

## Marketing and Pharmaceutical Analysis of Medical Cosmetics in Bulgaria and Japan

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**Abstract :** Introduction: Production, distribution and sale of cosmetics is a global industry, which played a key role in the European Union (EU), the US and Japan. A major participant EU whose market cosmetics is greater than in the US and 2 times greater than that in Japan. The output value of the cosmetics industry in the EU is estimated at about € 35 billion in 2001. Nearly 5 billion cosmetic products (number of packages) are sold annually in the EU, and the main markets are France, Germany, Italy, Spain and the UK. The aim of the study is legal and marketing analysis of cosmetic products dispensed in a pharmacy. Materials and methodology: Historical legislative analysis - the method is applied in the analysis of changes in the legislative regulation of the activities of cosmetic products in Japan and Bulgaria Comparative legislative analysis - the method is applied when comparing the legislative requirements for cosmetic products in the already mentioned countries. Both methods are applied to the following regulations: 1) Japanese Pharmaceuticals Affairs Law, Tokyo, Japan, Ministry of Health, Labour and Welfare; 2) Law on Medicinal Products for Human Use; effective from 3.01.2014. Results: The legislative framework for cosmetic products in Bulgaria and Japan is close and generally includes general guidelines: Definition of a medicinal product; Categorization of drugs (with differences in sub-categories); Pre-registration and marketing approval of the competent authorities; Compulsory compliance with gmp (unlike cosmetics); Regulatory focus on product quality, efficacy and safety; Obligations for labeling of such products; Created systems Pharmacovigilance and commitment of all parties - industry and health professionals; The main similarities in the regulation of products classified as cosmetics are in the following segments: Full producer responsibility for product safety; Surveillance of market regulatory authorities; No need for pre-registration or pre-marketing approval (a basic requirement for notification); Without restrictions on sales channels; GMP manuals for cosmetics; Regulatory focus on product safety (than over efficiency); General requirements in labeling: The main differences in the regulation of products classified as cosmetics are in the following segments: Details in the regulation of cosmetic products; Future convergence of regulatory frameworks can contribute to the removal of barriers to trade, to encourage innovation, while simultaneously ensuring a high level of protection of consumer safety.

**Keywords :** cosmetics, legislation, comparative analysis, Bulgaria, Japan

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