

INTISARI

Distribusi obat yang bermutu merupakan bagian penting dalam sistem pelayanan kesehatan untuk menjamin mutu obat hingga sampai ke pelanggan. Cara Distribusi Obat yang Baik (CDOB) ditetapkan oleh Badan Pengawas Obat dan Makanan (BPOM) sebagai standar wajib bagi Pedagang Besar Farmasi (PBF) dalam menjaga sistem mutu rantai distribusi. Penelitian ini bertujuan untuk menganalisis tingkat implementasi sembilan aspek CDOB serta mengidentifikasi faktor pendukung dan penghambat penerapannya sebagai sistem penjaminan mutu pada Kantor Pusat dan Cabang PT “X”.

Penelitian ini menggunakan desain *mixed methods sequential explanatory* yang terdiri atas tahap kuantitatif dan kualitatif. Tahap kuantitatif dilakukan menggunakan instrumen *self-assessment* CDOB BPOM terhadap seluruh Apoteker Penanggung Jawab pada sembilan PBF PT “X” melalui *total sampling*. Instrumen didistribusikan melalui Google Form, divalidasi melalui telaah dokumen, dan dianalisis menggunakan sistem pembobotan kategori *Critical*, *Major*, dan *Minor* untuk menentukan tingkat implementasi CDOB yang diklasifikasikan ke dalam kategori Lengkap, Cukup, Kurang, dan Sangat Kurang. Tahap kualitatif dilakukan melalui wawancara terhadap informan yang dipilih secara *purposive* dan dianalisis menggunakan *thematic analysis* melalui proses *coding* terhadap transkrip wawancara, pengelompokan kategori, identifikasi tema, untuk mengidentifikasi faktor-faktor pendukung dan penghambat implementasi CDOB.

Hasil penelitian secara kuantitatif menunjukkan bahwa tingkat implementasi CDOB pada PBF PT “X” berada pada rentang 78,06% hingga 95,48%. Tingkat implementasi tertinggi terdapat pada Kantor Cabang Solo (95,48%), sedangkan tingkat implementasi terendah terdapat pada Kantor Cabang Surabaya (78,06%). Secara umum sebanyak 8 PBF termasuk dalam kategori Lengkap (>80%), dan 1 PBF termasuk kategori Cukup (65–79%). Hasil penelitian secara kualitatif menunjukkan bahwa faktor pendukung implementasi CDOB dipengaruhi oleh kepemimpinan mutu, tata kelola mutu, dan kapasitas organisasi sedangkan faktor penghambat meliputi keterbatasan SDM, kompleksitas beban kerja operasional, tata kelola mutu tidak konsisten serta sistem dokumentasi yang belum optimal. Penelitian ini menyimpulkan bahwa implementasi CDOB pada PT “X” telah berjalan dengan baik, namun masih diperlukan penguatan untuk mendukung keberlanjutan sistem penjaminan mutu distribusi obat

Kata kunci: Cara Distribusi Obat yang Baik (CDOB), Pedagang Besar Farmasi, sistem penjaminan mutu, distribusi obat, *Mixed Methods Sequential Explanator*

ABSTRACT

High-quality pharmaceutical distribution is an essential component of the healthcare system to ensure that medicine quality is maintained until products reach customers. Good Distribution Practice for Pharmaceutical Products (CDOB) has been established by the Indonesian Food and Drug Authority (BPOM) as a mandatory standard for Pharmaceutical Wholesalers (PBF) to maintain quality systems throughout the pharmaceutical distribution chain. This study aimed to analyze the level of implementation of nine CDOB aspects and to identify the supporting and inhibiting factors affecting its implementation as a quality assurance system at the Head Office and Branch Offices of PT “X”.

This study employed a mixed methods sequential explanatory design consisting of quantitative and qualitative phases. The quantitative phase was conducted using the BPOM CDOB self-assessment instrument administered to all Responsible Pharmacists from nine PT “X” pharmaceutical wholesaler facilities through total sampling. The instrument was distributed via Google Forms, validated through document review, and analyzed using a weighted scoring system based on Critical, Major, and Minor categories to determine the level of CDOB implementation, which was classified into Complete, Adequate, Inadequate, and Poor categories. The qualitative phase was conducted through interviews with purposively selected informants and analyzed using thematic analysis involving coding of interview transcripts, category development, and theme identification to explore the supporting and inhibiting factors influencing CDOB implementation.

The quantitative findings demonstrated that the level of CDOB implementation at PT “X” pharmaceutical wholesaler facilities ranged from 78,06% to 95,48%. The highest implementation level was observed at the Solo Branch Office (95,48%), while the lowest implementation level was found at the Surabaya Branch Office (78,06%). Overall, eight pharmaceutical wholesaler facilities were classified in the Complete category (>80%), and one facility was classified in the Adequate category (65–79%). The qualitative findings revealed that the supporting factors for CDOB implementation were influenced by quality leadership, quality governance, and organizational capacity. In contrast, the inhibiting factors included limited human resources, the complexity of operational workloads, inconsistent quality governance practices, and suboptimal documentation systems. This study concludes that CDOB implementation at PT “X” has been generally well established; however, further strengthening is required to support the sustainability of the pharmaceutical distribution quality assurance system.

Keywords: Good Distribution Practice (GDP), pharmaceutical wholesaler, quality assurance system, drug distribution, mixed methods sequential explanatory.