

INTISARI

Kasus obat sirup untuk anak yang terkontaminasi etilen glikol (EG) dan dietilen glikol (DEG) menjadi peringatan bahwa industri farmasi harus melakukan kualifikasi *supplier* sebagai pemasok bahan baku obat dengan persyaratan berupa pemenuhan dokumen keagenan. Keputusan tersebut memberikan dampak signifikan terhadap *supply chain* bahan baku obat pada industri farmasi. Penelitian ini bertujuan untuk mengevaluasi pengaruh kebijakan Badan POM RI terhadap *supply chain* bahan tambahan di Perusahaan Farmasi X, serta memberikan informasi terkait kategorisasi kontribusi dari masing-masing *supplier* terhadap munculnya hambatan pada *supply chain* bahan tambahan di Perusahaan Farmasi X.

Penelitian ini dilakukan dengan metode deskriptif kuantitatif menggunakan *checklist* yang dikembangkan melalui penelusuran *Masterlist* Bahan Baku Perusahaan Farmasi X per Februari 2023. Data dianalisis secara statistik deskriptif dengan mengelompokkan *supplier* bahan tambahan dan menyajikan persentase kontribusi antar kelas interval *supplier* bahan tambahan dalam tabel distribusi frekuensi, serta menyajikan sebaran *supplier* berdasarkan negara asal. Untuk memperkuat analisis ini, digunakan analisis tabulasi silang (*crosstab*).

Hasil penelitian menunjukkan bahwa terdapat hambatan administratif pada *supply chain* bahan tambahan di Perusahaan Farmasi X yang mana sebanyak 44 dari 47 (93,62%) *supplier* dan 297 dari 455 (65,27%) bahan tambahan terhambat dalam pemenuhan dokumen keagenan. Terdapat 7 kategori kontribusi *supplier* dengan mayoritas *supplier* yang tidak memenuhi persyaratan terdapat pada kelas interval bahan tambahan 1-5 (68,2%). *Supplier* bahan tambahan yang mengalami hambatan tersebut berasal dari 20 negara yang tersebar pada 4 benua.

Kata Kunci: kontaminasi obat, dokumen keagenan farmasi, *supplier*, *supply chain*

ABSTRACT

The case of syrup for children contaminated with ethylene glycol (EG) and diethylene glycol (DEG) is a warning that the pharmaceutical industry must qualify suppliers as distributors of drug raw materials with the requirement of fulfilling agency documents. The decision significantly impacts the supply chain of drug raw materials in the pharmaceutical industry. This study aims to evaluate the effect of the Indonesian Food and Drug Administration's policy on the supply chain of excipients in Pharmaceutical Company X, as well as to provide information regarding the categorization of the contribution of each supplier to the emergence of obstacles in the supply chain of excipients in Pharmaceutical Company X.

This research was conducted using a descriptive quantitative method using a checklist developed through searching the Raw Material Masterlist of Pharmaceutical Company X as of February 2023. The data was analysed using descriptive statistics by grouping suppliers of excipients and presenting the percentage contribution between interval classes of suppliers of excipients in a frequency distribution table, as well as presenting the distribution of suppliers by country of origin. To strengthen this analysis, a crosstab analysis was used.

The results showed that there were administrative barriers in the supply chain of excipients at Pharmaceutical Company X, where 44 out of 47 (93,62%) suppliers and 297 out of 455 (65,27%) excipients were hampered in fulfilling agency documents. There are 7 categories of supplier contributions with the majority of suppliers that do not meet the requirements in the interval class of excipient 1-5 (68,2%). Suppliers of excipients that experienced obstacles came from 20 countries spread across 4 continents.

Keywords: *drug contamination, pharmaceutical agency documents, suppliers, supply chain*