic meeting in February 2017 that the environment should be improved for older people's oral care, including through deregulation, so that drug products containing fluoride can be developed and used more effectively.

Harmonisation of Quasi-drug & Cosmetic Ingredients

RECOMMENDATION

- MHLW should revise the medicated dentifrice approval standard in line with international norms, raising the upper limit of fluoride concentration allowed in medicated toothpaste (a quasi-drug) and allowing the use of fluoride in mouthwash (another quasi-drug) without restrictions.



EXPANSION OF ADVERTISING REPRESENTATION FOR COSMETICS & QUASI-DRUGS

Expansion of Advertising Representation For Cosmetics & Quasi-drugs

YEARLY STATUS REPORT: No Progress

- Fifty-five efficacy claims were defined as permissible for cosmetics in Japan in 2000.
- In 2011, a further 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 foreign-made cosmetics based on the latest research and technology from entering the Japanese market.

Expansion of Advertising Representation For Cosmetics & Quasi-drugs

YEARLY STATUS REPORT: No Progress

- Sector associations are currently studying the efficacy claim of “prevention of ultraviolet ray-derived photo-ageing” which may lead to a further expansion.
- However, current advertising regulations still do not permit claims relating to the significance of daily care using cosmetics or quasi-drugs such as moisturising creams for atopic skin or sunscreen products to prevent skin cancer, despite the fact that this plays an important role in maintaining health and preventing illness.

Expansion of Advertising Representation For Cosmetics & Quasi-drugs

RECOMMENDATION

- Advertising claims connected to the maintenance of health and prevention of illness should be deregulated so that the significance of daily care using cosmetics and quasi-drugs can be claimed.

ONLINE NOTIFICATIONS & APPLICATIONS FOR APPROVAL OF COSMETICS & QUASI-DRUGS

Online Notifications & Applications for Approval of Cosmetics & Quasi-drugs

YEARLY STATUS REPORT: No Progress

- The Government introduced a "Basic Act on the Advancement of Utilising Public and Private Sector Data" in December 2016, to regulate online administrative procedures.
- Since August 2016, applications for approval of prescription drugs, along with supporting clinical investigation reports and other materials have all been accepted in electronic form via the Internet.

Online Notifications & Applications for Approval of Cosmetics & Quasi-drugs

YEARLY STATUS REPORT: No Progress

- However, for cosmetics and quasi-drugs, notifications and applications must still be submitted on a floppy disc or in paper form, which are outdated methods compared to those used by many other countries.

- Moreover, the systems used by prefectural authorities, the PMDA, and Customs are not linked, and separate procedures are required for notifications and applications for the manufacture and sale of cosmetics and quasi-drugs, notifications of export goods, and presentation of materials for import customs clearance.

Online Notifications & Applications for Approval of Cosmetics & Quasi-drugs

RECOMMENDATION

- An online notification and application system should be established for submitting Notifications on the Manufacture and Sale of Cosmetics and Applications for Approval of Quasi-Drugs. This system should be linked to the Customs clearance system to provide a one-stop service for application procedures.

APPLYING THE SAME STANDARDS TO ALL MARKET PARTICIPANTS

Applying The Same Standards To All Market Participants

YEARLY STATUS REPORT: New Issue

- Ensuring safety is crucial, both from a legal and, more importantly, from a consumer perspective.
- Manufacturers and importers of cosmetics and quasi-drugs are therefore required to spend considerable resources implementing post-marketing surveillance and control schemes to monitor safety and quality.
- However, parallel importers do not always comply with these requirements, sometimes illegally using registered trademarks, importing versions of products that are not approved in Japan, and selling products with damaged or missing labels or that have passed their expiry dates.

Applying The Same Standards To All Market Participants

RECOMMENDATIONS

- Japan should ensure that everyone involved in the sale of cosmetics and/or quasi-drugs complies with the same legal requirements related to safety and quality.
- The authorities should support an industry-led campaign to educate consumers so that they have a better understanding of products sold by authorised suppliers and those that are not.

ESTABLISHMENT OF ALTERNATIVES TO ANIMAL TESTING

Establishment of Alternatives to Animal Testing

YEARLY STATUS REPORT: No Progress

- Animal testing for the purpose of studying the safety and efficacy of cosmetics is completely banned in the EU and the trend towards a ban is spreading to other countries and areas.
- However, in Japan, safety data based on animal testing must be submitted when applying for approval of quasi-drugs using new raw materials.
- A notification issued by MHLW in 2011 supports the active use of alternative methods replacing animal testing, but at present there are only a few available that do not use animals.

Establishment of Alternatives to Animal Testing

RECOMMENDATION

- Japan should proactively promote the development of alternative methods that do not use animals and MHLW should issue guidelines to enable their use in applications for quasi-drugs as soon as possible.