

## **BPOM REGULATIONS AND RESPONSIBILITIES IN THE CASE OF MEDICINES CONTAINING ETHYLENE GLYCOL AND DIETHYLENE GLYCOL**

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### **ABSTRACT**

*This study aims to find out two problems, namely how is the regulation, role and responsibility of BPOM in the case of drugs containing EG and DEG?; and how is BPOM's responsibility for the legal protection of consumers who consume these drugs? To answer this, researchers apply normative legal studies with secondary data and use qualitative analysis with deductive thinking to draw conclusions. The results of the study stated that there is a legal vacuum in the regulation of BPOM where there is no regulation regarding sanctions if BPOM issues a distribution permit for dangerous products. The role of BPOM in the case of the circulation of drugs containing EG and DEG is in accordance with its function as a product supervisor either before or after circulation, imposing sanctions on business actors, namely revoking distribution permits for harmful products as its authority is regulated in PP 80 of 2017. Preventive legal protection is not implemented properly by BPOM while repressive protection is carried out by reporting and participating in investigations with the police, business actors who distribute drugs with these ingredients.*

**KEYWORDS** BPOM; Consumer protection; responsibility



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### **INTRODUCTION**

In 2022, 325 children suddenly experienced acute kidney failure, and 178 children died from this disease. The disease is suspected to be caused by the consumption of drugs containing Ethylene Glycol (EG) and Diethylene Glycol (DEG), found in syrup-form paracetamol medicines (Liusudarso et al., 2022). Article 1 point 8 of Law No. 36 of 2009 on Health explains: “Medicine is a substance or a mixture of substances, including biological products used to influence or investigate physiological or pathological states for the purpose of diagnosis, prevention, cure, recovery, health improvement, and contraception for humans.” Argaputri, “Tinjauan Yuridis tentang Perjanjian Jual-Beli Obat-Obatan dan Kosmetik Melalui

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Internet Menurut Undang-Undang Nomor 36 Tahun 2009 tentang Kesehatan (Studi pada Online Shop 'Lav's Beauty' Di Pagutan Kecamatan Mataram). 2018”

According to the Indonesian Dictionary (KBBI), medicine is a substance used to minimize, eradicate, or treat diseases. One way to use medicine is orally, such as syrups, tablets, capsules, and powders. In this case, medicine does not serve its intended purpose as stated in the Health Law. Instead, it becomes the cause of health problems in children. Health is a right of every citizen that the state must protect in accordance with Article 27 paragraph (2) of the 1945 Constitution, which states, "every citizen has the right to work and to live in human dignity." A good standard of living includes the fulfillment of basic needs such as food and medicine, which are currently the most important human needs.

According to Article 2 of Law No. 8 of 1999 on Consumer Protection, one of the principles used to protect consumers is the principle of balance between business owners and consumers. To this end, the state has established a non-ministerial institution that reports directly to the president, the Food and Drug Supervisory Agency (BPOM), which is responsible for overseeing the distribution of drugs and food in Indonesia. Before a product can be marketed, it must obtain a distribution permit from BPOM (Zaura & Irwansyah, 2023).

Medicines containing EG and DEG initially obtained distribution permits from BPOM. However, BPOM eventually revoked the distribution permits for 73 syrup medicines because these medicines were found to contain raw materials and finished products with EG and DEG contamination levels exceeding acceptable limits (Kemalasari, 2023). These two compounds are widely used in antifreeze, brake fluids, and other industrial applications, but they can also be used as substitutes for glycerin, solvents, or thickeners in syrup medicines in some pharmaceutical formulations (Anggito, 2023). EG is toxic if absorbed by the body or ingested, while DEG causes poisoning if consumed above safe limits (Ranto, 2019). The failure of BPOM to effectively carry out its duties as a supervisor and its authority as a distributor permit issuer has resulted in many consumers, particularly children, suffering from illnesses and even death, indicating that legal protection for consumers has not been adequately implemented. Therefore, it is important to examine the regulations, roles, and responsibilities of BPOM concerning the case of medicines containing EG and DEG, and how BPOM is responsible for the legal protection of consumers who consume these medicines. This study aims to address two issues: what are the regulations, roles, and responsibilities of BPOM regarding the case of medicines containing EG and DEG?; and how does BPOM ensure legal protection for consumers who consume these medicines?

