

**IMPLEMENTASI PASAL 2 AYAT (1) PERATURAN MENTERI
KESEHATAN NOMOR 7 TAHUN 2012 TENTANG REGISTRASI OBAT
TRADISIONAL TERKAIT PEREDARAN OBAT TRADISIONAL TANPA
IZIN EDAR DI KABUPATEN BULELENG**

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ABSTRAK

Tujuan penelitian ini untuk mengetahui dan menganalisa terkait Implementasi Pasal 2 Ayat (1) Peraturan Menteri Kesehatan Nomor 7 Tahun 2012 Tentang Registrasi Obat Tradisional Terkait Peredaran Obat Tradisional Tanpa Izin Edar serta mengetahui bagaimana penegakan hukum terhadap pelaku usaha yang produk obat tradisionalnya tidak memiliki izin edar. Jenis penelitian yang digunakan adalah penelitian hukum empiris dengan sifat penelitian deskriptif. Lokasi penelitian ini dilakukan di Kabupaten Buleleng. Teknik Pengumpulan data yang digunakan dengan cara studi pustaka, observasi dan wawancara. Teknik penentuan sampel yang digunakan adalah Teknik *Non-Probability Sampling* dan penentuan subyeknya menggunakan *Purposive Sampling*. Teknik pengolahan dan analisis data secara kualitatif. Adapun hasil penelitian menunjukkan bahwa ketentuan Pasal 2 Ayat (1) Peraturan Menteri Kesehatan Nomor 7 Tahun 2012 Tentang Registrasi Obat Tradisional yang mengatur izin edar obat tradisionanl belum terimplementasikan dengan baik. Hal ini tercermin dari masih terdapat pelaku usaha yang tidak mengurus izin edar sebagaimana dengan ketentuan yang berlaku. Adapun penegakan hukum terhadap pelaku usaha berupa sanksi administratif sebagaimana yang diatur dalam Pasal 23 Peraturan Menteri Kesehatan Nomor 7 Tahun 2012 tentang Registrasi Obat Tradisonal. Adapun sanksi administratif berupa pemanggilan, pembinaan, beserta peringatan terhadap pelaku usaha obat tradisional tanpa izin edar. Dan penegakan hukum melalui Undang-Undang Nomor 17 Tahun 2023 Tentang Kesehatan dalam Pasal 435 terkait dengan sanksi pidana dan juga denda.

Kata Kunci: Obat Tradisional, Registrasi, Izin Edar.

**IMPLEMENTATION OF ARTICLE 2 PARAGRAPH (1) REGULATION OF
THE MINISTER OF HEALTH NUMBER 7 OF 2012 CONCERNING
REGISTRATION OF TRADITIONAL MEDICINE REGARDING THE
CIRCULATION OF TRADITIONAL MEDICINE WITHOUT A MARKETING
PERMIT IN BULELENG DISTRICT**

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ABSTRACT

The aim of this research is to find out and analyze the implementation of Article 2 paragraph (1) of Minister of Health Regulation Number 7 of 2012 concerning Registration of Traditional Medicines Regarding the Distribution of Traditional Medicines Without a Marketing Permit and to find out how to enforce the law against business actors whose traditional medicine products do not have a distribution permit. . The type of research used is empirical legal research with descriptive research characteristics. The location of this research was carried out in Buleleng Regency. Technical data collection was used by means of literature study, observation and interviews. The sampling technique used was the Non-Probability Sampling Technique and the subject determination used Purposive Sampling. Qualitative data processing and analysis techniques. The research results show that the provisions of Article 2 paragraph (1) of Minister of Health Regulation Number 7 of 2012 concerning Traditional Medicine Registration which regulates distribution permits for traditional medicines have not been implemented properly. This is reflected in the fact that there are still business actors who do not process distribution permits in accordance with applicable regulations. Meanwhile, law enforcement against business actors takes the form of administrative sanctions as regulated in Article 23 of the Minister of Health Regulation Number 7 of 2012 concerning Registration of Traditional Medicines. There are administrative sanctions in the form of summons, coaching and warnings against traditional medicine businesses without distribution permits. And law enforcement through Law Number 17 of 2023 concerning Health Article 435 related to criminal sanctions and fines.

Keywords: *Traditional Medicine, Registration, Marketing Permit.*