

**BENTUK PERLINDUNGAN HUKUM JAMINAN PRODUK HALAL
ATAS BERLAKUNYA UNDANG-UNDANG NO. 33 TAHUN 2014
TENTANG JAMINAN PRODUK HALAL DAN REFORMULASI
REGULASI BAGI PRODUK FARMASI**

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INTISARI

Tujuan dari penelitian ini adalah mengetahui serta menganalisis tentang pelaksanaan sertifikasi halal bagi industri farmasi ditinjau dari Undang-Undang Nomor 33 Tahun 2014 tentang Jaminan Produk Halal, faktor penghambat serta pendukung dalam pelaksanaannya. Penelitian ini menggunakan metode pendekatan normatif. Metode ini merupakan metode penelitian yang dilakukan dengan cara mendekatkan masalah yang diteliti dengan sifat hukum yang normatif yaitu berdasarkan diri pada norma dan aturan-aturan yang bersumber pada ketentuan perundang-undangan. Industri farmasi adalah industri yang padat modal memerlukan teknologi tinggi dalam hal penelitian dan pengembangan, studi klinis, produksi maupun pengemasan. Dampak UU JPH terhadap rantai nilai proses dan rantai pasokan obat dan vaksin mengakibatkan perubahan total pada industri farmasi, yaitu perubahan dari bahan menyebabkan proses ulang terhadap *quality*, *safety* dan *efficacy*, perubahan proses distribusi, penambahan personil/staff, kemampuan ekonomi industri menurun akibat peningkatan biaya produksi serta belum ada pengakuan negara lain terhadap sertifikat halal sediaan farmasi dan alkes.

Kehadiran Undang-Undang Nomor 33 Tahun 2014 tentang Jaminan Produk Halal masih menimbulkan keberatan bagi sebagian kelompok terutama dari kalangan pengusaha farmasi. Dalam pasal 4 Undang-Undang No. 33 tahun 2014 tentang Jaminan Produk Halal menyebutkan bahwa: “Menetapkan produk yang masuk, beredar dan diperdagangkan di wilayah Indonesia wajib bersertifikat halal.” Bagi kalangan farmasi, untuk memperoleh sertifikasi halal, mereka harus menata ulang seluruh rantai pasokannya, mulai dari pengadaan bahan baku sampai penjualan ditingkat eceran. Penyediaan fasilitas khusus (ruangan, peralatan, sumber daya manusia) tersebut akan sangat meningkatkan biaya, sehingga harga jual obat lebih mahal dan mengurangi akses masyarakat terhadap produk yang sangat mereka perlukan untuk pemeliharaan kesehatan tersebut. Saat ini, untuk memproduksi sekitar 30.000 jenis obat di dalam negeri, industri farmasi masih harus mengimpor 95% atau lebih bahan baku yang jumlahnya mencapai 150.000 item.

Kata kunci: Produk Farmasi, Jaminan Produk Halal, Perlindungan Hukum.

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**FORM OF LEGAL PROTECTION OF HALAL PRODUCT GUARANTEE
ON THE APPLICATION OF LAW NO. 33 OF 2014 CONCERNING
HALAL PRODUCT GUARANTEE AND REGULATION
REFORMULATION FOR PHARMACEUTICAL PRODUCTS**

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ABSTRACT

The purpose of this study is to find out and analyze the implementation of halal certification for the pharmaceutical industry in terms of Law Number 33 of 2014 concerning Halal Product Assurance, inhibiting and supporting factors in its implementation. This study uses a normative approach. This method is a research method carried out by approaching the problem under study with the normative nature of the law, which is basing itself on norms and rules that are based on statutory provisions. The pharmaceutical industry is a capital-intensive industry that requires high technology in terms of research and development, clinical studies, production and packaging. The impact of the JPH Law on the process value chain and the supply chain of drugs and vaccines results in a total change in the pharmaceutical industry, namely changes in ingredients causing a re-processing of quality, safety and efficacy, changes in the distribution process, addition of personnel / staff, decreased economic capacity of the industry due to increased costs production and there is no recognition from other countries for halal certificates for pharmaceutical and medical supplies.

The halalness of a product becomes a mandatory requirement for every consumer, especially Muslim consumers. In the international trade system the issue of certification and marking of halal products received good attention in order to provide protection to consumers of Muslims around the world as well as strategies to face the challenges of globalization. In Indonesia, legislation was established long before the birth of Law Number 33 of 2014 concerning Halal Product Guarantee. The presence of Law No. 33 of 2014 concerning Halal Product Guarantee still raises objections for some groups, especially from the pharmaceutical industry. In article 4 of Law No. 33 of 2014 concerning Halal Product Assurance states that: "Establishing products that are imported, circulating and traded in the territory of Indonesia must be halal certified." For pharmaceuticals, to obtain halal certification, they must re-arrange their entire supply chain, from procurement of raw materials to retail level sales. The provision of special facilities (rooms, equipment, human resources) will greatly increase costs, so that the selling price of drugs is more expensive and reduces people's access to the products they really need for health care. At present, to produce around 30,000 types of drugs in the country, the pharmaceutical industry still has to import 95% or more of its raw materials, which amounts to 150,000

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items.

Keywords: Pharmaceutical Products, Halal Product Guarantees, Legal Protection.