CONSUMER PROTECTION AGAINST THE USE OF SYRUP DRUGS CONTAINING ETHYLENE GLYCOL AND DIETHYLENE GLYCOL EXCEEDING THE SAFE THRESHOLD

THESIS

Arranged By:

Novia Aulya Rahmadanti

Student Number: 19410663

Undergraduate Program in Law

INTERNATIONAL PROGRAM

FACULTY OF LAW

UNIVERSITAS ISLAM INDONESIA

YOGYAKARTA

2023

CONSUMER PROTECTION AGAINST THE USE OF SYRUP DRUGS CONTAINING ETHYLENE GLYCOL AND DIETHYLENE GLYCOL EXCEEDING THE SAFE THRESHOLD

THESIS

Presented as the Partial Fulfillment of the Requirements to Obtain

a Bachelor's Degree at the Faculty of Law,

Universitas Islam Indonesia,

Yogyakarta

Arranged By:

Novia Aulya Rahmadanti

Student Number: 19410663

INTERNATIONAL PROGRAM

FACULTY OF LAW

UNIVERSITAS ISLAM INDONESIA

YOGYAKARTA

2023

PAGE OF APPROVAL

بسم الله الرحمن الرحيم

CONSUMER PROTECTION AGAINST THE USE OF SYRUP DRUGS CONTAINING ETHYLENE GLYCOL AND DIETHYLENE GLYCOL EXCEEDING THE SAFE THRESHOLD

Telah diperiksa dan disetujui Dosen Pembimbing Tugas Akhir untuk diajukan ke depan TIM Penguji dalam Ujian Tugas Akhir / Pendadaran
pada tanggal 17 October 2023

Yogyakarta, 25 September 2023Dosen Pembmbing Tugas Akhir,

Lucky Suryo Wicaksono, S.H., M.Kn., M.H.

PAGE OF APPROVAL

بسم الله الرحمن الرحيم

CONSUMER PROTECTION AGAINST THE USE OF SYRUP DRUGS CONTAINING ETHYLENE GLYCOL AND DIETHYLENE GLYCOL EXCEEDING THE SAFE THRESHOLD

Telah Dipertahankan di Hadapan Tim Penguji dalam
Ujian Tugas Akhir / Pendadaran
pada tanggal dan Dinyatakan LULUS

Yogyakarta, 17 October 2023

Tim Penguji			Tanda
1. Ketua	:	Siti Anisah, Dr., S.H., M.Hum.	.....
2. Anggota	:	Lucky Suryo Wicaksono, S.H., M.Kn., M.H.	.....
3. Anggota	:	Ratna Hartanto, S.H., LL.M.	.....

Mengetahui:
Universitas Islam Indonesia
Fakultas Hukum
Dekan,

Prof. Dr. Budi Agus Riswandi, S.H., M.H.
NIK. 014100109

PAGE OF APPROVAL

بِسْمِ اللَّهِ الرَّحْمَٰنِ الرَّحِيمِ

A BACHELOR'S DEGREE THESIS
CONSUMER PROTECTION AGAINST THE USE OF SYRUP DRUGS CONTAINING ETHYLENE GLYCOL AND DIETHYLENE GLYCOL EXCEEDING THE SAFE THRESHOLD

This bachelor's degree thesis has been approved by the Thesis Language Advisor to be examined by the Board of Examiners at the Thesis Examination on October, 17th 2023

Yogyakarta,
Language Advisor,

Ruli Hapsari, S.Pd., M.A.

ORIGINALITY STATEMENT

ORIGINALITY STATEMENT

SURAT PERNYATAAN ORISINALITAS

ORISINALITAS KARYA TULIS ILMIAH BERUPA TUGAS AKHIR

MAHASISWA FAKULTAS HUKUM UNIVERSITAS ISLAM INDONESIA

Bismillahirrahmanirrahim

Saya yang bertanda tangan di bawah ini:

Nama : Novia Aulya Rahmadanti

No. Induk Mahasiswa : 19410663

adalah benar-benar mahasiswa Fakultas Hukum Universitas Islam Indonesia Yogyakarta yang telah melakukan penulisan Karya Tulis Ilmiah (Tugas Akhir) berupa Skripsi dengan judul:

CONSUMER PROTECTION AGAINST THE USE OF SYRUP DRUGS CONTAINING ETHYLENE GLYCOL AND DIETHYLENE GLYCOL EXCEEDING THE SAFE THRESHOLD

Karya tulis ilmiah ini akan penulis ajukan kepada Tim Penguji dalam Ujian Pendadaran yang diselenggarakan oleh Fakultas Hukum Universitas Islam Indonesia.

Sehubungan dengan hal tersebut, dengan ini, penulis menyatakan, bahwa:

1. Bahwa karya tulis ilmiah ini adalah benar hasil karya sendiri yang dalam penyusunannya tunduk pada kaidah, etika, dan norma penulisan sebuah karya tulis ilmiah sesuai dengan ketentuan yang berlaku;
2. Bahwa saya menjamin hasil karya yang dapat dikategorikan sebagai melakukan perbuatan karya ilmiah ini adalah orisinil dan bebas dari unsur plagiasi;
3. Bahwa meskipun secara prinsipil hak milik atas karya tulis ilmiah ini ada pada penulis, tetapi demi kepentingan yang bersifat akademik dan pengembangannya, penulis memberikan kewenangan pada perpustakaan Fakultas Hukum Universitas

Islam Indonesia dan perpustakaan di lingkungan Universitas Islam Indonesia untuk menggunakan karya tulis ilmiah ini.

Selanjutnya, berkaitan dengan hal di atas, khususnya pada pernyataan huruf 1 dan 2, penulis sanggup menerima sanksi baik administratif, akademis, maupun pidana, jika penulis terbukti secara kuat dan meyakinkan telah melakukan perbuatan yang menyimpang dari pernyataan tersebut. Penulis juga akan bersikap kooperatif untuk hadir, menjawab, membuktikan, dan melakukan pembelaan terhadap hak penulis serta menandatangani Berita Acara terkait, yang menjadi hak dan kewajiban penulis di depan 'Majelis' atau 'Tim' Fakultas Hukum Universitas Islam Indonesia yang ditunjuk oleh pimpinan fakultas jika tanda-tanda plagiasi disinyalir ada pada karya tulis ilmiah ini.

Demikian, surat pernyataan ini penulis buat dengan sebenar-benarnya, dalam kondisi sehat jasmani dan rohani, dengan sadar serta tidak ada tekanan dalam bentuk apapun dan oleh siapapun.

Yogyakarta, 4 Oktober 2023

Yang Membuat Pernyataan,

NOVIA AULYA RAHMADANTI

NIM: 19410663

CURRICULUM VITAE

1.	Name	: Novia Aulya Rahmadanti
2.	Place of Birth	: Salatiga
3.	Date of Birth	: November 16th, 2000
4.	Gender	: Female
5.	Address	: Perum. Klaseman Hijau 35, Mangunsari, Sidomukti, Salatiga
6.	Parents Identity	
	a. Father	: Samsu, S.H.
	Occupation	: Civil Servant
	b. Mother	: Ela Sulastini
	Occupation	: Houswife
7.	Education	
	a. Elementary School	: SD Islam Al-Azhar 22 Salatiga
	b. Junior High School	: SMP Islam Al-Azhar 18 Salatiga
	c. Senior High School	: SMA N 3 Salatiga
8.	Organization Experiences	: Member of HRD Division of Juridical Council of International Program (JCI FH UII) in 2021-2022

MOTTO

"Allah tidak membebani seseorang melainkan sesuai dengan kesanggupannya."

(Q.S. Al-Baqarah, 2:286)

"Sesungguhnya Bersama kesulitan itu ada kemudahan, maka apabila kamu telah selesai (dari suatu urusan), tetaplah bekerja keras (untuk urusan yang lain)."

(Q.S. Al-Insyirah, 94:6-7)

Hatiku tenang karena mengetahui bahwa apa yang melewatkanku tidak akan pernah menjadi takdirku, dan apa yang ditakdirkan untukku tidak akan pernah melewatkanku.

(Umar bin Khattab)

Selalu ada harga dalam sebuah proses. Nikmati saja lelah-lelah itu, lebarkan lagi rasa sabar itu. Semua yang kamu investasikan untuk menjadikan dirimu serupa yang kau impikan mungkin tidak akan selalu berjalan lancar. Tapi gelombang-gelombang itu yang nanti bisa kau ceritakan."

(Boy Chandra)

DEDICATION

This thesis is wholeheartedly dedicated to:

With gratitude to Allah Subhanallahu wa ta'ala,

Alhamdulillah, I can finish my thesis because of the ease and smoothness given to me from Allah. Thanks Allah who always gives me calmness, courage, focus, health, smoothness, strength, people who help me to complete my thesis;

My beloved parents and family,

Who always pray for me to be given smoothness and ease in working on my thesis, giving support, affection and love;

All my lectures of Faculty of Law, Universitas Islam Indoneisa,

Who have taught and guide me from the beginning until I can complete my study;

All of my friends,

Who has always been by my side through these college years together;

My Almamater, Universitas Islam Indonesia,

Thank you for being my place to study until I can complete my degree and meet new friends.

FOREWORDS

First of all, *Alhamdulillahirabbil'alamin*, all praise and thank to Allah *Subhanallahu wa ta'ala* who has given me blessing to finish the entire thesis, one of the most important requirements to achieve the bachelor's degree in international undergraduate program in law Universitas Islam Indonesia, in which the thesis is entitled, "**CONSUMER PROTECTION AGAINST THE USE OF SYRUP DRUGS CONTAINING ETHYLENE GLYCOL AND DIETHYLENE GLYCOL EXCEEDING THE SAFE THRESHOLD".** *Shalawat* and Salam shall be granted to Prophet Muhammad *Shallallahu 'alaihi wasallam*, for bringing all humankind to a brighter era with the full of knowledge.

During the process of making this thesis, the writer realized that the thesis will never be finished without any contribution, assistance, guidance, and support from various parties. All gratitude shall be honored to:

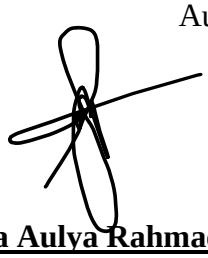
1. **Mr. Prof. Fathul Wahid, S.T., M.Sc., Ph.D.,** as the Rector of Universitas Islam Indonesia;
2. **Mr. Prof. Dr. Budi Agus Riswandi, S.H., M.Hum.,** as the Dean of Faculty of Law Universitas Islam Indonesia;
3. **Mr. Lucky Suryo Wicaksono, S.H., M.Kn., M.H.,** as my thesis advisor, who has helped me in writing my thesis, because of your guidance, advice and kindness, Alhamdullillah finally, I can finish writing my thesis;
4. **Mr. Dodik Setiawan Nur Heriyanto, S.H., M.H., LL.M., Ph.D.,** as my academic supervisor and as the secretary of International Undergraduate Program in Law at the Faculty of Law Universitas Islam Indonesia, for always give me the opportunity and chance to explore my ability;

5. **All my lectures**, who have taught and guided me to complete my study;
6. **The entire staff of the International Undergraduate Program in Law**, Faculty of Law Universitas Islam Indonesia, who always help me regarding the campus administration;
7. My **Father** and **Mother**, as my first support systems who always motivate and support me since very beginning, also with prayers from my parents I was able to reach this stage;
8. **Gilar Primayanto,** as my brother who always provides support and assistance;
9. **Azzahra Salsabil Sukma** and **Syahda Salsabilla,** as my college friends since early semester who always be on my side through all the time and always give me support;
10. All my friends, especially **Mutiara Firda Safira Tangguda, Zahra Ghina Syafira, Fadhila Annisa Salsabila, Salabila Alteza Prameswari, Zahra Nurilla Putri, Fadira Siswi Pramesty, Arhaenry Bagas Widi Ramadhan, Muhammad Farid Faza Hafiyyan,** who always help me to finish my thesis and accompany me in working on my thesis;
11. Lee Jeno who has provided indirect motivation to be more enthusiastic in compiling and completing my thesis.
12. Thank you for everyone who I haven't mentioned yet. Thank you for all prayers, hopes, and support that's mean a lot for me.
13. *Last but not least, I wanna thank me, for believing in me, for doing all this hard work, for having no days off, never quitting, for just being me at all times.*

Finally, the author realized that there are still a lot of things that need to be improve, hence any kind of suggestion will be gladly accepted and considered for better future knowledge. Hopefully this thesis can be useful for anyone who reads this.

Yogyakarta, March 4th, 2023

Author,



Novia Aulya Rahmadanti

TABLE OF CONTENT

Abstract

Drugs are supposed to cure, but when they contain substances exceeding safe limits, they do not cure but are potentially harmful. Based on case in 2022 found that in the market syrup medicines for children that contain EG and DEG exceeding the safe threshold. This research aims to know the consumer protection against the use of syrup drugs containing ethylene glycol and diethylene glycol exceeding the safe threshold and the responsibility of businesses and National Agency for Drug and Food Control for such a drug. This research is conducted by a normative method by examining library or secondary materials and using Statute Approach, Conceptual Approach, and Case Approach. This study reveals that renal failure due to the use of EG and DEG syrup medications may be caused by the ineffective monitoring when issuing drug distribution permits and also caused by the companies who were dishonest in determining medicine doses. As a form of responsibility, the company should pay compensation in the form of medical treatment or in line with the rules and regulations that apply. The National Agency for Drug and Food Control should regularly conduct risk-based testing and random sampling as a form of accountability.

Keywords: *Consumers Protection, EG and DEG, Exceeding Safe Threshold, Syrup Drug*

CHAPTER I
INTRODUCTION

A. Context of Study

Indonesia is a constitutional state that regulates people's behavior and this objective is listed in the fourth paragraph of the 1945 State Constitution of the Republic of Indonesia -protecting all the people of Indonesia improving public welfare, educating the life of the nation based on freedom, perpetual peace and social justice. The legal protection described by Hadjon is a set of regulations that exist as the protection of legal subjects, namely human rights and their dignity.[1] Bob Widyahartono also stated that the consumer rights declaration put forward by John F. Kennedy on March 15, 1962, resulted in the four consumer basic rights which included the following rights are the right to be secured, the right to be informed, the right to be choose, and the right to be heard.[2] In one of the objectives of the Indonesian state, namely "protection of the Indonesian Nation", every Indonesian citizen has the right to legal protection, including legal protection for consumers.

In relation to health and safety standards for medicines and food suitable for consumption, the government has imposed the Consumer Protection Act No. 8 of 1999. Article 4 (a) concerning consumer rights one of which is the right to comfort, security, and safety in consuming goods and/or services is protected. Health is very important and is what we all want because

[1] Philipus M. Hadjon, *Perlindungan Hukum Bagi Rakyat di Indonesia*, ctk. Pertama, Bina Ilmu, Surabaya, 1987, page. 20.

[2] Happy Susanto, *Hak-Hak Konsumen Jika Dirugikan*, Visi Media, Jakarta, 2008, page. 24.

if our body is in an unhealthy condition, of course, the activities that we will do as usual will be hampered. Health is a healthy state, both physically, mentally, spiritually, and socially which enables everyone to live productively socially and economically.[3] Health is an indicator of the level of human welfare so it becomes a priority in the national development of a nation. One very important component of health is the availability of drugs as part of public health services as it is used to save lives, and restoring or maintaining health.[4] With Law no. 8 of 1999 concerning consumer protection and other legal instruments, consumers who in this case are people who consume drugs have equal rights and positions and they can sue or sue if it turns out that their rights have been harmed or violated.