## **RESEARCH METHOD**

This study employs a normative legal approach by gathering data from the following sources:

1. Primary sources, including Law No. 8 of 1999 on Consumer Protection, Law No. 36 of 2009 on Health, Presidential Regulation No. 80 of 2017 on BPOM, and other legal regulations.

2. Secondary sources, such as books, journals, documents, theses, and legal literature related to the discussed topic, sourced from the BPOM website, newspapers like Tempo and VOA, and other sources.
3. Tertiary sources, such as the Indonesian Dictionary (Kamus Besar Bahasa Indonesia), and others.

The researcher uses legal materials such as the Consumer Protection Act and the BPOM website to process the data, which is then described and concluded concerning BPOM's regulations and responsibilities in the case of acute kidney failure disease, and BPOM's responsibilities viewed from the principles of legal protection for consumers suffering due to consuming syrup medicines. This method is a qualitative analysis method, and conclusions are drawn using deductive reasoning.

## RESULT AND DISCUSSION

### Regulation and Responsibilities of BPOM regarding Consumers in Cases of Drugs Containing EG and DEG

#### *BPOM's Regulation concerning its responsibility in cases of drugs containing EG and DEG*

BPOM is a government institution tasked with regulating the supervision of drugs and food more effectively (Setyawan & Wijaya, 2018). BPOM is regulated by Presidential Regulation No. 80 of 2017, in Article 1 paragraph (2) of PP 80/2017, BPOM is under the auspices and accountable to the president through the health minister with the task of supervising drugs and food in accordance with applicable laws. (Arini, "Criminal Accountability of Doctors in Providing Drugs to Patients.")

The background of the establishment of BPOM is the technological advancements revolutionizing the pharmaceutical, food, cosmetic, and medical device industries in Indonesia. In addition to technological changes in these industries, transportation technology is also rapidly advancing, resulting in thinner and faster cross-border trade, making many drug, food, and other products more easily accessible to the public. However, the ability of the public to choose properly, correctly, and safely for this purpose is not yet adequate. Thus, this can increase the risks and implications for the health and safety of consumers. Therefore, the state needs to have an optimal supervision system to recognize, anticipate, and supervise circulating goods to maintain the safety and security of buyers domestically and abroad. Based on this background, it can be inferred that the scope of BPOM is to conduct supervision, whether it is before or after the products are circulated in the market, ranging from issuing circulation permits for products, making policies or regulations in the fields of drugs, food, and cosmetics.

According to Article 2 of the Consumer Protection Law, there are many concepts governing consumer protection, including the principle of balance between consumers and business owners as well as the principle of consumer safety and security (Resinta, 2018). This balance concept aims to maximize the participation of consumers, business actors, and other stakeholders, and the government gets the opportunity to fulfill its obligations and rights fairly (Putri, "Food Safety Supervision: Formaldehyde Testing in Wet Noodles Qualitatively Using Test Kits

by the Big Drugs and Food Supervisory Agency in Semarang.”). The principle of consumer safety and security is aimed at ensuring consumers in the use of goods and services (Setiawan, 2020). It is evident from the background of the establishment of BPOM that not all consumers have a good understanding to choose products that are safe to use; therefore, the government must participate to ensure that the products available in the market are safe for consumers.

BPOM carries out functions: formulating and implementing national policies in the field of drug and food supervision (POM), designing and establishing norms, standards, procedures, and criteria in the field of pre-circulation and post-circulation supervision, pre-circulation and post-circulation supervision, and coordinating the implementation of POM with central and local governments (Yodo & Miru, 2004). In carrying out its duties, BPOM also has three authorities, namely issuing marketing authorization and product certification, conducting intelligence and investigation in the field of POM, and imposing administrative fines (Sari et al., 2022).

There is no detailed regulation in Presidential Regulation No. 80 of 2017 or other legislation that explains in detail the form of BPOM's responsibility when BPOM issues marketing authorization for products, whether drugs or food, which turn out to be harmful to consumers, and what form of responsibility can be given by BPOM to consumers affected by the side effects of using such harmful products. BPOM should also be sanctioned as BPOM is responsible under the president through the Minister of Health; hence, the President through the Minister of Health also sanctions if there is negligence when granting marketing authorization for products that turn out to be harmful to consumers, such as in cases of drugs containing EG and DEG.

