

ABSTRACT

The circulation of cosmetic products containing harmful ingredients above the safe threshold is a legal issue directly related to the protection of public health and legal certainty for business actors. In the practice of criminal justice, problems arise when cosmetic products are qualified as pharmaceutical preparations, as reflected in the Batulicin District Court Decision Number 334/Pid.Sus/2024/PN.Bln. In the decision, business actors were found guilty of producing and distributing pharmaceutical preparations containing harmful ingredients that exceeded the safe limit. Juridical problems arise because normatively cosmetics are not always included in the category of pharmaceutical preparations as stipulated in the Regulation of the Food and Drug Supervisory Agency Number 17 of 2022 concerning Technical Requirements for Cosmetic Ingredients. This article aims to analyze the judge's considerations in qualifying evidence in the form of cosmetic products as pharmaceutical preparations and assess its suitability with the applicable positive legal provisions. The research method used is normative juridical law research with a statutory approach and a conceptual approach. The legal materials used consist of primary legal materials in the form of laws and regulations and court decisions, as well as secondary legal materials in the form of relevant books and scientific journals. The results of the study show that the judge's consideration in the decision is not fully aligned with the definition and limitations of cosmetics as specified in BPOM regulations, so that it has the potential to cause legal uncertainty in the enforcement of criminal liability of business actors. Therefore, precision is needed in qualifying cosmetic products as pharmaceutical preparations so that the application of criminal law remains in line with the principles of legality and fair legal protection.

Keywords : *Business actors' liability, dangerous cosmetics, pharmaceutical preparations, judge's consideration, health law.*