Drugs are substances the body consumes to reduce pain or eliminate disease in the body. According to Minister of health regulation Number 73 of 2016 in Article 1 paragraph (6), drugs are

> *" Drug are substances or combinations of materials including biological products that are used to affect or hide physiological systems or pathological conditions in order to strengthen the diagnosis, prevention, cure, recovery, improvement of health and protection for humans."*

Drugs, of course, have various forms ranging from tablets, capsules, caplets, syrups, etc. Children definitely have difficulty of consuming drugs in the form of tablets, capsules, and caplets. In this case, parents will usually crush them

[3] Look on Article 1 paragraph 1 of the Law of the Republic of Indonesia Number 36 of 2009 concerning *Health*

[4] I Kadek Sukadana Putra dan Gusti Ayu Putu Nia Priyantini, "Aspek Perlindungan Hukum Peredaran Obat Tanpa Izin Edar Lembaga Berwenang Menurut Undang-Undang Nomor 8 Tahun 1999 Tentang Perlindungan Konsumen (Studi Kasus: Putusan Pn Singaraja Nomor 80/Pid.Sus/2017/Pn Sgr)", *Jurnal Hukum,* Volume 3 No.2, Universitas Pendidikan Ganesha, 2021, page. 78

before use. One concern is that the crushed drugs will taste more bitter. One alternative to make children feel comfortable when taking medicine is giving syrup medicine to children. The syrup is usually available in various tastes in accordance with children's favorites. Thus, syrup-based medicine is the best option for children. However, recently, in early 2023, the case of kidney failure in children and death of children has proven that syrup medicines contained Ethylene Glycol (EG) and Diethylene Glycol (DEG) exceeding the safe threshold. The National Agency for Drug and Food Control Agency has submitted an explanation regarding the case of drug syrup for children contaminated with DEG and EG in Gambia, Africa.[5] The syrup medicine caused many children suffered from Kidney Failure. The Ministry of Health stated that 75 percent of children who experienced this problem had consumed syrup drugs that have levels of Ethylene Glycol (EG) and Diethylene Glycol (DEG) that exceed the safe threshold. The Ministry of Health also noted that out of 241 patients with acute kidney failure in 22 provinces, 133 people died, and 70 children were identified as having this problem per month. The case fatality rate reached over 50 percent.[6] The tragic death of 69 children due to the

[5] BPOM, "Penjelasan BPOM RI Tentang Isu Obat Sirup yang Berisiko Mengandung Cemaran Etilen Glikol (EG) dan Dietilen Glikol (DEG)", https://www.pom.go.id/new/view/more/klarifikasi/157/Penjelasan-BPOM-RI-Tentang-Isu-Obat-Sirup-yang-Berisiko-Mengandung-Cemaran-Etilen-Glikol--EG--dan-Dietilen-Glikol--DEG-.html, accessed 17th Januari 2023, at 22.00 WIB

[6] Tim Redaksi CNBC Indonesia, "Obat Sirup Kenapa Baru Jadi Masalah Sekarang? Ini Alasannya", https://www.cnbcindonesia.com/news/20221022123237-4-381789/obat-sirup-kenapa-baru-jadi-masalah-sekarang-ini-alasannya, accessed 1 Januari 2023, at 23.00 WIB

drug paracetamol syrup was discovered thanks to the intervention of the World Health Organization.

Medical professionals were asked to cease administering, distributing, and using medications made by Maiden Pharmaceutical manufacturer as of October 4, 2022, due to the possibility of contamination. The Ministry of Health also halted the export of all medications from this manufacturer. The Ministry of Health backed a house-to-house recall and collection of all items from the producer of all paracetamol, promethazine, and cough syrups in cooperation with WHO, UNICEF, Child Fund the Gambia, and The Gambia Red Cross Society. In addition to product recall, MoH used radio, television, social media, and in-person outreach to raise consciousness about the tainted medicines. Additionally, the Ministry of Health started conducting routine pharmacy spot inspections to make sure no goods from pharmaceutical company were being distributed.[7] Gambian President Adama Barrow committed to strengthening health measures, including tighter quality monitoring of imported pharmaceuticals, and gave health officials the go-ahead to "suspend the licenses of the alleged importers" implicated in the case. The Gambia government promised to amend the drug legislation to guarantee that regulation can stop such situations in the future and to fix the current problem.

Several things should be observed in cases of consumer protection, namely the people who become victims are the public. The problems that occur

[7] Parsa Bastani et.al, Acute Kidney Injury Among Children Likely Associated with Diethylene Glycol–Contaminated Medications the Gambia, vol. 7 no.9, 2023, page. 219

with consumers are a national problem that the government should pay attention to and must be monitored and followed up on so that no serious problems occur. In this case, of course, the law was made to protect the public from all adverse effects in terms of health, especially in choosing and consuming drugs.

Based on the problems above, this study aims to investigate **Legal Protection for Consumers against the Use of Drug Syrup containing Ethylene Glycol and Diethylene Glycol which exceeds the safe threshold.**

B. Problem Formulation

1. How is the consumer protection for the use of syrup drugs containing ethylene glycol and diethylene glycol exceeding the safe threshold?
2. How is the responsibility of businesses and the National Agency for Drug and Food Control for syrup drug products containing ethylene glycol (EG) and diethylene glycol (DEG) exceeding the safe threshold?

C. Research Objectives

1. To analyze the consumer protection for the use of syrup drugs containing ethylene glycol and diethylene glycol exceeding the safe threshold
2. To analyze the responsibility of businesses and National Agency for Drug and Food Control for syrup drug products containing ethylene glycol (EG) and diethylene glycol (DEG) exceeding the safe threshold

D. Originality of The Research

No.	Sources	Discussion
1.	Amrijal, Perlindungan Hukum Terhadap Konsumen Atas Peredaran Jamu Tradisional Yang Mengandung Bahan Kimia Obat Yang Berbahaya Berdasarkan Undang-Undang Nomor 8 Tahun 1999 Tentang Perlindungan Konsumen (Studi Di Kecamatan Tampan Pekanbaru), Fakultas Syari'ah Dan Ilmu Hukum Uin Suska Riau, 2020.	**Formulation of the problem:** 1. What is the legal protection for consumers against the distribution of traditional herbal medicine containing dangerous medicinal chemicals in the Tampan District of Pekanbaru? 2. What is the responsibility of entrepreneurs for the distribution of traditional herbal medicine containing dangerous medicinal chemicals in the Tampan District of Pekanbaru? **Conclusion:** 1. Legal protection for consumers against the circulation of traditional herbal medicine containing dangerous medicinal chemicals in the Tampan Pekanbaru District is by strictly implementing regulations that apply in accordance with the provisions of Law Number 8 of 1999 concerning Consumer Protection, namely providing strict sanctions against businesses that harms consumer rights in accordance with statutory provisions as well as providing compensation to consumers. Compensation as referred to in Article 19 paragraph (1) of the Consumer Protection Act is in the form of refund or replacing goods and/or services of a similar or equivalent value, or health care and/or providing compensation in accordance with the provisions of laws and regulations.

		2. The responsibilities of entrepreneurs for the circulation of traditional herbal medicine containing dangerous medicinal chemicals in the Tampan District of Pekanbaru, based on the results of interviews with the entrepreneurs, are not to sell and return to distributors the types of traditional herbal medicine which contain these dangerous medicinal chemicals and to carry out Compensation for consumers who have already bought traditional herbal medicine containing dangerous medicinal chemicals by way of refund.
2.	Kadek Dwi Giovanni, Perlindungan Hukum Bagi Konsumen Terhadap Peredaran Obat Online Yang Tidak Sesuai Dengan Komposisi Obat Asli, Fakultas Hukum Universitas Udayana, 2022.	**Formulation of the problem:** 1. What is the form of legal protection for consumers against drug distribution via online that does not match the original drug composition? 2. What are the legal remedies that can be taken by consumers for losses incurred by businesses? **Conclusion:** Based on the things that have been described, it can be interpreted that legal protection for consumers regarding the distribution of drugs through online with compositions that do not match the original drugs, in general, has been regulated in the Consumer Protection Act, by carrying out preventive and repressive protections in efforts to enforce the rule of law. Consumers can take legal action if they feel their rights have been violated, namely through a court or outside the court, as regulated in Article 45 to Article 48 of the

		Consumer Protection Law. Businesses in terms of causing losses in electronic transaction activities, can be subject to sanctions based on the provisions of Article 45A paragraph (1) of the ITE Law.
3.	Arisa, Perlindungan Hukum Bagi Konsumen Mengkonsumsi Obat Tradisional Yang Mengandung Bahan Kimia Obat (BKO) Di Kota Pangkalpinang, Fakultas Hukum Universitas Bangka Belitung Balunijuk, 2017.	**Formulation of the problem:** 1. What is the legal protection for consumers consuming traditional medicines containing BKO (medicinal chemicals) in Pangkalpinang City? 2. What are the efforts of the Pangkalpinang City Health Office in preventing the circulation of traditional medicines containing BKO (Medicinal Chemicals) from entering Pangkalpinang City? **Conclusion:** Consumer legal protection in question is to protect consumer rights regulated in Article 4 Consumer Protection Act. Cases of distribution of counterfeit drugs in Indonesia can be said to violate consumer rights as stipulated in Article 4 letter a Consumer Protection Act concerning the right to comfort, security and safety in consuming goods and/or services; Article 4 letter c Consumer Protection Act regarding the right to correct, clear and honest information regarding the conditions and guarantees of goods and/or services; Article 4 letter d Consumer Protection Act regarding the right to be heard opinions and complaints; as well as Article 4 letter e Consumer Protection Act regarding the right

		to obtain advocacy, protection, and efforts to resolve consumer protection disputes properly. The purpose of legal protection for drug consumers is to make consumers feel comfortable and safe. Related to the distribution of drugs containing hazardous substances, the government and its staff have striven to resolve it by issuing regulations regarding guidance and supervision based on Decree of the Head of the Republic of Indonesia POM Agency Number HK.03.1.23.10.11.08481 concerning Criteria and Procedures for Drug Registration and sanctions based on the Law Number 36 of 2009 concerning Health which is expected to make businesses aware so that they do business in good faith. Protection of drug consumers' rights to correct, clear and honest information regarding the conditions and guarantees of goods and/or services in National Agency for Drug and Food Control RI Head Regulation Number Hk.00.05.1.23.3516 concerning Distribution Permits for Medicinal Products, Traditional Medicines, Drugs, Food Supplements and Food that is sourced, contains certain ingredients and or contains alcohol has actually been clearly regulated in relation to the obligation of businesses to provide as complete information as possible to avoid causing harm to drug consumers. For drug consumers who suffer losses, based on Article 19 Consumer Protection

		Act, businesses are required to provide compensation. Meanwhile, the government has the responsibility to guide, supervise, and facilitate so that drug consumers get what they are entitled to.

E. Definition of Terms

In order to align the perceptions and conceptions of material in this study, some operational definitions are needed.

1. Legal Protection for Consumers

In Indonesia, the regulation regarding legal protection for consumers are based on the interests of economic development and development, especially in the fields of industry and trade, and efforts to accommodate the effects of globalization and free trade as a result of technological advances. The Indonesian government issued Law Number 8 of 1999 concerning Consumer Protection. Consumer protection is all efforts that guarantee legal certainty to protect consumers.[8]

2. Consumers

Consumers are everyone who uses goods and/or services available in society, both for the benefit of themselves, their families, other people, and other living things and not for marketing.[9] The definition of a consumer in the Consumer Protection Act has a broader meaning than the definition of a consumer in the two Draft Consumer Protection Laws

[8] Article 1 Number 1 Law Number 8 of 1999 concerning *Consumer Protection*
[9] Article 1 Number 2 Law Number 8 of 1999 concerning *Consumer Protection*

because the meaning of the one in the Consumer Protection Act also includes the use of goods for the benefit of other living things. Article 4 Consumer Protection Act states that the rights of consumers themselves are; the right to choose goods and/or services and obtain the goods and/or services by the exchange rate and conditions as well as promised guarantees; the right to correct, clear and honest information regarding the conditions and guarantees of goods and/or services; the right to obtain compensation, compensation and/or reimbursement, if the goods and/or services received do not fit the agreement or not as they should be.

3. Syrup medicine

Syrup is a concentrated preparation in water from sugar or sugar substitute with or without the addition of fragrances and medicinal substances. Syrup medicine can be in the form of a single drug or combination with other drugs in the form of standardized preparations.[10]

4. Substance Ethylene Glycol and Diethylene Glycol

Ethylene glycol and Diethylene Glycol are slightly viscous alcohols with a pleasant odor and sweet taste that act as solvents and are colorless liquids. They are chemicals that have toxic or toxic effects if consumed more than safe limits.

5. Safe threshold

[10] Djelang Zainuddin Fickri dan Farm.Klin, "kFormulasi Dan Uji Stabilitas Sediaan Sirup Anti Alergi Dengan Bahan Aktif Chlorpheniramin Maleat (CTM)", Vol.1 No.1, S1 Farmasi STIKES Rumah Sakit Anwar Medika 2018, page. 17

Safe threshold or can be referred to as maximum limit is the maximum concentration of permitted Chemical Contaminants that can be accepted in Processed Food.[11]

F. Theoretical Review

Based on the background and problem formulation, research on "Legal Protection for Consumers against the Use of Drug Syrup containing Ethylene Glycol and Diethylene Glycol which exceeds the safe threshold" will use theories including 1.) Consumer Legal Protection, 2.) Development of Consumer Protection by the Government, 3.) Theory of Legal Protection.

1. Consumer Legal Protection

Legal protection is an illustration of the function of law, in that law can provide justice, order, certainty, benefit, and peace.[12] Consumer protection is a term used to describe how legal protection is given to consumers themselves to meet their needs from things that may harm them. Consumer protection is all efforts that guarantee legal certainty to protect consumers based on the principles contained in consumer protection.[13] Consumer protection law is needed if the conditions of the parties having legal relations or problems in society are unbalanced.

---

[11] Pasal 1 Angka 5 Peraturan Badan Pengawas Obat Dan Makanan Nomor 8 Tahun 2018 tentang *Batas Maksimum Cemaran Kimia Dalam Pangan Olahan*

[12] Richard Revel Wijaya Theda, et.al, "Perlindungan Hukum Terhadap Konsumen Akibat Kelalaian Pelaku Usaha Jasa Laundry di Denpasar Utara", *Jurnal Hukum,* Vol. 7 No. 7, Fakultas Hukum Universitas Udayana, 2019, page. 3.

[13] Niru Anita Sinaga dan Nunuk Sulisrudatin,"Pelaksanaan Perlindungan Konsumen Di Indonesia", *Jurnal Hukum,* Volume 5 No.2, Fakultas Hukum Universitas Suryadarm, 2015, page. 7

Specifically and juridically, based on Law Number 8 of 1999 on Consumer Protection in article 1 point 1, it means that consumer protection is all efforts that guarantee legal certainty to protect consumers. The purpose of making the Consumer Protection Law is so that consumer protection can be fulfilled both in terms of private and public law.

The elucidation of Article 2 of the Consumer Protection Act states that consumer protection is organized as a joint effort based on 5 (five) relevant principles in national development, namely:[14]

1. *The principle of benefit is intended to mandate that all efforts in the implementation of consumer protection must provide maximum benefit for the interests of consumers and business actors as a whole.*
2. *The principle of justice is intended so that the participation of all people can be maximized and provide opportunities for consumers and businesses to obtain their rights and carry out their obligations in a fair manner.*
3. *Balance is meant to provide a balance between the interests of consumers, businesses, and the government in the material and spiritual sense.*
4. *The principle of consumer security and safety is intended to provide guarantees for security and safety to consumers in the use, and utilization of goods and/or services that are consumed or used.*
5. *The principle of legal certainty is intended so that both businesses and consumers obey the law and obtain justice in the implementation of consumer protection, and the state guarantees legal certainty.*

The Bereich Pharmaziewesen der Behörde für Justiz und Verbraucherschutz Pharmacy, often known as BJV, is the division of the

[14] Looks on Article 2 of Law Number 8 of 1999 concerning Consumer Protection, Explanation section

Authority for Justice and Consumer Protection that oversees pharmaceutical production and sales in Germany. Additionally, they oversee the correct conduct of pharmaceutical clinical trials, donor protection following the Transfusion Act, and the safe production of tissue preparations, and they guide the institutions under their supervision on matters about pharmaceutical legislation.[15]

2. Development of Consumer Protection by the Government

Consumer protection development is carried out by the Government to ensure that the rights of consumers and businesses are obtained and the implementation of their respective obligations. Article 2 of Government Regulation Number 58 of 2001 on Guidance and Supervision of the Implementation of Consumer Protection states that the Government is responsible for fostering the implementation of consumer protection which ensures that the rights of consumers and business actors are obtained and the obligations of consumers and businesses are carried out.

It is also stated in the Consumer Protection Act in article 30 as follows:

(1) Supervision of the implementation of consumer protection and implementation of the provisions of the laws and regulations are carried out by the government, the public, and non-governmental consumer protection institutions.
(2) Supervision by the government as referred to in paragraph (1) is carried out by the Minister and/or related technical ministers.

