ABSTRACT

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The outbreak of drug-related poisoning associated with Acute Kidney Injury (AKI) in children in Indonesia, which resulted in the deaths of hundreds of children, triggered widespread public concern and legal action against the government. This study aims to analyze the role of public lawsuits in encouraging improvements in government policies, particularly those related to pharmaceutical regulation and drug supervision.

This research employs a descriptive method with a normative juridical approach, focusing on the examination of legal theories, concepts, principles, and relevant statutory regulations. The study primarily relies on secondary data, including legal documents, legislation, and scholarly literature. To complement and strengthen the analysis, interviews with several key informants were also conducted.

The findings reveal that lawsuits filed against the government both through the Administrative Court (PTUN) and class action lawsuits submitted to the District Courts did not result in any judicial ruling declaring the government legally liable for the drug poisoning incidents linked to AKI in children. However, despite the absence of legal liability established by the courts, the government has undertaken several regulatory reforms. The Ministry of Health issued Supplement I, Supplement II, and Supplement III to the Indonesian Pharmacopoeia Sixth Edition and tightened licensing requirements for pharmaceutical wholesalers. In addition, the National Agency of Drug and Food Control (BPOM) introduced new regulations aimed at strengthening pharmacovigilance and improving drug monitoring systems.

This study concludes that although public lawsuits did not legally establish government fault, they have played a significant role in stimulating regulatory improvements and strengthening drug oversight policies in Indonesia.

Keywords: Drug Poisoning, Acute Kidney Injury (AKI), Pharmaceutical Regulation, Ministry of Health, BPOM

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INTISARI

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Penelitian ini bertujuan untuk mengetahui dan menganalisis peranan gugatan masyarakat dalam kasus Gagal Ginjal Akut Atipikal Progresif (GGAPA) dalam perbaikan kebijakan pemerintah, terutama kebijakan yang berkaitan dengan pengawasan obat.

Penelitian ini menggunakan metode deskriptif dan termasuk jenis penelitian Yuridis-Normatif yang mempelajari teori, konsep, asas, dan peraturan perundang-undangan yang relevan. Penelitian hukum normatif juga merupakan jenis penelitian hukum yang menggunakan bahan pustaka dan data sekunder. Data sekunder yang digunakan tidak hanya berasal dari studi kepustakaan tetapi juga mewawancarai beberapa narasumber untuk mendukung, membantu, menjelaskan, dan menguatkan data sekunder yang diperoleh.

Penelitian ini menunjukkan bahwa gugatan yang ditujukan kepada pemerintah baik melalui PTUN maupun gugatan *class action* melalui Pengadilan Negeri, tidak ada satupun yang menyatakan bahwa pemerintah bersalah atau kasus keracunan obat yang menyebabkan ratusan anak meninggal dunia. Pemerintah terus berbenah dengan memperbaiki beberapa regulasi, meskipun putusan pengadilan menyatakan pemerintah tidak bersalah. Kementerian Kesehatan menerbitkan Suplemen I, Suplemen II dan Suplemen III Farmakope Indonesia Edisi VI dan memperketat izin Pedagang Besar Farmasi. Sementara itu, BPOM telah menerbitkan beberapa regulasi baru yang berkaitan dengan peningkatan farmakovigilan dan memperketat pengawasan obat.

Kata Kunci : Keracunan Obat, Gagal Ginjal Akut, Kementerian Kesehatan, BPOM

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