

ABSTRACT

Description of Causal Factors and Forms of Criminal Acts Committed by Pharmaceutical Product Sellers

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The distribution of pharmaceutical preparations without a marketing authorization poses a serious threat to public health and social order. Although criminal sanctions have been explicitly regulated under Article 197 in conjunction with Article 106 paragraph (1) of Law Number 36 of 2009 concerning Health, the illegal sale of pharmaceutical preparations continues to occur with varying patterns of law enforcement. This study aims to identify and describe the factors contributing to the criminal offense of selling pharmaceutical preparations without a marketing authorization, the methods employed in committing the offense, and the legal consequences imposed on the offenders and the seized evidence.

This study employs normative legal research with a descriptive-analytical approach, which aims to provide a systematic description of the object under study and to analyze the relationship between the independent variable, namely the legal regulation governing the criminal offense of distributing illegal pharmaceutical preparations, and the dependent variable, namely the judges' considerations in imposing criminal sanctions on the offenders. The legal materials used consist of primary legal materials in the form of statutory regulations and five District Court decisions concerning cases of illegal pharmaceutical distribution, as well as secondary legal materials in the form of legal literature. Data were collected through library research and analyzed using a qualitative normative legal approach.

*The results indicate that the primary factors contributing to this criminal offense are economic motives to obtain substantial financial gain, the low level of legal awareness and knowledge among business operators, and the lack of public education regarding marketing authorization requirements. The sale of illegal pharmaceutical preparations is carried out through both conventional channels, such as traditional herbal medicine shops and retail stores, and modern channels through e-commerce platforms. The criminal sanctions imposed on offenders vary depending on the judges' considerations regarding the degree of culpability, the quantity of seized evidence, and the potential impact of the products. The sanctions include imprisonment ranging from several months to three years and six months, as well as fines ranging from several million rupiah to IDR 100,000,000. Under Indonesia's new Criminal Code (Law Number 1 of 2023), offenses related to public health remain governed by special legislation (*lex specialis*) outside the Criminal Code.*

Keywords: Pharmaceutical Preparations, Marketing Authorization, Criminal Offense, Health, Judicial Decision Analysis.

ABSTRAK

DESKRIPSI TENTANG FAKTOR PENYEBAB, TATA CARA DAN AKIBAT HUKUM TINDAK PIDANA PENJUALAN SEDIAAN FARMASI

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Peredaran sediaan farmasi tanpa izin edar merupakan ancaman serius bagi kesehatan masyarakat dan ketertiban sosial. Meskipun regulasi pidana telah diatur secara tegas dalam Pasal 197 juncto Pasal 106 ayat (1) Undang-Undang Nomor 36 Tahun 2009 tentang Kesehatan, praktik penjualan sediaan farmasi ilegal masih marak terjadi dengan variasi penegakan hukum yang beragam. Penelitian ini bertujuan untuk mengidentifikasi dan mendeskripsikan faktor penyebab terjadinya tindak pidana penjualan sediaan farmasi tanpa izin edar, cara, serta akibat hukum terhadap para pelaku dan barang bukti.

Metode penelitian yang digunakan adalah penelitian hukum normatif yang bersifat deskriptif analisis, yaitu penelitian yang bertujuan untuk memberikan gambaran secara sistematis mengenai objek yang diteliti serta menganalisis hubungan antara variabel bebas, yaitu pengaturan hukum mengenai tindak pidana peredaran sediaan farmasi ilegal, dengan variabel terikat, yaitu pertimbangan hakim dalam menjatuhkan putusan terhadap pelaku tindak pidana tersebut. Sumber bahan hukum yang digunakan meliputi bahan hukum primer berupa peraturan perundang-undangan dan lima putusan Pengadilan Negeri terkait kasus peredaran obat ilegal, serta bahan hukum sekunder berupa literatur hukum. Pengumpulan data dilakukan melalui studi kepustakaan dan dianalisis secara normatif kualitatif.

Hasil penelitian menunjukkan bahwa faktor penyebab utama terjadinya tindak pidana ini didominasi oleh motif ekonomi untuk meraup keuntungan finansial yang besar, rendahnya tingkat pengetahuan dan kesadaran hukum pelaku usaha, serta minimnya sosialisasi terkait izin edar. Cara penjualan dilakukan baik secara konvensional melalui depot jamu dan toko eceran, maupun secara modern memanfaatkan aplikasi belanja daring (*e-commerce*). Akibat hukum pidana terhadap para pelaku bervariasi bergantung pada pertimbangan hakim mengenai tingkat kesalahan, jumlah barang bukti, dan dampak produk, dengan sanksi berupa pidana penjara berkisar antara hitungan bulan hingga 3 tahun 6 peradilan, serta denda material mulai dari jutaan rupiah hingga Rp100.000.000,00. Dalam konteks hukum nasional, berlakunya KUHP Baru (UU No. 1 Tahun 2023) tetap menempatkan ketentuan tindak pidana kesehatan ini sebagai aturan khusus (*lex specialis*) di luar KUHP.

Kata Kunci: Sediaan Farmasi, Izin Edar, Tindak Pidana, Kesehatan, Analisis Putusan.