### **Role and Responsibility of BPOM towards Consumers in Cases of Drugs Containing EG and DEG**

BPOM conducts comprehensive supervision both before and after circulation of drugs in Indonesia, following reports of children's syrup containing DEG and EG in Gambia, Africa from the World Health Organization (WHO) on October 5, 2022 (Obat & Indonesia, 2019). The children's syrup includes Promethazine Oral Solution, Kofexmalin Baby Cough Syrup, Makoff Baby Cough Syrup, and Magrip N Cold Syrup. All these drugs are manufactured by Maiden Pharmaceuticals Limited, India. BPOM's supervision did not find these products registered in Indonesia (Setiawan, 2020).

BPOM continued market tracing in October 2022, with a probability of detecting EG and DEG content as contaminants in glycerin or propylene glycol added to products through risk-based investigations, gradual sampling, and testing (Rahayuningtyas, 2019). Test findings of items contaminated with EG and DEG still required further evaluation to verify compliance with safe standards based on reference standards. The findings of the investigation revealed 73 drug products containing DEG and EG and 168 syrup drugs found not to contain solvents such as Propylene Glycol, Polyethylene Glycol, Sorbitol, and/or Glycerin/Glycerol. This indicates that these syrups are safe for use as instructed (Anggito, 2023).

These steps by BPOM are in line with the functions stipulated in Presidential Regulation No. 80 of 2017, which include supervising drug and food products before and after circulation. In carrying out these functions, BPOM utilizes its authority to investigate drug and food supervision.

Another function carried out by BPOM in handling this matter is taking legal action against violations that occur, where BPOM has the authority to impose sanctions according to the law. BPOM will immediately impose sanctions such as warnings, temporary suspension of drug production, detention or revocation of certificates for good manufacturing practices, temporary cessation of advertising activities, and suspension or revocation of marketing authorization, on products that exceed the permissible limits of EG and DEG contamination, as evidenced by the withdrawal of marketing authorization for the 73 drugs found to contain DEG and EG. Withdrawing marketing authorization means BPOM imposes administrative sanctions on the relevant business entity regarding its product. Obat And Indonesia, “Peraturan Badan Pengawas Obat Dan Makanan Nomor 11 Tahun 2019 Tentang Bahan Tambahan Pangan”; Makanan, “Peraturan Badan Pengawas Obat Dan Makanan Nomor 4 Tahun 2018 Tentang Pengawasan Pengelolaan Obat, Bahan Obat, Narkotika, Psikotropika, Dan Prekursor Farmasi.”

On November 21, 2022, BPOM issued Circular Letter No. PW.04.08.1.5.11.22.10 of 2022 regarding the Requirements of EG and Diethylene Glycol in Sorbitol, Glycerol, and Propylene Glycol Food Additives in the Registration and/or Entry Process, aimed at informing pharmacy owners about the criteria for EG and DEG in food additive Sorbitol, Glycerol, and Propylene Glycol during the registration process Makanan, “Peraturan Badan Pengawas Obat Dan Makanan Nomor 4 Tahun 2018 Tentang Pengawasan Pengelolaan Obat, Bahan Obat, Narkotika, Psikotropika, Dan Prekursor Farmasi.”. These requirements apply if the EG and DEG requirements are reinforced with analysis findings from accredited or government-owned laboratories (Resinta, 2018):

- a. "EG and DEG in Sorbitol food additives each not exceeding 0.10%;
- b. EG and DEG in Glycerol food additives each not exceeding 0.10%; and
- c. EG and DEG in Propylene Glycol food additives each not exceeding 0.10%."

After withdrawing marketing authorization for drugs containing EG and DEG, BPOM can prevent consumers who have not been exposed to these drugs from consuming them. However, BPOM's responsibility for negligence in granting marketing authorization, leading to consumers experiencing negative effects, should be accounted for, as stipulated in Article 2 of Presidential Regulation No. 80 of 2017. BPOM should also be held accountable to consumers who suffer side effects from consuming these drugs, and BPOM should receive sanctions for its negligence. However, there is no regulation regarding sanctions for issuing marketing authorization that resulted in many consumers suffering.