[15] Author, "Consumer Protections Pharmaceutical & Medical Devices", https://www.hamburg.com/civil-services/consumer-protection/16270862/pharmaceuticals-and-medical-devices/, accessed March 31st, at 16.00 WIB

(3) Supervision by the public and non-governmental consumer protection institutions is carried out on goods and/or services circulating in the market.
(4) If the results of the supervision as referred to in paragraph (3) turn out to deviate from the applicable laws and regulations and endanger consumers, the Minister and/or technical minister will take action by the applicable laws and regulations.
(5) The results of supervision carried out by the community and non-governmental consumer protection institutions can be disseminated to the public and can be submitted to the Minister and technical ministers.
(6) Provisions for the implementation of supervisory duties as referred to in paragraph (1), paragraph (2), and paragraph (3) are stipulated in government regulation.

The government has a responsibility to protect the public as consumers. In this regard, the government has an important role as a mediator between the interests of businesses and the interests of consumers so that each party can go hand in hand without harming one another. One of the agencies, a Non-Ministerial Government Institution that continues to be strengthened to be able to carry out government affairs in the field of drug and food control more effectively is commonly referred to as the National Agency for Drug and Food Control.

The National Agency for Drug and Food Control has the task of protecting people in the field of drug and food control by the provisions of the applicable laws and regulations.[16]

3. Theory of Legal Protection

[16] Agustina Balik dan Vica Jilyan Edsti Saija, "Tanggungjawab Pemerintah Dan Pelaku Usaha Makanan Siap Saji Terkait Penggunaan Wadah Plastik Yang Berbahaya Bagi Konsumen Di Kota Ambon", *Jurnal Hukum,* Vol.23 No. 2, Fakultas Hukum Universitas Pattimura, 2017, page. 98

Legal protection according to Satjipto Rahardjo is to protect human rights that are harmed by other people and this protection is given to the community so that they can enjoy all the rights granted by law.[17] Philipus M. Hadjon argues that legal protection is an action to protect or provide assistance to legal subjects, by using legal instruments.[18] Law no. 39 of 1999 on Human Rights also explains that legal protection is all efforts made consciously by every person or government institution, even the private sector, which aims to seek security, control, and fulfillment of life welfare by existing human rights. Legal protection can also be said as a separate picture of the function of the law itself, which has the concept that law provides justice, order, certainty, benefit, and peace.

Protection itself can be interpreted as an act of providing guarantees, peace, security, well-being, and peace from protection to those who are protected against all the dangers or risks that threaten it. In addition, protection also means protection given to those weaker. Protection can be said as legal protection if it contains the following elements:

1. There is protection from the government for its citizens.
2. Guarantee of legal certainty.
3. Relating to the rights of citizens.
4. There are sanctions for those who violate them.

---

[17] Satjipto Rahardjo, *Ilmu Hukum*, PT. Citra Aditya Bakti, Bandung, 2000, hlm. 54.

[18] Philipus M. Hadjon, *Pengantar Hukum Administrasi Indonesia*, ctk. kesepuluh, Gajah Mada University Press, Yogyakarta, 2008, page.10.

Legal protection is divided into two- preventive and repressive legal protection. Preventive legal protection is the protection aiming at preventing disputes, which directs government actions to be careful in making decisions based on discretion, while repressive legal protection is the protection that aims at resolving disputes.[19]

In relation to healthcare, modern national states guarantee the possibility of restoring rights that have been infringed through legal protection of the patient's rights. Legal protection of patients' rights is a significant part, not only in Ukraine but in many other European countries. The Association Agreement between Ukraine and the European Union, which requires the Contracting Parties to develop cooperation in the field of health care to improve its safety and protect human health as a foundation for sustainable development and economic growth, is one of the key factors for the reform of healthcare legislation and adoption of the Law of Ukraine "On the Rights of the Patient." The examination of the existing situation of the healthcare system in Ukraine and the practice of legal protection of patients' rights has provided grounds for uncovering the following probable breaches of patients' rights: refusing to give healthcare services; illegally demanding money for the provision of health care services unless expressly permitted under existing legislation. Given the variations in law, the way healthcare

[19] Phillipus M. Hadjon, *Perlindungan Hukum bagi Rakyat Indonesia*, PT. Bina Ilmu, Surabaya, 1987, page. 2

services are organized, and economic, social, cultural, religious, and moral values, patient rights protection in many nations has its distinctive elements.[20]

G. Research Method

The research methodology is explained below.

1. Type of Research

This research is legal writing with normative or doctrinal research which determines whether legal requirements have been violated and how accountability will be distributed.

Normative Legal Research is legal research that examines law which is conceptualized as a norm or rule that applies in society, and becomes a reference for everyone's behavior.[21] It is also called doctrinal legal research, library research, or documentary studies. It is called doctrinal legal research as this research is carried out only on written regulations or other materials or library research or document studies. After all, this research is mostly carried out on secondary data in libraries, such as books and the official documents from the government.[22]

2. Object of Research

The object research is Pres Release explanation number HM.01.1.2.11.22.178 from the National Agency for Drug and Food

[20] Viktor V. Horodovenko et.al, Protection Of Patients' Rights In The European Court Of Human Rights, vol.71 no.6, 2018, Page. 1202

[21] Muhaimin, *Metode* Penelitian, ctk. Pertama, Mataram University Press, NTB, 2020, e-book, page.29

[22] Ishaq, *Metode Penelitian Hukum dan Penulisan Skripsi Tesis serta Disertasi*, ctk. Kesatu, Alfabeta, Bandung, 2017, e-book, page.27

Control concerning development and results of supervision of medicine syrup and action on propylene glycol raw materials containing Ethylene Glycol (EG) and Diethylene Glycol (DEG) exceeding the threshold. Regulations related to the Consumer Protection Law and the Health Law as well as their implementing regulations.

3. Research Approach

The approach in this study uses the Statute Approach, Conceptual Approach, and Case Approach. Statute Approach is carried out by examining all laws and regulations related to the legal issues being discussed[23] and by examining all laws and regulations that are related to the legal issues being handled.

Conceptual Approach is the research approach chosen in order to seek answers to legal issues on legal research.[24] Or an approach that departs from the views and doctrines that have developed in the science of law. The conceptual approach used is the views and opinions of experts, legal principles, and legal concepts related to the responsibility of businesses to carry out business activities that endanger the health of consumers.

For Case Approach, the purpose of normative research is to examine how legal standards or principles are applied in actual legal practice. This strategy is typically applied to instances where the judgment has already been rendered. These examples are empirical in nature, but they can be

[23] Muhaimin, *Op.Cit*, page. 56
[24] *Ibid*, page. 57

examined in a normative study to gain an overview of the influence of the normal component of a rule of law in legal practice and to use the analysis's findings as information for legal justifications.[25] Since the purpose of this study is to examine how consumer safety can be applied in a specific case, namely the case of syrup with excessive levels of ethylene glycol and diethylene glycol; a case study method has been chosen. Although this case does not involve a judicial ruling, this is still a possibility when using this case-by-case method as not every case handled using this case method must result in a court ruling.

4. Sources of Research Data

Primary legal materials which include the 1945 Constitution of the Republic of Indonesia, Law Number 8 of 1999 on Consumer Protection, Law of the Republic of Indonesia Number 36 of 2009 on Health, Government Regulation No. 58 of 2001 on Guidance and Supervision of the Implementation of Consumer Protection, Regulation of the Minister of Health Number 73 of 2016, Regulation of the Food and Drug Supervisory Agency Number 8 of 2018 on Maximum Limits of Chemical Contaminants in Processed Foods.

Secondary Legal Materials used comprise materials that provide an explanation of primary legal materials, books that contain descriptions of the research findings by professors, or prominent legal experts in a legal

[25] Johni Ibrahim, *Teori & Metodologi Penelitian Hukum Normatif*, cet. ketiga, Bayumedia Publishing, Malang, 2007, page.321

system, and analyses of concrete legal rules, principles and regulations that apply in a legal system such as books, journals, articles, documents.[26]

Tertiary Legal Materials used cover materials that provide instructions and explanations of primary legal materials and secondary legal materials, such as legal dictionaries, language dictionaries, encyclopedias and legal (law) encyclopedias.[27]

5. Data analysis

Qualitative data is a component of data analysis. This method doesn't deal with numbers; instead, it deals with justifications, causes, and factors that underpin the subject. Qualitative data analysis techniques are defined as data analysis methods that seek to understand and investigate certain phenomena occurring spontaneously or in what is typically referred to as natural environments. The study then narrates the findings of the investigation and concludes by summarizing all concerns regarding consumer protection laws and their application to the use of drugs containing ethylene and diethylene glycol exceeding the safe threshold.

[26] Teguh Prasetyo, *Penelitian Hukum*, ctk. Pertama, Nusa Media, 2019, page. 44
[27] Muhaimin, *Op.Cit*, page.62

CHAPTER II
GENERAL OVERVIEW OF LEGAL PROTECTION FOR CONSUMERS AGAINST THE USE OF SYRUP DRUGS CONTAINING ETHYLENE GLYCOL AND DIETHYLENE GLYCOL EXCEEDING THE SAFE THRESHOLD

A. Consumer Legal Protection

The emergence of a consumer movement in the United States in 1892 and the establishment of the Consumers League in New York marked the beginning of the history of consumer protection. The National Consumers League was established in 1898 at the national level in the United States. It expanded quickly, and by 1903 it had grown to 64 branches spanning 20 states.[28] With such broad product diversity and technological advancements, there has been an expansion of the space for goods and/or services transactions. The rapid development of the economy has created various types and variations of each good and/or service that can be consumed. The occurrence of these circumstances may lead to an imbalance between the positions of businesses and customers, placing consumers in a vulnerable position. Following the development of this consumer consciousness, the field of consumer protection law has started to be developed in the study of law.

The Indonesian Consumers Association, a group with the mission to safeguard consumers, uphold consumer integrity, and support the government, was founded in May 1973, marking the beginning of Indonesia's consumer protection movement. This demonstrates the growing general awareness of the

[28] Gunawan Widjaja dan Ahmad Yani, *Hukum Tentang Perlindungan Konsumen,*ctk. Kedua, Gramedia Pustaka Utama, Jakarta, 2001, page.13

need to safeguard consumer rights. Then, this organization fulfills its role as a locomotive for promoting consumer and company understanding. A Consumer Protection Act that served as the foundation for the implementation of consumer protection legislation in Indonesia was ultimately passed on April 20, 1999.[29] The Consumer Protection Law was born 25 years after the Indonesian Consumers Foundation was established, this can mean that the desire to protect the public from providers of services or goods is still very weak.

The Consumer Protection Law still has several weaknesses, and the level of consumer protection in Indonesia is still fragile due to a lack of strong regulations. Consumer protection in Indonesia has not been fully implemented properly. This can be seen from the many cases regarding consumer protection in Indonesia. Four factors result in an unsatisfactory consumer protection situation. First, there is an imbalance in the relationship between producers and consumers. Second, in general, consumers have little bargaining power in transactions with business actors. Third, the government tends to support business actors. Fourth, law enforcement institutions such as prosecutors, courts, and police do not pay sufficient attention to consumer protection issues. Consumer protection regulations in Indonesia currently only go as far as ministerial regulations and need to strengthen existing Consumer Protection laws.

[29] Yudha Hadian N. dan Dwi Wahyuniarti P., Penerapan Prinsip Tanggung Jawab Mutlak (Strict Liability) Dalam Rangka Perlindungan Konsumen, Vol.5 No.2, Buletin Ilmiah Litbang Perdagangan, 2011, page. 180

1. Definition of Consumer Protection

The Consumer Protection Law is an example of a national development philosophy that emphasizes the importance of creating a fully functional Indonesian society founded on the Pancasila state foundation and the 1945 Constitution. This philosophy includes legal development that protects consumers.[30] Legal certainty is one type of promise that clients and attorneys require. The standards for fairness and legal certainty are derived from the legal review. Legal certainty requires that the subjects of the law can control their behavior.[31] In Indonesia, efforts to protect consumers are based on several guiding principles and goals that are thought to guide them when put into practice. The foundation of consumer protection legislation is very solid, with distinct principles and goals both the macro and micro implications of consumer safety laws.[32]

The goal of the universal problem of consumer security is to advance economic efficiency. It is also connected to issues of social fairness and human rights. In this instance, Harland said: "Consumer protection is thus seen as concerned with issues of social justice and human rights, rather than just with promoting economic efficiency, though this is an important aspect of it."[33]

---

[30] *Ibid*, page. 17

[31] H. Matnuh, Rectifying Consumer Protection Law and Establishing of a Consumer Court in Indonesia, *Journal of Consumer Policy*, 44:483–495, 2021, page. 487

[32] Budi Agus Riswandi, *Buku Hukum Perlindungan Konsumen,* ctk. Pertama, FH UII Press, Yogyakarta, 2022, page. 18

[33] H. Matnuh, *Op.Cit*, page. 486

Consumer protection law is the overall principles and rules that regulate and protect consumers in the relationship and issues of supply and use of consumer products (goods and/or services) between suppliers and users in social life.[34] Based on Article 1 number 1 Law number 8 of 1999 on Consumer Protection, Consumer Protection is all efforts that guarantee legal certainty to protect consumers. Consumer protection refers to measures aimed at protecting and promoting the welfare and/or financial interests of consumers. Consumer protection measures, including consumer education, mobilization, and representation are put in place to ensure that consumers can make informed decisions about their choices and that producers and sellers will fulfill their promises regarding the products and services they offer.[35]

The elucidation of article 2 of the Consumer Protection Act states that consumer protection is organized as a joint effort based on 5 (five) relevant principles in national development, namely:[36]

1. The principle of benefit is intended to mandate that all efforts in the implementation of consumer protection must provide maximum benefit for the interests of consumers and businesses as a whole.

[34] Az. Nasution, *Hukum Perlindungan Konsumen suatu Pengantar*, Diadit Media, Jakarta, 2002, page. 22

[35] Buku Pegangan tentang Hukum dan Peraturan Perundang-Undangan Perlindungan Konsumen di ASEAN, Jakarta, page. 2

[36] Looks on Article 2 of Law Number 8 of 1999 concerning Consumer Protection, Explanation section

2. The principle of justice is intended so that the participation of all people can be maximized and provide opportunities for consumers and businesses to obtain their rights and carry out their obligations in a fair manner.
3. Balance is meant to provide a balance between the interests of consumers, businesses, and the government in the material and spiritual sense.
4. The principle of consumer security and safety is intended to provide guarantees for security and safety to consumers in the use, and utilization of goods and/or services.
5. The principle of legal certainty is intended so that both businesses and consumers obey the law and obtain justice in the implementation of consumer protection, and the state guarantees legal certainty.

The concept of consumer protection came into existence as a result of consumers' inferior status to businesses. A law exists to show how weak parties are protected, including in this case, consumers, as providing security and protection to citizens is both one of the law's characteristics and one of its purposes.[37] Consumer protection covers both substandard goods and those that could endanger people's lives. The phrase "consumer protection" refers to the legal safeguards

[37] Hulman Panjaitan, *Hukum Perlindungan Konsumen* Reposisi dan Penguatan Kelembagaan *Badan Penyelesaian Sengketa Konsumen Dalam Memberikan Perlindungan dan Menjamin Keseimbangan Dengan Pelaku Usaha*, ctk. Pertama, Jala Permata Aksara, Jakarta, 2021, e-book, page. 82

provided to customers to satisfy their demands for products that are harmful to the customers themselves.[38] Coverage in consumer protection can be distinguished in two aspects, namely:[39]

1. Protection against the possibility that the goods delivered to consumers do not follow what has been agreed.
2. Protection against the imposition of unfair conditions on consumers.

