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〈シンポジウム〉

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」

動物実験代替法を用いた，医薬部外品・化粧品の安全性評価ガイダンスの作成状況について

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Regarding the Current Status of Safety Evaluation Guidance for Quasi-Drugs and Cosmetics Using Alternative Methods for Animal Experiments

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Abstract

In the application for manufacturing and marketing approval of quasi-drugs and the request for revision of cosmetic standards, safety tests using animals have been most commonly used in accordance with the safety evaluation of pharmaceuticals. However, several useful alternative methods for animal testing have been reported, some of which have been adopted as the OECD Test Guidelines (TG). In Japan as well, the regulatory use of alternative methods for animal testing will be promoted by the guidance issued after discussions at the "Committee to discuss the guidance on safety testing methods for quasi-drugs, *etc.*," whose secretariat is the Japanese Center for the Validation of Alternative Methods (JaCVAM). To date, guidance for alternative methods such as phototoxicity tests, eye irritation tests and skin sensitization tests has been issued. In this presentation, we will introduce the status of guidance discussed at the "Committee to discuss the guidance," especially about the status of discussion for the guidance for "skin irritation" and "single dose toxicity."

[About the guidance for skin irritation]

The *in vitro* tests using a reconstructed human epidermis (RhE) model have been adopted as OECD TG439. However, these tests might be insufficient for regulatory use of quasi-drugs application that require a 24 h skin irritation test. This problem was resolved by comparison data between the TG439 and the 24 h patch test, and set of applicability domain, and the guidance for skin irritation was issued.

[About the guidance for single-dose toxicity]

Regarding the *in vitro* tests for the single-dose toxicity, we examined the use of cytotoxicity assay introduced in OECD Guidance No. 129. Although it is not possible to evaluate all of the acute toxicity by cytotoxicity alone, we examined the evaluation by combining with other information, not by the cytotoxicity test alone, and created the guidance including the evaluation flow.

Key words: quasi-drugs, guidance, skin irritation, single-dose toxicity, JaCVAM.