

ABSTRAK

TANGGUNG JAWAB HUKUM PRODUSEN OBAT TRADISIONAL TERHADAP KEAMANAN OBAT TRADISIONAL BAGI PASIEN

Penelitian ini bertujuan untuk mengetahui sinkronisasi pengaturan tanggung jawab hukum produsen obat tradisional terhadap keamanan obat tradisional bagi pasien dan bentuk tanggung jawab hukum produsen obat tradisional terhadap keamanan obat tradisional bagi pasien. Penelitian ini menggunakan metode penelitian yuridis normatif. Metode pendekatan yang digunakan adalah pendekatan peraturan perundang-undangan (*Statue Approach*), pendekatan analitis (*Analytical Approach*) dan pendekatan konseptual (*Conceptual Approach*). dengan spesifikasi penelitian inventarisasi peraturan perundang-undangan, sinkronisasi hukum, dan penemuan hukum *in concreto*. Berdasarkan hasil penelitian yang dilakukan, diperoleh hasil bahwa pengaturan tanggung jawab hukum produsen obat tradisional terhadap keamanan obat tradisional bagi pasien telah menunjukkan taraf sinkronisasi. Artinya, peraturan yang lebih rendahderajatnya telah sesuai dengan peraturan yang lebih tinggi derajatnya dan peraturan yang lebih tinggi derajatnya telah menjadi dasar pembentukan peraturanyang lebih rendah. Bentuk tanggung jawab hukum produsen obat tradisional terhadap keamanan obat tradisional bagi pasien meliputi : tanggung jawab mengganti kerugian yang merupakan tanggung jawab dari hukum perdata. Tanggung jawab menjalankan sanksi pidana berupa pidana penjara dan denda sesuai dengan apa yang sudah tercantum dalam peraturan tersebut. Tanggung jawab menjalankan sanksi administratif berupa peringatan, peringatan keras, perintah penarikan produk dari peredaran, penghentian sementara dari kegiatan, atau pencabutan izin industri dan izin usaha, teguran lisan serta teguran tertulis.

*Kata Kunci: Tanggung Jawab Hukum, Produsen Obat Tradisional,
Pelayanan Kesehatan Tradisional*

ABSTRACT

LEGAL RESPONSIBILITY OF TRADITIONAL MEDICINE MANUFACTURERS TOWARDS THE SAFETY OF TRADITIONAL MEDICINES FOR PATIENTS

This study aims to determine the synchronization of the legal responsibility from traditional medicine manufacturers towards the safety of traditional medicines for patients and the forms of legal responsibility of traditional medicine producers for the safety of traditional medicines for patients. This study uses a normative juridical research method. The approach method used is a statutory approach (Statue Approach), an analytical approach (Analytical Approach) and a conceptual approach (Conceptual Approach). with research specifications on the inventory of statutory regulations, legal synchronization, and in-concreto legal discoveries. Based on the results of the research conducted, it is found that the regulation of the legal responsibility of traditional medicine manufacturers for the safety of traditional medicines for patients has shown a level of synchronization. This means that regulations with a lower degree are in accordance with regulations of a higher degree and regulations of a higher degree have become the basis for the formation of lower regulations. The form of legal responsibility of traditional drug manufacturers for the safety of traditional medicines for patients includes: responsibility for compensation which is the responsibility of civil law. Responsibility for carrying out criminal sanctions in the form of imprisonment and fines in accordance with what is stated in the regulation. Responsibility for carrying out administrative sanctions in the form of warnings, stern warnings, orders to withdraw products from distribution, temporary suspension of activities, or revocation of industrial and business permits, verbal and written warnings.

*Keywords: Legal Responsibility, Traditional Medicine Producers,
Traditional Health Services*