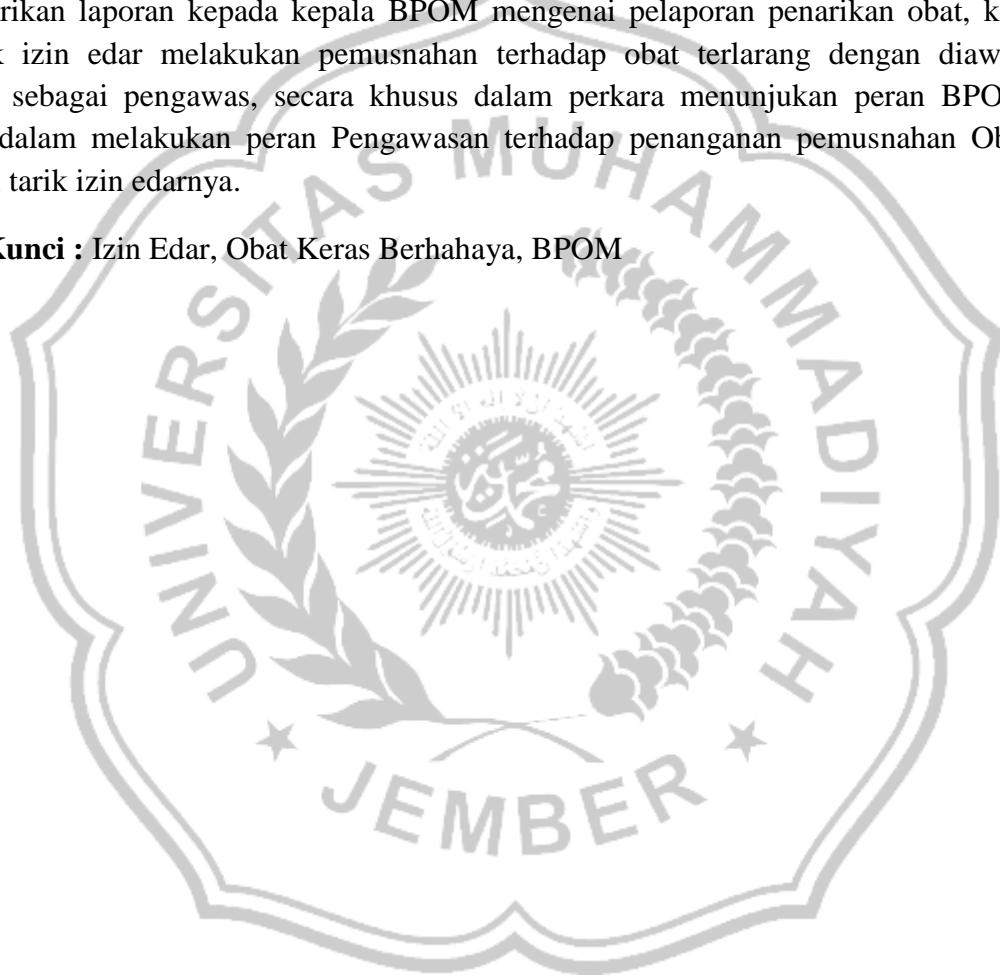


ABSTRAK

Penelitian ini bertujuan untuk mengetahui penanganan terhadap peredaran obat keras berbahaya illegal Thrihexyphenidyl pasca pencatatan izin edar oleh Badan Pengawas Obat dan Makanan. penelitian ini penulis menggunakan dua pendekatan hukum normatif yang berlaku yaitu, Pendekatan Perundang-Undangan (*Statute Approach*), dan Pendekatan Konseptual (*Conceptual Approach*). Hasil dari penelitian ini adalah protokol atau langkah penanganan pemusnahan obat yg di tarik izin edar telah diatur dalam Peraturan BPOM Nomor 14 Tahun 2022 Tentang Penarikan dan Pemusnahan Obat Yang Tidak Memenuhi Standar Dan/Atau Persyaratan Keamanan, Khasiat, Mutu dan Label, BPOM sebagai pengawas memberikan instruksi penarikan kepada pemilik izin dan pemilik izin edar wajib memberikan laporan kepada kepala BPOM mengenai pelaporan penarikan obat, kemudian pemilik izin edar melakukan pemusnahan terhadap obat terlarang dengan diawasi oleh BPOM sebagai pengawas, secara khusus dalam perkara menunjukan peran BPOM yang lemah dalam melakukan peran Pengawasan terhadap penanganan pemusnahan Obat yang telah di tarik izin edarnya.

Kata Kunci : Izin Edar, Obat Keras Berbahaya, BPOM



ABSTRACT

This study aims to find out the handling of the circulation of illegal dangerous hard drugs Thrihexyphenidyl after the registration of distribution permits by the Food and Drug Supervisory Agency. In this study, the author uses two applicable normative legal approaches, namely, the Statute Approach, and the Conceptual Approach. The result of this study is that the protocol or steps for handling the destruction of drugs that have been withdrawn from distribution permits have been regulated in BPOM Regulation Number 14 of 2022 concerning the Withdrawal and Destruction of Drugs That Do Not Meet the Standards and/or Requirements for Safety, Efficacy, Quality and Label, BPOM as a supervisor gives withdrawal instructions to the permit owner and the owner of the distribution permit is obliged to provide a report to the head of BPOM regarding the reporting of the drug withdrawal, then the owner of the distribution permit destroys the prohibited drug by being supervised by BPOM as the supervisor, especially in the case of showing the weak role of BPOM in carrying out the role of supervision over the handling of the destruction of drugs that have been withdrawn from the distribution permit.

Keywords: *Distribution Permit, Hard Drugs Berhahaya, BPOM*

