

〈シンポジウム〉

『香粧品の更なる安心・信頼を追求するための新しい視点』

最近の薬務行政について

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Abstract

The two bills to amend Pharmaceutical Affairs Act have passed 185th Session of the Diet held in 2014. There were four major pillars in the one of the bill: Strengthen Safety Measures regarding Drugs, Medical Devices, etc.; Formulating a framework of legislation considering the natures of medical devices; and Formulating a framework and legislation considering regenerative medicinal products. Under another bill, there were two major pillars: Reviewing a framework of legislation concerning sales licence for pharmaceuticals; and Prohibiting possession/use of illegal drug (new psychoactive substances). Japanese Pharmacopoeia is a set of standards established by the Ministry of Health, Labour and Welfare of Japan to ensure qualities/products demonstration of pharmaceuticals. The Supplement 2 of the 16th Edition has just issues at February of 2014. The standards for hair dyes, permanent wave solution is expected to be under the review soon. Also, discussions for authorization of quasi drug are ongoing about how the transparency should be ensured and what approval examination method should be newly added.

Key words: pharmaceutical affairs act, regenerative medicinal products, Japanese pharmacopia, quasi drug, approval standards.