### **The Suitability of BPOM's Responsibilities in Legal Protection Principles for Consumers**

According to Law No. 8 of 1999 concerning Consumer Protection, Article 1 number 2, a consumer is defined as any user of goods and/or services available in the market, whether for themselves, others, or family, and not for resale (NIM, “Implementation of Article 22 of the Food and Drug Supervisory Agency Regulation No. 8 of 1999”).

Consumer rights are stipulated in Article 4 of Law No. 8 of 1999, which states (Argaputri, “A Juridical Review of the Sale and Purchase Agreement of Drugs and Cosmetics via the Internet According to Law No. 36 of 2009 on Health (Study at the Online Shop 'Lav's Beauty' in Pagutan, Mataram District), 2018”):

1. The right to comfort, security, and safety in consuming products.
2. The right to choose goods and obtain appropriate prices, terms, and guarantees.
3. The right to accurate, clear, and honest information about the condition and guarantees of the products.
4. The right to voice concerns and complaints about the products they use.
5. The right to effective advocacy, protection, and dispute resolution.
6. The right to consumer education and counseling.
7. The right to receive proper, honest, and non-discriminatory service.
8. The right to compensation, indemnity, or substitution.
9. The rights contained in other laws and regulations.

Based on the above article, there are several rights not received by users of drugs containing EG and DEG. The first is the right to consume goods comfortably, safely, and securely. Consumers who need to take medication are now in a situation where their safety feels threatened after many cases of suspected acute kidney failure have caused the deaths of 178 people, allegedly due to drugs containing EG and DEG in doses exceeding the threshold. In this regard, the government or BPOM must enhance its oversight. As previously explained, BPOM has issued regulations in the form of circular letters regarding EG and DEG requirements, conducted comprehensive supervision, and sanctioned 73 products by revoking their distribution permits.

Secondly, the right to receive accurate, clear, and truthful information about the condition and guarantees of the product. This means information about raw materials and additives must match what is listed in the composition. Clear means the information must not be confusing or ambiguous and should use Indonesian. Honest means business actors must provide straightforward and truthful information about their products. Consumers must be given information to avoid misleading impressions, and if a product contains hazards, it must include clear usage instructions.

Consumers who have consumed drugs contaminated with DEG and EG must have their complaints heard and be compensated for their losses. Lawyer Awan Puryadi, representing the parents of the victims, filed a class action lawsuit against the Ministry of Health, BPOM, and several pharmaceutical companies in November 2022, accusing them of failing to test the contaminated syrup themselves (BPOM) and demanding Rp2,000,000,000 (two billion rupiah) for each family as compensation for the death or organ damage of their children (Yodo & Miru, 2004). Article 5 of the Consumer Protection Act explains that:

"Consumers' obligations are: a. Reading or following the information and usage instructions for the safety and security of goods and/or services; b. Acting in good faith when conducting transactions for goods and/or services; c. Paying according to the agreed exchange value; d. Following legal dispute resolution efforts for consumer protection properly."

The most crucial task that buyers must fulfill for their own interest is to understand or follow product information instructions for their own safety and security. On October 19, BPOM advised consumers to use medication according to usage instructions and not to exceed the prescribed dose, such as taking a 250 ml dose once daily, and to read warnings on packaging carefully. Information is vital for consumers in using medication, and if consumers ignore the provided information or knowingly violate it, any harmful side effects are not the business actors' fault since they have provided the necessary information.

Consumer protection regulations are enacted to provide extra security for users in meeting their needs, supported by Law No. 8 of 1999, which includes criminal sanctions. In short, the efforts mentioned by the law are not enough with only preventive actions; punitive measures are also necessary for all consumer protection sectors (Ranto, 2019).