Internationally, attention to consumer rights and interests has been the focus of studies by the United Nations (UN) as an international organization through the 160th UN General Assembly on April 9, 1985, as stated in UN Resolution 39/248 concerning Consumer Protection which emphasizes several consumer interests including safeguarding customers from threats to their health and safety, as well as making sure that there are efficient ways to make amends.[40]

On an international level, the position of consumers as weak parties is also acknowledged, as evidenced by the UN General Assembly Resolution concerning Guidelines for Consumer Protection, which reads in part: "Taking into account the interests and needs of consumers in all countries, particularly those in developing countries, acknowledging that consumers frequently face imbalances in economic

[38] Zulham, *Hukum Perlindungan Konsumen*, ctk. Pertama, Kencana, Jakarta, 2013, e-book, page. 21

[39] Adrianus Meliala, *Praktik Bisnis Curang*,Pustaka Sinar Harapan, Jakarta, 1993, page. 52

[40] Hulman Panjaitan, *Op.Cit*, page. 83

terms, educational levels, and bargaining power, and bearing in mind that consumers should have the right to be free from unfair or deceptive acts or practices, and taking into account the interests and needs of consumers in all countries, particularly[41]

If businesses harm consumers, the consumers protection should be explicitly guaranteed by consumer protection law. Legal certainty is one type of guarantee that clients and attorneys require. The standards for fairness and legal certainty are derived from the legal assessment. Legal certainty requires that the subjects of the law have the ability to control their behavior. Internationally, legal certainty is acknowledged as a crucial component of the rule of law and as a fundamental value for public authorities creating solid laws.[42]

The sources of consumer protection law in Islamic law are the same as the general sources of the Islamic law that we already know, including the Qur'an, Sunnah, Ijma, and qiyas. In Islam, protection for consumers does not only refer to the concepts of halal and haram, but is also based on Islamic economic principles which cover the process of production, distribution, production goals, and the consequences of consuming goods and/or services.[43] In Islam, according to Islamic law experts (*fukaha*), Islamic Law has never defined and made consumers an object

[41] H. Matnuh, *Loc.Cit*

[42] *Ibid*, page. 487

[43] Barkatullah Abdul Haim, *Perlindungan Hukum Bagi Konsumen Transaksi E-Commerce Lintas Negara di Indonesi*a, FH UII Press, 2009, Hlm. 24

of special legal study. Sources of Islamic law talk about consumer principles and consumer protection.[44] Consumer protection in Islamic economic activity involves safeguarding ingredients, production procedures, distribution channels, production goals, and the effects of consuming goods and/or services. Therefore, in the Islamic economy, commodities and/or services that are lawful in terms of their nature can turn into haram when their production process and intended use are prohibited by *syara*'. Muslim consumers have distinct objectives from non-Muslim consumers. When ingesting food or beverages, Muslims strive to uphold their religious duties and abstain from anything forbidden by Allah SWT.

After the Prophet Muhammad SAW was appointed as an Apostle, Islamic teachings paid significant attention to consumer rights, both in the Qur'an and Hadith. In Islamic teachings, a fair and honest business is a business that does not carry out oppression or become a victim of oppression. Allah SWT revealed this message in QS. Al-Baqarah verse 279.

فَاِنْ لَّمْ تَفْعَلُوْا فَاْذَنُوْا بِحَرْبٍ مِّنَ اللّٰهِ وَرَسُوْلِهٖۚ وَاِنْ تُبْتُمْ فَلَكُمْ رُءُوْسُ اَمْوَالِكُمْۚ لَا تَظْلِمُوْنَ وَلَا تُظْلَمُوْنَ

If you do not, then beware of a war with Allah and His Messenger! But if you repent, you may retain your principal—neither inflicting nor suffering harm.

[44] Zulham, *Op.Cit*, page. 18

In the business sphere, the message at the end of the sentence instructs the protection of consumers, by prohibiting business actors and consumers from harming or harming each other. This concerns consumer rights and also the rights of business actors (producers). At the end of the verse it says not to persecute and not to be persecuted (not to oppress and not to be wronged).

The main goals of all Islamic economic and trade doctrine are to uphold both the rights of commercial players and those of consumers. Islam demands aspects of truthfulness, justice, and transparency in business dealings. Islam offers room for businesspeople and consumers to protect their rights, or *khiyar*, in the area of consumer rights. If there is a consent qabul between producers and consumers, then khiyar is a privilege established for businesses and consumers, granting each party the ability to uphold or dissolve the contract.

2. Roles and Principles in Consumer Protection

Legal Protection for Consumers has several roles for consumers, which can be identified as follows:[45]

1) Equalizing the position of consumers before businesses

Consumers are the underdog when it comes to business actors. Consumers have the potential to suffer harm at almost every step of the transaction with businesses. These various unfavorable

[45] Budi Agus Riswandi, *Op.Cit*, page. 22

chances result from businesses' lack of transparency. Realizing this, it is possible to find a way to level the playing field for consumers by implementing various consumer rights, such as the right to information and the right to respond, and by preventing contract provisions that harm consumers under the provisions of the Consumer Protection Act. Business actors are unable to evade this responsibility as the Consumer Protection Law exists and controls it. The Consumer Protection Act's legal duties are fulfilled by acknowledging that consumers and businesses are on an equal footing.

2) Strengthening consumer rights

Consumer rights were only regarded by business actors as ethical and moral duties before the Consumer Protection Act's passage in Indonesia. Additionally, customer rights are perceived to be getting more important since the customer Protection Act was passed. The purpose of this affirmation of consumer rights is to enable businesses to implement the Act correctly. If businesses disregard or abuse consumer rights, it will have a legal consequence in the form of compensation for accusations of criminal acts.

3) Strengthening the role of consumer institutions

To strengthen consumer protection, of course, other things are needed so that consumers' rights can be protected, namely by

encouraging the role of consumer institutions. Consumers who place a high value on consumer safety are represented by a consumer organization. According to rules based on the Consumer Protection Act, consumer institutions are given a significant role in carrying out consumer education and in resolving consumer disputes, specifically by having the ability to sue. Therefore, the consumer agency may bring a lawsuit without the need for the injured consumers to grant them power of attorney.

4) Strengthening consumer dispute resolution

In consumer dispute resolution, there are other regulations, such as those in question that provide provisions for class action lawsuits and a reverse proof system, enhancing consumer protection in the area of consumer dispute resolution. This regulatory tool for consumer protection may pave the way to the achievement of justice in consumer dispute settlement. It is possible to create a system of reverse evidence and class action lawsuits through these two regulations, making them both forms of consumer dispute settlement acceptable.

Consumer protection attempts in Indonesia are based on principles that are believed to provide direction and implementation at the practice level. Article 2 of the Consumer Protection Act states that

consumer protection is based on benefits, fairness, balance, consumer security, and safety, as well as legal certainty.

1. Benefit Principle

   This benefit principle is meant to establish the requirement that all initiatives to implement consumer protection should maximize the benefits to the interests of consumers and business actors as a whole.

2. Principle of Justice

   This justice principle aims to encourage as much participation from all Indonesians as possible while giving consumers and business people the chance to fairly exercise their legal rights and fulfill their contractual responsibilities.

3. Principle of Balance

   This balance principle is intended to provide a balance between the interests of consumers, businesses, and the government in the material and spiritual sense.

4. Principles of Consumer Security and Safety

   The principle of consumer security and safety aims to ensure consumers' security and safety when they use, use, and utilize the products and/or services.

5. Principle of Legal Certainty

The legal certainty principle, which the state guarantees aim for both business actors and customers to uphold the law and receive justice when enforcing consumer protection.

3. Relations between Consumers and Businesses

The Consumer Protection Law reflects the extraordinary nature of the relationship between business actors and consumers, where consumers are often at a disadvantage. Consumer protection in Indonesia is important and mandatory, especially because it has become an international commitment at the UN. There were situations where business actors in Indonesia are involved in fraudulent practices against consumers.[46]

There are principles regarding the position of consumers in relation to business actors based on doctrines or theories known in the historical development of consumer protection law:[47]

1. *Let the buyer beware (caveat emptor)*

   Let the buyer beware, also known as the caveat emptor doctrine, is the foundation for conflicts to arise in the area of consumer interactions. According to this theory, consumers do not need protection because business actors and consumers are two very balanced parties. This principle has a flaw in that

[46] Denico Doly, "EFFORTS TO STRENGTHEN CONSUMER PROTECTION IN INDONESIA RELATED TO STANDARD CLAUSES", *Jurnal Hukum,* Volume. 3 No. 1, 2016, page. 49

[47] Shidarta, Hukum Perlindungan Konsumen Indonesia, Grasindo, Jakarta, 2006, page. 61

consumers do not have access to enough knowledge during development to make decisions about the products and/or services they consume. Limited consumer knowledge or business actors who are closed off to the goods they sell may be to blame for this. So, if a customer suffers from loss, the business player can claim that the loss was caused by the customer's carelessness.

In the Consumer Protection Act, this principle is no longer used, but instead uses the precautionary principle of business actors or what is called a caveat vendor. This can be seen by being regulated in a separate chapter regarding actions that are prohibited for business actors with the aim that they have rules for doing business.

2. *The due care theory*

According to this doctrine or principle, commercial players have to be cautious in producing and distributing goods and/or services. They are not to blame as long as they are cautious when handling their goods. This principle follows the laws that prohibit certain actions by business actors, specifically Articles 8 through Article 17 of Law No. 8 of 1999 on Consumer Protection.

3. *The privity of contract*

According to this theory, businesses have to protect customers, but they can only do so if a contractual relationship has already been established. Contracts frequently contain

standard clauses that weaken the position of consumers by shifting the accountability of business actors. Beyond what has been decided, business actors are not to blame. Because of this, customers may file a lawsuit. This follows the clauses in Article 1340 BW, which says that the agreement's scope is limited to the parties to it.

B. Development of Consumer Protection by the Government

Founding is the efficient and effective use of effort, action, and activities to produce improved outcomes, while supervision is a type of inspection or management of an activity to learn more about and evaluate how the activity is being carried out. Executing consumer security, direction, and supervision are extremely strategic. It is essential to provide adequate consumer guidance and supervision to carry out the goals of the Consumer Protection Act (Law No. 8 of 1999).

For the interests of business actors and those of consumers to coexist without interfering with one another, the government plays a crucial role as a mediator in efforts to safeguard consumers. The government provides customer protection through oversight and guidance. Based on the provisions in article 2 of Government Regulation Number 58 of 2001 concerning Guidance and Supervision of the Implementation of Consumer Protection, it can be said that the government is responsible for fostering consumer protection assuring that the rights of consumers and business actors are obtained and their obligations are carried out. Because of this, the

government must safeguard community rights as customers. Therefore, this is consistent with what is stated in the provisions of Article 29 of the Consumer Protection Law when viewed from the viewpoint of rights and responsibilities in that the community as consumers must be protected by the government.

Given the huge number of products and services available, as well as Indonesia's enormous territory, consumer protection is jointly organized by the government, the general public, and consumer protection organizations. Inspection is a process that begins with the production of goods and/or services and ends with their sale. Inspection is done by inspecting, testing, or studying goods and/or services that are thought to be safe for consumers, safety, and health. So, when viewed from the perspective of rights and responsibilities in that the community as consumers must be protected by the government, this is in line with the provisions of Article 29 of Law Number 8 of 1999 concerning Consumer Protection which states as follows:

1.) *The government is responsible for developing the implementation of consumers protection which guarantee the rights of the consumers and entrepreneurs and the implementation of the obligations of the consumers and entrepreneurs*
2.) *Development to implement the consumers protection as intended by Section 1 above shall be carried out by the Minister and/or technically related ministers.*
3.) *The ministers as intended by Section 2 above shall coordinate the implementation of the consumers' protection*
4.) *Development to implement the consumers protection is intended by Section 2 above shall include the effort to:*
    a. *create the business climate and the develop a healthy relationship between the entrepreneurs and consumers;*
    b. *develop non-governmental, consumer protection foundations;*

c. *improve the quality of the human resources and to increase the research and development activities in the consumer protection sector.*

5.) *Provisions regarding the development to implement consumer protection shall be further regulated by Government Regulations.*

The authority to direct and oversee a variety of community activities is used to carry out government duties aimed at expanding and improving the welfare of the society. Government oversight is crucial because it helps determine the activities that are carried out by the community and how those activities are progressing and having an effect on the community.

1. The Role of Government Consumer Protection Institutions

The government's role in protecting consumers is demonstrated by establishing Consumer Protection Institutions which have their own roles in terms of consumer protection.

a. National Consumer Protection Agency.

It is a government-created entity that reports directly to the president and was established in 2004. The duties of the National Consumer Protection Agency include reviewing various consumer protection policies, compiling and providing advice and recommendations to the government, disseminating information through the media regarding consumer protection and disseminating partiality towards consumers, and receiving complaints from the public.[48]

[48] Dr. Yusu Shofie, " Tugas dan Fungsi Badan Perlindungan Konsumen Nasional (BPKN)", https://www.hukumonline.com/klinik/a/tugas-dan-fungsi-badan-perlindungan-konsumen-nasional-bpkn-lt5ee046de7671e/, accessed February 12, at 16.30 WIB

b. Non-Governmental Organization for Consumer Protection

Article 44 paragraph (3) of the Consumer Protection Act describes the function of non-governmental consumer protection institutions in defending customers against drug sellers online. Non-governmental Consumer Protection Institutions can disseminate information to increase awareness of consumer rights and obligations and carefulness in consuming goods and/or services; provide advice to consumers who need it; cooperate with relevant agencies in implementing consumer protection; assist consumers in fighting for their rights, including receiving consumer complaints or complaints; carrying out joint supervision of the government and the public on the implementation of consumer protection.

c. Indonesian Consumers Foundation

The role of the Indonesian Consumers Foundation in protecting consumers according to Indah Sukmaningsih is "to make conditions more favorable for consumers' conditions with the results of surveys and research conducted, try to change the situation through dialogue with decision-makers and also help consumers to solve problems when dealing with the government bureaucracy.[49]

[49] Celina Tri Siwi Kristiyanti, *Hukum Perlindungan Konsumen*, dikutip dari Indah Sukmaningsih, 1998, *Dimensi Pelayanan Publik dalam Masalah Perlindungan Konsumen, dalam Percakapan tentang Pendidikan Konsumen dan Kurikulum Fakultas Hukum*, YLKI USAID, Jakarta, 1998, page. 38

d. Consumer Dispute Resolution Agency

Article 52 of the Consumer Protection Act lists the responsibilities and authority of the Consumer Dispute Settlement Agency. The Consumer Protection Act's paragraphs (1), (2), and (3) are all found in Article 54. When resolving consumer disputes, the Consumer Dispute Settlement Agency is created by an assembly of at least three (three) members aided by a clerk. The Consumer Dispute Settlement Agencies Council ruling is definitive and enforceable. Both administrative and criminal penalties are applied for breaches of the Consumer Protection Act. The existence of these two penalties is anticipated to have a dissuasive impact - preventing further consumer rights violations and ensuring that consumers receive their legal entitlements.

C. Theory of Legal Protection

1. Definition of Legal Protection

Linguistically, the words "protection" and "protection" have the same components: (1) actions of protection; (2) parties who provide protection; and (3) methods of providing protection. As a result, the term "protection" has a defined meaning, namely, an act of protection or an act of defending particular parties targeted at particular parties using

particular methods.[50] One of the most crucial elements of a system of law is legal protection. This is significant because when a state is created, the rules that govern each of its citizens are also created. A legal relationship results in legal security. Interactions between legal topics that are relevant to or have an impact on the law are referred to as legal relations (the emergence of rights and obligations).[51]

Protection, in its broadest sense, refers to the desire to defend something against threats that are harmful or generally more negative in nature. This something could take the form of a person's interests, objects, or tangible goods. Additionally, security can refer to defense offered by an individual to another who is weaker. According to the Legal Dictionary, the definition of law is "compelling regulations that determine human behavior in society, which are made by obligatory official bodies, and violations of these regulations result in particular actions taken".[52] The law itself possesses coercive powers that are recognized by the state to be permanently enacted. It differs from temporary security provided by other institutions, such as economic or political protection.[53]

---

[50] Wahyu Sasongko, *Ketentuan-ketentuan Pokok Hukum Perlindungan Konsumen. Universitas Lampung*, Bandar Lampung, 2007, page. 30

[51] Soeroso, *Pengahantar Ilmu Hukum*, Ctk. Kedelapan, Sinar Grafika, Jakarta, 2006, page. 49

[52] R. Subekti dan Tjitrosoedibio, *Kamus Hukum*, Pradnya Paramita, Jakarta, 1999, page. 49.

