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**第46回日本香粧品学会（2021）・シンポジウム「グローバル環境から見た医薬部外品（添加物）開発の将来」**

# グローバルに見た機能性を求める化粧品の現状と新規承認に関する考え方

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# Current Status of Functional Cosmetics and Its Regulatory Approval from International Perspectives

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**Abstract**

The system for pharmaceuticals and cosmetics is basically classified into only pharmaceuticals and cosmetics in some countries/regions, and some countries/regions have intermediate categories between them. The expression "cosmetics having functionality" falls into this intermediate category, and in the case of Japan, quasi-drugs are included in this category. Of the countries/regions that are closely related to Japan in the import and export of cosmetics, only EU and ASEAN do not have intermediate categories, it exits as "special cosmetics" in China, "Cosmetic Drugs" in the United States, "functional cosmetics" in South Korea, and "specific purpose cosmetics" in Taiwan. The types, actions, and functions of these intermediate categories may differ depending on the country/region, but many are common. Sunscreens are in the intermediate category in all countries/regions.

For products in these intermediate categories, the registration system is in the United States, but the approval system is the basis in many countries/regions, and each has its own application and approval standards. There are also differences in the safety materials that need to be attached at the time of application, depending on the country/region.

More than eight years have passed since the ban on animal testing in the EU in 2013, but no alternative method has been developed that can be used for all safety evaluations. It is very difficult at this stage to prepare application materials for quasi-drugs without conducting animal experiments, but guidance on alternative studies for application is gradually being prepared in Japan. In addition, since safety evaluation methods using *in vitro* and *in silico* are advancing day by day, we hope that it will be possible to apply for approval of quasi-drugs without relying on animal experiments in the not to distance future.

**Key words:**　cosmetics, quasi-drugs, intermediate category, alternative testing, regulatory approval.