



THE BAN OF COUGH SYRUPS PRODUCTION IN INDONESIA: WHO SHOULD BE (LEGALLY) RESPONSIBLE?

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BANCKGROUND

The Acute Kidney Injury (AKI) caused by *ethylene glycol* and *ethylene glycol* compounds beyond the permissible threshold found in cough syrups has been linked to dozens of child deaths in Indonesia since early 2022. This issue prompted Indonesia's Food and Drug Authority (BPOM) to launch an investigation and imposition of ban on the prescription and sale of cough syrup or other liquid medication as well as revocation of pharmaceutical companies' licenses has also been issued.



LEGAL ISSUE

This paper aims to examine the essence of legal liability under the national and international legal framework in two folds.

First, under the realm of medicines law concerning Health; Consumer Protection and Indonesia's Criminal Code.

Second, examining the State responsibility in conjunction with the BPOM's effort in enforcing international regulatory standards in monitoring business actors in pre-market and post-market surveillance phase.



METHOD

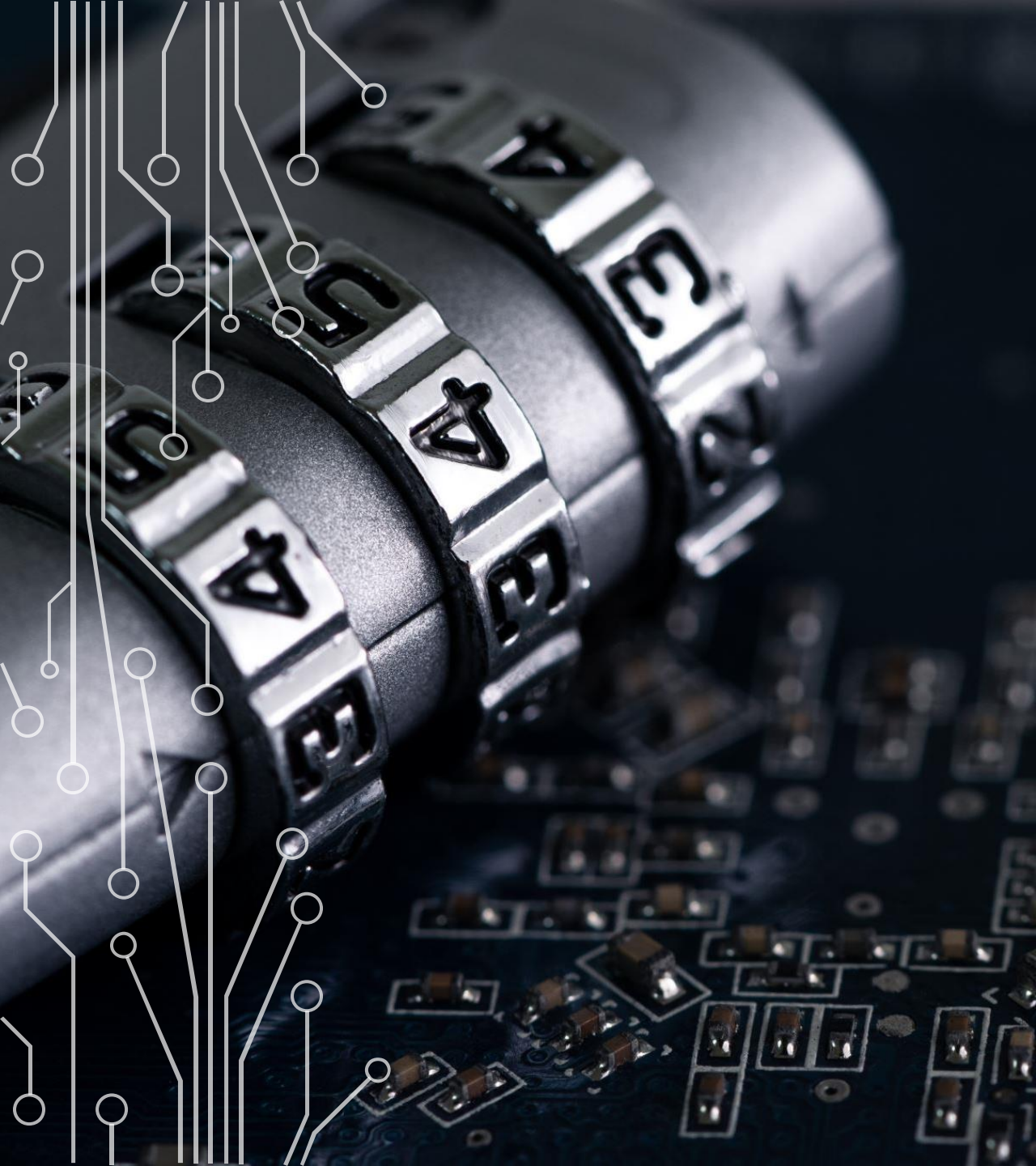
This doctrinal research paper utilizes juridical-normative research methods with statute, conceptual and case approaches. This article builds on primary legal sources by prioritizing the legal normative approach, i.e., statutes, and secondary legal sources such as scholarly works, treatises, and books that are relevant to the discussion in this article.