[53] Wahyu Sasongko, *Loc.Cit*

The definition of legal protection includes the defense of dignity as well as the acknowledgement of human rights the legal subjects have based on arbitrary legal provisions that serves as a set of guidelines or regulations that can shield one object from another.[54] According to the Big Indonesian Dictionary (KBBI), legal protection refers to both protective actions (things, etc.) and a sanctuary. Similarly, in the linguistic term, legal protection includes the act of protecting and the means of protecting.[55]

According to Satjipto Rahardjo, legal protection is protecting human rights (HAM) that are harmed by other people and this protection is given to the community so that they can enjoy all the rights granted by law.[56]

Phillipus M. Hadjon also asserts that the protection legislation for the people is a preventive and oppressive government measure. Repressive legal protection aims to prevent disputes from happening, including by handling them in the courts. Preventive legal protection urges government actions to be cautious in making decisions based on discretion.[57]

The word "rule of law," which is a translation of the two terms "rechstaat" and "rule of law," refers to the idea of legal protection, which

---

[54] Philipus M. Hadjon, *Perlindungan Hukum Bagi Rakyat Indonesia*, Bina Ilmu, Surabaya, 1987, page. 25

[55] Kamus Besar Bahasa Indonesia (KBBI), Edisi Kedua, Cet. 1, (Jakarta: Balai Pustaka), page. 595

[56] Satjipto Raharjo, *Ilmu Hukum*, PT. Citra Aditya Bakti, Bandung, 2000, page. 69

[57] *Ibid*, page. 54

is inseparabale from the defense of human rights in the Unitary State of the Republic of Indonesia. As a result, the Republic of Indonesia's 1945 Constitution clarified that "The State of Indonesia is based on law, (rechtsstaat), not based on mere power (Machtsstaat)" before it was amended. With several current regulations, legal protection can be seen as an attempt to defend the government or authorities. In other words, the realization of the role of legislation in ensuring protection is what is meant by legal protection. The basis for Indonesia's legal protection principles is Pancasila, the country's doctrine and philosophy, which is based on the ideas of Rechstaat and the Rule of Law. Thus, the Pancasila-based concept of legal protection of human dignity is at the center of Indonesian legal protection.

Protection can be said as legal protection if it contains the following elements:

a. There is protection from the government for its citizens.
b. Guarantee of legal certainty.
c. Concerning the rights of citizens.
d. There are penalties.

All people have a right to protection under the law, as mentioned in Article 28D, paragraph 1 of the 1945 Constitution, which states that everyone has a right to recognition and equal protection under the law. Law enforcement must be enacted for legal protection to take effect because they are intertwined and cannot exist separately. The legal protection provided by the law is an instrument, and the steps taken to execute the instrument are law enforcement.

In Islam there is a theory called the Muqāsid al-Syarī'ah theory from Jasser Audah which is a form of legal protection in Islam. The theory of Muqāsid al-Syarī'ah has a perspective of necessity (basic classical classification) which has been divided into 5 (five) by scholars, namely Hifz al-Dīn (maintenance of religion), Hifz al-Nafs (maintenance of life), Hifz al-Māl (maintenance of property), Hifz al-'Aql (maintenance of reason), Hifz al-Nasl (maintenance of offspring), some scholars add Hifz al-'Ird (maintenance of honor).[58] According to 'Auduh, maintaining these five (or six) things is a must, if human beings intend a better life. Especially in the matter of protecting consumer rights, Muqāsid al-Syarī'ah applies in terms of necessity, namely Hifz al-Māl (maintenance of assets).

2. Forms or Means of Legal Protection

A rule of law is an idea that all people agree upon. Legal protection serves as an example of how the legal system works to achieve its three main goals - justice, benefits, and legal certainty. In terms of enforcing legal regulations, legal protection is essentially classified into two types of security - preventive legal protection and repressive legal protection. Legal protection is a type of defense provided to legal subjects through preventive and repressive legal tools, both written and unwritten.

1. Preventive Law

[58] Jaser ‘Audah, *Al-Maqashid untuk Pemula*, Suka Pres, Yogyakarta, 2013, page. 8

Government-sponsored protection is meant to stop breaches before they happen. Laws and regulations contain this aiming at preventing a violation and providing rules or restrictions when performing a duty.

As preventive legal protection encourages the government to exercise caution when making choices based on discretion, it is crucial that the government actions are based on freedom of action. There is no particular law governing preventive legal protection in Indonesia.

2. Repressive Law

Repressive legal protection is the final protection in the form of sanctions such as fines, imprisonment, and additional penalties given when a dispute has occurred or a violation has been committed.[59] The legal protection that is oppressive seeks to settle conflicts. This category of legal security includes the administration of legal protection by the General Courts and Administrative Courts in Indonesia.

The principle of legal protection against government actions is based on the concept of acknowledging and protecting human rights, which aims to limit and impose obligations on the society and the government. The rule of law principle, which refers to the

[59] Soerjono Soekanto, *Pengantar Penelitian Hukum*, Ui Press, Jakarta, 1984, page. 133

acknowledgment and protection of human rights and has primary status and can be connected to the aim of a rule of law, is the second principle that underlies legal protection against actions of the government.

Legal protection is an illustration of how the law works to accomplish legal goals, such as fairness, interests, and legal certainty. In detail, legal protection is an attempt to protect the legal subject in the form of legal instruments, whether preventive or repressive, whether written or unwritten. .

CHAPTER III
CONSUMERS PROTECTION AGAINST THE USE OF SYRUP DRUGS CONTAINING ETHYLENE GLYCOL AND DIETHYLENE GLYCOL EXCEEDING THE SAFE THRESHOLD

A. Consumer protection against the use of syrup drugs containing ethylene glycol and diethylene glycol exceeding the safe threshold

1. Case Overview

From the case, it was believed that a syrup drug from the Gambia in Africa that resulted in kidney failure in an infant contained hazardous ingredients leading to kidney failure. The drug also had several side effects, one of which was death. Beginning in September 2022, health authorities in the West African nation of Gambia looked into the possibility that the use of paracetamol syrup for fever, cough, cold, and pain may have contributed to hundreds of infant fatalities from acute renal damage. According to the WHO, 66 kids in The Gambia died after consuming cough syrup leading to acute renal injury because of poisonous chemical pollution. All of the kids who had taken the cough and cold medication experienced problems passing urine.[60]

By the end of July 2022, physicians observed an increase in the frequency of severe kidney injuries in children under the age of five, and they suspected a link with medication. The United Nations health office examined samples of all four products, and the findings revealed that diethylene glycol (DEG) and ethylene glycol were present in

[60] Abdul Rahman A. Saied et.al, Gambian children's deaths due to contaminated cough syrups are a mutual responsibility, *International Journal of Surgery*, 2022, page. 115,

unacceptable quantities.[61] Acute kidney injury, which is characterized by oliguria (low urine output) or anuria and progresses over 1-3 days to renal failure, is the most consistent manifestation in patients with DEG poisoning. Other signs and symptoms include altered mental status, headache, and gastrointestinal symptoms (indicated by elevated serum creatinine and blood urea nitrogen.)[62] Therefore, WHO issued a global medical product warning for four syrup-based drugs made by Maiden Pharmaceuticals on October 5, 2022.

On October 18, news from Indonesia revealed that 99 of 206 adolescents in 20 various areas who had acute renal failure had died. That figure was anticipated to increase further as the health ministry continued to look into the illegal medicinal syrups sold in the nation.[63] The public believed that the Food and Drug Supervisory Agency (BPOM) had lost the battle over liquid drug regulation. Consequently, people worried, particularly parents who were hesitant to give their children syrup medication. It was also claimed that the Food and Drug Supervisory Agency mishandled pre-market and post-market oversight, or the period before and after the medicines are placed on the market. The public felt disappointed by business actors and the government, who were not professional at performing their duties. So, the public urged the

[61] Hitesh Chopra et.al, Cough syrups: silent killer of Gambian children, *International Journal of Surgery*, BGC Trust University Bangladesh, 2023, page. 150

[62] Parsa Bastan et.al, Acute Kidney Injury Among Children Likely Associated with Diethylene Glycol–Contaminated Medications — The Gambia, Vol. 72 No. 9, 2023, page. 220

[63] Hitesh Chopra et.al, *Op.Cit*, page. 151

Ministry of Health to revoke the distribution permits of syrup drugs that have dangerous ingredients.[64]

Authorities in the Gambia estimated the mortality rate at about 90%, while estimates from Indonesia placed it at about 61.4%. Even in critical care units, these mortality rates for pediatric patients with acute renal injury were considerably greater than those earlier documented (6.4%–32.3%).[65] Budi Gunadi Sadikin, the minister of health, explained why children's syrup medication consumption was currently an issue. Children who consumed this syrup medication were exposed to impurities or pollution, which caused unusual progressive acute renal diseases. Raw resources were primarily to blame. A total of 189 cases of toddlers under the age of five were typically affected by acute renal failure. Eleven juvenile patients were examined at Cipto Mangunkusumo Hospital (RSCM), and seven of them tested positive for harmful substances like ethylene glycol (EG) and diethylene glycol (DEG).

In the liquid raw materials used to make syrup medications, impurities like ethylene glycol (EG) and diethylene glycol (DEG) are common. Alternatively, it can be described as chemicals such as ethylene glycol and diethylene glycol, which can be poisonous if their

[64] Neneng Putri Siti Nurhayati et.al, Pemasaran Obat Dalam Usaha Farmasi: Persoalan Profesionalisme dan Etika Bisnis, *Jurnal Kajian Kontemporer Hukum dan Masyarakat*, vol. 1 no.1, 2023, page. 10

[65] Uber AM and Sutherland MS, Acute kidney injury in hospitalized children: consequences and outcomes, Pediatr Nephrol, 2018, page. 217

dose is higher than what WHO recommends. These chemicals can cause harms starting from digestive problems to the most serious of all, acute renal failure. Propylene glycol or glycerin is typically used in Indonesia to make medications that are badly soluble in water, such as Paracetamol, to be more soluble. These compounds may be impurities in the propylene glycol or glycerin raw materials. The Ministry of Health has set a minimum limit of 0.5 mg/kg BW per day for the intake of ethylene glycol and diethylene glycol. Around 72 hours after intake, these chemicals typically start to have toxic effects on the body.[66] The main factor in determining the danger of DEG/EG is their metabolite glycolaldehyde, which can impair a variety of cellular metabolic processes while also escalating cellular harm.

According to the investigation's findings, up to 91% of EG and DEG pollutants were found in CV Samudra Chemicals syrup for the medication solvent distributed to the pharmaceutical business. In actuality, only 0.1 percent of EG and DEG pollution was safe for liquid medications.[67]Additionally, the data gathered indicates that this contaminated liquid medication has caused deaths. According to information gathered, up to 199 children died due to liquid syrup medications that were tainted with ethylene glycol (EG) and diethylene

[66] Eva Sartika Dasopang et.al, Sosialisasi Kepada Masyarakat Tentang Membeli Dan Menggunakan Obat Secara Aman Di Kelurahan Sumber Karya, Kecamatan Binjai Timur, *Jurnal Pengabdian Masyarakat Tjut Nyak Dhien*, Vol. 2 No.1, 2023, page. 95

[67] Administratos, "Sanksi Hukum bagi Pelaku Kasus Gagal Ginjal", https://www.indonesia.go.id/kategori/editorial/6650/sanksi-hukum-bagi-pelaku-kasus-gagal-ginjal?lang=1, accessed March 19th 2023, at 17.00 WIB

glycol (DEG). Data from the Ministry of Health as of November 16, 2022 show that 324 toddlers were among the casualties who had acute renal failure.[68]

2. Consumer protection against the use of EG and DEG syrup drugs

Acute kidney failure is a condition in which the kidneys suddenly become damaged and are unable to function normally. As a result, the kidneys are unable to balance water and electrolytes, unable to remove metabolic waste from the body, and unable to remove waste that cannot be excreted from the body. This disease typically develops as a result of other severe problems that are discovered in the urine.[69]

The excessive use of diethylene glycol and ethylene glycol can cause acute kidney failure in infants, leading to death. When these two substances reach the body, they are oxidized by enzymes and transform into glycol aldehydes, glycol oxalic acid, and then back into oxalic acid. Kidney stones develop as a result of this oxalic acid. This oxalic acid will turn into sharp spikes crystalline forms if it crystallizes. When it reaches the kidneys, kidney stones will form. The kidneys will then become injured by the pointed stones. The effects will be serious if this disease affects infants who also happen to have reduced renal sizes. In

[68] Nomensen Freddy Siahaan, Consumer Protection Against the Production and Sale of Syrup Drugs Suspected of Being Contaninated with Hazardous Materials, *Journal of Social Research*, Universitas Mulawarman, 2023, page. 751

[69] Endang Naryono, Kids Killer Drug, Pasim College of Economics, page. 2

addition to having an impact on the organs, contact to the heart can also hasten demise.[70]

Decision Number 106/PUU-XX/2022 states that the regulations regarding sanctions for criminal acts against pharmaceutical preparations as regulated in Article 196 of Law Number 36 of 2009 concerning Health (Health Law) do not violate the 1945 Constitution. Article 196 of the Health Law, which according to The Petitioner is deemed to be in conflict with Article 28A, Article 28G paragraph (1), and Article 28I paragraph (1) of the 1945 Constitution, which contains a fundamental difference between the concepts of extraordinary crimes and extraordinary events. This is reinforced by the fact that the Health Quarantine Law regulates the types of health emergencies and mechanisms for handling them. The Court did not find sufficient evidence regarding the extraordinary circumstances mentioned. This is because in the concrete case discussed by the Petitioner, the Government has taken various steps, including withdrawing all medicinal syrup from the public, issuing Decree of the Director General of Health Services Number HK.02.02/I/3305/2022, and (SE) Number SR. 01.05/III/3461/2022.[71]

[70] BEM Farmasi UAD, "Obat Sirup Membuat Gagal Ginjal Pada Anak?", http://bem.ffarmasi.uad.ac.id/obat-sirup-membuat-gagal-ginjal-pada-anak/, accessed March 19 2023, at 18.00 WIB

[71] Mahkamah Konstitusi Indoensia Lembaga Negara Pengawal Konstitusi, "Aturan Sanksi Tindak Pidana Kejahatan Terhadap Sediaan Farmasi Konstitusional" https://www.mkri.id/index.php?page=web.Berita&id=18807, accessed October 23 2023, at 01.06 WIB

By releasing Circular Letter (SE) Number SR.01.05/III/3461/2022 regarding Obligations for Epidemiological Investigation and Reporting of Atypical Progressive Acute Kidney Injury Cases in Children, the Ministry of Health of the Republic of Indonesia attempted to address this issue. In the circular letter, which was signed by the director general of health services, there are nine (9) points about precautions to take if acute renal issues occur. One of the key messages in this circular letter is that parents who have already given their children sugar should stop giving it to them and instead bring them to hospitals or other healthcare centers.[72]

Decree of the Director General of Health Services Number HK.02.02/I/3305/2022 concerning the Administration and Clinical Management of Atypical Progressive Acute Kidney Injury in Children in Health Service Facilities.

