COSMETICS & QUASI-DRUGS

ISSUES AND RECOMMENDATIONS
REFORM THE QUASI-DRUG APPROVAL SYSTEM
Reform the Quasi-Drug Approval System

YEARLY STATUS REPORT: Slight Progress

- Having created examination guidelines for medicated shampoos and conditioners in 2014, MHLW asked the Japan Cosmetic Industry Association (JCIA) to draft an industry standard with a view to creating examination guidelines for medicated soap.

- In response, the JCIA has started to study examples of approved medicated soap.

- At the same time, in August 2015, the Director of MHLW’s Evaluation and Licensing Division issued a notification concerning an “Investigation on Review of the List of Excipients for Quasi-drugs (Request)”.

Reform the Quasi-Drug Approval System

YEARLY STATUS REPORT: Slight Progress

- Based on the notification, for the first time ever since the list was created in 2008, the upper values of existing ingredients and ingredients additionally listed in the Japanese Standards of Quasi-Drug Ingredients are now being reviewed.

- The Pharmaceuticals and Medical Devices Agency (PMDA) collected information from businesses on the raw material specifications of already approved excipients and published the results in a book entitled “Standards of Excipients for Quasi-drugs” in 2014.

- Additional information was solicited from businesses in 2015 and again in 2016, but so far, responses have been limited.
Consequently, the book still covers only the small number of 27 ingredients.

Furthermore, since April 2016 the PMDA has been provisionally asking applicants to attach a check list confirming the contents of their application documents and this procedure will be formally adopted in 2017, placing an additional burden on applicants.

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 the 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.
HARMONISE QUASI-DRUG & COSMETIC INGREDIENTS
The EU and Japan maintain different rules governing which ingredients are allowed in cosmetics.

Furthermore, the fluoride concentration levels permitted in oral care products in Japan are not aligned with the higher levels permitted in other developed countries.

The effectiveness of fluoride in preventing tooth decay is scientifically verified: it is important for the health of the mouth and the entire body and is therefore key to self-care.
Harmonise Quasi-drug & Cosmetic Ingredients

YEARLY STATUS REPORT: Slight Progress

- 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 allowed in Europe.

- Mouthwash with fluoride concentrations of 226 ppm is sold at drugstores and supermarkets throughout Europe and the United States, whereas Japan approved the use of fluoride in mouthwash for general consumption in 2015, but only as a drug requiring guidance.
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) as soon as possible.
EXPANSION OF EFFICACY CLAIMS FOR COSMETICS
Expansion of Efficacy Claims for Cosmetics

YEARLY STATUS REPORT: No Progress

- Fifty-five efficacy claims were defined as permissible for cosmetics in Japan in the “Notification on Revision of the Scope of Efficacy Claims for Cosmetics” issued in 2000.

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

- The Japanese Cosmetic Science Society and Japan Cosmetic Industry Association are now studying the efficacy claim of “prevention of ultraviolet ray-derived photoaging” which may lead to a further expansion.
Expansion of Efficacy Claims for Cosmetics

YEARLY STATUS REPORT: No Progress

- Yet the scope of efficacy claims approved in Japan is still narrower than in other countries, which hinders entry to the Japanese market of foreign-made cosmetics based on the latest research and technology.

- There is also a need, as part of the Government’s efforts to encourage self-care, to develop a proper method of distributing information to consumers on scientifically-proved efficacy, such as the effectiveness of warmth in improving atopic skin and the efficacy of sunscreen products in preventing skin cancer.
Japan should expand the scope of its positive efficacy claims for cosmetics to harmonise with that of the EU.
SIMPLIFIED PROCEDURES FOR COSMETIC & QUASI-DRUG IMPORTS
Simplified Procedures for Cosmetic & Quasi-drug Imports

YEARNLY STATUS REPORT: Significant Progress

- MHLW announced the abolishment of import notifications effective from January 2016.

- This has significantly simplified import procedures.

- At the same time, however, the Nippon Automated Cargo and Port Consolidated System (NACCS)-based online procedures were abolished, and customs clearance now depends on presentation of a Production (Production and Sale) Permit and paper copies of the Notification on Manufacture and Sale of Cosmetics and other documents.

- This is a step backwards in terms of accelerating online procedures.
Simplified Procedures for Cosmetic & Quasi-drug Imports

RECOMMENDATION

- A system of online (rather than paper-based) procedures, involving for example the effective use of NACCS, should be established for handling documentation to support customs clearance of imported cosmetics and quasi-drugs.
ONLINE NOTIFICATIONS & APPLICATIONS FOR APPROVAL OF COSMETICS & QUASI-DRUGS
In its Basic Policy on IT Utilisation, the Japanese Government declared its intention to handle administrative procedures, such as applications, online rather than face-to-face or by document processing.

For prescription drugs, applications for approval, along with supporting clinical investigation reports and other materials, will soon be accepted in electronic form via the Internet.
However, for cosmetics and quasi-drugs, notifications and applications must still be submitted on floppy discs or in paper form, which are outdated methods compared to those used by many other countries.

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.
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.
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, cosmetics manufacturers are still expected to submit safety data based on animal testing when applying for approval of quasi-drugs using new raw materials.
Social pressure to abolish animal testing and shift to alternative methods is increasing.

A notification issued by MHLW in 2011 supports the active use of alternative methods replacing animal testing when preparing applications for approval of quasi-drugs, but available alternative methods are limited in regard to phototoxicity, skin sensitisation, and eye irritation tests.
Establishment of Alternatives to Animal Testing

RECOMMENDATION

- Japan should as soon as possible formally approve the proposed alternative methods, based on the Organisation for Economic Cooperation and Development (OECD)’s test guidelines, by issuing relevant MHLW Guidelines, so that these alternative methods are available when preparing applications for approval of quasi-drugs.