UNDER THE REALM OF MEDICINES LAW CONCERNING HEALTH; CONSUMER PROTECTION AND INDONESIA'S CRIMINAL CODE

The protection offered to consumers can be carried out through preventive and repressive measures to ensure compliance with the rule of law:

a. Preventive protection is designed to prevent breaches before they occur. Legal protection of drug distribution is also monitored by accreditation bodies such as BPOM. Product Distribution Authorization is therefore a precautionary measure by her BPOM before the product is distributed to the public. Therefore, general consumers should check the packaging, marketing authorization and expiry date of the product they are purchasing before purchasing medicines. This new version gives consumers legal protection if something goes wrong while taking the drug.



b. Repressive protection consists in dealing with disputes and dealing with them within the court system. This protection is the last line of defence in the form of additional sanctions and penalties should crime occur.

Based on these statements, it can be argued that legislation regulates legal protections for consumers when selling medicines online that do not match the original medicine.



EXAMINING THE STATE RESPONSIBILITY IN CONJUNCTION WITH THE BPOM'S EFFORT IN ENFORCING INTERNATIONAL REGULATORY STANDARDS IN MONITORING BUSINESS ACTORS IN PRE-MARKET AND POST-MARKET SURVEILLANCE PHASE

A case of drug syrup that caused acute renal failure in this fatal child. Actors who manufacture drugs or those in the pharmaceutical industry may be held liable. If the economic operator's guilt can be proved, it can be civil or criminal. It is necessary to determine whether economic operators are legally liable. Government investigations and investigations, in this case BPOM, Support from Ministry of Health, Ministry of Industry and Trade Police officers cooperate with investigations and investigations within the following framework: Find and collect evidence to identify perpetrators and impose sanctions given law.

If the investigation / investigation reveals evidence that the economic operator has not fulfilled its obligations (Article 6 of the UUPK), Committing prohibited acts (Article 8 of the UUPK), including malicious acts.

Connection Article 7, UPPK
Company manufactures syrup causing acute renal failure the child is obliged to pay damages to the consumer and is obliged to pay damages in the following cases: consumer dies.

CONCLUSION AND RECOMENDATION



The conclusion that it is crucial for pharmaceutical companies and the State's authorities to take joint responsibility for the customers who were negatively impacted by this issue by enacting criminal sanctions and strengthening its regulatory and monitoring functions in the health sector.



Acts that a business operator must not do during business related to syrup for paediatric acute renal failure Paediatric use components of drug mixtures that do not meet quality standards Uses drugs that are dangerous to health, mixed drug ingredients thresholds for safe drug use. Economic people don't have the right ethics in doing business. Not Counterfeiting Medicines Indicate the correct drug composition on the label. Accountability of economic entities that can be held liable under civil law, Criminal and Administrative Sanctions. Civil liability, compensating consumers for medical expenses and providing compensation in case of illness. And if it leads to death. Administrative sanctions in the form of business license freezes and drug confinement Distributed by the community and destroyed.



THANK YOU