In following the laws and regulations, Consumer Protection must have a guarantee of legal certainty provided to consumers, in this case, a guarantee of the safety of syrup drugs on the market so that they are safe for consumers to consume, as stated in Article 3 of Law Number 8 of 1999 concerning Consumer Protection.[73]

According to the WHO material, the medication syrup for kids comprises Promethazine Oral Solution, Kofexmalin Baby Cough Syrup,

[72] Surat Edaran SR.01.05/III/3461/2022, Kewajiban Penyelidikan Epidemiologi dan Pelaporan Kaus Gangguan Ginjal Akut Atipikal (Atypical Progressive Acute Kidney Injury) Pada Anak

[73] Nomensen, *Op.Cit*, page. 752

Makoff Baby Cough Syrup, and Magrip N Cold Syrup. These four goods were created by the Indian company Maiden Pharmaceuticals Limited. According to the National Agency for Drug and Food Control's inquiries, none of the four products have been registered with the agency up to this point, and neither are registered in Indonesia.[74]

The WHO claims that the syrup drug products failed to adhere to the qualifications and specs for secure drugs, posing a risk to public health. In this case, National Agency for Drug and Food Control removed 5 (five) syrup drugs from circulation because they were thought to contain contaminants of ethylene glycol (EG) and diethylene glycol (DEG) that were above the threshold. After conducting sampling and testing expansion on 36 samples of 26 over-the-counter syrup medications[75], the National Agency for Drug and Food Control then rediscovered 3 (three) drug products that contained ethylene glycol (EG) and diethylene glycol (DEG) contaminants above the threshold, making a total of 8 (eight) drugs removed from distribution of drug syrup throughout Indonesia.[76]

---

[74] BPOM, "Penjelasan BPOM RI Tentang Sirup Obat Untuk Anak Di Gambia, Afrika Yang Terkontaminasi Dietilen Glikol Dan Etilen Glikol", https://www.pom.go.id/new/view/more/klarifikasi/155/Penjelasan-BPOM-RI-Tentang-Sirup-Obat-Untuk-Anak-Di-Gambia--Afrika-Yang-Terkontaminasi-Dietilen-Glikol-Dan-Etilen-Glikol.html , accessed March 19th at 19.00 WIB

[75] BPOM, "Informasi Keempat Hasil Pengawasan Bpom Terhadap Sirup Obat Yang Diduga Mengandung Cemaran Etilen Glikol (EG) dan Dietilen Glikol (DEG)", https://www.pom.go.id/new/view/more/klarifikasi/158/INFORMASI-KEEMPAT-HASIL-PENGAWASAN-BPOM-TERHADAP-SIRUP-OBAT-YANG-DIDUGA-MENGANDUNG-CEMARAN-ETILEN-GLIKOL--EG--DAN-DIETILEN-GLIKOL--DEG-.html, accessed May 6th 2023, at 20.00 WIB

[76] Redaksi CNN, "Daftar 7 Obat Sirop dengan Kandungan EG dan DEG Melebihi Ambang Batas", https://www.cnnindonesia.com/nasional/20221102095625-20-

1) Termorex Syrup (fever medicine), box packaging and plastic bottle @ 60 ml, produced by PT. Konimex.
2) DMP Flurin Syrup (cough and flu medicine), box packaging, and plastic bottles @ 60 ml, produced by PT. Yarindo Farmatama.
3) Unibebi Cough Syrup (cough and flu medicine), packaged in a plastic bottle size @ 60 ml, produced by Universal Pharmaceutical Industries
4) Unibebi Fever Syrup (fever medicine), packaged in a box and a plastic bottle measuring @ 60 ml, produced by PT. Universal Pharmaceutical Industries
5) Unibebi Fever Drops (medicine for fever), in a box and plastic bottle @ 15 ml, PT. Universal Pharmaceutical Industries
6) Paracetamol Drops, PT. Afif Farma
7) Pharmaceutical Industry Paracetamol Syrup (mint flavour), PT. Afif Farma
8) Pharmaceutical Industry Vipcol Syrup, PT. Afi Farma Pharmaceutical Industry

The National Agency for Drug and Food Control also found 6 (six) pharmaceutical companies producing medicinal syrups with levels of EG/DEG contamination that exceed the safe threshold. The six companies are:[77]

1. PT Yarindo Farmatama (PT YF).
2. PT Universal Pharmaceutical Industries (PT UPI).
3. PT Afi Farma (PT AF).
4. PT Ciubros Farma (PT CF).
5. PT Samco Farma (PT SF).
6. PT Rama Emerald Multi Sukses (PT REMS).

PT Yarindo Farmatama and PT Universal Pharmaceutical, two of the six businesses, have been identified as suspects. According to Law No.

868401/daftar-7-obat-sirop-dengan-kandungan-eg-dan-deg-melebihi-ambang-batas, accessed May 6th 2023, at 20.30. WIB

[77] BPOM, Penjelasan Bpom Ri Nomor Hm.01.1.2.12.22.188 Tanggal 22 Desember 2022 Tentang Tindak Lanjut Investigasi Dan Pengawasan Bpom Terhadap Sirup Obat Yang Tidak Memenuhi Syarat Pada 6 (Enam) Industri Farmasi", https://www.pom.go.id/new/view/more/klarifikasi/169/PENJELASAN-BPOM-RI-NOMOR-HM-01-1-2-12-22-188-TANGGAL-22-DESEMBER-2022-TENTANG-TINDAK-LANJUT-INVESTIGASI-DAN-PENGAWASAN-BPOM-TERHADAP-SIRUP-OBAT-YANG-TIDAK-MEMENUHI-SYARAT-PADA-6--ENAM--INDUSTRI-FARMASI.html, accessed May 6th 2023, at 21.00 WIB

8 of 1999 Concerning Consumer Protection Article 4(a), which states that "Consumer rights include the right to convenience, security, and safety in consuming goods/services," pharmaceutical firms are required to keep consumer safety. The public believes that there has been a violation of marketing business ethics and expertise as well as the right to personal safety if Article 4(a) is connected to the events.

The purpose of consumer protection legislation is to safeguard consumers, specifically the buyer's physical and social economy. Customers connect to the protection and safety of their body and/or spirit when using consumer products or services in a physical sense. In the meantime, every customer can achieve the best outcomes in socio-economic terms by making the most of their financial resources to meet their basic requirements.[78]

The kidney failure occurred as a result of inadequate oversight when drug delivery permits were granted, and many commercial players who provided dosages in an unethical manner were still found. Safety supervision is therefore required. Even without considering the casualties, those who purchased and consumed should earn accountability from offenders.

Pursuant to Article 1365 of the Civil Code, every unlawful act that causes damage onto another person obliges the wrongdoer to

[78] Husni Mubaraq et.al, Analisis Perlindungan Hukum Bagi Konsumen Terhadap Peredaran Obat-Obatan Ilegal Menurut Undang Undang Nomor 8 Tahun 1999 Tentang Perlindungan Konsumen(Lembaran Negara Republik Indonesia Tahun 1999 Nomor 42), 2021, page. 7

compensate such damage. The actions referred to in Article 1365 of the Civil Code can be carried out by anyone. People are legal subjects who have rights and obligations.[79] Legal entities as legal subjects include Limited Liability Companies (PT), Commanditaire Vennootschap (CV), and State Institutions. National Agency of Drug and Food Control as government representative and PT. Pharmaceutical companies can be considered legal entities because they can carry out civil legal acts. The Civil Code is very clear that every person, including public legal entities, namely the National Agency of Drug and Food Control, must provide compensation because his negligence resulted in harm to other people.

Business actors are required to provide accurate and straightforward information about the product's makeup, ensure the quality of the products, and offer recompense if the product causes harm to customers, according to Article 7 of the Consumer Protection Act. Unfortunately, the commercial actors, in this case, failed to uphold their duties when the syrup drugs resulted in fatal acute kidney failure in children. They produced drugs by ignoring appropriate quality standards and not complying with the provisions of the laws and regulations. Based on a National Agency for Drug and Food Control inquiry, the Ministry of Health, working with the authorities,

[79] Allan Mustafa Umami, Tanggung Gugat Keperdataan Badan Pengawas Obat Dan Makanan (Bpom) Indonesia Dalam Peredaran Obat-Obatan Yang Menyebabkan Gagal Ginjal Akut Pada Anak, *Journal of Notary Treatise*, Volume 4, No. 1, 2023, page. 384

discovered evidence that commercial players creating children's syrup medications used a combination of unhealthy substances over the safe limit.[80]

According to Article 46 of the Consumer Protection Law concerning Lawsuits for Violations by Business Actors, which states that lawsuits for violations by business actors can be carried out by a group of consumers who have the same interests - typically called a class action lawsuit - victims can file civil lawsuits in the case of syrup drugs containing excessive ethylene glycol (EG) and diethylene glycol (DEG). The class action letter refers to the requirements stipulated in the applicable Civil Procedure, and must contain:

1. It has a large number of members because if a lawsuit is filed separately or together in one case it is not effective and efficient.
2. There are similarities in facts or events, substantive legal basis used, and similar types of claims between Group Representatives and Group Members;
3. Same Type, must have the same type of demands from all members represented.
4. An honest group representative. The group representative is honest and serious about protecting the interests of the group members he represents.

The victim's family, which consists of 3 groups, took the initiative by bringing the group's case to court regarding the losses they suffered, both material and immaterial. In Case Number 771/Pdt.G/2022/PN

[80] Mohd. Yusuf DM et.al, Pertanggungjawaban Hukum Bagi Produsen Obat Sirup Mengandung Etilen Glikol (EG) Dan Dietilen Glikol (DEG) Penyebab Ginjal Akut Progresif Atipikal (GgGAPA) Pada Anak, *Journal of Education and Counseling*, Vol.5 No.1, UniversitasPahlawan Tuanku Tambusai, 2023, Page. 99

Jkt.Pst at the Jakarta District Court, with 10 defendants (Food and Drug Supervisory Agency, Minister of Health, PT. Mega Setia Agung Kimia, CV. BUDIARTA, PT. Logicom Solution, CV. Mega Integra, PT. Tirta Buana Kemindo, CV. Samudera Chemical, PT. Universal Pharmaceutical Industries, and PT. Afi Farma Pharmaceutical Industry) and 1 co-defendant namely the Ministry of Finance of The Republic of Indonesia. This class action lawsuit was declared valid by the judge filed by the plaintiff because it complied with Article 1 letter a, Article 2, and Article 3 of the Republic of Indonesia Supreme Court Regulation No.1 of 2002 concerning Procedures for Group Lawsuits.

Article 8 is one of the articles that has been violated; it forbids business actors from creating and/or exchanging products and services that do not follow standards. The standards refer to the criteria established by the National Agency for Drug and Food Control in the context of narcotics (BPOM). The other standards are the provisions in producing drugs that comply with quality standards and are not a health hazard to consumers as stipulated in Article 8 paragraph (1) letter c of Law No. 8 of 1999 concerning Consumer Protection regarding "actions for business actors who are prohibited from trading goods or services that are not in accordance with the size, dosage, weight and amount calculated according to what they should be."

The main goal of consumer legal protection is to safeguard customers' legal entitlements to products and/or services. As stated in

Article 4 of Law No. 8 of 1999 Concerning Consumer Protection, consumers have the following rights:

a. The right to comfort, security and safety in using goods and/or services;
b. The right of choosing goods and/or services and obtaining the said goods and/or services in accordance with the exchange value and condition and guarantee pledged;
c. The right to correct, clear and honest information about the condition and guarantee of the goods and/or services;
d. The right that their opinions and complaints about goods and/or services used should be listened to;
e. The right of obtaining advocacy, protection and an endeavor to properly settle disputes over consumers' protection;
f. The right of obtaining consumers' fostering and education;
g. The right of being correctly, honestly and indiscriminatory treated and served;
h. The right of obtaining compensation and or refund if the goods and/or services received do not conform to the agreement or are not as they should be;
i. The rights regulated in other laws.

As previously mentioned in connection to the syrup drug case, there are several customer rights that business actors fail to uphold. These rights include first, the right to comfort, security, and safety when consuming products and/or services; second, the right to receive compensation.

In this instance, the National Consumer Protection Agency (BPKN) will also help the victims' relatives in accordance with the legal requirement. The neighborhood is entitled to security from this National Consumer Protection Agency Institute. To help the victims acquire the right to attach compensation, the National Consumer Protection Agency will offer aid or support. A fact-finding committee will be assembled by the agency to look into this situation. In addition, the

agency intends to open physical and online complaint postings as part of its advocacy for consumer rights concerning this syrup medication case.[81]

Rather than resolving by repressive acts, the government should strengthen its preventive duty to prevent cases from arising by conducting inspections on the scope of pharmaceutical companies and the distribution of medicinal drugs in the community. To put it simply, the preventative legal protection can be done by strengthening the government's monitoring function before and during the distribution of the medication to ensure that it does not harm public health. Additionally, the coordination between government agencies on community drug delivery should be improved. Before and after medicine is made available to the public, the National Agency for Medicine and Food Control must improve its quality control. To better coordinate drug delivery in the community, the agency has to work with the Ministries of Industry, Trade, and Health.

[81] Nadya Zahira, "BPKN Berikan Pendampingan Hukum pada Korban Kasus Gagal Ginjal Akut", https://katadata.co.id/tiakomalasari/berita/63639374ca50d/bpkn-berikan-pendampingan-hukum-pada-korban-kasus-gagal-ginjal-akut, accesed March 20, 15.00 WIB

B. The responsibility of business actors and National Agency for Drug and Food Control for syrup drug products containing excessive ethylene glycol (EG) and diethylene glycol (DEG)

1. Accountability Mechanisms of Business actors

There is a type of accountability that should be carried out by business actors, as previously explained. The businesses and people accountable must be held responsible, and the investigation's results must be made public. In this case the business actor referred to is the Pharmaceutical Industry. Pharmaceutical companies, also known as drug companies, are for-profit businesses that concentrate on creating, manufacturing, and selling medicines, particularly those that are beneficial to human health. They can produce both brand-name and cheap medications. Pharmaceutical firms are accountable as business actors if their goods bring harm to customers (product defects). Business actors, such as dealers or producers involved in the pharmaceutical industry must find a suggestion before submitting a process to the Directorate of the National Agency for Drug and Food Control. It is possible to verify that business actors (traders or producers) have effectively followed/carried out their duties in compliance with the provisions of the relevant laws and regulations with the help of the Directorate of the National Agency for Drug and Food Control's suggestion.

Business actors are prohibited from dealing with used, tainted, damaged, or faulty medicinal and food products, with or without giving full information, in line with Article 8 clause (3) of Law No. 8 of 1999 Concerning Consumer Protection.

Pharmaceutical industry participants should be able to perform professionally and improve public health. Players in the pharmaceutical business have a responsibility to ensure that medicines are produced in line with the rules to satisfy safety requirements. In order to help the participants in the pharmaceutical industry find ease in their operations without adding to the primary job of supervision, the National Agency for Drug and Food Control should attempt to offer incentives.[82]

According to Article 24 of the customer Protection Act, business actors who offer products to other business actors are accountable for customer claims for damages or other claims if:

a. other business agents sell the goods and/or services without any changes;
b. other business agents do not know during the transaction that a change has been introduced to the goods and/or services by a business agent or that the goods and/or services do not conform to the specimen, the quality and the composition.

If this occurs, producer accountability (also known as product liability) is required by upholding the rule of total responsibility (strict liability principle). The absolute responsibility principle is the principle that lays the errors on the producers. So, in this principle, the responsibility lies on the producers for defective items without requiring

[82] Endang Naryono, *Op.Cit*, page. 4

customers to provide proof of the errors[83] In essence, the concept of total accountability is employed to trap business actors, particularly those who advertise their goods and bring harm to consumers.

According to Article 19 of the Consumer Protection Act, business actors are responsible for paying the hospital expenses when the victims receive treatment if their errors from the products leading to harm to consumers are proven. Additionally, as has been stressed, specifically:

1) A business agent shall be responsible for providing compensation for the damage, contamination, and/or losses the consumers suffer as a result of using the goods and/or services produced or traded.
2) The compensation as meant in sub-article (1) may be in the form of cash refund or replacement by goods and/or services which are of a similar type or of a comparable value, or health maintenance and/or the provision of compensation pursuant to the applicable laws.
3) The provision of compensation shall be undertaken within an interval of 7 (seven) days from the date of transactions.
4) The provision of compensation as meant in sub-articles (1) and (2) shall not abolish the possibility of a criminal lawsuit on the basis of further verification of a mistake.
5) The provisions as meant in sub-articles (1) and (2) shall not apply if the business agent can prove that the mistake is that of the consumer.

Compensation for harm, pollution, and customer losses is one of the clauses of Article 19. The loss in issue in this instance is tangible. Business actors should be liable for all losses the customers suffer since there are other grounds for their liability besides the sale of defective goods.

[83] Inosentius Samsul, Perlindungan Konsumen, Kemungkinan Penerapan Tanggung Jawab Mutlak, Universitas Indonesia, Jakarta, 2004, hlm 92-96

The business player (pharmacy) in this scenario is in charge of paying compensation for using risky medicines. Health care benefits or pay in accordance with relevant laws and rules are both acceptable forms of compensation. The compensation may include paying medical bills when the customer is ill, and if the customer dies in the end, the business actor is obliged to pay death compensation to the child's parents.

