

Implementasi Cara Distribusi Alat Kesehatan yang Baik (CDAKB) terhadap Pengembalian dan Penarikan Kembali Alat Kesehatan di Kimia Farma Trading & Distribution Jakarta 2 = Implementation of Good Method of Distribution Medical Devices (CDAKB) for the Return and Recall of Medical Devices at Kimia Farma Trading & Distribution Jakarta 2

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Abstrak

Alat kesehatan dibutuhkan oleh tenaga kesehatan, pasien dan masyarakat luas yang berperan dalam meningkatkan kualitas pelayanan kesehatan. Penyalur alat kesehatan menjamin keamanan, mutu, dan manfaat alat kesehatan yang beredar di masyarakat. Kimia Farma Trading & Distribution (KFTD) bergerak di bidang usaha distribusi dan perdagangan, antara lain produk-produk farmasi, alat kesehatan, kosmetik, cold chain product, dan produk lainnya. KFTD menerapkan prinsip-prinsip Good Distribution Practice (GDP) melalui sertifikasi Cara Distribusi Obat yang Baik (CDOB) dan Cara Distribusi Alat Kesehatan yang Baik (CDAKB). Salah satu aspek dalam CDAKB yaitu pengembalian dan penarikan kembali alat kesehatan yang dilakukan apabila terjadi masalah dari alat kesehatan tersebut. Tujuan penyusunan tugas khusus ini adalah untuk menganalisis implementasi CDAKB terhadap pengembalian dan penarikan kembali alat kesehatan di Kimia Farma Trading & Distribution Jakarta 2. Metode pelaksanaan tugas khusus ini dilakukan secara observasional dan wawancara narasumber. Pengembalian/retur alat kesehatan dari pelanggan dilakukan dengan penerimaan alat kesehatan kembalian, pemastian alat kesehatan tersebut dapat diterima sebagai alat kesehatan kembalian atau tidak serta dilaporkan dalam Form Pengembalian Alat Kesehatan. Penarikan kembali (recall) alat kesehatan dilakukan segera setelah adanya instruksi penarikan kembali dari instansi berwenang atau pemegang izin edar baik penarikan wajib (mandatory recall) maupun penarikan sukarela (voluntary recall). Berdasarkan hasil studi literatur, dapat disimpulkan bahwa implementasi Cara Distribusi Alat Kesehatan yang Baik (CDAKB) terhadap pengembalian dan penarikan kembali alat kesehatan di Kimia Farma Trading & Distribution Jakarta 2 telah sesuai dengan CDAKB Nomor 4 Tahun 2014.

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Medical devices are needed by health workers, patients, and the wider community, which play a role in improving the quality of health services. Medical device distributors guarantee the safety, quality, and benefits of medical devices that are distributed in the community. Kimia Farma Trading & Distribution (KFTD) operates in the distribution and trading business, including pharmaceutical products, medical devices, cosmetics, cold chain products, and other products. KFTD applies the principles of Good Distribution Practice (GDP) through certification of Good Method of Distribution Medicine (CDOB) and Good Method of Distribution Medical Device (CDAKB). One aspect of CDAKB is the return and recall of medical devices, which is carried out if a problem occurs with the medical device. The purpose of this special assignment is to analyze the implementation of CDAKB regarding the return and recall of medical devices at Kimia Farma Trading & Distribution Jakarta 2. The method is carried out observationally and by interviewing informants. Returns of medical devices from customers are carried out by accepting the returned medical equipment, ensuring that the medical device can be accepted as a returned medical device

or not, and reporting it in the Medical Device Return Form. A recall of medical devices is carried out immediately after a recall instruction is issued from the authorized agency or distribution permit holder, whether mandatory or voluntary. In conclusion, the implementation of Good Medical Device Distribution Methods (CDAKB) regarding the return and recall of medical devices at Kimia Farma Trading & Distribution Jakarta 2 is in accordance with CDAKB Number 4 of 2014.