Legal protection is a restriction from the meaning of protection in all domains, but in this case, it is only protection by law. This shows that the protection offered is related to rights and responsibilities (Arini, "Criminal Responsibility of Doctors in Providing Medication to Patients"). Philipus M. Hadjon states that legal protection is the protection and recognition of basic rights a person has based on a set of norms that can protect one thing and another (Hadjon, 1987). There are two categories of consumer protection measures:

1. Repressive protection is legal protection implemented by imposing sanctions on offenders to restore the law to its original state. This is usually done when disputes or cases arise and are resolved through litigation or non-litigation methods (Kemalasari, "Pertanggungjawaban Bpom Terhadap Peredaran Obat Sirup Yang Menyebabkan Kematian Kematian Pada Anak Akibat Gagal Ginjal Akut.>").
2. Preventive protection is legal protection that tries to prevent disputes from developing in the first place (Obat & Indonesia, 2019). Before a government decision becomes final, the legal subject is given the option to raise objections or opinions (Setyawan & Wijaya, 2018). This refers to government policies based on democracy, as this preventive protection supports the government in carefully making discretionary decisions (Liusudarso et al., 2022).

BPOM provides two types of protection for users harmed by drugs contaminated with DEG and EG:

First, based on interviews conducted by Muhammad Habiburrahman with BPOM regarding preventive legal protection:

"BPOM performs tasks and functions to prevent the distribution of hazardous drugs and food through two stages of supervision: first, Pre Market Control. Pre Market Control is conducted before food products are distributed, including standardization, coaching, and auditing good food production practices, as well as

assessing and testing safety quality before food products are distributed. The second stage, Post Market Control, is conducted after food products are distributed in the community, including inspections of production and distribution facilities, sampling and laboratory testing of food products, product circulation, advertisement or promotion assessments, monitoring side effects of food products, and disseminating information through public education and warnings.” (Habiburrahman, “Peran Balai Besar Pengawas Obat Dan Makanan (Bbpom) Dalam Memberikan Perlindungan Hukum Bagi Konsumen Akibat Peredaran Produk Pangan Olahan Yang Tidak Memenuhi Standar Mutu (Studi Bbpom Kota Mataram).”).

In the pre-market stage, it can be concluded that BPOM was negligent in issuing distribution permits, resulting in the distribution of health-hazardous drug products in the community, ultimately causing many children to suffer from this medication case. The Presidential Decree on BPOM establishes its function as designing and setting norms, standards, procedures, and criteria in drug and food supervision, specifically the circular letter on DEG and EG requirements for additives, only released in 2022 after these drug ingredients caused casualties. However, in post-market control, BPOM quickly collected several hundred drug samples for immediate testing to check compliance with DEG and EG requirements, and swiftly withdrew dangerous products from the market while informing the public through BPOM's official website.

Secondly, BPOM executes repressive legal protection by reporting to the authorities if drugs that do not meet standards or pose dangers to consumers, such as syrup medicines containing DEG and EG, are found. Consequently, POLRI and BPOM have named three syrup manufacturers and one raw material supplier as suspects, involving three pharmaceutical companies and one raw material supplier company (Setiawan, 2020). Consumers who became victims of EG and DEG-contaminated drugs also filed a lawsuit in the Central Jakarta District Court against the business actors producing these drugs, with BPOM and the Minister of Health as co-defendants.

## CONCLUSION

There is a legal gap in the regulations concerning BPOM (the Indonesian Food and Drug Authority), as there are no provisions regarding sanctions if BPOM issues distribution permits for dangerous products. This needs to be addressed to ensure BPOM exercises greater caution when issuing distribution permits to business actors and takes responsibility for consumers who suffer harmful effects from products initially approved by BPOM but later found to be dangerous for consumption.

In the case of drugs containing EG and DEG, BPOM's role has aligned with its function as a product supervisor, both before and after distribution, by imposing sanctions on business actors, such as revoking distribution permits for dangerous products, as authorized by Government Regulation No. 80 of 2017. However, the preventive protection conducted by BPOM in the pre-market stage was not fulfilled, as these drugs were circulated with BPOM's approval. In the post-market stage, BPOM has acted according to its function and authority.



BPOM's repressive legal protection regarding EG and DEG-contaminated drugs has been appropriate by sanctioning the pharmaceutical owners. Additionally, consumers who were victims of these drugs have filed a class action lawsuit in the District Court.

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