Investigations of the children's syrup drug case that resulted in acute kidney failure by the National Agency for Drug and Food Control and the police into found that 2 (two) pharmaceutical companies allegedly violated the law by mixing the ingredients for drugs that endanger health. In this situation, the two pharmaceutical firms must answer for their deeds according to the applicable law. The responsibility in issue entails the duty to prevent loss and harm, to prevent loss and pollution, and to prevent loss to consumers.[84] Pharmaceutical firms bear full and sole accountability for this children's syrup medication under the law (strict liability).[85]

The provisions in Article 19 are also intended to require producers, who are business actors, to offer compensation in the form of refunds, replacement of goods, treatment, or compensation if a consumer suffers from loss in the form of damage, pollution, or financial or health losses

[84] Mohd. Yusuf DM et.al, *Op.Cit*, 2023, Page. 100
[85] Yudha Hadian N. dan Dwi Wahyuniarti P., *Op.Cit*, page. 182

as a result of consuming the products.[86] The provision of compensation by business actors is carried out within a maximum period of seven days after the date of the transaction.

Additionally, businesses are expected to abide by laws governing the manufacture and distribution of medicines in accordance with predetermined standards. This includes both makers and associations of pharmaceutical firms. Similar to offline sales organizations, online sales associations should play a more active role in monitoring and reducing drug sales material that the government categorizes illegal. Drug businesses must continue to make and market drugs in accordance with predetermined drug standards in order to prepare for the possibility of scarcity and high prices of pharmaceutical preparations.[87]

2. Accountability Mechanisms for National Agency for Drug and Food Control (BPOM)

In the case of syrup medicine, beside commercial actors, the National Agency for Drug and Food Control should also be held accountable because the Agency also contributed to a causal factor, namely the regulation of the distribution of food and drugs. Without the National Agency for Drug and Food Control, drugs cannot be distributed. As the

[86] Janus Sidabalok, *Hukum Perlindungan Konsumen di Indonesia*, PT Citra Aditya Bakti, Bandung, 2006, page. 95

[87] M. Agus Yozami, "Kemendag Akan Atur Importasi Bahan Baku Obat Penyebab Terjadinya Gagal Ginjal Akut", https://www.hukumonline.com/berita/a/kemendag-akan-atur-importasi-bahan-baku-obat-penyebab-terjadinya-gagal-ginjal-akut-lt63687d956c72f?page=3#!, accessed March 17 2023, at 19.00 WIB

drugs lead to serious risks to children, the agency should be held accountable for negligence.

Drug and food control is a policy or program that affects numerous sectors, both public and private, so it is important to create an environment that fosters cooperation, communication, the dissemination of knowledge, and education. The industries should also supervise the entire supply chain, from the inspection of raw materials and production processes to the final distribution of the product to the community.[88]

The National Agency for Drug and Food Control did not actively test, monitor, or control drugs marketed, regardless of whether there were reports from pharmaceutical companies regarding the drug ingredients used. The National Agency for Drug and Food Control also did not control the distribution permits of pharmaceutical companies and the distribution of raw materials for medicinal syrups used over the last 3 years.[89]

The National Agency for Drug and Food Control is actually accountable for carrying out its responsibilities as the supervisor over the distribution of drugs and food and for advising commercial players, as this institution is the leading sector in the field of drug control. Consumer protection is partially provided by the National Agency for

[88] Endang Naryono, *Loc.Cit*

[89] https://nasional.kompas.com/read/2022/11/14/18550811/bpkn-ungkap-kesalahan-sistemik-di-bpom-hingga-sebabkan-ratusan-pasien-gagal, accessed August 2nd 2023, at 20.00 WIB

Drug and Food Control's oversight of food goods.[90] The Agency has established a comprehensive system for drug and food control, which includes pre-market and post-market supervision and standardization, with the specific tasks of creating standards, regulations, and policies about drug and food control.[91] These initiatives are made in order to accomplish and improve its responsibility for safeguarding the public from the distribution of medications that do not follow quality, regulatory, and safety standards.

One of the responsibilities of the National Agency for Drug and Food Control is also contained in Health Law no. 36 of 2009 articles 178 and 182 concerning Guidance and Supervision.

Article 178

"The Government and regional government shall provide guidance to the public and each executive of activities relating to health resources in the field of health and health efforts."

Article 182 states that:

1.) *The Central Government or Regional Governments in accordance with their authority shall supervise the community and every organizer of activities related to resources in the health sector and health efforts based on norms, standards, procedures and criteria stipulated by the Central Government.*
2.) *The Central Government or Regional Government in accordance with their authority in carrying out supervision can issue Business Permits for each implementation of health efforts*

[90] Setiawan, D., Tugas Dan Wewenang Balai Besar Pengawasan Obat Dan Makanan Dalam Mengawasi Makanan Yang Mengandung Zat Berbahaya, *Journal of Business Law*, Vol.4 No.2, Universitas Narotama Surabaya, 2020, page. 425

[91] Endang Naryono, *Op.Cit*, page. 3

based on norms, standards, procedures and criteria stipulated by the Central Government.

3.) *The Central Government in carrying out supervision can delegate its supervision task to Regional Governments and involve the community.*

In this situation, all pharmacies and drug shops are subject to stringent regulation and oversight. In order to determine whether there was negligence or deliberate behavior, the parties bringing medicinal raw materials into Indonesia will also be investigated. In addition, the National Agency for Drug and Food Control continues to conduct research by evaluating drug syrup, a process that is continuous and exhaustively carried out. The Agency reports that there are still quite a few medicines that need to be evaluated. This will continue to be investigated. Penny K. Lukito, the head of the National Agency for Drug and Food Control, stated during a House of Representatives (DPR) Hearing that "PG and PEG were not admitted through the National Agency for Drug and Food Control but through the Ministry of Trade. As a result, it did not involve import approval from the National Agency for Drug and Food Control. Therefore, it is crucial to increase the oversight of imported products used as pharmaceutical raw materials, streamline inconsistent or incorrect labeling of excipients obtained from various producers, and increase access to quality testing facilities at an affordable price".[92]

[92] Arun Sundar Mohana Sundaram et.al, The Silent Epidemic of Substandard and Falsified Medicines in Low- and Middle-Income Countries: Heed Lessons from the Tragic Deaths of Children in Indonesia: Correspondence, *International Journal of Surgery Publish Ahead of Print*, 2023, page. 4

The National Agency of Drug and Food Control does not actively test, monitor, and control drugs circulating on the market, even though pharmaceutical companies are required to provide reports on the raw materials for the drugs used. The National Agency of Drug and Food Control also does not control the distribution permits of pharmaceutical companies and the distribution of raw materials for medicinal syrups used by these companies in the last 3 years.[93] For instances of acute renal failure, the National Agency for Drug and Food Control must assume complete accountability, because this institution is a leading sector in the field of drug control. The Agency is responsible for investigating the case through risk-based testing and random sampling, both of which are regularly conducted by the agency. Another responsibility is also to ensure the effectiveness, benefits, and purity of food and drugs. Beginning with pre-market to post-market oversight regulations, the National Agency for Drug and Food Control examines and enhances drug and food regulations linked to EG and DEG contamination. This involves the addition of additives, standards, and/or criteria for quality and safety.[94] The Technical Enforcement Unit (UPT) of Indonesia's National Agency for Drug and Food Control

[93] Fika Nurul Ulya and Diamanty Meiliana, "BPKN Ungkap Kesalahan Sistemik di BPOM hingga Sebabkan Ratusan Pasien Gagal Ginjal Meninggal", https://nasional.kompas.com/read/2022/11/14/18550811/bpkn-ungkap-kesalahan-sistemik-di-bpom-hingga-sebabkan-ratusan-pasien-gagal, accessed August 1st 2023, at 19.00 WIB

[94] Agil Ahmad et.al, Tanggung Jawab Perusahaan Farmasi dan BPOM Terhadap Produk Obat Sirup Anak, *Journal of Amsir Litigation*, Vol. 10 No.1, 2022, page. 120

continues to keep track of the withdrawal of drug syrups with EG/DEG contamination above the safe level.[95] The withdrawal covers all outlets including Pharmaceutical Wholesalers, Government Pharmacy Installations, Pharmacies, Hospital Pharmacy Installations, Community Health Centers, Clinics, Drugstores, and health worker independent practices.

The National Agency for Drug and Food Control also urges medical professionals and the pharmaceutical sector to keep aggressively reporting drug adverse effects or unintended occurrences following drug use. Business actors are under the National Agency for Drug and Food Control's supervision also should guarantee the safety of the basic materials used.[96] This is due to the reality that the producer or the pharmaceutical business cannot be held solely responsible for the high level of contamination in medicine syrup. Industries and makers are urged to try raw materials and completed goods on their own. In order to better coordinate medication delivery in the community, the National Agency for Drug and Food Control must also work with the Ministries of Industry, Trade, and Health.

[95] Fimelia Reporter, "Tanggung Jawab dan Tindakan BPOM Terkait Penyebab Gangguan Ginjal Akut", https://m.fimela.com/amp/5111196/tanggung-jawab-dan-tindakan-bpom-terkait-penyebab-gangguan-ginjal-akut, accessed March 21th 2023, at 19.00 WIB

[96] Yuliantina, D., Peran Balai Pengawas Obat dan Makanan (BPOM) terhadap peredaran produk makanan berbahaya di kota Palangka Raya (Doctoral dissertation, IAIN Palangka Raya), 2017, page. 59

All pharmacists are urged not to offer free and/or restricted free medicines in the form of syrup to the public until a formal statement is made from the Government in line with legislative provisions, according to Circular Letter (SE) of the Ministry of Health Number SR.01.05/III/3461/2022. So, it is against the law for medical professionals to prescribe liquid or syrup-based medications. The same rule also applies to pharmacies not taking orders for syrup. Additionally, until a formal statement from the Government is made in line with legislative provisions, children under the age of five did not currently taking openly available medications without the advice of qualified health professionals.

Even though the Ministry of Health has appealed to stop all use and distribution of children's syrup medications allegedly contain contaminants such as ethylene glycol (EG) and diethylene glycol (DEG), related parties must still be held responsible for the losses suffered by those who have purchased and consumed the medications, even the victims. Forms of responsibility start from the manufacturing process, and distribution, till the products reach the end consumers.

Based on National Agency for Drug and Food Control Regulation Number 8 of 2020 concerning Control of Drugs and Food Distributed Online as amended by National Agency Regulations of Drug and Food Control Number 32 of 2020, the National Agency for Drug and Food Control conducts online surveillance in addition to inspecting

production facilities. To monitor sales of goods considered dangerous, the National Agency for Drug and Food Control regularly conducts internet inspections on websites, social media platforms, and e-commerce platforms.[97] The Agency also exhorts the general public to exercise greater caution and only use medications registered with the agency and obtained from authorized sources such as pharmaceutical service facilities. Consumers are also suggested to Check KLIK (Check Packaging, Labels, Distribution Permits, and Expired) before buying or consuming any medication.

200 vials of 1.5 ml containers of Fomepizole were also carried in by the Ministry of Health. The antidote (antidote), Fomepizole, was brought from Japan for the Cipto Mangunkusumo facility (RSCM), a referral facility. The Provincial Health Offices, District/City Health Offices, and Health Service Facilities were also requested by the Ministry of Health to conduct oversight and educate the people about the use of syrup medicines in conjunction with their respective authorities.

Before the drugs are distributed to the market and reach the end consumers, the four organizations (the National Agency for Drug and Food Control, Ministry of Health, Ministry of Trade, and Ministry of

[97] BPOM, Tindakan Tegas BPOM dan Bareskrim Polri Terhadap Industri Farmasi Produsen Sirup Obat yang Tidak Memenuhi Standar dan/atau Persyaratan Keamanan, Khasiat, dan Mutu", https://www.pom.go.id/new/view/more/pers/664/Tindakan-Tegas-BPOM-dan-Bareskrim-Polri-Terhadap-Industri-Farmasi--Produsen-Sirup-Obat-yang-Tidak-Memenuhi-Standar-dan-atau-Persyaratan-Keamanan--Khasiat--dan-Mutu.html, accessed March 20 2023, at 14.30 WIB

Health Industry) are supposed to fulfill their responsibilities and perform the coordination function in order to prevent unintended situations. In fact, the government took measures after a case had occurred. The government should have reinforced its preventive responsibility to avoid cases from arising by conducting checks on the scope of pharmaceutical firms and drug distribution in the community (repressive function).

The government should have also get involved in the manufacturing and distribution of syrup drugs allegedly contain Ethylene Glycol (EG) and Diethylene Glycol (DEG) above the safe limit and causing acute renal failure in children. Additionally, because this product was sold in large quantities, monitoring was highly required to prevent misuse by irresponsible individuals.[98]

[98] Nomensen Freddy Siahaan, *Op.Cit*, page 754

CHAPTER IV
CLOSING

A. Conclusions

1. Consumer protection against the use of ethylene glycol (EG) and diethylene glycol (DEG) syrup medications, consist of two Legal Protection, the first legal protection come from the regulation as a preventive legal protection, the legal protection in here come from certain regulations there are The Law number 8 of 1999 concerning Consumer Protection, The Law number Number 36 of 2009 concerning Health, Regulation of the Minister of Health Number 73 of 2016, Regulation of the Food and Drug Supervisory Agency Number 8 of 2018 concerning Maximum Limits of Chemical Contaminants in Processed Foods. Based on the analyses that already been discuss in previous chapter it can concluded that the regulation in Indonesia regarding the use of EG and DEG in syrup medication has already fullfill the consumer protection but the implementation of the regulation is not sufficient in here the implementation is focus on how the Government supervise the coordination between government agencies on community drug delivery should be improved. Before and after medicine is made available to the public, the National Agency for Medicine and Food Control must improve its quality control. To better coordinate drug delivery in the community. The next Legal protection is here repressive legal protection which can be attempt to recover from the disruption. The National Agency for Drug and Food Control takes several actions to maintain

drug quality and public safety. This includes withdrawing drugs that do not meet standards from circulation and destroying them, revoking certificates from drug manufacturers who do not comply with Good Drug Manufacturing Practices (CPOB) guidelines, as well as encouraging the public to buy drugs at legitimate pharmaceutical service locations, such as pharmacies. and drug stores recognized by the government. In addition, medicines purchased online must go through the Pharmacy Electronic System Provider (PSEF) platform which has obtained permission from the government.

2. Business actors should pay compensation in the form of medical treatment or in line with the rules and regulations that apply. If one dies as a result of the drugs, they are required to pay death benefits to the child's parents. Additionally, the National Agency for Drug and Food Control regularly should conduct risk-based testing and random sampling as a form of accountability. It is necessary to ensure the efficacy, advantages, and safety of medicines and food products, as well as their quality. Beginning with pre-market through post-market supervision rules, the National Agency for Drug and Food Control examines and improves medication and food laws linked to EG and DEG contamination. This comprises the addition of additives, standards, and/or criteria for quality and safety. The agency also with hold the selling of syrup medications containing EG and DEG, and ask all

medical facilities and practitioners not to write syrup medication prescriptions.

B. Recommendations

1. It is recommended that the government – the Ministry of Health, National Agency for Drug and Food Control, and the Ministry of Trade, work together to improve the supervision function of medications before they are issued and when they are circulated safely in the community. . They also need to inspect each local pharmacy to make sure the pharmaceuticals adhere to the rules for purchasing and selling them.
2. It is suggested that the companies provide customers with adequate, clear, accurate, and honest information on drug labels regarding composition, use, side effects, and expiration dates.

REFERENCES

A. Books

Adrianus Meliala, *Praktik Bisnis Curang*,Pustaka Sinar Harapan, Jakarta, 1993.

Barkatullah Abdul Haim, *Perlindungan Hukum Bagi Konsumen Transaksi E- Commerce Lintas Negara di Indonesia*, FH UII Press, 2009.

Az. Nasution, *Hukum Perlindungan Konsumen suatu Pengantar*, Diadit Media, Jakarta, 2002.

Budi Agus Riswandi, *Buku Hukum Perlindungan Konsumen*, ctk. Pertama, FH UII Press, Yogyakarta, 2022.

Buku Pegangan tentang Hukum dan Peraturan Perundang-Undangan Perlindungan Konsumen di ASEAN, Jakarta.

Celina Tri Siwi Kristiyanti, *Hukum Perlindungan Konsumen*, Sinar Grafika, Jakarta, 2011.

Gunawan Widjaja dan Ahmad Yani, *Hukum Tentang Perlindungan Konsumen*,ctk. Kedua, Gramedia Pustaka Utama, Jakarta, 2001.

Happy Susanto, *Hak-Hak Konsumen Jika Dirugikan*, Visi Media, Jakarta, 2008.

Hulman Panjaitan, *Hukum Perlindungan Konsumen* Reposisi dan Penguatan Kelembagaan *Badan Penyelesaian Sengketa Konsumen Dalam Memberikan Perlindungan dan Menjamin Keseimbangan Dengan Pelaku Usaha*, ctk. Pertama, Jala Permata Aksara, Jakarta, 2021, e-book.

Ishaq, *Metode Penelitian Hukum dan Penulisan Skripsi Tesis serta Disertasi*, ctk. Pertama, *Alfabeta*, Bandung, 2017.

Janus Sidabalok, *Hukum Perlindungan Konsumen di Indonesia*, PT Citra Aditya Bakti, Bandung, 2006.

Jaser ‘Audah, *Al-Maqashid untuk Pemula*, Suka Pres, Yogyakarta, 2013.

Johni Ibrahim, *Teori & Metodologi Penelitian Hukum Normatif*, cet. ketiga, Bayumedia Publishing, Malang, 2007.

Muhaimin, *Metode* Penelitian, ctk. Pertama, Mataram University Press, NTB, 2020.

Phillipus M. Hadjon, *Perlindungan Hukum bagi Rakyat Indonesia*, ctk. Pertama, Bina Ilmu, Surabaya, 1987.

_____, *Pengantar Hukum Administrasi Indonesia*, ctk.kesepuluh, Gajah Mada University Press, Yogyakarta, 2008.

R. Subekti dan Tjitrosoedibio, *Kamus Hukum*, Pradnya Paramita, Jakarta, 1999.

Satjipto Rahardjo, *Ilmu Hukum*, PT. Citra Aditya Bakti, Bandung, 2000.

Shidarta, *Hukum Perlindungan Konsumen Indonesia*, Grasindo, Jakarta, 2006.

Soerjono Soekanto, *Pengantar Penelitian Hukum*, Ui Press, Jakarta, 1984,

Soeroso, *Pengahantar Ilmu Hukum*, Cetakan Kedelapan, Sinar Grafika, Jakarta, 2006.

Teguh Prasetyo, *Penelitian Hukum*, ctk. Pertama, Nusa Media, 2019.

Wahyu Sasongko, Ketentuan-ketentuan Pokok Hukum Perlindungan Konsumen. Universitas Lampung, Bandar Lampung, 2007.

Zulham, *Hukum Perlindungan Konsumen*, ctk. Pertama, Kencana, Jakarta, 2013, e-book.

B. Journals

Abdul Rahman A. Saied et.al, Gambian children's deaths due to contaminated cough syrups are a mutual responsibility, *International Journal of Surgery*, 2022.

Agil Ahmad et.al, Tanggung Jawab Perusahaan Farmasi dan BPOM Terhadap Produk Obat Sirup Anak, *Journal of Amsir Litigation*, Vol. 10 No.1, 2022.

Agustina Balik dan Vica Jilyan Edsti Saija, "Tanggungjawab Pemerintah Dan Pelaku Usaha Makanan Siap Saji Terkait Penggunaan Wadah Plastik Yang Berbahaya Bagi Konsumen Di Kota Ambon", *Jurnal Hukum*, Vol.23 No. 2, 2017.

Arun Sundar Mohana Sundaram et.al, The Silent Epidemic of Substandard and Falsified Medicines in Low- and Middle-Income Countries: Heed Lessons from the Tragic Deaths of Children in Indonesia: Correspondence, *International Journal of Surgery Publish Ahead of Print*, 2023.

Djelang Zainuddin Fickri dan Farm.Klin, "Formulasi Dan Uji Stabilitas Sediaan Sirup Anti Alergi Dengan Bahan Aktif Chlorpheniramin Maleat (CTM)", Vol.1 No.1, 2018.

Denico Doly, "Efforts to Strengthen Consumer Protection in Indonesia Related to Standard Clauses", *Jurnal Hukum*, Volume. 3 No. 1, 2016.

Endang Naryono, Kids Killer Drug, Pasim College of Economics.

Eva Sartika Dasopang et.al, Sosialisasi Kepada Masyarakat Tentang Membeli Dan Menggunakan Obat Secara Aman Di Kelurahan Sumber Karya, Kecamatan Binjai Timur, *Jurnal Pengabdian Masyarakat Tjut Nyak Dhien*, Vol. 2 No.1, 2023.

Hitesh Chopra et.al, Cough syrups: silent killer of Gambian children, *International Journal of Surgery*, BGC Trust University Bangladesh, 2023.

H. Matnuh, Rectifying Consumer Protection Law and Establishing of a Consumer Court in Indonesia, *Journal of Consumer Policy*, 44:483–495, 2021.

I Kadek Sukadana Putra dan Gusti Ayu Putu Nia Priyantini, "Aspek Perlindungan Hukum Peredaran Obat Tanpa Izin Edar Lembaga Berwenang Menurut Undang-Undang Nomor 8 Tahun 1999 Tentang Perlindungan Konsumen (Studi Kasus: Putusan Pn Singaraja Nomor 80/Pid.Sus/2017/Pn Sgr)", *Jurnal Hukum*, Volume 3 No.2, 2021.

Inosentius Samsul, *Perlindungan Konsumen, Kemungkinan Penerapan Tanggung Jawab Mutlak*, Universitas Indonesia, Jakarta, 2004.

Mohd. Yusuf DM et.al, Pertanggungjawaban Hukum Bagi Produsen Obat Sirup Mengandung Etilen Glikol (EG) Dan Dietilen Glikol (DEG) Penyebab Ginjal Akut Progresif Atipikal (GgGAPA) Pada Anak, *Journal of Education and Counseling*, Vol.5 No.1, UniversitasPahlawan Tuanku Tambusai, 2023.

Neneng Putri Siti Nurhayati et.al, Pemasaran Obat Dalam Usaha Farmasi: Persoalan Profesionalisme dan Etika Bisnis, *Jurnal Kajian Kontemporer Hukum dan Masyarakat*, 1:1, 2023 Niru Anita Sinaga dan Nunuk Sulisrudatin,"Pelaksanaan Perlindungan Konsumen Di Indonesia", *Jurnal Hukum*, Volume 5 No.2, 2015.

Nomensen Freddy Siahaan, Consumer Protection Against the Production and Sale of Syrup Drugs Suspected of Being Contaninated with Hazardous Materials, *Journal of Social Research*, Universitas Mulawarman, 2023.

Parsa Bastani et.al, Acute Kidney Injury Among Children Likely Associated with Diethylene Glycol–Contaminated Medications — The Gambia, vol. 7 no.9, 2023.

Richard Revel Wijaya Theda, et.al, "Perlindungan Hukum Terhadap Konsumen Akibat Kelalaian Pelaku Usaha Jasa Laundry di Denpasar Utara", *Jurnal Hukum*, Vol. 7 No. 7, 2019.

Setiawan, D., Tugas Dan Wewenang Balai Besar Pengawasan Obat Dan Makanan Dalam Mengawasi Makanan Yang Mengandung Zat Berbahaya, *Journal of Business Law*, Vol.4 No.2, Universitas Narotama Surabaya, 2020.

Uber AM and Sutherland MS, Acute kidney injury in hospitalized children: consequences and outcomes, Pediatr Nephrol, 2018,

Viktor V. Horodovenko et.al, Protection of Patients' Rights in The European Court Of Human Rights, vol.71 no.6, 2018.

Yudha Hadian N. dan Dwi Wahyuniarti P., Penerapan Prinsip Tanggung Jawab Mutlak (Strict Liability) Dalam Rangka Perlindungan Konsumen, Vol.5 No.2, Buletin Ilmiah Litbang Perdagangan, 2011.

C. Laws and Regulation

The 1945 Constitution of the Republic of Indonesia.

Law Number 8 of 1999 concerning Consumer Protection.

Law of the Republic of Indonesia Number 36 of 2009 concerning Health.

Government Regulation Number 58 of 2001 concerning Guidance and Supervision of the Implementation of Consumer Protection.

Supreme Court Regulation No.1 of 2002 concerning Procedures for Group Lawsuits.

Regulation of the Minister of Health Number 73 of 2016.

Regulation of the Food and Drug Supervisory Agency Number 8 of 2018 concerning Maximum Limits of Chemical Contaminants in Processed Foods.

Surat Edaran SR.01.05/III/3461/2022, Kewajiban Penyelidikan Epidemiologi dan Pelaporan Kaus Gangguan Ginjal Akut Atipikal (Atypical Progressive Acute Kidney Injury) Pada Anak

D. Dictionary

Kamus Besar Bahasa Indonesia (KBBI), Edisi Kedua, Cet. 1, Balai Pustaka, Jakarta.

E. Thesis

Yuliantina, D., Peran Balai Pengawas Obat dan Makanan (BPOM) terhadap peredaran produk makanan berbahaya di kota Palangka Raya (Doctoral dissertation, IAIN Palangka Raya), 2017.

Husni Mubaraq et.al, Analisis Perlindungan Hukum Bagi Konsumen Terhadap Peredaran Obat-Obatan Ilegal Menurut Undang Undang Nomor 8 Tahun 1999 Tentang Perlindungan Konsumen (Lembaran Negara Republik Indonesia Tahun 1999 Nomor 42), 2021.

F. Internet

Administratos, “Sanksi Hukum bagi Pelaku Kasus Gagal Ginjal”, https://www.indonesia.go.id/kategori/editorial/6650/sanksi-hukum-bagi-pelaku-kasus-gagal-ginjal?lang=1.

Author, “Consumer Protections Pharmaceutical & Medical Devices”, https://www.hamburg.com/civil-services/consumer-protection/16270862/pharmaceuticals-and-medical-devices/.

BEM Farmasi UAD, “Obat Sirup Membuat Gagal Ginjal Pada Anak?”, http://bem.ffarmasi.uad.ac.id/obat-sirup-membuat-gagal-ginjal-pada-anak/.

BPOM, “Informasi Keempat Hasil Pengawasan Bpom Terhadap Sirup Obat Yang Diduga Mengandung Cemaran Etilen Glikol (EG) dan Dietilen Glikol (DEG)”, https://www.pom.go.id/new/view/more/klarifikasi/158/INFORMASI-KEEMPAT-HASIL-PENGAWASAN-BPOM-TERHADAP-SIRUP-OBAT-YANG-DIDUGA-MENGANDUNG-CEMARAN-ETILEN-GLIKOL--EG--DAN-DIETILEN-GLIKOL--DEG-.html.

BPOM, “Penjelasan Bpom Ri Nomor Hm.01.1.2.12.22.188 Tanggal 22 Desember 2022 Tentang Tindak Lanjut Investigasi Dan Pengawasan Bpom Terhadap Sirup Obat Yang Tidak Memenuhi Syarat Pada 6 (Enam) Industri Farmasi”, https://www.pom.go.id/new/view/more/klarifikasi/169/PENJELASAN-BPOM-RI-NOMOR-HM-01-1-2-12-22-188-TANGGAL-22-DESEMBER-2022-TENTANG-TINDAK-LANJUT-INVESTIGASI-DAN-PENGAWASAN-BPOM-TERHADAP-SIRUP-OBAT-YANG-TIDAK-MEMENUHI-SYARAT-PADA-6--ENAM--INDUSTRI-FARMASI.html.

BPOM, “Penjelasan BPOM RI Tentang Isu Obat Sirup yang Berisiko Mengandung Cemaran Etilen Glikol (EG) dan Dietilen Glikol (DEG)”, https://www.pom.go.id/new/view/more/klarifikasi/157/Penjelasan-BPOM-RI-Tentang-Isu-Obat-Sirup-yang-Berisiko-Mengandung-Cemaran-Etilen-Glikol--EG--dan-Dietilen-Glikol--DEG-.html.

BPOM, “Penjelasan BPOM RI Tentang Sirup Obat Untuk Anak Di Gambia, Afrika Yang Terkontaminasi Dietilen Glikol Dan Etilen Glikol”, https://www.pom.go.id/new/view/more/klarifikasi/155/Penjelasan-BPOM-RI-Tentang-Sirup-Obat-Untuk-Anak-Di-Gambia--Afrika-Yang-Terkontaminasi-Dietilen-Glikol-Dan-Etilen-Glikol.html .

BPOM, “Tindakan Tegas BPOM dan Bareskrim Polri Terhadap Industri Farmasi Produsen Sirup Obat yang Tidak Memenuhi Standar dan/atau Persyaratan Keamanan, Khasiat, dan Mutu”, https://www.pom.go.id/new/view/more/pers/664/Tindakan-Tegas-BPOM-dan-Bareskrim-Polri-Terhadap-Industri-Farmasi--Produsen-Sirup-Obat-yang-Tidak-Memenuhi-Standar-dan-atau-Persyaratan-Keamanan--Khasiat--dan-Mutu.html.

Dr. Yusu Shofie, “ Tugas dan Fungsi Badan Perlindungan Konsumen Nasional (BPKN)”, https://www.hukumonline.com/klinik/a/tugas-dan-fungsi-badan-perlindungan-konsumen-nasional-bpkn-lt5ee046de7671e/.

Fimelia Reporter, “Tanggung Jawab dan Tindakan BPOM Terkait Penyebab Gangguan Ginjal Akut”, https://m.fimela.com/amp/5111196/tanggung-jawab-dan-tindakan-bpom-terkait-penyebab-gangguan-ginjal-akut.

M. Agus Yozami, “Kemendag Akan Atur Importasi Bahan Baku Obat Penyebab Terjadinya Gagal Ginjal Akut”, https://www.hukumonline.com/berita/a/kemendag-akan-atur-importasi-bahan-baku-obat-penyebab-terjadinya-gagal-ginjal-akut-lt63687d956c72f?page=3#!.

Nadya Zahira, “BPKN Berikan Pendampingan Hukum pada Korban Kasus Gagal Ginjal Akut”, https://katadata.co.id/tiakomalasari/berita/63639374ca50d/bpkn-berikan-pendampingan-hukum-pada-korban-kasus-gagal-ginjal-akut.

Redaksi CNN, “Daftar 7 Obat Sirop dengan Kandungan EG dan DEG Melebihi Ambang Batas", https://www.cnnindonesia.com/nasional/20221102095625-20-868401/daftar-7-obat-sirop-dengan-kandungan-eg-dan-deg-melebihi-ambang-batas.

Sri Pujianti, Mahkamah Konstitusi Indoensia Lembaga Negara Pengawal Konstitusi, “Aturan Sanksi Tindak Pidana Kejahatan Terhadap Sediaan Farmasi Konstitusional” https://www.mkri.id/index.php?page=web.Berita&id=18807

Tim Redaksi CNBC Indonesia, “Obat Sirup Kenapa Baru Jadi Masalah Sekarang? Ini Alasannya”, https://www.cnbcindonesia.com/news/20221022123237-4-381789/obat-sirup-kenapa-baru-jadi-masalah-sekarang-ini-alasannya.

ATTACHMENT

FAKULTAS HUKUM
Gedung Fakultas Hukum
Universitas Islam Indonesia
Jl.Kaliurangkm 14,5 Yogyakarta55584
T. (0274)7070222
E. fh@uii.ac.id
W law.uii.ac.id

SURAT KETERANGAN BEBAS PLAGIASI

No. : 475/Perpus-S1/20/H/X/2023

Bismillaahhirrahmaanirrahaim

Yang bertanda tangan di bawah ini:

Nama	: **M. Arief Satejo Kinady, A.Md.**
NIK	: **001002450**
Jabatan	: **Kepala Divisi Adm. Akademik Fakultas Hukum UII**

Dengan ini menerangkan bahwa :

Nama	: Novia Aulya Rahmadanti
No Mahasiswa	: 19410663
Fakultas/Prodi	: Hukum
Judul karya ilmiah	: CONSUMER PROTECTION AGAINST THE USE OF SYRUP DRUGS CONTAINING ETHYLENE GLYCOL AND DIETHYLENE GLYCOL EXCEEDING THE SAFE THRESHOLD.

Karya ilmiah yang bersangkutan di atas telah melalui proses uji deteksi plagiasi dengan hasil **12**.%

Demikian surat keterangan ini dibuat agar dapat dipergunakan sebagaimana mestinya.

Yogyakarta, 4 Oktober 2023 M
19 Rabbiul Awwal 1445 H

Kepala Divisi Adm. Akademik

M. Arief Satejo Kinady, A.Md